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, 2019
OR
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
OR
☐ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report:
Commission File number: 001-38976

Genmab A/S
(Exact name of Registrant as specified in its charter)
Not Applicable
(Translation of Registrant’s name into English)
The Kingdom of Denmark
(Jurisdiction of incorporation or organization)
Kalvebod Brygge 43
1560 Copenhagen V
Denmark
(Address of principal executive offices)
Anthony Pagano
Executive Vice President and Chief Financial Officer
Genmab A/S
Kalvebod Brygge 43
1560 Copenhagen V
Denmark
Tel: +45 70 20 27 28
Fax: +45 70 20 27 29
(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.

<table>
<thead>
<tr>
<th>Title of each class</th>
<th>Trading symbol</th>
<th>Name of each exchange on which registered</th>
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<tbody>
<tr>
<td>American Depositary Shares, each representing one-tenth of one ordinary share</td>
<td>GMAB</td>
<td>The NASDAQ Stock Market LLC</td>
</tr>
<tr>
<td>Ordinary shares, nominal value DKK 1 per share</td>
<td>GMAB</td>
<td>The NASDAQ Stock Market LLC*</td>
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</tbody>
</table>

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

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.

65,074,502 Ordinary Shares (including shares underlying American Depositary Shares)

27,931,230 American Depositary Shares

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☐ No ☒

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

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

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

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

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

Indicate by check mark 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 ☒
# TABLE OF CONTENTS

## INTRODUCTION

PART I

ITEM 1  IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISORS

ITEM 2  OFFER STATISTICS AND EXPECTED TIMETABLE

ITEM 3  KEY INFORMATION

ITEM 4  INFORMATION ON THE COMPANY

ITEM 4A UNRESOLVED STAFF COMMENTS

ITEM 5  OPERATING AND FINANCIAL REVIEW AND PROSPECTS

ITEM 6  DIRECTORS, EXECUTIVE MANAGEMENT AND EMPLOYEES

ITEM 7 MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

ITEM 8  FINANCIAL INFORMATION

ITEM 9  THE OFFER AND LISTING

ITEM 10 ADDITIONAL INFORMATION

ITEM 11 QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISKS

ITEM 12 DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

ITEM 12A DEBT SECURITIES

ITEM 12B WARRANTS AND RIGHTS

ITEM 12C OTHER SECURITIES

ITEM 12D AMERICAN DEPOSITARY SHARES

PART II

ITEM 13 DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

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

ITEM 15 CONTROLS AND PROCEDURES

ITEM 16A AUDIT COMMITTEE FINANCIAL EXPERTS

ITEM 16B CODE OF ETHICS

ITEM 16C PRINCIPAL ACCOUNTANT FEES AND SERVICES

ITEM 16D EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

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

ITEM 16F CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

ITEM 16G CORPORATE GOVERNANCE

ITEM 16H MINE SAFETY DISCLOSURE

PART III

ITEM 17  FINANCIAL STATEMENTS

ITEM 18  FINANCIAL STATEMENTS

ITEM 19  EXHIBITS

SIGNATURES

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
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 2019 (the “Annual Report 2019”), included as Exhibit 99.1 to Form 6-K furnished to the SEC on February 19, 2020. Therefore, the information in this Annual Report on Form 20-F should be read in conjunction with the Annual Report 2019. Items not contained or not specifically referenced to within the Annual Report 2019 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, clinical development, regulatory approvals and commercialization of daratumumab and ofatumumab by Janssen and Novartis, respectively;
- our expectations regarding the clinical development, regulatory approval and commercialization of tisotumab vedotin and our other proprietary and partnered product candidates;
- our expectations with regard to our ability to create and develop additional product candidates and to submit INDs and/or CTAs for our pre-clinical product candidates;
- our receipt of future milestone payments and royalties from our partners, and the expected timing of such payments;
- our estimates and expectations regarding the potential market size and the size of the patient populations for our products and product candidates;
- our expectations regarding the potential advantages of our products and product candidates over existing therapies or therapies currently in development;
- our expectations regarding the potential advantages of our proprietary technologies over existing antibody technologies and the prospects for our ongoing and future technology collaborations;
- our plans to expand our translational research platform and the potential benefits of such platform;
- our expectations with regard to the willingness and ability of our current and future partners to pursue the development, approval and commercialization of our products and product candidates;
· our and our partners’ product discovery, development and commercialization plans with respect to our products and product candidates and our proprietary technologies;

· our potential to enter into new collaborations;

· our and our partners’ ability to develop, acquire and advance product candidates into, and successfully complete, clinical trials;

· the initiation, timing, progress and results of our pre-clinical studies and clinical trials, and our research and development programs;

· the timing or likelihood of regulatory filings and approvals for our products and product candidates;

· our ability to identify, and to negotiate contracts with, suitable 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 cGMPs;

· the commercialization and market acceptance of our products and product candidates;

· our plans to build our commercialization capabilities and to potentially commercialize tisotumab vedotin or other proprietary product candidates in-house;

· the pricing of and reimbursement for our approved products;

· the implementation of our business model and strategic plans for our business, products, product candidates and technologies;

· our ability to operate our business without violating applicable laws and regulations;

· our and our partners’ ability to operate our businesses without infringing the intellectual property rights and proprietary technology of third parties;

· the scope of protection we and our partners are able to establish and maintain for intellectual property rights covering our products, product candidates and technologies;

· our analysis of potential patent infringement claims and our or our partners’ rights with respect to such claims;

· estimates of our future expenses and revenue;

· our expectations regarding regulatory developments in the United States, the European Union 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 expectations regarding the length of time for which we will remain an emerging growth company under the JOBS Act and a foreign private issuer;
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 U.S. Securities and Exchange Commission (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 consolidated financial statements 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 appear without the ®, ™ and SM symbols, but the absence of those symbols is not intended to indicate, in any way, that we will not assert our rights or that the applicable owner will not assert its rights to these trademarks, tradenames and service marks to the fullest extent under applicable law. We do not intend our use or display of other parties’ trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

This Annual Report on Form 20-F contains estimates, projections and other information concerning our industry, our business and the markets for our products and product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from our own internal estimates and research as well as from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable.
In addition, assumptions and estimates of our and our industry’s future performance are necessarily subject to a high
degree of uncertainty and risk due to a variety of factors, including those described in “Item 3. D —Risk Factors.” These
and other factors could cause our future performance to differ materially from our assumptions and estimates. See
“Forward-Looking Statements” above.

ENFORCEABILITY OF CIVIL LIABILITIES

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

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

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

PART I

ITEM 1  IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISORS

Not applicable.

ITEM 2  OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3  KEY INFORMATION

A. Selected Financial Data

The following tables present selected consolidated financial data for the periods indicated. We derived the selected
consolidated balance sheet data as of December 31, 2019 and 2018, and selected consolidated income statement data for
the years ended December 31, 2019, 2018, and 2017 from our audited consolidated financial statements and notes thereto
as filed herewith (the “Audited Financial Statements”). The selected consolidated balance sheet data as of December 31,
2017 is derived from audited consolidated financial statements not appearing in this Annual Report.

The following selected consolidated financial data should be read in conjunction with our “Item 5—Operating and
Financial Review and Prospects” below and the Audited Financial Statements. Our historical results are not necessarily
indicative of our future results.

5
### Consolidated Income Statement Data

| (in DKK millions, except per share amounts) | Year Ended December 31, |
|                                          | 2019    | 2018*   | 2017*   |
| Revenue                                  | 5,366   | 3,025   | 2,365   |
| Operating expenses                       |         |         |         |
| Research and development expenses        | (2,386) | (1,431) | (874)   |
| General and administrative expenses      | (342)   | (214)   | (147)   |
| Total operating expenses                 | (2,728) | (1,645) | (1,021) |
| Other Income                             |         |         |         |
| Financial income                         | 228     | 243     | 72      |
| Financial expenses                       | (7)     | (11)    | (352)   |
| Net result before tax                    | 2,859   | 1,612   | 1,064   |
| Corporate tax                            | (693)   | (140)   | 40      |
| Net result                               | 2,166   | 1,472   | 1,104   |
| Basic net result per share (1)           | 34.40   | 24.03   | 18.14   |
| Diluted net result per share (1)         | 34.03   | 23.73   | 17.77   |

(1) See note 2.5 to our Audited Financial Statements for further details regarding the calculation of basic and diluted net result per share.

* As disclosed in note 1.2 to our Audited Financial Statements, prior period amounts have not been adjusted under the modified retrospective method to adopt IFRS 16 as of January 1, 2019. Further, 2017 and prior period amounts have not been adjusted under the modified retrospective method to adopt IFRS 15 as of January 1, 2018, and in accordance with the transitional provisions of IFRS 9, comparative figures for 2017 and prior have not been restated.

### Consolidated Balance Sheet Data

| (in DKK millions, except per share amounts) | 2019 | As of December 31, 2018* | 2017* |
| Total assets                                | 15,144 | 8,461 | 6,603 |
| Retained earnings/(Accumulated Deficit)     | 2,130  | (198) | (1,855) |
| Total shareholders’ equity (net assets)      | 14,048 | 8,014 | 4,748 |
| Total liabilities                           | 1,096  | 447   | 331   |
| Share capital                               | 65     | 61    | 61    |
| Treasury shares                             | 163,921| 177,550| 100,000|
| Number of shares                            | 65,074,502 | 61,497,571 | 61,185,674|

* As disclosed in note 1.2 to our Audited Financial Statements, prior period amounts have not been adjusted under the modified retrospective method to adopt IFRS 16 as of January 1, 2019. Further, 2017 and prior period amounts have not been adjusted under the modified retrospective method to adopt IFRS 15 as of January 1, 2018, and in accordance with the transitional provisions of IFRS 9, comparative figures for 2017 and prior have not been restated.

#### B. Capitalization and Indebtedness

Not applicable.

#### C. Reasons for the Offer and Use of Proceeds

Not applicable.
D. Risk Factors

Risks Related to Our Business

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

In 2019, royalties and milestone payments from Janssen related to daratumumab, marketed as DARZALEX for certain indications of multiple myeloma, or MM, accounted for 92% of our revenue, as compared to 76% in 2018, and we anticipate that DARZALEX will continue to account for a substantial portion of our revenue in the near term. Under our collaboration agreement regarding daratumumab, Janssen is fully responsible for developing and commercializing daratumumab and all costs associated therewith. Consequently, our revenue and resulting operating profit, if any, and near-term prospects are substantially dependent on the success of this collaboration and on Janssen’s continued ability to effectively maintain and grow sales of daratumumab for its approved indications and to continue to expand its indications. Janssen has obtained marketing approval for DARZALEX for certain indications of frontline MM and relapsed/refractory, or R/R, MM in the United States, the European Union, Japan, and in certain other countries. In addition, applications for the subcutaneous formulation of daratumumab are currently pending with the United States and European regulators. There can be no assurance that Janssen will be successful in obtaining approvals for DARZALEX in this formulation or jurisdictions or in maintaining existing regulatory approvals. While DARZALEX product sales have grown over time, and our future plans assume that sales of DARZALEX will continue to increase, there can be no assurance that, even with the recent expansion to the prescribing label for DARZALEX in the United States and the European Union, DARZALEX sales will continue to grow or that Janssen will be able to maintain sales of DARZALEX at or near current levels. In particular, DARZALEX is subject to intense competition in the MM therapy market. There are numerous other products approved by the FDA for the same indications as DARZALEX and the competition from these and other therapies is intensifying. We are also aware of numerous additional investigational agents and technologies that are currently being studied for the treatment of MM, any of which may compete with DARZALEX in the future. In particular, Sanofi’s isatuximab, a mAb targeting CD38, was approved as SARCLISA by the FDA in March 2020 for the treatment of adult patients with MM who have received at least two prior therapies including lenalidomide and a proteasome inhibitor (PI). If Janssen is unable to successfully compete with these other agents and technologies, DARZALEX sales could decline materially.

Janssen is also currently conducting clinical trials of daratumumab for the treatment of smoldering MM, or SMM, and additional indications of frontline MM and R/R MM, as well as certain other malignant and pre-malignant diseases in which CD38 is expressed, including amyloidosis, acute lymphocytic leukemia and NKT-cell lymphoma, which are in different stages of clinical development.

Although we are able to participate in the development strategy for daratumumab through regular meetings of the joint development and steering committee, we cannot control the amount and timing of resources that Janssen dedicates to the development of daratumumab and our prospects for future milestone payments and royalties related to daratumumab depend on Janssen’s decision to continue to conduct clinical trials of daratumumab for expanded indications and to seek new regulatory approvals for daratumumab, and on the success of such studies and applications.

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

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

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

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

Ofatumumab has been approved for the treatment of certain CLL indications in the United States and certain other countries and is currently commercialized by Novartis for such CLL indications under the name Arzerra. On January 22, 2018, Novartis announced that it intends to transition Arzerra in non-U.S. markets from commercial availability to limited availability through managed access programs or alternative solutions, where applicable and allowed by local regulations, due to increased availability of treatments for CLL resulting in a low number of patients using Arzerra outside the United States. In 2019, marketing authorizations for Arzerra were withdrawn in the European Union and certain other territories. We expect Arzerra to remain commercially available for approved CLL indications in the United States and Japan. Under our collaboration agreement, Novartis is fully responsible for development and commercialization of ofatumumab and all costs associated therewith. Consequently, the commercial success of ofatumumab is dependent on the success of this collaboration and the activities of Novartis. Global net sales of Arzerra have been decreasing since 2013, primarily related to increasing competition from new entrants to the CLL treatment market, with 2019 global net sales of Arzerra by Novartis of $17 million, as compared to $26 million in 2018, resulting in royalties to us of DKK 23 million in 2019, as compared to DKK 33 million in 2018. We expect competitive pressures in the CLL treatment space to remain or intensify, which may cause sales to further decline, particularly as Novartis continues to transition Arzerra to compassionate use in most jurisdictions. For these and other reasons, we believe that our prospects for revenue from ofatumumab are largely dependent on Novartis’ ability to expand the labeled indications of use for ofatumumab and to successfully commercialize it for such indications. We cannot control the amount and timing of resources that Novartis dedicates to the development and commercialization of ofatumumab and our ability to obtain milestone payments and royalties related to ofatumumab depends on Novartis’ decision to continue to study ofatumumab for new indications, to seek regulatory approvals for such indications and to effectively commercialize ofatumumab for new and existing indications, and on the success of such efforts.
Novartis is currently investigating a subcutaneous (subQ) formulation of ofatumumab in two Phase III clinical studies, ASCLEPIOS I and II, in relapsing multiple sclerosis, or relapsing MS. Novartis reported positive data from these studies in August 2019 and based on this data, submitted a supplemental Biologics License Application (sBLA) to the FDA in December 2019 and an MAA to the EMA in January 2020. There can be no assurance that the marketing authorization will be granted based on the ASCLEPIOS I and II studies. In addition, Novartis may not be able to effectively commercialize ofatumumab for RMS, if approved, as a result of unfavorable pricing or reimbursement limitations, competition or other factors, or may choose not to prioritize ofatumumab in its marketing efforts.

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

Our clinical stage product candidates include seven proprietary product candidates, ongoing clinical studies for daratumumab and ofatumumab by Janssen and Novartis, respectively, and ten additional product candidates being developed in collaboration with our partners. We also have approximately 20 proprietary and partnered product candidates in pre-clinical development. Other than daratumumab and ofatumumab, which are currently in Phase III clinical studies for certain additional indications, tisotumab vedotin, which is currently in Phase II development, and teprotumumab, which is in development by one of our partners and which was approved in thyroid eye disease by the FDA in January 2020, our current product candidates are in relatively early stages of development. All of our product candidates will require significant further development, financial resources and personnel to obtain regulatory approval and develop into commercially viable products, if at all.

Due to the uncertain, time-consuming and costly clinical development and regulatory approval process, we or our partners may not successfully develop any of our product candidates, or we or our partners may choose to discontinue the development of product candidates for a variety of reasons, including due to safety, risk versus benefit profile, exclusivity, competitive landscape, commercialization potential, production limitations or prioritization of our or our partners’ resources. It is possible that none of our current product candidates will ever obtain regulatory approval and, even if approved, such product candidates may never be effectively commercialized. In addition, our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates suitable for clinical development or commercialization. Likewise, we and our partners have to make decisions about which clinical stage and pre-clinical product candidates to develop and advance. We may not have the resources to invest in all of our current product candidates, or clinical data and other development considerations may not support the advancement of one or more product candidates.

Decision-making about which product candidates to prioritize involves inherent uncertainty, and our and our partners’ development program decision-making and resource prioritization decisions may not improve our results of operations or future growth prospects or enhance the value of the ADSs and our underlying shares.

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

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

We are currently in the early stages of building and expanding our commercial capabilities to allow us to market our own products in the future for the indications and in the geographies we determine would be most effective to create
value for our shareholders. Our goal is to become a commercial-stage company with an initial focus on achieving commercial launch readiness to support the potential launch of tisotumab vedotin for the treatment of cervical cancer subject to obtaining regulatory approval and, where applicable, reimbursement approval. We are developing tisotumab vedotin in collaboration with Seattle Genetics. Under our agreement, Seattle Genetics and Genmab will each be responsible for leading tisotumab vedotin commercialization activities in certain territories. We are currently in discussions with Seattle Genetics regarding the detailed terms on which we will work together to commercialize tisotumab vedotin under this agreement. Our sales and marketing operations are currently in the early stages of development and setting up full commercialization capabilities will require substantial investment of time and money and will divert significant management focus and resources. We will be competing with larger pharmaceutical and biotechnology companies with established commercialization and marketing capabilities. In addition, we may be unable to develop productive relationships with local medical experts, patients and other key stakeholders or may face barriers due to cultural or regulatory differences. We will also compete for staffing with transnational and local pharmaceutical and biotechnology firms and local medical, healthcare and research organizations. Accordingly, there can be no assurance that our efforts to set up commercialization capabilities will be successful.

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

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

Tisotumab vedotin is currently our most advanced proprietary product candidate, and our initial commercialization efforts are focused on setting up our commercialization capabilities to market tisotumab vedotin for the treatment of cervical cancer. We are developing tisotumab vedotin in collaboration with Seattle Genetics under an agreement in which the companies share all future costs and profits for the product on a 50:50 basis. Under our agreement, Seattle Genetics and Genmab will each be responsible for leading tisotumab vedotin commercialization activities in certain territories. However, there can be no assurance that tisotumab vedotin will obtain regulatory approval on our expected timeline or at all. We and Seattle Genetics are currently conducting a potentially registrational Phase II clinical trial of tisotumab vedotin for the treatment of patients with recurrent and/or metastatic cervical cancer and completed enrollment for this study in March 2019. There can be no assurance that this study will be completed, on the proposed timeline or at all, or that the results will be supportive of regulatory filings. Even if we achieve results in this study that support regulatory filings, we may be required to conduct one or more additional clinical trials in order to obtain marketing approval for tisotumab vedotin. Such trials would be time-consuming and costly and may not be completed successfully, if at all. If we are not able to complete the ongoing Phase II study and any other studies that may be required and achieve results that support regulatory filings, we will be unable to obtain regulatory approval for tisotumab vedotin in the proposed indications. Even if we file a Biologics License Application, or BLA, or other regulatory application, there is no guarantee that we will obtain marketing approval or, if we obtain marketing approval, that we and Seattle Genetics will be able to successfully commercialize tisotumab vedotin. If we are unable to commercialize tisotumab vedotin for cervical cancer, we may lose a portion of our investment and may incur additional costs to refocus our efforts on other products or indications, which could have a negative impact on our business, financial condition, results of operations and future growth prospects.

If we and Seattle Genetics are unable to agree on the development and commercialization strategies for tisotumab vedotin, such efforts may be delayed, or we may be required to take full responsibility for ongoing development and commercialization efforts, including the costs of such efforts. We are currently in discussions with Seattle Genetics regarding the detailed terms on which we will work together to commercialize tisotumab vedotin under this agreement.
The results of these discussions may impact the pace and timing of our commercial expansion into the United States or other jurisdictions. In addition, either party may opt out of co-development and profit-sharing in return for receiving milestone payments and royalties from the continuing party.

Furthermore, tisotumab vedotin is developed using Seattle Genetics’ proprietary ADC technology in combination with our proprietary HuMax-TF antibody. Any failures or setbacks in Seattle Genetics’ ADC development program, including adverse effects resulting from the use of ADC technology in commercial settings or human clinical trials and/or the imposition of clinical holds on any trials for product candidates using this technology, could have a detrimental impact on the continued development of tisotumab vedotin, which could adversely affect our business, financial condition, results of operations and future growth prospects.

**Any failures or setbacks in our DuoBody platform or our other proprietary technologies could negatively affect our business and financial condition.**

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

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

Part of our clinical development strategy for certain of our product candidates, including daratumumab and ofatumumab, is to seek to identify patients or patient subsets within a disease category whose treatment may benefit from our products in combination with other therapeutic products. For example, daratumumab has been approved in certain jurisdictions in combination with lenalidomide and dexamethasone, or Rd, for the frontline treatment of transplant-ineligible MM patients and for the treatment of MM patients who have received at least one prior line of therapy; (ii) bortezomib and dexamethasone, or Vd, for the treatment of MM patients who have received at least one prior line of therapy; (iii) pomalidomide and dexamethasone, or Pom-d, for the treatment of MM patients who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor, or PI; (iv) bortezomib, melphalan and prednisone, or VMP, for frontline treatment of transplant-ineligible MM patients; and (v) bortezomib, thalidomide and dexamethasone, or VTd, for frontline treatment of transplant-eligible MM. Ofatumumab has been approved in certain jurisdictions in combination with (i) fludarabine and cyclophosphamide, and (ii) chlorambucil and bendamustine for the treatment of certain CLL indications. In addition, daratumumab is currently in Phase III clinical trials in combination with (i) bortezomib, lenalidomide and dexamethasone, or VRd, Rd and VMP for frontline treatment of transplant-ineligible MM patients; (ii) bortezomib, thalidomide and dexamethasone, or VTd, VRd and lenalidomide for frontline treatment of transplant-eligible MM patients; (iii) carfilzomib and dexamethasone, or Kd, Pom-d and Vd for the treatment of R/R MM; and (iv) in combination with cyclophosphamide, bortezomib and dexamethasone, or CyBord, for the treatment of amyloidosis. We and our partners are also testing other product candidates as combination treatments.

Approval of a product for the treatment of a disease indication in combination with other therapeutic products exposes us and our partners to certain risks related to those other therapeutic products, including the risks that such products will become less competitive or obsolete or will be found to have safety concerns, which could potentially
result in removal of such products from the market. For example, in May 2012, the FDA issued a safety announcement relating to the risk of second primary malignancies in patients with newly diagnosed MM that had received lenalidomide, marketed as Revlimid, and on July 18, 2013, Celgene, in consultation with the FDA, discontinued treatment with Revlimid in a Phase III trial for the treatment of previously untreated elderly patients with CLL due to an imbalance observed in the number of deaths in patients treated with Revlimid versus patients treated with chlorambucil. Furthermore, seeking to heighten immune or other therapeutic responses through combination treatments carries an inherent risk that the combination may cause unexpected side effects or safety issues not observed in treatment with the individual products alone. For example, in May 2019, Regeneron Pharmaceuticals Inc. reported that the combination of its bispecific mAb with a PD-1 inhibitor led to enhanced cytokine release syndrome in patients in a Phase I trial and was a potential cause of two patient fatalities in the study. In addition, in May 2018, the CALLISTO Phase Ib/II study of daratumumab in combination with azetolizumab in patients with previously treated NSCLC was terminated following a planned review by a data monitoring committee. The data monitoring committee had determined that there was no observed benefit in the combination treatment arm versus azetolizumab alone and observed a numerical increase in mortality-related events, which were subsequently determined to be primarily due to disease progression, in the combination treatment arm of the study.

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

We have entered into a number of different partnerships for development, co-development, commercialization and co-commercialization of our products and product candidates, as well as for the in- and out-licensing of third-party technologies and our proprietary technologies. Our ability to continue our current partnerships and to enter into additional partnerships will depend in large part on whether we are able to successfully demonstrate our ability to select and develop product candidates and that our antibody technology and other platform technologies are attractive formats for developing antibody therapeutic products. Existing or potential partners may pursue alternative technologies, including those of our competitors, or enter into other transactions that could make collaboration with us less attractive to them. For example, if an existing partner purchases or is purchased by one of our competitors, that company could be less willing to continue its collaboration with us. Moreover, from time to time we have discussions, disagreements or disputes with our partners with respect to the ownership of rights, royalty entitlements or other matters with respect to any technology or products developed with our partners or with respect to the interpretation of related agreements. Lengthy negotiations with potential new partners or disagreements between us and our partners may lead to delays in or termination of the research, development or commercialization of products and product candidates or affect the financial and non-financial rights and obligations under the related agreements. If we are not able to establish additional partnerships on terms that are favorable to us or if a significant number of our existing partnerships are terminated and we cannot replace them, we may be required to increase our internal product development and commercialization efforts. This would likely limit the number of product candidates that we would be able to develop and commercialize, significantly increase our need for capital and/or place additional strain on management’s time, any of which could materially harm our business, financial condition and results of operations. Furthermore, as discussed above, we cannot assure you that we would be able to establish the necessary internal product development and commercialization capabilities to develop and commercialize our product candidates ourselves in a timely matter or at all, or that any product development or commercialization activities we carry out would be successful.

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

We rely on our partners to support our business, including to assist with, or to conduct, clinical and regulatory development, manufacturing and/or commercialization of certain of our products and product candidates or to provide access to antigens, technologies, skills and information that we do not possess. For example, we have granted Janssen worldwide exclusive rights to develop and commercialize daratumumab, have granted Novartis worldwide exclusive rights to co-develop and commercialize ofatumumab, and have also entered into partnerships with Seattle Genetics and BioNTech for certain of our proprietary product candidates. In addition, we have granted Janssen and Novo Nordisk certain rights to develop product candidates using our DuoBody technology platform. We have also created product candidates that have been out-licensed to Janssen, Roche, BMS, ADC Therapeutics, Lundbeck and Amgen, and have
entered into a research collaboration and exclusive license agreement with Immatics Biotechnologies GmbH, or Immatics, to discover and develop potential next-generation bispecific immunotherapies to target multiple cancer indications. We have also entered a research collaboration and license agreement with CureVac AG to develop differentiated mRNA-based antibody products and an exclusive license and option agreement with Janssen to develop a next-generation CD38 product using our HexaBody technology platform. If we do not realize the contemplated benefits from our collaborations, our business, financial condition and results of operations may be materially harmed.

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

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

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

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

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

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

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

· business combinations, financial difficulties or significant changes in a partner’s business strategy, including as a result of COVID-19, may adversely affect that partner’s willingness or ability to continue to pursue our products or product candidates; and

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

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

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

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

**Our product candidates will need to undergo clinical trials that are time-consuming and expensive, the outcomes of which are unpredictable, and for which there is a high risk of failure. If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy to the FDA, the EMA and any other comparable regulatory authority, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of these product candidates.**

The FDA, the EMA and comparable regulatory authorities in other jurisdictions must approve new product candidates before they can be marketed, promoted or sold in those territories. We or our partners must provide these regulatory authorities with data from pre-clinical studies and clinical trials that demonstrate that our product candidates are safe and effective for a specific indication before they can be approved for commercial distribution. DARZALEX Arzerra and teprotumumab are our only approved products. We cannot be certain that our or our partners’ clinical trials for our product candidates will be successful or that any of our other proprietary or partnered product candidates will receive approval from the FDA, the EMA or any other regulatory authority. In addition, certain other third parties make decisions about products or product candidates based on results of clinical trials, including determinations relating to pricing or reimbursement of approved products or validations or endorsements of treatment options. Such third parties may require additional data or studies for their determinations.
Pre-clinical studies and clinical trials are long, expensive and unpredictable processes that can be subject to extensive delays. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. It may take several years and require significant expenditures to complete the pre-clinical studies and clinical trials necessary to commercialize a product candidate, and delays or failures are inherently unpredictable and can occur at any stage. Topline or interim results of clinical trials do not necessarily predict final results, and success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials, and we cannot be certain that we or our partners will not face similar setbacks. If topline or interim data that we or our partners report differ from final results, if others, including regulatory authorities, disagree with our assumptions, calculations, conclusions, or analyses or interpret or weigh the data differently, or if subsequent studies are unsuccessful, we or our partners may be unable to obtain marketing approval for product candidates on a timely basis or at all, which could impact our reputation, business, financial condition, results of operations and future growth prospects.

The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed. In addition, advancements or changes in the industry standards or techniques may impact the value and recognition of our and our partners’ clinical data. Failure to adopt new industry standards may result in less comparable or useful study results. Alternately, early adoption of emerging protocols or endpoints may result in data that is not recognized by certain regulatory bodies or industry professionals, or if such protocols are later found to be ineffective, may require us or our partners to change the design of our clinical trials. For example, Janssen has selected minimal residual disease, or MRD, an emerging efficacy endpoint in MM, as the primary endpoint in the Phase III CEPHEUS trial of daratumumab in combination with VRd for the treatment of frontline MM and in the Phase III AURIGA trial of daratumumab in combination with lenalidomide as maintenance treatment for MM patients who are MRD positive after frontline autologous stem cell transplant.

Although these trials include more conventional measures as secondary endpoints, such as PFS and OS, this design may not be sufficient to obtain regulatory approval, and Janssen may be required to change the design of these trials or conduct additional trials to obtain regulatory approval for these indications. Similarly, failure of the industry to adopt MRD as a valid endpoint may result in study results being discounted or disregarded by industry professionals. Changing the design of a clinical trial can be expensive and time-consuming. An unfavorable outcome in one or more trials would be a major setback for our product candidates and for us and may require us or our partners to delay, reduce the scope of or eliminate one or more product development programs, which could have a material adverse effect on our business, financial position, results of operations and future growth prospects. In addition, any delays in product development may allow our competitors to bring products to market before we do or shorten any periods during which we or our partners have the exclusive right to commercialize our product candidates.

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

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

- investigators or other third parties could conduct clinical studies on our products or product candidates that could lead to adverse events or results that could negatively impact the development, regulatory approval or marketability of such products;

- extension studies on long-term tolerance could invalidate the use of our product;

- final results of studies may not confirm positive interim results or the results of earlier trials;

- results may not meet the level of statistical significance required by the FDA, the EMA or other relevant regulatory agencies to establish the safety and efficacy of our product candidates for continued trial or marketing approval;

- even if data is sufficient for regulatory approval, it may not be sufficient to secure pricing reimbursement or to secure validation of our products by key industry players, which could delay or prevent the commercial launch of a product; and

- our partners or contract research organizations, or CROs, may be unable or unwilling to perform under their contracts.

Furthermore, we sometimes estimate for planning purposes the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies or clinical trials, the submission of regulatory filings or the achievement of commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions, which may cause the timing of achievement of the milestones to vary considerably from our estimates. If we fail to achieve announced milestones in the timeframes we expect, or at all, the commercialization of our product candidates may be delayed, and we may not be entitled to receive certain contractual payments, which could have a material adverse effect on our business, financial condition, results of operations and future growth prospects.

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

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

Clinical trials may not demonstrate statistically sufficient levels of safety and efficacy to obtain the requisite regulatory approvals. The failure of clinical trials to demonstrate safety and efficacy for our desired indications could
harm the development of the relevant product candidate as well as other product candidates employing the same technology, which could have a significant impact on our product pipeline and future growth prospects.

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

We do not currently have the ability to independently conduct clinical trials. With respect to our proprietary product candidates or any other product candidates for which we control the clinical development, we rely on third parties, such as CROs, to conduct clinical trials on our product candidates. For our out-licensed products and product candidates, or for any product candidates where our partner is responsible for clinical development, we rely on such partners to conduct clinical trials. These partners may also hire CROs or other third parties to conduct clinical studies on our products and product candidates. The third parties with whom we and our partners contract for execution of our clinical trials play a significant role in the conduct of these trials and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our clinical trials, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol. The FDA and regulatory authorities in Europe and other jurisdictions require us to comply with regulations and standards, commonly referred to as current good clinical practices, or cGCPs, for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials.

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

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

We and our partners have conducted, currently are conducting and intend in the future to conduct, clinical trials outside the United States, particularly in the European Union where we are headquartered. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted by qualified investigators in accordance with cGCPs, including review and approval by an independent ethics committee and receipt of informed consent from trial patients. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trial conducted outside the United States must be representative of the population for which we intend to seek approval in the United States. In addition, while these clinical trials are subject to applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also comply with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside the United States. If the FDA does not accept the data from any clinical trials that we or our partners conduct outside the United States, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay or permanently halt our ability to develop and market these product candidates for the proposed indications in the United States.
In other jurisdictions, for instance, in Japan, there is a similar risk regarding the acceptability of clinical trial data conducted outside of that jurisdiction. In addition, there are risks inherent in conducting clinical trials in multiple jurisdictions, inside and outside of the United States, such as:

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

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

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

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

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

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

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

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

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

Product candidates employing our antibody technology are subject to extensive and rigorous government regulation. The FDA, the EMA and similar regulatory agencies in other countries regulate the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of biopharmaceutical products. The regulatory review and approval or licensing process is lengthy, expensive and uncertain and requires the submission of extensive pre-clinical and clinical data and supporting information for each indication to establish the product candidate’s safety and efficacy. We or our partners may be unable to obtain regulatory approval on the basis of such data if the relevant regulatory authorities disagree with the design or implementation of the clinical trials, determine that the results of such trials do not meet the requisite level of statistical significance, disagree with our or our partners’ interpretation of such data, determine that we or our partners have not demonstrated the safety and efficacy of the product candidate or that its benefits outweigh its risks or fail to approve the manufacturing processes or facilities for the product candidate. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate’s clinical development and may vary among jurisdictions. Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, particularly as we move towards the commercial stage of our product candidates, we may be required to report some of these relationships to the FDA or other regulatory authorities, as well as to certain national registers or other applicable agencies. The FDA or other regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the integrity of the study. We have not
obtained regulatory approval for any of our proprietary product candidates and it is possible that none of our existing
product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

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

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

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

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

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

As with most biological drug products, use of our products and product candidates could be associated with
undesirable side effects or adverse events which can vary in severity from minor reactions to death and in frequency from
infrequent to prevalent. In particular, many of our and our partners’ clinical trials are conducted in patients with serious
life-threatening diseases for whom conventional treatments have been unsuccessful or for whom no conventional treatment
exists, and in some cases, our product candidates are used in combination with approved therapies that themselves have
significant adverse event profiles. During the course of treatment, these patients could suffer adverse medical events or die
for reasons that may or may not be related to our product candidates. Reports of adverse events or safety concerns could
have negative impacts on our or our partners’ clinical trials, regulatory processes, reputation and results.
Such adverse events or safety concerns involving our products or product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials, or could negatively impact patient enrollment, or completion of, clinical trials. For example, in May 2018, the CALLISTO Phase Ib/II study of daratumumab in combination with atezolizumab in patients with previously treated NSCLC was terminated following a planned review by a data monitoring committee. The data monitoring committee had determined that there was no observed benefit in the combination treatment arm versus atezolizumab alone and observed a numerical increase in mortality-related events, which were subsequently determined to be primarily due to disease progression, in the combination arm of the study. Based on these findings, a Phase I study of daratumumab and Janssen’s proprietary anti-PD-1 antibody for the treatment of patients with MM was also terminated. In addition, in June 2018, a Phase I study of JNJ-63709178, one of the product candidates being developed by Janssen through our DuoBody collaboration was put on clinical hold due to the occurrence of a Grade 3 adverse event. This hold was subsequently lifted and the study is ongoing. However, there can be no assurance that this study will not be halted again or terminated in the future. The Phase I/II clinical trial for our HexaBody-DR5/DR5 product was put on a brief partial clinical hold for discussions with the U.S. FDA around liver toxicity. After the protocol was amended with additional provisions to mitigate liver toxicity risk the partial hold was lifted in October 2019 and enrollment of patients was re-opened. The study is currently recruiting, but there can be no assurance that this study will not be halted again in the future.

In addition, reports of adverse events or safety concerns involving our products or product candidates could result in regulatory authorities limiting, denying, withdrawing approval of or recalling such product for any or all indications, including the use of such product in its previously approved indications, or may require additional clinical trials, updates to the prescribing information, including boxed warnings, contraindications, or other labeling statements, implementation of a Risk Evaluation and Mitigation Strategy or the issuance of field alerts, warnings or other communications to physicians, pharmacies or patients. For example, the prescribing information for Arzerra includes a warning that Arzerra may cause hepatitis B virus, or HBV, infection to reoccur, which may cause serious liver problems and death, and may cause progressive multifocal leukoencephalopathy, or PML, a rare brain infection that causes severe disability and can lead to death. In certain cases, regulatory authorities may order us or our partners to conduct additional trials or to cease further development or commercialization of the product or product candidate entirely.

Furthermore, actual or potential drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete a trial for our products or product candidates. Reports of adverse events or safety concerns, or changes to regulatory approvals or labeling, may also have a significant impact on market acceptance of our products by patients and physicians or may trigger potential product liability claims, fines, injunctions or the imposition of civil or criminal penalties. Any of these events could prevent us or our partners from developing, commercializing or maintaining market acceptance of daratumumab, ofatumumab or the particular product candidate or could substantially increase commercialization costs, which could significantly harm our business, financial condition, results of operations and future growth prospects.

Adverse events may also impact the sales of our products. We may be required to further update the prescribing information for our products, including boxed warnings, limitations of use, contraindications, warnings and precautions, and adverse reactions, based on reports of adverse events or safety concerns, or implement a Risk Evaluation and Mitigation Strategy, or REMS, which could adversely affect the acceptance of our products in the market, make competition easier or make it more difficult or expensive for us to distribute our products.

In addition, the reporting of adverse safety events involving daratumumab, ofatumumab or our product candidates, or public rumors about such events, could cause our stock price to decline or experience periods of volatility. There are no assurances that patients receiving daratumumab, ofatumumab or our product candidates will not experience serious adverse events in the future.
We have received Fast Track Designation, or FTD, and Breakthrough Therapy Designation, or BTD, for certain indications in the past and may seek FTD or BTD, or may seek to participate in other programs for expedited development or review, in the future. We may fail to obtain such designation and may not be eligible for participation in such programs, and even if received, such designations or programs may not lead to a faster development or regulatory review or approval process.

If a product candidate is intended for the treatment of a serious or life-threatening disease or condition, and pre-clinical or clinical data demonstrate the potential to address an unmet medical need for this condition, a product sponsor may apply for FTD from the FDA for such indication. Similarly, the FDA may grant BTD to expedite the development and review of products that treat serious or life-threatening diseases when “preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.” In addition, the FDA or other regulatory bodies periodically introduce other programs for expedited review of applications, including the FDA’s recently released Real-Time Oncology Review, or RTOR, Pilot Program, which is currently available for certain supplemental applications for already-approved cancer drugs, and the FDA’s priority review designation. The RTOR Pilot Program allows the FDA to review data before the applicant formally submits its completed supplemental application, resulting in a more efficient review when the applicant submits the full supplemental application. Priority review is an FDA designation under which the FDA sets the target date for FDA action on a BLA or sBLA at six months after the FDA accepts the application for filing, rather than the standard 10-month FDA review period. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious condition.

Although these designations and pilot programs are intended to expedite the review and approval of drug candidates, they do not ensure that marketing approval will be granted in a particular timeframe or at all. The FDA and other regulatory authorities have broad discretion whether or not to grant these designations or include product candidates within pilot programs, and, even if we or our partners believe a particular product candidate is eligible for these designations or programs, we cannot assure you that such authority would agree. Even if we or our partners receive such designations or are eligible for inclusion in expedited review pilot programs in the future, we may not experience a faster development, review or approval process compared to conventional procedures. In addition, such designations or processing under such pilot programs may be withdrawn if the FDA or the relevant regulatory body no longer believes such product candidate meets the criteria for the designation or program. Furthermore, these designations and pilot programs do not change the scientific and medical standard for approval or the quality of evidence necessary to support approval. As a result, applications for product candidates granted expedited review or BTD or FTD designation may be denied based on study data, study design or other factors. See also “—We and our partners have conducted and intend to conduct additional clinical trials for selected products and product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations due to the study design and conduct, trial population or for other reasons, or may require additional U.S.-based trials.” See “Business—Government Regulation” for more information about BTD and FTD and other programs for expedited review.

Daratumumab has received BTD for three indications of R/R MM and FTD for one indication of R/R MM, ofatumumab has received BTD and FTD, each for one CLL indication and teprotumumab has received BTD and FTD for the treatment of Graves’ Orbitopathy (also known as thyroid eye disease). These products have been approved for each of the designated indications and these designations are not applicable to ongoing studies for daratumumab, ofatumumab and teprotumumab in other indications. We or our partners may seek FTD or BTD or seek eligibility for other expedited review or approval programs for some or all of our other product candidates in the future, but we may never receive such designation or be accepted to such program, and, even if received or accepted, the development or regulatory review of our product candidates may not be expedited or benefited by such designation or program. In addition, such designation or acceptance to such program does not assure ultimate approval by the FDA or the applicable regulatory body.
Enhanced governmental and private scrutiny over, or investigations or litigation involving, pharmaceutical manufacturer donations to patient assistance programs offered by charitable foundations may require us or our partners to modify such programs and could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

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

In addition, there has been regulatory review and enhanced government scrutiny of donations by pharmaceutical companies to patient assistance programs operated by charitable foundations. For example, the Office of Inspector General of the U.S. Department of Health & Human Services, or OIG, has established specific guidelines permitting pharmaceutical manufacturers to make donations to charitable organizations that provide co-pay assistance to Medicare patients, provided that such organizations are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria, and do not link aid to use of a donor’s product. If we, our partners or our vendors or donation recipients are deemed to fail to comply with laws or regulations in the operation of these programs, we or such partner could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. Further, numerous organizations, including pharmaceutical manufacturers, have received subpoenas from the OIG and other enforcement authorities seeking information related to their patient assistance programs and support. We cannot ensure that our compliance controls, policies and procedures will be sufficient to protect against acts of our partners, employees, business partners or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could negatively impact our business practices, harm our reputation, divert the attention of management and increase our expenses.

We currently rely primarily on one contract manufacturer to produce our product candidates for clinical trials and are currently negotiating arrangements for commercial scale production.

To ultimately be successful, our antibody products must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. Janssen is responsible for the manufacture of daratumumab, and Novartis for the manufacture of ofatumumab. For the products we are responsible to manufacture, we currently rely primarily upon one single source third-party contract manufacturing organization, or CMO, Lonza, to manufacture and supply large quantities of our product candidates. As part of our efforts in building our in-house commercialization capabilities, we are currently in negotiations with a CMO for commercial production of tisotumab vedotin if and when approved. If these negotiations are unsuccessful, we believe that additional facilities would be available for commercial production of tisotumab vedotin if and when approved. We expect to negotiate contracts for commercial production on a product-by-product basis for products that we choose to commercialize ourselves.

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

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

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

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

We face intense competition and rapid technological change, which may result in others discovering, developing or commercializing competing products before or more successfully than we do, or earlier than we anticipate.

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Many third parties compete with us in developing various approaches to antibody therapy. They include pharmaceutical companies, biotechnology companies, academic institutions and other research organizations. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approval and marketing than we do. In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies complementary to our programs. In addition, many other pharmaceutical and biotechnology companies are developing and/or marketing therapies for the same types of cancer that our products and product candidates are designed and being developed to treat. For example, Sanofi’s isatuximab, a mAb targeting CD38, was approved as SARCLISA by the FDA in March 2020 for the treatment of adult patients with MM who have received at least two prior therapies including lenalidomide and a PI. We are also aware of other companies that have or are developing technologies that may be competitive with ours, including bispecific, ADC, CAR modified T-cell, or CAR-T, and ribonucleic acid (or RNA)-based, technologies. In addition, our DuoBody and other technology partners may develop compounds utilizing our technologies that may
compete with product candidates that we are developing. See “Business—Competition” below for more information about our competitors.

In addition, in the United States, the Biologics Price Competition and Innovation Act of 2009, or BPCI Act, created an abbreviated approval pathway for biological products that are demonstrated to be “highly similar” or “biosimilar” to or “interchangeable” with an FDA-approved biological product. Under the BPCI Act, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. The 12-year exclusivity period runs from the initial approval of the innovator product and not from approval of a new indication. In addition, the 12-year exclusivity period does not prevent another company from independently developing a product that is highly similar to the innovative product, generating all the data necessary for a full BLA and seeking approval. Exclusivity only assures that another company cannot rely on the FDA’s prior approvals in approving a BLA for an innovator’s biological product to support the biosimilar product’s approval. Further, under the FDA’s current interpretation, it is possible that a biosimilar applicant could obtain approval for one or more of the indications approved for the innovator product by extrapolating clinical data from one indication to support approval for other indications. The BPCI Act is complex and is still being interpreted and implemented by the FDA. As a result, the ultimate impact of the BPCI Act 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 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 BPCI Act, some of which may impact the BPCI Act exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

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

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

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

We may face increased competition from lower-cost products imported from other countries.

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

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

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

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

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

Even if our product candidates obtain significant market share for their approved indications, because certain potential target populations are small, we may never recoup our investment in such product candidate without obtaining regulatory approval for additional indications for such product candidates. In addition, we expect that we or our partners will initially seek approval of some of our product candidates as second- or third-line therapies for patients who have failed other approved treatments, which further limits the size of the potential patient population for such indication. For product candidates that prove to be sufficiently beneficial as second- or third-line therapies, we expect that we or our partners would seek approval of such products as a second-line therapy (with respect to products initially approved as third-line therapies) and/or as frontline therapies. However, such applications may require us or our partners to conduct additional clinical trials at significant cost and risk, and there can be no assurance that such clinical trials or regulatory applications would be successful. If we or our partners are unable to obtain regulatory approval for such products for frontline or second-line therapy, we may be unable to recoup our investment in such products.

We may need to raise additional funding, which may not be available on acceptable terms, or at all, and failure to obtain this capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

We are currently advancing our proprietary product candidates through clinical development and are conducting preclinical studies with respect to other programs. Developing product candidates is expensive, time-intensive and
risky, and we expect our research and development expenses to increase in connection with our ongoing activities, particularly as we seek to advance our proprietary product candidates toward commercialization. In addition, we expect our general and administrative expenses to increase over the next few years as we begin to build and eventually expand our commercialization capabilities in a number of jurisdictions. Although we believe that our existing revenue streams will be sufficient to fund our current projects and commercialization activities, our operating plans may change as a result of a variety of factors, and we may need to seek additional funds sooner than planned through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. Further, we may seek additional capital if market conditions are favorable or if we have specific strategic objectives which could benefit from additional capital.

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

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

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

We also expect our general and administrative expenses to increase over the next few years as we begin to build and eventually expand our commercialization capabilities in a number of jurisdictions. In addition, we expect the structure and composition of our staff and expenses to change as we focus on advancing our proprietary product candidates and develop our late-stage development and commercialization capabilities.
We have revenues and expenses in foreign currencies and we have invested a part of our cash position in both Danish and foreign marketable securities and are therefore exposed to different kinds of financial risks including foreign exchange risk, changes in interest rates and credit risks.

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

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

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

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

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

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

Our computer systems, including those hosted by third parties, and those of our partners and other contractors or consultants, may be vulnerable to cyber security breaches, computer viruses and unauthorized access, as well as damage or loss of data due to natural disasters, terrorism, war and telecommunication and electrical failures. Our vulnerability to such events may increase while employees work remotely to help reduce the spread of COVID-19. Employees may have to use their own devices without dedicated support and security, the number of devices used by employees and the amount of traffic on secured corporate networks can increase, and preventing unauthorized access to networks may be more challenging. These and other factors can be exploited to facilitate phishing, malware or other attacks on our systems. If such an event were to occur, it could result in a material disruption of our development programs and our business operations. In addition, any loss or disclosure of trade secrets, clinical data or other proprietary information as a result of such disruption or breach could subject us to litigation or regulatory review and sanctions and may impact our reputation and our and our partners’ ability to further develop and commercialize our products and product candidates, any of which could have a material adverse effect on our business, financial condition, results of operations and the market price of our ADSs.
We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions or alliances.

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 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 strategic alliances with businesses with promising markets or technologies, we may not be able to realize the benefits of such acquisitions or alliances, 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 alliances. We cannot assure you that we will achieve the expected synergies to justify any such transaction, which could have a material adverse effect on our business, financial condition, results of operations and future growth prospects and our investors’ ability to realize on their investment.

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

As a result of the listing of the ADSs on the Nasdaq Global Select Market, we are subject to the Foreign Corrupt Practices Act, or FCPA, which generally prohibits companies and their intermediaries from making or offering improper payments to non-U.S. officials for the purpose of obtaining or retaining business. The FCPA generally also requires companies listed on a U.S. stock exchange to maintain a system of adequate internal accounting controls and to make and keep books, records and accounts that accurately and fairly reflect transactions and dispositions of assets. Because of the predominance of government-sponsored health care systems around the world, many of our commercial relationships outside the United States are with governmental entities, and personnel of such entities may be considered non-U.S. officials for purposes of the FCPA. Violations of the FCPA and other applicable anti-bribery laws are punishable by criminal fines and imprisonment, civil penalties, disgorgement of profits, injunctions and debarment from government contracts as well as other remedial measures. We have adopted an amended written code of business conduct and other policies and procedures to assist us and our personnel in complying with the FCPA and other applicable anti-bribery laws. However, our personnel and others acting on our behalf could take actions that violate these requirements, which could adversely affect our reputation, business, financial condition and results of operations.

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

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, the COVID-19 coronavirus has spread worldwide and has been declared a global pandemic. COVID-19 has resulted in global business and economic disruption, as many jurisdictions have prohibited international travel and implemented social distancing, quarantine and similar measures for their residents to contain the spread of the coronavirus. COVID-19 is also expected to put a strain on the healthcare systems in the major countries where our partners sell our products and where we and they conduct our clinical trials. The global outbreak of COVID-19 continues to rapidly evolve. The COVID-19 pandemic may be prolonged and may have long-term impacts on the development, regulatory approval and commercialization of our product candidates and on sales of our approved products. The longer the pandemic continues, the more severe the impacts described below will be on our business. The extent, length and consequences of the pandemic are uncertain and impossible to predict Genmab has established a COVID-19 response team, led by the CEO, that is closely monitoring the evolving situation and has developed and implemented precautionary measures, including remote working for the majority of Genmab employees with a small subset of employees on-site to maintain critical laboratory activities that cannot be done remotely. The response team issues regular updates to employees with guidance to help limit the impact of COVID-19 at our workplace and on our communities and ensure business continuity.
The continued spread of COVID-19 globally could adversely affect our and our partners’ ability to recruit and retain patients and principal investigators, site staff and other resources for clinical trials, as hospitals and other healthcare providers prioritize resources toward the outbreak and travel restrictions and social distancing impede patient and staff mobility. This is expected to result in delays or deferrals of affected clinical trials. Any changes in clinical trial practices and policies imposed by regulators in response to COVID-19 may also contribute to such delays or deferrals or cause the costs of clinical trials to increase. As the COVID-19 pandemic and global measures to contain it are still developing, the full extent of the impact of COVID-19 on the clinical development of our product pipeline cannot currently be determined, although such impact may be significant.

COVID-19 may also affect our employees and the employees of our third-party CROs located in affected geographies that we rely upon to carry out our clinical trials. Such employees may be unable to work as a result of sickness or becoming caregivers to sick family members, or may be delayed or limited in their ability to work as a result of measures such as mandatory remote work or suspension of travel. This may, among other things, limit the CROs’ ability to commence and conduct our or our partners’ clinical trials, as well as to analyze the data from clinical trials that have been completed. For example, this could cause a delay of the analysis of data from innovaTV 204, a potentially registrational Phase II study to assess tisotumab vedotin for the treatment of cervical cancer in certain patients, thereby delaying any corresponding regulatory submission. Limitations on the work of our employees as a result of COVID-19 may also affect progress on our preclinical pipeline, as access to activities in our research laboratories may be partially or completely restricted.

Delay in presentation of data analysis, disruptions in the business of the FDA or other health authorities as a result of COVID-19 and related containment measures, or delays in necessary interactions with the FDA, other health authorities, local regulators, and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees, could result in delays of reviews and approvals, including with respect to our product candidates. For example, this could cause a delay in the approval by U.S. and European regulatory authorities of the subQ formulation of daratumumab based on the Phase III COLUMBA study and preliminary data from the Phase II PLEIADES study, and of ofatumumab for the treatment of RMS based on data from the ASCLEPIOS studies.

Disruption in shipping and manufacturing may also negatively affect our supply chain, causing our partners or producers of comparator drugs used in our clinical trials and their respective suppliers to be unable to produce and ship materials required for use in our clinical trials, in sufficient quantities or at all, leading to delay in, or termination of, our and our partners’ clinical trials. Supply chain disruption may also affect the manufacturing, shipment and commercialization of approved products.

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

The impact of COVID-19 could affect sales of DARZALEX for existing indications, which could reduce our royalty income pursuant to our collaboration with Janssen. Should the resources of healthcare systems worldwide, including in the United States and Europe, become more severely strained by their response to the pandemic or if such strain is prolonged, resources previously devoted to the diagnosis and treatment of MM may be redeployed to addressing COVID-19, resulting in fewer prescriptions and sales of DARZALEX. Additionally, many patients who currently receive DARZALEX are elderly and immunocompromised and, therefore, more susceptible to severe negative impacts from COVID-19. Such patients may be unable to travel to healthcare facilities to receive DARZALEX treatment as a result of mandatory or self-imposed restrictions on local travel or other social distancing measures. Should they contract COVID-19, they may become unable to continue with their DARZALEX treatment, and many such patients may die. Should treatment of current patients with DARZALEX be temporarily deferred or should such patients die, or should there be a delay or reduction in diagnoses of new MM patients and treatment prescriptions as healthcare resources are redeployed, demand for DARZALEX may be reduced. This would lead to a corresponding reduction in DARZALEX sales and a resulting decrease in our revenues from royalties under our collaboration with Janssen, which would adversely affect our financial performance. In addition, the pandemic could result in delays in clinical development, regulatory approval and commercialization of DARZALEX for additional indications.
The full extent and nature of the impact of the COVID-19 pandemic and related containment measures on our business and financial performance is uncertain as the situation continues to develop. The factors discussed above, as well as other factors which are currently unforeseeable, may result in further and other unforeseen material adverse impacts on our business and financial performance, including on the sales of Arzerra and teprotumumab, marketed as TEPEZZA, by our partners and on our royalty and milestone income therefrom.

**Risks Related to Our Intellectual Property**

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

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

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

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

- we or our partners may not have been the first to make or file patent applications for the inventions covered by pending patent applications or issued patents;
- others may independently develop identical, similar or alternative technologies, products or compositions and use thereof;
- any or all of our or our partners’ pending or any future patent applications may not result in issued patents;
- any patents issued to us or our partners may not provide a basis for commercially viable products, or may not provide any competitive advantages in countries of significant business opportunity;
- third parties may initiate interference, re-examination, post-grant review, inter partes review, or derivation actions in the U.S. Patent and Trademark Office, or USPTO, or oppositions in the European Patent Office, or EPO, or observations or protests, or any similar actions in other patent administrative or court proceedings worldwide that challenge the validity, enforceability or scope of such patents, which may
result in our patent claims being narrowed or invalidated which could limit our ability to prevent competitors from developing and marketing similar products;

· our or our partners’ technologies, compositions and methods may not be patentable;

· others may design around our or our partners’ patent claims to produce competitive products or uses which fall outside of the scope of our patents;

· third parties may have blocking patents that could prevent us from marketing our products or practicing our own patented technology;

· patent terms may be inadequate to protect our competitive position on our technologies, products and product candidates for an adequate amount of time; or

· the Supreme Court of the United States, other U.S. federal courts, Congress, the USPTO or similar foreign authorities may change the standards of patentability and any such changes could narrow or invalidate, or change the scope of, or change the patent lifetime of, our or our partners’ patents.

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

Any or all of our or our partners’ pending or any future patent applications may not result in issued patents. The determination of patentability by the relevant patent office is complex and may take several years, the breadth of allowed claims is uncertain, and the patent applications may ultimately be denied or result in issued patents with allowed claims that differ from those in the original application. Even if patents do successfully issue and even if such patents cover our technologies, products, product candidates, compositions and methods of use, third parties may initiate interference, re-examination, post-grant review, inter partes review, or derivation actions in the USPTO, third-party oppositions in the EPO or observations or protests, or similar actions challenging the validity, enforceability or scope of such patents in other patent administrative proceedings worldwide, which may result in our or our partners’ patent claims being narrowed or invalidated. Such proceedings could result in revocation or amendment of such patents in such a way that they no longer cover our technologies, product candidates or competitive products. Further, if we or our partners initiate legal proceedings against a third party to enforce a patent covering our product, product candidate or technology, the defendant could counterclaim that the patent covering our product, product candidate or technology is invalid or unenforceable. In patent litigation in the United States, certain European and other countries worldwide, it is commonplace for defendants to make counterclaims alleging invalidity and unenforceability in the same proceeding, or to commence parallel defensive proceedings such as patent nullity actions to challenge validity and enforceability of asserted patent claims.

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

Further, we cannot be certain that all of the potentially relevant art relating to our patents and patent applications has been cited in every patent office. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technologies, products, product candidates, compositions and methods of use.
Patents issued to our partners may offer protection for sales of the relevant products by our partners against competition from biosimilars or otherwise, but we will only be entitled to royalties and other payments on those sales to the extent provided by the terms of the relevant agreements with our partners.

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

We currently in-license certain intellectual property from third parties to be able to use such intellectual property in our products and product candidates and to aid in our research activities. In the future we may in-license 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 intellectual property we license from them. We have limited control over these activities or any other 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 intellectual property that is licensed to us.

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

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

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful and have a material adverse effect on the success of our business.

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

In addition, the standards that courts use to interpret patents are not always applied predictably or uniformly and can change, particularly as new technologies develop. As a result, we cannot predict with certainty how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court. Further, even if we prevail against an infringer in a U.S. district court or foreign trial-level court, there is always the risk that the infringer will file an appeal and the initial court judgment will be overturned at the appeals court and/or that an adverse decision will be issued by the appeals court relating to the validity or enforceability of our patents. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted in a manner insufficient to achieve our business objectives.

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

Claims that our products or product candidates or their uses infringe the intellectual property rights of third parties could result in costly litigation, and unfavorable outcomes could require us to pay damages or royalties and could limit our research and development activities or our ability to commercialize certain products.

Even if we or our partners have or obtain patents covering our technologies, products, product candidates, compositions or uses, we or our partners may still be barred from making, using, importing or selling or otherwise exploiting our products, product candidates or technologies because of the patent rights of others. Our competitors have filed, and in the future may file, patent applications covering technology, compositions or products and uses that are similar or identical to ours. There are many issued U.S., European and other worldwide patents relating to therapeutic drugs, and some of these may relate to compounds we or our partners intend to commercialize. Numerous worldwide patents and pending patent applications owned by others exist in the cancer field and may cover products or product candidates which we or our partners are developing. It is difficult for industry participants, including us, to identify all third-party patent rights relevant to our products, product candidates and technologies. We cannot guarantee that our technologies, products, product candidates, compositions and their uses do not or will not infringe third-party patent or other intellectual property rights. Because patent applications usually take 10 months to publish and many years to issue, there may be currently pending applications with patent claims unknown to us or which will change over time and may later result in issued patents that purportedly cover our technologies, products, product candidates or compositions and uses. These patent applications may have been filed earlier than or have priority over patent applications filed by us or our partners. We may be required to develop or obtain alternative technologies, review product design or, in the case of claims concerning registered trademarks, rename our products or product candidates.

34
Claims that our or our partners’ technologies, products, product candidates, compositions or their uses infringe or interfere with the patent rights of third parties, or that we or our partners have misappropriated third-party trade secrets, could result in costly litigation and could require substantial time and money to resolve, even if litigation were avoided. The basis of such litigation could be existing patents or patents that are granted in the future. If we or our partners were to face infringement claims or challenges by third parties, an adverse outcome could subject us or our partners to significant liabilities to such third parties. Litigation or threatened litigation could result in significant demands on the time and attention of our management team. A negative outcome could expose us or our partners to payment of costs, damages and other financial remedies, including in some jurisdictions, increased damages, such as treble damages and attorneys’ fees, if we were found to have willfully infringed a patent. Litigation with third parties concerning alleged infringement of their intellectual property rights could require us and our partners to bear substantial costs and impose burdens on our and their management and personnel, even if we or our partners were to ultimately succeed in such proceedings. Costs of patent litigation and awards of damages in patent infringement cases can be significant, and equitable remedies such as temporary restraining orders and injunctions can negatively impact or prevent product development and commercialization. A negative outcome could also lead us or our partners to delay, curtail or cease the development and commercialization of some or all of our products and product candidates, or could cause us or our partners to seek legal or administrative actions against third parties. We or our partners may need to obtain licenses from third parties and such licenses may not be available on commercially reasonable terms, or at all. Even if we are able to obtain licenses from a third party to resolve a dispute, such settlement arrangements could involve substantial costs including one-time and/or ongoing royalty payments.

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

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

Further, our competitors may independently develop knowledge, methods and know-how similar, equivalent, or superior to our proprietary technologies. Competitors could purchase our products and attempt to reverse engineer and replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technologies, or develop their own competitive technologies that fall outside of our intellectual property rights. In addition, our key employees, consultants, suppliers or other individuals with access to our proprietary technologies and know-how may incorporate such technologies and know-how into projects and inventions developed independently or with third parties. As a result, disputes may arise regarding the ownership of the proprietary rights to such technologies or know-how, and any such dispute may not be resolved in our favor. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us and our competitive position could be adversely affected. If our intellectual property is not adequately protected so as to protect our market against competitors’ products and processes, our competitive position could be adversely affected, as could our business.
We will not seek to protect our intellectual property rights or technologies in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

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

The requirements for patentability may differ from country to country, particularly in developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals or biotechnologies. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. Also, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties if the patents are not being exploited within a certain time period. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country or region-by-region basis, which is an expensive and time consuming process with uncertain outcomes. If we fail to timely file a patent application in a specific country or major market, we may be precluded from doing so at a later date. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Proceedings and legal actions to enforce our patent rights in the United States or in Europe and in foreign jurisdictions can be expensive, could result in substantial costs, and could divert management time and our efforts and attention from other aspects of our business. In addition, such proceedings or legal actions could put our patents at risk of being invalidated, found unenforceable or interpreted narrowly, could put our patent applications at risk of not being issued and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. We may or may not choose to pursue litigation or other actions against those that have infringed our patents, or used them without authorization, due to the associated expense and time commitment of monitoring these activities. If we fail to protect or to enforce our intellectual property rights successfully, our competitive position could suffer, which could harm our results of operations.

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

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

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

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

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

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

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

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

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

Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our partners fail to maintain the patents and patent applications
covering our products, product candidates, technologies or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our own, which would have a material adverse effect on our business.

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

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

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

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

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

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

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

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

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

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

**Risks Related to Government Regulation**

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

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

Further, from time to time, typically on an annual basis, payment rates are updated and revised by third-party payors. Such updates could impact the demand for our products, to the extent that patients who are prescribed our products, if approved, are not separately reimbursed for the cost of the product. For example, Medicare reimbursement under the Medicare Physician Fee Schedule is updated on an annual basis. The Medicare Access and CHIP Reauthorization Act of 2015 instituted a 0.5% payment update for July 2015 through the end of 2019, and a 0% payment update for 2020 through 2025, along with a merit-based incentive payment system beginning January 1, 2019, that will replace current incentive programs. For 2026 and subsequent years, the payment update will be either 0.75% or 0.25% depending on which Alternate Payment Model the physician participates.

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

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

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

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

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

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

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

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

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

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our products and product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States, the European Union or in other countries. We expect more rigorous coverage criteria in the future in the U.S. healthcare market and an additional downward pressure on the prices that we or our partners receive for approved products, which may trigger a similar reduction in payments from private payors. If we or our partners are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we and our partners are not able to maintain regulatory compliance, we or they may lose any marketing approval that we or they may have obtained, which could adversely impact our business and financial results.

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

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2027 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the U.S. government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our out-licensed products and product candidates (if and when approved) and accordingly, our financial results.
Furthermore, the Trump Administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA’s ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuing guidance, and reviewing and approving marketing applications. It is difficult to predict how these orders will be implemented and the extent to which they will impact the FDA’s ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA’s ability to engage in oversight and implementation activities in the normal course, we and our partners could be limited and/or delayed in obtaining new regulatory approvals or maintaining existing approvals, either of which could have a material adverse effect on our business, financial condition, results of operations and future growth prospects.

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

Numerous countries in which we, our partners and our third-party contractors, including CROs and CMOs, operate, manufacture and sell our products have, or are developing, laws protecting personal data and the individual’s right to privacy as well as the confidentiality of certain patient health information. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU General Data Protection Regulation, or the GDPR, which became applicable on May 25, 2018, introduced new data protection requirements in the European Economic Area (the 28 member states of the European Union plus Iceland, Liechtenstein and Norway), or the EEA, and substantial fines for infringements of the data protection rules. For several EEA jurisdictions, the GDPR expanded significantly the jurisdictional reach of EEA data protection law by extending the law’s application to the processing of personal data in connection with the offering of goods or services to data subjects located in the EEA and processing personal data in connection with monitoring the behavior of data subjects located in the EEA. The GDPR imposes several increased obligations and specific restrictions on controllers and processors processing personal data including, for example, additional requirements in relation to the information obligation, where applicable, higher standards for organizations to demonstrate compliance, such as obtaining of valid consent or assessment of another legal basis to justify the data processing activities, increased requirements pertaining to health data (including, in certain situations, where such data is key-coded), mandatory data breach notification requirements, appointment of a data protection officer where the core activities of the controller or the processor consist of processing of sensitive personal data (i.e., health data) on a large scale, additional mandatory requirements for the content of data processing agreements with service providers processing personal data, implementation of appropriate technical and organizational measures and expanded rights for individuals over their personal data. This could affect our and our partners or third-party contractors’ ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting, or could cause our costs to increase, potentially leading to harm to our business and financial condition. If the measures implemented by us or our partners or service providers in order to comply with the GDPR requirements are not considered sufficient to ensure the necessary compliance level, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to €20 million or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity and a potential loss of business. Claims that we have violated individuals’ privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

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

In addition to the GDPR, we, our partners and our third-party contractors are subject to similar data privacy and confidentiality laws in other countries in which we or they operate or market our products. Such laws and regulations may also impose costly compliance obligations and potentially significant fines or other penalties for non-compliance.
Our operations involve hazardous materials and we and third parties with whom we contract must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

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

We are subject to healthcare laws and regulations, which may require substantial compliance efforts and could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings, among other penalties.

Healthcare providers, such as physicians and others, play a primary role in the recommendation and prescription of our products. Our or our partners’ arrangements with such persons and third-party payors and our general business operations will expose us or our partners to broadly applicable fraud and abuse regulations, as well as other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our products. Restrictions under applicable U.S. federal and state and non-U.S. healthcare laws and regulations include, but are not limited to, the Anti-Kickback Statute, the Beneficiary Inducement Statute, the Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, federal civil and criminal false claims laws and civil monetary penalties laws, including the civil False Claims Act, the federal transparency requirements under the Physician Payments Sunshine Act and analogous U.S. state laws. Rules and regulations covering many of the same matters are found in numerous other countries, including in Denmark, and may be more stringent or result in higher exposures than those in the United States.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could substantially disrupt our operations. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. For more information about these and other applicable regulations, see “Business—Government Regulation” below.
Our employees and partners may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements, which could significantly harm our business.

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

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

ADS holders do not directly hold our shares.

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

In addition to voting rights, holders’ right to receive any dividends we declare on our shares, whether in the form of cash or bonus securities, is also more limited than that of our shareholders. For example, we may elect to offer subscription rights to our shareholders without offering such rights directly to ADS holders as such subscription rights will be offered to the depositary as shareholder. The depositary has substantial discretion as to what will happen with any offered subscription rights and may determine that it is not legal or reasonably practicable to make such rights available to ADS holders, in which case the depositary will endeavor to sell such rights and distribute the proceeds to ADS holders, which it may not be able to do at the then-current market price or at all. If the depositary is unable to distribute or sell such rights, they will lapse, and ADS holders will receive no value. For more information, see the description of our securities registered under section 12 of the Exchange Act included as an exhibit to this Annual Report.

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

The market prices of the ADSs and shares may be volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for the ADSs and shares may be influenced by many factors, including, but not limited to:
• actual or anticipated fluctuations in our financial condition and operating results;
• the release of new data from the clinical trials of our products and product candidates;
• actual or anticipated changes in our growth rate relative to our competitors;
• competition from existing products or new products that may emerge;
• announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
• failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
• issuance of new or updated research or reports by securities analysts;
• fluctuations in the valuation of companies perceived by investors to be comparable to us;
• currency fluctuations;
• price and volume fluctuations attributable to inconsistent trading volume levels of our ADSs;
• additions or departures of key management or scientific personnel;
• disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies, products and product candidates;
• changes to coverage policies or reimbursement levels by commercial third party payors and government payors and any announcements relating to coverage policies or reimbursement levels;
• announcement or expectation of additional debt or equity financing efforts;
• issuances or sales of our shares or ADSs by us, our insiders or our other shareholders or ADS holders; and
• general economic and market conditions.

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

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the price of the ADSs and their trading volume could decline.

The trading market for the ADSs and shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. We are currently followed by analysts, but there can be no assurance that these analysts will continue to follow us or that additional securities or industry analysts will commence coverage of us. If no or only limited securities or industry analysts cover our company, the trading price for the ADSs would be negatively impacted. If one or more of the analysts who covers us downgrades our equity securities, publishes inaccurate
or unfavorable research about our business or expresses a negative opinion regarding the performance of our securities, or if our clinical trial results or operating performance fail to meet analyst expectations, the price of the ADSs would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, or downgrades our securities, demand for ADSs could decrease, which could cause the price of the ADSs and their trading volume to decline.

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

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

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

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

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

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

The deposit agreement governing the ADSs provides that the depositary may, in its sole discretion, require that any dispute or difference arising from the relationship created by the deposit agreement be referred to and finally settled by an arbitration conducted under the terms described in the deposit agreement, although the arbitration provisions do not preclude you from pursuing claims under U.S. federal securities laws in federal courts. Furthermore, if a holder is unsuccessful in such arbitration, the holder may be responsible for the fees of the arbitrator and other costs in connection with such arbitration pursuant to the deposit agreement.
In addition, the deposit agreement provides that, subject to the depositary’s right to require a claim to be submitted to arbitration, the federal or state courts in the City of New York have non-exclusive jurisdiction to hear and determine claims arising under the deposit agreement and in that regard, to the fullest extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws.

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

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

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

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

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

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

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

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

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

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

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

As a foreign private issuer, we are not required to comply with all the periodic disclosure and current reporting requirements of the Exchange Act and related rules and regulations. While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually on the last business day of an issuer’s most recently completed second fiscal quarter and, accordingly, we could lose our foreign private issuer status in the future. We will next make a determination with respect to our foreign private issuer status on June 30, 2020.

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

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

A non-U.S. corporation will be a passive foreign investment company, or 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, or the 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, 2020 or in the foreseeable future.
However, the determination of whether or not we are a PFIC according to the PFIC rules is made on an annual basis and will depend on the nature and composition of our income and assets and the value of our assets from time to time. Therefore, changes in the nature and composition of our income or assets or the value of our assets may cause us to become a PFIC. The determination of the value of our assets (including goodwill not reflected on our balance sheet) may be based, in part, on the total market value of our shares and ADSs, which is subject to change and may be volatile.

If we are a PFIC for any taxable year during which a U.S. person holds ADSs, certain adverse U.S. federal income tax consequences could apply to such U.S. person. See “Item 7.E—Taxation—Material U.S. Federal Income Tax Considerations—Passive Foreign Investment Company Considerations.”

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

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

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

**ITEM 4 INFORMATION ON THE COMPANY**

**A. History and Development of the Company**

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

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

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

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

As a company with less than $1.07 billion in revenue during our last fiscal year, we qualify as an “emerging growth company,” as defined in the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act.

We may choose to take advantage of some but not all of these reduced burdens, and therefore the information that we provide holders of shares and ADSs may be different than the information you might receive from other public companies in which you hold equity.

We may take advantage of these provisions for up to five years following the date of our initial public offering in the United States or such earlier time that we are no longer an emerging growth company. We will cease to be an emerging growth company upon the earliest of the following:

- the last day of the first fiscal year in which our annual revenues were at least $1.07 billion;
- the last day of the fiscal year following the fifth anniversary of our initial public offering in the United States;
- the date on which we have issued more than $1 billion of non-convertible debt securities over a three-year period; and
- the last day of the fiscal year during which we meet the following conditions: (i) the worldwide market value of our common equity securities held by non-affiliates as of our most recently completed second fiscal quarter is at least $700 million, (ii) we have been subject to U.S. public company reporting requirements for at least 12 months and (iii) we have filed at least one annual report as a U.S. public company.

B. BUSINESS OVERVIEW

We are an international biotechnology company specializing in antibody therapeutics for the treatment of cancer and other diseases. Our core purpose is to improve the lives of patients by creating and developing innovative antibody products. Our vision is to transform cancer treatment by launching our own proprietary product by 2025 and advancing our pipeline of differentiated and well-tolerated antibodies. We are building and expanding our late-stage development and commercial capabilities to allow us to bring our proprietary products to market in the future. We are continuing to build a well-diversified portfolio of products, product candidates and technologies.

In addition to a broad pipeline of differentiated product candidates, our portfolio includes three approved partnered products; daratumumab, marketed by Janssen Biotech, Inc. as DARZALEX for the treatment of certain indications of multiple myeloma, or MM, ofatumumab, marketed as Arzerra by Novartis AG for the treatment of certain indications of chronic lymphocytic leukemia, or CLL, and teprotumumab, approved as TEPEZZA for the treatment of thyroid eye disease. We also have a strong pipeline of novel antibody-based product candidates for the treatment of solid tumors and hematological cancers, which are designed to address unmet medical needs and improve treatment outcomes for cancer patients. Our goal in building our pipeline is to retain at least 50% of product rights in selected programs and in geographic areas where we believe we will be able to maximize their value; we consider such products to be “our own” proprietary products. We currently have seven proprietary product candidates in clinical development: tisotumab vedotin, enapotamab vedotin, HexaBody-DR5/DR5, epcoritamab (DuoBody-CD3xCD20), DuoBody-PD-L1x4-1BB, DuoBody-CD40x4-1BB and DuoHexaBody-CD37. In addition, the first Clinical Trial Applications (CTAs) for DuoBody-CD3x5T4 were submitted to authorities in Denmark and Spain in January 2020, followed by the Investigational New Drug (IND) application, which was submitted to the FDA in February 2020. We also have approximately 20 proprietary and partnered pre-clinical programs, including two proprietary product candidates for which we intend to submit INDs to the FDA and/or CTAs to the EMA in 2020. In addition to our proprietary clinical
product candidates and our partners’ ongoing label expansion studies for daratumumab and ofatumumab, our partners have
ten additional product candidates in clinical development through collaboration agreements with us. Our portfolio also
includes four proprietary antibody technology platforms: (i) our DuoBody platform, which can be used for the creation and
development of bispecific antibodies; (ii) our HexaBody platform, which can be used to increase the potential potency of
antibodies through hexamerization; (iii) our DuoHexaBody platform, which enhances the potential potency of bispecific
antibodies through hexamerization; and (iv) our HexElect platform, which combines two HexaBody molecules to
maximize potential potency while minimizing potential toxicity by more selective binding to desired target cells. Antibody
products created with these technologies may be used in a wide variety of indications including cancer and autoimmune,
central nervous system and infectious diseases. These platforms play a key role in building our product pipeline, enhancing
our partnerships and generating revenue. We selectively enter into strategic alliances 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 chart summarizes the disease indications and most advanced development status of our marketed
products, each of the proprietary product candidates in our clinical pipeline and the most advanced product candidates in
our pre-clinical pipeline.

### Approved Products in Collaboration and Proposed Label Expansions

<table>
<thead>
<tr>
<th>Product</th>
<th>Target</th>
<th>Rights</th>
<th>Disease Indications</th>
<th>Most Advanced Development Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Pre-Clinical I II III Approved</td>
<td></td>
</tr>
<tr>
<td>Daratumumab</td>
<td>CD38</td>
<td>Janssen (Tiered royalties to Genmab on net global sales)</td>
<td>Multiple myeloma&lt;sup&gt;1&lt;/sup&gt; AL Amyloidosis Non-MM blood cancers</td>
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<tr>
<td>Ofatumumab</td>
<td>CD20</td>
<td>Novartis (Royalties to Genmab on net global sales)</td>
<td>Chronic lymphocytic leukemia&lt;sup&gt;1,2&lt;/sup&gt;</td>
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</tr>
<tr>
<td>Teprotumumab</td>
<td>IGF-1R</td>
<td>Horizon Therapeutics (under sublicense from Roche, royalties to Genmab on net global sales)</td>
<td>Thyroid eye disease&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
</tr>
</tbody>
</table>

<sup>1</sup> Indicates approved for the indication.

<sup>2</sup> Indicates ongoing label expansion studies.

51
### Proprietary Product Candidates

<table>
<thead>
<tr>
<th>Product</th>
<th>Target</th>
<th>Rights</th>
<th>Disease Indications</th>
<th>Most Advanced Development Phase</th>
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<tr>
<td>Tesatumab vedotin</td>
<td>TF</td>
<td>5b-50 Gemtab/Seattle Genetics</td>
<td>Cervical cancer</td>
<td>Pre-Clinical, I, III, II, III, Approved</td>
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<td>Gemtab</td>
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<td>Solid tumors</td>
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<tr>
<td>HexalBody-DRS/DR5</td>
<td>DR5</td>
<td>Gemtab</td>
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<td>Epicrinthelab</td>
<td>CD3,CD20</td>
<td>Gemtab</td>
<td>Hematological malignancies</td>
<td>Solid tumors</td>
</tr>
<tr>
<td>DonBody-PD-L1x4-1BB</td>
<td>PD-L1,</td>
<td>Gemtab</td>
<td>Solid tumors</td>
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<tr>
<td>DonBody-C4d4x-1BB</td>
<td>CD47</td>
<td>Gemtab</td>
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<tr>
<td>DonhexaBody-C037</td>
<td>CD37</td>
<td>Gemtab</td>
<td>Hematological malignancies</td>
<td>Solid tumors</td>
</tr>
<tr>
<td>IND/CATa Filled</td>
<td>CD3,ST4</td>
<td>Gemtab</td>
<td>Solid tumors</td>
<td></td>
</tr>
</tbody>
</table>

### Pipeline Products in Collaboration

<table>
<thead>
<tr>
<th>Product</th>
<th>Target</th>
<th>Partner</th>
<th>Disease Indications</th>
<th>Most Advanced Development Phase</th>
</tr>
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<tbody>
<tr>
<td>Olometumab</td>
<td>CD20</td>
<td>Novartis</td>
<td>Relapsing MS</td>
<td>Pre-Clinical, I, III, II, III, Approved</td>
</tr>
<tr>
<td>Camidotumab tibesine</td>
<td>CD25</td>
<td>ADC Therapeutics</td>
<td>Relapsed Refractory Hodgkin Lymphoma</td>
<td>Solid tumors</td>
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<tr>
<td>Min8</td>
<td>Fk(a),</td>
<td>FX</td>
<td>Novo Nordisk</td>
<td>Healthy volunteers &amp; hemophilia A</td>
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<tr>
<td>JNJ-61185372</td>
<td>EGFR,</td>
<td>Janssen</td>
<td>Non-small cell lung cancer (NSCLC)</td>
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</tr>
<tr>
<td>JNJ-63705178</td>
<td>CD123,CD2</td>
<td>Janssen</td>
<td>Acute Myeloid Leukemia (AML)</td>
<td></td>
</tr>
<tr>
<td>JNJ-64007087</td>
<td>BCMA,CD3</td>
<td>Janssen</td>
<td>Relapsed or refractory MM</td>
<td></td>
</tr>
<tr>
<td>JNJ-64407864</td>
<td>DPSCD,CD3</td>
<td>Janssen</td>
<td>Relapsed or refractory MM</td>
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<tr>
<td>JNJ-67071244</td>
<td>CD33,CD3</td>
<td>Janssen</td>
<td>Relapsed or refractory AML or MDS</td>
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<tr>
<td>JNJ-63890081</td>
<td>PSMA,CD3</td>
<td>Janssen</td>
<td>Solid tumors</td>
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<tr>
<td>HuMax-IL8</td>
<td>IL8</td>
<td>BMS</td>
<td>Advanced cancers</td>
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<tr>
<td>Lu-PF82622</td>
<td>alpha-Synuclein</td>
<td>Lundbeck</td>
<td>Parkinson’s disease</td>
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</tr>
<tr>
<td>~20 active pre-clinical programs</td>
<td></td>
<td></td>
<td>Partnered &amp; proprietary programs: HuTab, DuBody, Ducotebody and HexalBody</td>
<td></td>
</tr>
</tbody>
</table>

1. See local country prescribing information for precise indications
2. Not in active clinical development. In 2019, the marketing authorization for Arzerra was withdrawn in the EU and several other territories.
3. Certain product candidates in development with partners, as noted
4. Novartis initiated sBLA submission to FDA for ofatumumab in RMS in December 2019, MAA to EMA in January 2020
Our Business Strategy

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

- **Collaborate with Janssen to advance daratumumab.** Janssen is seeking to extend the commercial reach of daratumumab through label expansion. We will continue to contribute to the development strategy for daratumumab through a joint development and steering committee with Janssen.

- **Collaborate with Novartis to advance ofatumumab.** Novartis is investigating the use of ofatumumab for the treatment of RMS. In December 2019, Novartis initiated submission of an sBLA to the FDA for ofatumumab in RMS and submitted an MAA to the EMA in January 2020.

- **Actively advance and expand our proprietary product pipeline.** We are actively advancing our promising proprietary product candidates through development and seek to expand our proprietary product pipeline by developing new products in-house and by partnering selectively. We have identified several key clinical milestones for our proprietary product candidates in 2020 that, if met, will continue to advance our pipeline and validate our technology platforms, including: (i) safety and efficacy analysis from the potentially registrational Phase II study of tisotumab vedotin in recurrent and metastatic cervical cancer and engagement with the FDA for BLA submission subject to trial results; (ii) tisotumab vedotin data for solid tumor types other than cervical cancer; (iii) data to support late stage development for enapotamab vedotin; (iv) decision on recommended Phase II dose for epcoritamab (DuoBody-CD3xCD20) and initiation of expansion cohorts; (v) advance dose escalation in Phase I/II trial of HexaBody-DR5/DR5 (vi) initiate expansion cohorts in the Phase I/II trial of DuoBody-PD-L1x4-1BB and report initial data; (vii) submission of INDs and/or CTAs for our proprietary HexaBody-CD38 and DuoBody-CD3x5T4, preclinical product candidates.

- **Strengthen our product portfolio with strategic collaborations.** We enter into strategic product and technology alliances to build our network in the biotechnology space and to strengthen our portfolio with complementary novel technologies or products. Key partnerships include our DuoBody collaborations with Janssen, BioNTech and Novo Nordisk, our product collaboration with Seattle Genetics for tisotumab vedotin, our strategic collaborations with Immatics to discover and develop potential next-generation bispecific cancer immunotherapies and with CureVac AG to develop differentiated mRNA-based antibody products and our collaboration with Janssen to develop a next-generation CD38 product using our HexaBody technology platform. Our partners are also developing a number of product candidates in our pipeline, including ten product candidates currently in clinical development, in addition to ongoing label expansion studies for daratumumab and ofatumumab by Janssen and Novartis, respectively. We constantly evaluate partnership opportunities for our existing or future pipeline assets and regularly engage in related discussions with potential partners.

- **Leverage our proprietary technology platforms.** Our leading proprietary antibody technology platforms play a key role in building our product pipeline, enhancing our partnerships and generating revenue. Multiple new product candidates are currently being developed by us and our partners using our technology platforms, including three proprietary product candidates created with our DuoBody, HexaBody and DuoHexaBody technologies for which we submitted three INDs in 2019 and plan to submit two INDs and/or CTAs in 2020. We actively seek partners interested in developing potential antibody therapeutics using our technologies.

- **Build our translational research capabilities.** Leveraging our expertise in antibody technologies and product development, we are expanding our translational research capabilities with the goal of building a library of antibody therapeutics that can be tailored to patients. Our translational research capabilities will be designed to profile and catalog patient tumor and immune genotype/phenotype and match our antibody therapies with appropriate patient populations. In addition, we intend to expand our data science capabilities with the aim to probe our clinical and translational data. To this end in September 2019, we entered into a multi-year collaboration with Tempus, a privately-owned technology company that has built the world’s largest library of clinical and molecular data. This agreement, which builds upon existing service agreements between the
companies, will combine Tempus’ sequencing capabilities and industry-leading platform of integrated clinical and molecular data with Genmab’s state-of-the-art translational, biomarker and target discovery expertise.

- **Build our commercial capabilities to market select products.** We are currently in the early stages of building and expanding our commercial capabilities to allow us to market our own products in the future for the indications and in the geographies we determine would be most effective to create value for our shareholders. Our goal is to become a commercial-stage company and our initial focus will be on achieving commercial launch readiness to support the potential launch of tisotumab vedotin for the treatment of cervical cancer, subject to obtaining regulatory approval and, where applicable, reimbursement approval. We are developing tisotumab vedotin in collaboration with Seattle Genetics. Under our agreement, Seattle Genetics and Genmab will each be responsible for leading tisotumab vedotin commercialization activities in certain territories. We are currently in discussions with Seattle Genetics regarding the detailed terms on which we will work together to commercialize tisotumab vedotin under this agreement.

**Our Products and Product Candidates**

**Daratumumab (DARZALEX)**

Our lead product, daratumumab, marketed as DARZALEX for the treatment of certain multiple myeloma indications, is a human IgG1k monoclonal antibody, or mAb, that binds with high affinity to the CD38 molecule, which is highly expressed on the surface of MM cells. It triggers a person’s own immune system to attack cancer cells, resulting in rapid tumor cell death through multiple immune-mediated mechanisms of action and through immunomodulatory effects, in addition to direct tumor cell death via apoptosis, or programmed cell death. When first approved by the FDA in 2015, it was the first human CD38-targeting mAb to reach the market and the first mAb to receive FDA approval to treat multiple myeloma. DARZALEX is commercialized by Janssen, under an exclusive development, manufacturing and commercialization agreement, which we entered into in 2012.

MM is an incurable blood cancer that starts in the bone marrow and is characterized by an excess proliferation of plasma cells. The 5-year survival rate for MM patients is estimated at 52.2% in the United States, based on 2009–2015 data from the National Cancer Institute Surveillance, Epidemiology, and End Results, or SEER. SEER estimated that 124,733 people were living with MM in the United States in 2015. The World Health Organization, or WHO, estimated that approximately 26,000 people in the United States and 160,000 people worldwide would be newly diagnosed with MM in 2018 and approximately 13,650 people in the United States and 106,000 people globally would die from the disease.

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

**Existing Marketing Approvals**

Janssen has obtained regulatory approvals for DARZALEX in the jurisdictions set forth in the table below, as well as in certain other countries, including the first approval for DARZALEX in China. In July 2019, Chinese regulatory authorities approved DARZALEX as monotherapy for the treatment of adult patients with R/R MM whose prior therapy included a PI and an immunomodulatory agent and who have demonstrated disease progression on the last therapy.

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54
Table of Contents

Jurisdiction Approval Key Underlying Clinical Trial(s)

United States

Relapsed / Refractory MM

November 2015\nRelapsed / Refractory MM Monotherapy for patients who have received at least three prior lines of therapy, including a PI and an immunomodulatory agent, or who are double refractory to a PI and an immunomodulatory agent SIRIUS (MMY2002)

November 2016\nIn combination with Rd or Vd, for patients who have received at least one prior therapy CASTOR (MMY3004); POLLUX (MMY3003)

June 2017\nIn combination with Pom-d for patients who have received at least two prior therapies, including lenalidomide and a PI EQUULEUS (MMY1001)

Frontline MM

May 2018\nIn combination with VMP for newly diagnosed patients who are ineligible for ASCT ALCYONE (MMY3007)

June 2019\nIn combination with Rd for newly diagnosed patients who are ineligible for ASCT MAIA (MMY3008)

September 2019\nIn combination with VTd for newly diagnosed patients who are eligible for ASCT CASSIOPEIA (MMY3006)

Split Dosing Regimen

February 2019\nOption to split first infusion over two consecutive days EQUULEUS (MMY1001)

European Union

Relapsed / Refractory MM

April 2018 Monotherapy for patients whose prior therapy included a PI and an immunomodulatory agent and who have demonstrated disease progression on the last therapy SIRIUS (MMY2002)

February 2017\nIn combination with Rd or Vd for patients who have received at least one prior therapy CASTOR (MMY3004); POLLUX (MMY3003)

Frontline MM

July 2018\nIn combination with VMP for newly diagnosed patients who are ineligible for ASCT ALCYONE (MMY3007)

November 2019\nIn combination with Rd for newly diagnosed patients who are ineligible for ASCT MAIA (MMY3008)

January 2020\nIn combination with VTd for newly diagnosed patients who are eligible for ASCT CASSIOPEIA (MMY3006)

Split Dosing Regimen

December 2018 Option to split first infusion over two consecutive days EQUULEUS (MMY1001)

Japan

Relapsed / Refractory MM

September 2017\nIn combination with Rd or Vd CASTOR (MMY3004); POLLUX (MMY3003)

Frontline MM

November 2019\nIn combination with VMP for newly diagnosed patients ineligible for ASCT ALCYONE (MMY3007)

December 2019\nIn combination with Rd for newly diagnosed patients who are ineligible for ASCT MAIA (MMY3008)

PI = proteasome inhibitor; Rd = lenalidomide and dexamethasone; Vd = bortezomib and dexamethasone; VMP = bortezomib, melphalan and prednisone; VTd = bortezomib, thalidomide and dexamethasone; ASCT = autologous stem cell transplant; Pom-d = pomalidomide and dexamethasone

Pending Regulatory Applications

In addition to the approved indications, three applications for marketing approval of DARZALEX for certain indications are currently pending with applicable regulators. In July 2019, Janssen submitted regulatory applications seeking approval of the subQ formulation of daratumumab based on the Phase III COLUMBA study and preliminary data from the Phase II PLEIADES study, to both U.S. and European regulatory authorities, with the U.S. BLA receiving a standard review. In September 2019 Amgen reported results of the Phase III CANDOR study. Amgen conducted the study through a master clinical trial collaboration and supply agreement with Janssen to evaluate the efficacy and safety of daratumumab in combination with Amgen’s carfilzomib. Based on this trial, Janssen submitted an sBLA to the FDA in February 2020 and an sNDA was submitted to the MHLW in Japan in March 2020.

The COLUMBA, PLEIADES and CANDOR studies are described below.
COLUMBA (MMY3012)

Study Design

522-patient randomized, open-label, multicenter, non-inferiority, Phase III study intended to compare the efficacy, pharmacokinetics, and IRRs of daratumumab in subQ form versus IV-administered daratumumab in patients with R/R MM. Eligible patients with R/R MM must have received at least 3 prior lines of therapy, including a PI and an immunomodulatory agent, or must be double refractory to both a PI and an immunomodulatory agent. The co-primary endpoints are ORR at 6 months after randomization and maximum trough concentration of daratumumab on Cycle 3 Day 1 (each cycle 28 days), or C\text{trough}. Secondary endpoints include IRR rates, PFS, VGPR and CR (including sCR), time to next therapy, OS, time to response, and DoR. Patients were randomly assigned (1:1) to the 2 treatment groups.

Initial Results

(Reported February 2019)

In February 2019, we reported topline results that subQ administration of daratumumab co-formulated with rHuPH20 was observed to be non-inferior to IV administration of daratumumab with regard to the co-primary endpoints of ORR and C\text{trough}. The ORR for patients treated with subQ daratumumab was 41.1% (n=263) versus 37.1% in patients treated with IV daratumumab (n=259). The geometric mean of C\text{trough} for patients treated with subQ daratumumab was 499 mg/mL (n=149) versus 463 mg/mL in patients treated with IV daratumumab (n=146). The lower limit of the 95% CI for the ratios of the two arms of the study met the specified non-inferiority criterion for both co-primary endpoints.

Additional Data

(Presented at ASCO, June 2019)

Subcutaneous daratumumab combination therapies were well tolerated and no new In June 2019, Janssen presented additional data at ASCO for 522 patients in the study. At median follow up of 7.5 months, median PFS was 5.6 months for patients treated with subQ daratumumab versus 6.1 months for patients treated with IV daratumumab (HR, 0.99; 95% CI: 0.78 - 1.26). Rates of ≥VGPR and ≥CR were similar between the subQ and IV administration groups. Janssen reported that the estimate of relative risk of subQ daratumumab compared to IV daratumumab was 1.11 (95% CI: 0.89 - 1.37).

Safety Data

(Presented at ASH, December 2019)

No new safety signals were detected compared with known daratumumab safety profiles.

Updated Analysis

(Presented at ASH, December 2019)

In December 2019, Janssen presented additional data at ASH for 522 patients in the study. At median follow up of 13.7 months ORR increased from 41.1% to 43.3% for subQ daratumumab and from 37.1% to 39.4% for IV daratumumab. With longer follow-up, both subQ and IV formulations continued to have similar rates of ≥VGPR (21.7% and 20.8%) and ≥CR (3.0% and 4.6%). Noninferiority of ORR for subQ daratumumab (43.3%) versus IV daratumumab (39.4%) was maintained with longer follow-up (relative risk, 1.10; 95% CI, 0.90 – 1.35; p=0.0001). ORR was comparable between the subQ and IV administration groups across all subgroups, including body weight subgroups. Median PFS was 5.6 months with subQ daratumumab versus 6.1 months with IV daratumumab (HR, 1.00; 95% CI: 0.81 – 1.23; p=0.9710). Median OS was not reached in either treatment arm (HR, 0.91; 95% CI: 0.66 – 1.25; p=0.5544). A significantly lower rate of infusion-related reactions (IRRs) was observed with subQ daratumumab versus IV daratumumab (12.7% vs. 34.5%; odds ratio, 0.28; 95% CI, 0.18 – 0.44; p<0.0001). At the time of data cutoff, 118 patients, evenly distributed across both arms, continued treatment on the study.
**Study Design**

240-patient non-randomized, open-label, multicenter, parallel assignment, Phase II study of patients with either newly diagnosed or with relapsed or refractory multiple myeloma. Patients with newly diagnosed multiple myeloma are being treated with 1,800 mg subcutaneous daratumumab in combination with either VRd or VMP. Patients with relapsed or refractory multiple myeloma are being treated with 1,800 mg subcutaneous daratumumab plus Rd. An additional cohort of patients with relapsed and refractory multiple myeloma treated with daratumumab plus Kd was subsequently added to the study. The primary endpoint for the D-VMP, D-Kd and D-Rd cohorts is overall response rate. The primary endpoint for the D-VRd cohort is very good partial response or better rate.

**Initial Results**

(Presented at ASH, December 2019)

At the clinical cutoff date of November 11, 2019, median duration of follow-up was 7.4 months for D-VRd, 14.3 months for D-VMP, and 14.7 months for D-Rd cohorts. The rate of VGPR or better with D-VRd (71.6%; 90% CI, 61.2-80.6) post-induction (4 cycles) was consistent with the rate of VGPR or better reported with DARA IV plus VRd (71.7%) post-induction (4 cycles) in the phase 2 GRIFFIN study. The ORR with D-VMP (89.6%; 90% CI, 81.3-95.0) was consistent with the ORR reported with IV daratumumab plus VMP (90.9%) in the phase 3 ALCYONE study. The ORR with D-Rd (93.8%; 90% CI, 86.5-97.9) was consistent with the ORR reported with IV daratumumab plus Rd (92.9%) in the phase 3 POLLUX study. ORR in the D-VRd cohort was 97.0% (90% CI, 90.9-99.5) and rates of VGPR or better were 77.6% (90% CI, 67.6-85.7) and 78.5% (90% CI, 68.4-86.5) in the D-VMP and D-Rd cohorts, respectively. The rate of CR or better was 16.4% (90% CI, 9.5-25.7) in the D-VRd cohort, 47.8% (90% CI, 37.2-58.5) in the D-VMP cohort, and 38.5% (90% CI, 28.3-49.4) in the D-Rd cohort.

**Safety Data**

(Presented at ASH, December 2019)

Subcutaneous daratumumab combination therapies were well tolerated and no new safety concerns were identified. All patients experienced ≥1 any-grade treatment-emergent AE. Grade 3/4 TEAEs occurred in 58% of patients in the D-VRd cohort, 75% of patients in the D-VMP cohort, and 89% of patients in the D-Rd cohort. The most common grade 3/4 TEAE was neutropenia in all cohorts (D-VRd, 28%; D-VMP, 37%; D-Rd, 49%). IRRs were mild (grade 1/2) and no additional IRRs were reported with longer follow-up after the primary analysis.
CANDOR

Study Design
Randomized, open label, Phase III study run by Amgen, including 460 newly diagnosed patients with MM who have relapsed after 1 to 3 prior therapies. Patients were randomized to receive either daratumumab in combination with carfilzomib (a proteasome inhibitor) and dexamethasone (a corticosteroid) or carfilzomib and dexamethasone alone. In the daratumumab treatment arm, patients received 8 milligrams per kilogram (mg/kg) on days 1 and 2 of cycle 1, then 16 mg/kg once weekly for the remaining doses of the first 2 cycles, then every 2 weeks for 4 cycles (cycles 3 to 6), and then every 4 weeks for the remaining cycles or until disease progression. In both treatment arms carfilzomib was dosed twice weekly (20 mg/m2 on cycle 1 days 1 and 2 and 56 mg/m2 beginning on cycle 1 day 8 and thereafter) and dexamethasone was given weekly (40 mg orally or via IV infusion). The primary endpoint of the study is PFS.

Initial Results
(Reported September 2019)
In September 2019 Amgen reported topline results showing a 37% reduction in the risk of progression or death in patients with relapsed or refractory MM treated with daratumumab in combination with Kd (HR, 0.630; 95% CI: 0.464, 0.854; p=0.0014). The median PFS for patients treated with daratumumab in combination with Kd had not been reached by the cut-off date compared to a median PFS of 15.8 months for patients who received Kd alone.

Additional Data
(Presented at ASH, December 2019)
In December 2019, Amgen presented additional data at ASH for 466 patients in the study. MRD-negative CR at 12 months (10-5 threshold) was 12.5 for daratumumab in combination with Kd versus 1.3 for patients treated with Kd (p<0.0001).

Safety Data
(Presented at ASH, December 2019)
Overall the safety profile was consistent with known safety profiles of each agent, with the exception of an imbalance in treatment-emergent fatal AEs, which might be partially explained by longer treatment exposure, age, and frailty status. The incidence of grade ≥3 AEs was 82.1% and 73.9% in the D-Kd and Kd arms, respectively. Serious AEs occurred in 56.2% (D-Kd) and 45.8% (Kd). The rate of treatment discontinuation due to AEs was similar in both arms (D-Kd, 22.4%; Kd, 24.8%). The frequency of grade ≥3 cardiac failure was 3.9% (D-Kd) and 8.5% (Kd); rate of cardiac failure event leading to K discontinuation was similar in the arms (3.9% and 4.6%). 5 deaths were reported as treatment-related, all in the D-Kd arm (pneumonia, sepsis, septic shock, acinetobacter infection, and cardio-respiratory arrest [n=1 each]).

Development Status
Beyond the current labeled indications and pending regulatory applications, Janssen is conducting a comprehensive clinical development program for daratumumab, including multiple Phase III studies for the treatment of various stages of MM, including SMM, frontline MM and R/R MM, with daratumumab alone or in combination with other therapies. The majority of these Phase III studies are utilizing the subQ formulation of daratumumab.

58
The chart below illustrates the development phase of DARZALEX for each MM disease stage and therapy type.

**DARATUMUMAB DEVELOPMENT COVERING ALL STAGES OF MULTIPLE MYELOMA – KEY ONGOING TRIALS**

<table>
<thead>
<tr>
<th>Disease Stage</th>
<th>Therapy</th>
<th>Development Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High Risk Smoldering</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monotherapy</td>
<td>Pre-Clinical</td>
</tr>
<tr>
<td></td>
<td>Monotherapy</td>
<td>I</td>
</tr>
<tr>
<td></td>
<td>Dara + VMP</td>
<td>II</td>
</tr>
<tr>
<td></td>
<td>Dara + VMP (Asia Pacific)</td>
<td>III</td>
</tr>
<tr>
<td></td>
<td>Dara + Rd</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dara + VRd</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dara + VTd</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dara + VRd</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dara + R (maintenance)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dara + VRd</td>
<td></td>
</tr>
<tr>
<td><strong>Front line (transplant &amp; non-transplant)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dara + Vd (China)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dara + Kd</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dara + Pom + d</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Subcutaneous vs IV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dara + combinations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dara + I.O. (PD1 &amp; PD11)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>V = Velcade®, MP = melphalan-prednisone, T = thalidomide, d = dexamethasone, R = Revlimid®, K = Kyprolis®, Pom = Pomalyst®</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Fully recruited</td>
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</table>

**DARATUMUMAB DEVELOPMENT – BEYOND MULTIPLE MYELOMA**

<table>
<thead>
<tr>
<th>Disease</th>
<th>Therapy</th>
<th>Development Phase</th>
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</thead>
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<tr>
<td>AL Amyloidosis</td>
<td>Dara + CyBorD</td>
<td>Pre-Clinical</td>
</tr>
<tr>
<td>ALL</td>
<td>Dara + SoC chemo</td>
<td>I</td>
</tr>
<tr>
<td>NK/TCL (nasal type)</td>
<td>Dara monotherapy</td>
<td>II</td>
</tr>
<tr>
<td></td>
<td>✓ ANDROMEDA</td>
<td>III</td>
</tr>
<tr>
<td></td>
<td>✓ DEPHINUS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ VOLANS</td>
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</tr>
</tbody>
</table>

Additional Data of Potential Significance from 2019

In addition to the COLUMBA, PLEIADES and CANDOR data, which formed the basis of the regulatory submissions referenced above, in July 2019, Janssen released efficacy data for the Phase II GRIFFIN study of daratumumab in combination with bortezomib, lenalidomide and dexamethasone, or VRd, for frontline treatment of transplant-eligible MM patients. In December 2019, overall survival data from the Phase III ALCYONE study, which supported regulatory approvals in the U.S., EU and Japan, was presented at ASH and published in *The Lancet*.

The GRIFFIN and ALCYONE studies are described below.
**Study Design**

Randomized, open label, parallel assignment Phase II study that included 223 patients with newly diagnosed multiple myeloma who were eligible for high-dose chemotherapy and ASCT. Patients were randomized to receive either daratumumab plus lenalidomide, bortezomib and dexamethasone, or lenalidomide, bortezomib and dexamethasone alone. The trial also included a 16-patient safety run-in phase performed to assess potential dose limiting toxicities during Cycle 1 of D-VRd. The primary endpoint of the study is the number of patients who achieve sCR by the end of the consolidation treatment.

**Initial Results**

In July 2019, Genmab reported topline data showing that 42.4% of patients treated with daratumumab in combination with VRd achieved an sCR, compared to 32.0% of patients who received VRd alone, with an odds ratio of 1.57 (95% CI: 0.87-2.82, p=0.1359, exceeding the statistical significance at the pre-set 2-sided alpha level of 0.2).

**Additional Data**

In December 2019, Janssen presented updated efficacy and safety data for 196 patients after median follow-up of 22.1 months. 62.6% of patients treated with daratumumab in combination with VRd achieved a sCR, compared to 45.4% of patients who received VRd alone, with an odds ratio of 1.98 (95% CI: 1.12-3.49; p=0.0177). Median PFS and OS were not reached for either arm.

**Safety Data**

The overall safety profile of D-RVd is consistent with previous reports of daratumumab plus standard of care. Grade 3/4 TEAEs (≥10%) with D-RVd vs RVd included neutropenia (32% vs 15%), lymphopenia (23% vs 23%), thrombocytopenia (16% vs 8%), and leukopenia (15% vs 7%). There was no difference in the rate of grade 3/4 infections between arms. IRRs occurred in 41% of DARA-treated patients, which were primarily grade 1-2.

**Study Design**

706-patient randomized, open-label, multicenter, Phase III trial of daratumumab for the treatment of newly diagnosed patients with MM who were ineligible for ASCT. Patients were randomized to receive nine cycles of either bortezomib, melphalan and prednisone, or VMP, combined with daratumumab, or D-VMP, or VMP alone. At the end of these nine cycles, patients in the D-VMP arm were given daratumumab as a monotherapy until disease progression, or PD.

**Efficacy Data**

After a median follow-up of 27.8 months, study results showed the addition of daratumumab to VMP reduced the risk of disease progression or death by 57% compared to VMP alone (HR = 0.43; 95% CI: 0.35-0.54; p<0.0001).
Table of Contents

Safety Data
(Data cutoff June 12, 2018)

In Cycles 1 through 9, the most frequently reported AEs were hematologic, including neutropenia (39.9% in the D-VMP group vs. 38.7% in the VMP group), thrombocytopenia (34.4% vs. 37.6%), and anemia (15.9% vs. 19.8%). The rate of grade 3 or 4 infections was 23.1% in the D-VMP group and 14.7% in the VMP group. For Cycle 10 and onward, the most common Grade 3/4 TEAEs for D-VMP included anemia (4%), neutropenia (2%) and bronchitis (1%).

Overall Survival Data
(Published in The Lancet, December 2019; data cutoff June 24, 2019)

At median follow-up of 40.1 months the HR for death in the D-VMP group compared with the VMP group was 0.60 (95% CI 0.46–0.80; p=0.0003). The Kaplan-Meier estimate of the 36-month rate of overall survival was 78.0% (95% CI 73.2 – 82.0) in the D-VMP group and 67.9% (62.6-72.6) in the VMP group.

Key Ongoing Trials

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

Daratumumab for High Risk SMM

Janssen is currently conducting several clinical trials to assess whether earlier treatment with daratumumab could be used for patients with high-risk SMM to delay progression to MM, compared with active monitoring. The Phase II 123-patient, randomized, multicenter, open-label CENTAURUS (SMM2001) study is assessing three dose schedules of daratumumab for the treatment of patients with high-risk or intermediate-risk SMM who had a confirmed diagnosis of high-risk or intermediate-risk SMM for <5 years. Initial efficacy data from the CENTAURUS study was reported in December 2018 and it was determined that dose intensity was associated with efficacy. The safety profile of daratumumab monotherapy in SMM remained consistent with other single-agent daratumumab studies, and no new safety signals were observed with longer follow-up.

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

Daratumumab for Frontline Treatment for Transplant Eligible Patients

In addition to the CASSIOPEIA trial, which supported approvals in the U.S. and EU, Janssen is conducting the following Phase III trials for frontline treatment of transplant eligible MM patients:

The Phase III PERSEUS (MMY3014) study is currently ongoing to evaluate the subQ formulation of daratumumab in combination with VRd, or D-VRd, compared to VRd alone in approximately 690 participants with previously untreated MM. The primary endpoint of the study is PFS from randomization to the date of disease progression or death. Secondary endpoints include MRD-negative rate, ORR, PFS on next line of therapy, OS, time to and duration of response, health-related quality of life, pharmacokinetics, immunogenicity, stem cell yield after mobilization and time to engraftment post-ASCT. The PERSEUS trial completed enrollment in November 2019.
Janssen also recently announced the Phase III randomized, open-label AURIGA (MMY3021) trial to evaluate subQ daratumumab in combination with lenalidomide as maintenance treatment in approximately 214 patients with newly diagnosed MM who are MRD positive after frontline ASCT and have no prior anti-CD38 exposure, compared with maintenance treatment by lenalidomide alone. The first patient was dosed in June with enrollment put on a temporary hold in September due to a U.S. FDA request for additional information related to analytical methods included in the study protocol. The hold was lifted in early 2020, with the trial listed as recruiting on www.clinicaltrials.gov in January.

Daratumumab for Frontline Treatment for Non-Transplant Eligible Patients

In addition to the MAIA and ALCYONE trials, which supported approvals in the U.S., EU and Japan, Janssen is conducting the following Phase III trials for frontline treatment of non-transplant eligible MM patients:

The Phase III CEPHEUS (MMY3019) study is evaluating the subQ formulation of daratumumab in combination with bortezomib, lenalidomide and dexamethasone, or VRd, compared to VRd alone in approximately 360 participants with frontline MM for whom hematopoietic stem cell transplant is not planned as initial therapy. The primary endpoint of the study is the percentage of participants with negative MRD status, measured after randomization and prior to PD or subsequent anti-MM therapy. Secondary endpoints include PFS, CR, MRD-negativity rate at one year, ORR, VGPR, PFS on the next line of therapy, DoR, health-related quality of life, pharmacokinetics, immunogenicity, and OS. The CEPHEUS trial completed enrollment in September 2019.

The 210-patient randomized, open-label, multicenter, controlled Phase III OCTANS (MMY3011) study of bortezomib, melphalan and prednisone, or VMP, will compare to daratumumab in combination with VMP, in subjects in the Asia Pacific region with previously untreated MM who are ineligible for high-dose therapy. Patients are expected to be recruited from China, Hong Kong, South Korea and Taiwan. The primary endpoint of the study is VGPR or better rate, defined as the proportion of participants achieving VGPR and CR (including sCR) criteria during or after the study treatment, at 6 months and at 3 years after the last participant first dose. The OCTANS trial completed enrolment in December 2019.

Daratumumab for Relapsed or Refractory Multiple Myeloma

In addition to the POLLUX and CASTOR trials, which supported approvals in the U.S., EU and Japan, Janssen is also conducting the following Phase III trials for the treatment of relapsed or refractory MM:

APOLLO (MMY3013) is a randomized, open-label, multicenter, Phase III study expected to include approximately 302 patients with R/R MM who have previously been treated with both lenalidomide and a PI. Patients will be randomized 1:1 to either receive the subQ formulation of daratumumab in combination with pomalidomide and dexamethasone (Pom-d) or Pom-d alone. The primary endpoint of the study is PFS. The study is being conducted in Europe by the European Myeloma Network in collaboration with Janssen and completed enrollment in June 2019.

Additionally, a 210-patient randomized, open-label, multicenter, Phase III study in Chinese patients (LEPUS, MMY3009) assessing daratumumab in combination with bortezomib and dexamethasone, or Vd, versus Vd alone, completed recruitment in August 2019. The primary endpoint of the study is PFS from the date of randomization to either PD or death, whichever occurs first.

Janssen is conducting other Phase I and Phase II studies assessing daratumumab in combination with other regimens for the treatment of R/R MM.

Other Malignant Diseases

In addition to the ongoing studies of daratumumab for the treatment of MM, Janssen is conducting a number of studies to assess the use of daratumumab for the treatment of other malignant and pre-malignant diseases in which CD38 is expressed, including amyloidosis, acute lymphocytic leukemia and NKT-cell lymphoma.
Table of Contents

Such additional daratumumab studies include ANDROMEDA (AMY3001), a Phase III study that completed enrollment in July 2019 and intends to evaluate the efficacy and safety of subQ daratumumab in combination with cyclophosphamide, or Cy, bortezomib, or Bor, and dexamethasone, or d, or together CyBord and, together with daratumumab, D-CyBord, compared to CyBord alone in the treatment of frontline AL amyloidosis; DELPHINUS (ALL2005), a Phase II, parallel assignment study to evaluate the efficacy and safety of daratumumab in pediatric and young adult subjects with R/R Precursor T cell ALL or Lymphoblastic Lymphoma, or LL; and VOLANS (NKT2001), a Phase II, single group assignment study to assess the clinical efficacy and safety of daratumumab in patients with R/R extranodal NKTCL, nasal type. Data from the VOLANS study was presented by Janssen at ASH in December 2019. A total of 32 patients were treated with daratumumab at the time of clinical cutoff, June 4, 2019. At a median follow-up of 16.7 months, ORR based on BICR in the intent-to-treat population was 25.0% (95% CI, 11.5-43.4). Exploratory subgroup analysis of ORR demonstrated that there was no significant difference between each subgroup (site involvement, CD38 expression, ECOG performance status, lines of prior therapy, and age. Eighteen (56%) patients had grade 3/4 TEAEs; thrombocytopenia (22%) and anemia, leukopenia, and neutropenia (16% each) were most common. Two (6%) patients discontinued treatment due to TEAEs, one patient due to leukopenia and epistaxis and 1 patient due to death. IRRs occurred in 63% of patients and were generally mild. Two (6%) patients had grade 3 IRRs (urticaria, hypertension, hypotension) and no grade 4 or 5 IRRs were reported.

**Ofatumumab**

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

**Arzerra for the Treatment of Chronic Lymphocytic Leukemia**

Ofatumumab, marketed as Arzerra, has been approved for the treatment of certain CLL indications in the United States, the European Union and a number of other countries. In the United States, Arzerra solution for infusion is approved for use in combination with chlorambucil for the treatment of previously untreated patients with CLL for whom fludarabine-based therapy is considered inappropriate, for use in combination with fludarabine and cyclophosphamide for the treatment of patients with relapsed CLL, and for extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive CLL. In the United States, Arzerra is also indicated as a monotherapy for the treatment of patients with CLL who are refractory to fludarabine and alemtuzumab. In January 2018, Novartis announced its intention to transition the commercial availability of Arzerra to limited availability through managed access programs or alternative solutions for the treatment of approved CLL indications in non-U.S. markets where applicable and allowed by local regulations. Novartis announced that it will work with regulatory authorities to establish managed access programs or alternative solutions so that patients benefiting from Arzerra can remain on treatment. In 2019, marketing authorizations for Arzerra were withdrawn in the European Union and certain other territories. We expect Arzerra to remain commercially available for approved CLL indications in the United States and Japan. Ofatumumab is not in active clinical development in CLL.

The overall safety profile of Arzerra in CLL is based on exposure in clinical trials and the post-marketing setting. The most common side effects for Arzerra include AEs associated with IRRs, cytopenias (neutropenia, anemia, thrombocytopenia), and infections (lower respiratory tract infection, including pneumonia, upper respiratory tract infection, sepsis, including neutropenic sepsis and septic shock, herpes viral infection and urinary tract infection). In addition, the prescribing information for Arzerra includes a warning that Arzerra may cause HBV infection to reoccur, which may cause serious liver problems and death, and may cause PML, a rare brain infection that causes severe disability and can lead to death.
Multiple sclerosis, or MS, is a chronic inflammatory, demyelinating and neurodegenerative disorder of the central nervous system that affects the white and grey matter of the brain and spinal cord. Initial symptoms typically occur between 20 and 50 years of age, and women are three times more likely to develop MS than men. In 2016, it was estimated that MS affects approximately 400,000 individuals in the United States and 2.5 million worldwide, with 53,299 diagnosed incident cases of MA in 2019 in the U.S., Japan and five major EU markets. 85% of MS cases are relapsing remitting MS, characterized by unpredictable recurrent attacks. There is currently no cure for MS. Treatment typically focuses on speeding recovery from attacks, slowing the progression of the disease and managing MS. Ofatumumab is the first fully human anti-CD20 monoclonal antibody administered with a monthly 20 mg subQ dosing regimen in clinical trials.

In August 2019, Novartis reported that the Phase III ASCLEPIOS I and II studies of subQ ofatumumab versus oral teriflunomide in adults with relapsing forms of multiple sclerosis met the primary endpoints where ofatumumab showed a highly significant and clinically meaningful reduction in the number of confirmed relapses, evaluated as the annualized relapse rate (ARR). In September 2019, Novartis presented detailed results from the studies at the 35th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS). Based on the ASCLEPIOS data, Novartis initiated the submission of an sBLA to the FDA in December 2019 and submitted an MAA to the EMA in January 2020.

The ASCLEPIOS studies are described below.

**ASCLEPIOS I and II**

**Study Design**

Randomized, multicenter, Phase III, double-blind, double-dummy, active-controlled, studies comparing the efficacy and safety of subQ ofatumumab versus teriflunomide, a standard treatment in MS, in approximately 900 patients with RMS per study. Patients will be randomized to receive either 20 mg subQ injections of ofatumumab every four weeks or 14 mg of teriflunomide orally once daily. In order to blind for the different formulations, double-dummy masking will be used (i.e. all patients will take injections (containing either active ofatumumab or placebo) and oral capsules (containing either active teriflunomide or placebo)). The primary endpoint of the studies is annualized relapse rate which is the number of confirmed relapses in a 12 month period. Key secondary endpoints include 3- and 6-month confirmed disability worsening and MRI-related outcomes.

**Initial Results**

*Presented at ECTRIMS, September 2019*

Patients with RMS on ofatumumab had a reduction in ARR by 50.5% (0.11 vs. 0.22, 95% CI: 0.495 (0.374; 0.654)) and 58.5% (0.10 vs 0.25, 95% CI: 0.415(0.308; 0.559)) compared to teriflunomide (both studies p<0.001) in ASCLEPIOS I and II, respectively. A key secondary endpoint, ofatumumab showed a relative risk reduction of 34.4% in 3-month confirmed disability worsening (CDW) (HR 95% CI: 0.656 (0.499; 0.862) p=0.002) and 32.5% in 6-month CDW (HR 95% CI: 0.675 (0.498; 0.916) p=0.012) versus teriflunomide in pre-specified pooled analyses.
The safety profile of ofatumumab as seen in the ASCLEPIOS studies was in line with the observations from prior Phase II results and AEs were balanced between the ofatumumab and teriflunomide arms of the trials. Serious adverse events were low and overall balanced (any serious AEs at 9.1%) with the most common SAEs (≥1% in any treatment group, by primary system organ class) being infections and infestations (2.5%), injury, poisoning and procedural complications (1.4%), neoplasms benign, malignant and unspecified, including cysts and polyps (1.0%), nervous system disorders (0.7%) and psychiatric disorders (1.1%). In patients who reported systemic injection reactions, 99% were mild to moderate with only one patient (0.1%) in the ofatumumab group with a non-serious injection reaction who discontinued the study due to an injection reaction.

In addition to the ASCLEPIOS studies, Novartis is conducting a Phase III long-term safety, tolerability and effectiveness study of ofatumumab in patients with RMS. The purpose of this study is to collect long-term safety, tolerability, effectiveness and health outcomes data in eligible subjects who have participated in a Novartis ofatumumab clinical MS study. The estimated enrollment for this single group assignment study is 2010 participants and the study is currently recruiting. Novartis is also conducting a randomized parallel assignment Phase II study of 284 adult RMS patients in order to evaluate the bioequivalence of 20mg subQ ofatumumab injected by pre-filled syringe or autoinjector. Data from this study is anticipated in 2020.

**Teprotumumab**

Teprotumumab is developed and manufactured by Horizon Therapeutics (Horizon) for thyroid eye disease (TED). In February 2019, Horizon reported positive topline results from the Phase III confirmatory OPTIC study of teprotumumab in the treatment of active thyroid eye disease. The study met its primary endpoint showing more patients treated with teprotumumab compared with placebo had a meaningful improvement in proptosis, or bulging of the eye, as 82.9% of patients treated with teprotumumab compared to 9.5% of placebo patients achieved the primary endpoint of a 3mm or more reduction in proptosis (p<0.001). The safety profile of teprotumumab in OPTIC was similar to that seen in Phase II study with no new safety observations. The drop-out rate was <5% and balanced across placebo and treatment arms. There were no deaths during the study and a total of three SAEs: in the placebo arm, one patient had a visual field defect and received orbital decompression surgery and discontinued study; in the teprotumumab arm, one patient had pneumothorax (considered not related to study drug) and another had an infusion reaction that led to discontinuation of study drug. The vast majority of treatment-emergent AEs were mild to moderate in intensity and no other adverse events resulted in discontinuation. Horizon submitted a BLA to the FDA in July 2019. The FDA granted priority review to the BLA in September 2019 and teprotumumab was subsequently approved as TEPEZZA in January 2020. Teprotumumab was created by Genmab under a collaboration with Roche and development of the product is now being conducted by Horizon under a license from Roche. Under the terms of Genmab’s agreement with Roche, Genmab will receive mid-single digit royalties on sales of TEPEZZA.
Tisotumab Vedotin

Tisotumab vedotin is an ADC created to target tissue factor, or 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 Seattle Genetics’ ADC technology that utilizes a cleavable linker and the cytotoxic drug monomethyl auristatin E, or MMAE. ADCs are mAbs that are linked to cytotoxic or cell-killing agents. Seattle Genetics’ 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.

Tisotumab Vedotin for the Treatment of Cervical Cancer and Other Solid Tumors

SEER estimated that 13,170 women would be diagnosed with cervical cancer in the United States in 2019, and that 4,250 would die from cervical cancer. The 5-year survival rate for cervical cancer in the United States is 65.8%, based on 2009–2015 SEER data. Globally, the WHO estimated that 570,000 women would be diagnosed with cervical cancer in 2018, the vast majority of those women being in low- and middle-income countries. We and Seattle Genetics are currently evaluating tisotumab vedotin for the treatment of cervical cancer and other solid tumors in six clinical studies, innovaTV 201, innovaTV 204, innovaTV 205, innovaTV 206, innovaTV 207 and innovaTV 208.

InnovaTV 201 is a two-part Phase I/II study of tisotumab vedotin in several types of solid tumors, with estimated enrollment of 170 patients. Phase I tests various doses of tisotumab vedotin once every three weeks to establish the recommended Phase II dose, or RP2D, maximum tolerated dose, as well as the safety profile of tisotumab vedotin. Phase II of the study investigates seven indications in parallel expansion cohorts. The primary endpoint of the study was the safety and tolerability of tisotumab vedotin, assessed by the frequency of AEs, SAEs, IRRs, Grade 3 or worse AEs, and TEAEs related to tisotumab vedotin. Secondary endpoints include ORR, disease control rate, or DCR (defined as CR, PR or stable disease, or SD), PFS and DoR. Phase I/II data were published in February 2019 and established 2.0 mg/kg of tisotumab vedotin IV once every 3 weeks as the RP2D. Initial data from Phase IIa were published in March 2019 and indicated that tisotumab vedotin had encouraging activity in previously treated recurrent or metastatic cervical cancer. The most common TEAEs of any Grade were epistaxis (69%), fatigue (56%) and nausea (52%). The three most common in AEs of Grade 3 or worse were fatigue (10%), anemia (5%) and abdominal pain (4%). There were nine deaths across all study phases (three in the dose-escalation phase unrelated to the drug and six in the dose-expansion phase) with one case of pneumonia in the dose-expansion phase considered possibly related to study treatment. The most common Grade 3/4 AEs were anemia (11%), fatigue (9%) and vomiting (7%). No grade 5 treatment-related AEs occurred. Most AESIs were low grade and no treatment related deaths occurred. The study protocol was amended in September 2017 to expand the cervical cancer cohort to 55 patients. Data from this cohort was published in Clinical Cancer Research in December 2019. Investigator-assessed confirmed ORR was 24% (95% CI: 13%-37%). Median duration of response (DOR) was 4.2 months (range: 1.0+-9.7); four patients responded for >8 months. The 6-month PFS rate was 29% (95% CI: 17%-43%). Independent review outcomes were comparable, with confirmed ORR of 22% (95% CI: 12%-35%), median DOR of 6.0 months (range: 1.0+-9.7), and 6-month PFS rate of 40% (95% CI: 24%-55%). Tissue factor expression was confirmed in most patients; no significant association with response was observed. The most common grade 3/4 AEs were anemia (11%), fatigue (9%), and vomiting (7%). No grade 5 treatment-related AEs occurred.

InnovaTV 204 is a single arm, multicenter, international, potentially registrational Phase II trial in patients with cervical cancer who have relapsed or progressed on or after platinum-containing chemotherapy and who have received or are ineligible for bevacizumab, with estimated enrollment of 100 patients. The primary endpoint of the study is ORR as assessed by an independent review committee. The trial will also assess DoR, PFS, OS and safety. Patient enrollment was completed in March 2019.
innovaTV 205 is a Phase I/II study of tisotumab vedotin as monotherapy or in combination with other therapies in subjects with recurrent or stage IVB cervical cancer and innovaTV 206 is a Phase I/II open label, single arm study of tisotumab vedotin monotherapy for patients in Japan with advanced solid malignancies. Both studies are recruiting. The first patient in the innovaTV 206 study was dosed in March 2019 with an expansion phase of tisotumab vedotin as monotherapy initiated in August 2019. In December 2019 the innovaTV 205 study was updated to include an arm with weekly dosing of tisotumab vedotin monotherapy.

Beyond recurrent and/or metastatic cervical cancer, we believe there may be opportunities for tisotumab vedotin in earlier lines of cervical cancer and in other solid tumors that express TF. In 2018, we and Seattle Genetics announced innovaTV 207 and innovaTV 208, Phase II studies to assess, respectively, the activity, safety and tolerability of tisotumab vedotin for the treatment of selected solid tumors and the efficacy of tisotumab vedotin for platinum-resistant ovarian cancer. Both studies are currently recruiting.

**Enapotamab Vedotin**

Enapotamab vedotin is an ADC created to target to AXL (from anexelekto, or uncontrolled growth), a signaling molecule expressed on many solid cancers and implicated in tumor biology. AXL contributes to tumor progression and has been associated with poor clinical prognosis in many cancer types. Over-expression has been described in solid cancers, including lung, esophageal, ovarian, breast, cervical, thyroid, endometrial and pancreatic cancers. AXL is emerging as a marker in tumors with resistance to therapy (e.g., tyrosine kinase inhibitors, chemotherapy). In addition, over-expression of AXL is observed in advanced tumors with epithelial-mesenchymal transition, or EMT-like features.

Enapotamab vedotin is fully owned by Genmab, and the ADC technology used with enapotamab vedotin has been licensed from Seattle Genetics. In December 2016, we announced a Phase I/II clinical trial, GCT021-01, to evaluate the safety of enapotamab vedotin for the treatment of patients with solid tumors. We launched Part 1 of the study in December 2016 and Part 2a in April 2018. In May 2018, we launched a Phase I/II clinical trial of enapotamab vedotin for the treatment of multiple types of solid tumors, with several expansion cohorts currently ongoing. Preliminary efficacy data from the non-small cell lung cancer expansion cohort phase (n=26) was presented at the International Association for the Study of Lung Cancer 2019 World Conference on Lung Cancer in September 2019. ORR was 19% with median time to onset of response of 11 weeks (95% CI: 5.0 – 17.0) and median duration of response of 18.1 weeks. Enapotamab vedotin had a manageable safety profile with mostly Grade 1/2 AEs. The most common (≥20%) treatment-emergent AEs were fatigue (n=17), constipation (n=15), nausea (n=11) and decreased appetite (n=11). Discontinuations occurred due to the following AEs: neuropathy (n=5), pleural effusion (n=1), pneumonitis (n=1), clinical progression (n=1), fatigue (n=1) and fatigue and constipation (n=1). All deaths (n=3, 12%) were unrelated to treatment.

**HexaBody-DR5/DR5**

HexaBody-DR5/DR5 is a proprietary antibody therapeutic candidate created with our proprietary HexaBody technology. HexaBody-DR5/DR5 consists of two non-competing HexaBody molecules that are designed to target two distinct epitopes on death receptor 5, or DR5, a cell surface receptor that mediates a process called programmed cell death. Increased expression of DR5 has been reported in several types of tumors. We believe that HexaBody-DR5/DR5 may have potential in treatment of a number of solid cancers. HexaBody-DR5/DR5 is the first HexaBody molecule to enter the clinic. In 2018, we initiated a Phase I/II clinical trial of HexaBody-DR5/DR5, GCT1029-01, for the treatment of solid tumors, with the first patient dosed in May 2018. The Phase I/II clinical trial was put on a brief partial clinical hold for discussions with the U.S. FDA around liver toxicity. After the protocol was amended with additional provisions to mitigate liver toxicity risk the partial hold was lifted in October 2019 and enrollment of patients was re-opened. The study is currently recruiting.

**Epcoritamab (DuoBody-CD3xCD20)**

Epcoritamab (DuoBody-CD3xCD20) is a proprietary bispecific antibody therapeutic candidate created using our proprietary DuoBody technology. Epcoritamab is designed to target CD3, which is expressed on all T-cell subtypes and is part of the T-cell receptor, and CD20, a clinically well-validated therapeutic target. CD20 is expressed in a majority of B-cell malignancies, including CLL, diffuse large B-cell lymphoma (DLBCL), follicular lymphoma (FL) and mantle cell
lymphoma (MCL). In a number of laboratory models, epcoritamab has shown high potency in killing CD20+ tumors and induced potent tumor cell lysis across a panel of B-cell tumor lines. A variety of B-cell xenograft models also indicated that epcoritamab induces tumor regression. In addition, in cynomolgus monkeys, both subQ and IV formulations of epcoritamab resulted in rapid and sustained B-cell depletion in the periphery and the lymph nodes. We believe that epcoritamab could also have potential to treat B-cell malignancies. We dosed the first patient in a Phase I/II study of a subQ formulation of epcoritamab for the treatment of B-cell malignancies in July 2018. In December 2019 initial dose-escalation data (n=31) from the Phase I/II clinical trial was presented at ASH. At data cut-off (June 28, 2019), eighteen patients were enrolled into the dose-escalation part of the trial, with safety data available for patients receiving doses starting at 4 μg. The most common (n≥5) treatment-emergent AEs were pyrexia (n=8), local injection-site reactions (n=7), diarrhea (n=5), fatigue (n=5), and increased aspartate aminotransferase (n=5). The most common Grade 3/4 AEs were anemia (n=3) and neutropenia (n=3). Despite increasing epcoritamab doses, all CRS events were non-severe (initial observation: 3/8 pts, G1: n=1, G2: n=2; following modification of premedication plan (corticosteroids for 3 days): 6/10 pts, G1: n=4, G2: n=2). Increases in peripheral cytokine (IL6, IL8, IL10, IFNγ, TNFα) concentrations after epcoritamab dosing correlated with clinical symptoms of CRS in most patients. No patients had tumor lysis syndrome or neurological symptoms. No dose limiting toxicities (DLTs) were observed. Additional data presented at ASH, with a data cutoff of December 2, 2019, included twenty-two patients enrolled in the study with nineteen evaluable. Of the nineteen ORR was 36.8%. Of the thirteen evaluable patients in the DLBCL/HGBCL arm two achieved a response and all five of the evaluable patients in the FL arm achieved a response. Clinical activity was observed across aggressive and indolent NHL subtypes at low dose levels and greater DLBCL clinical activity was seen with higher doses, consistent with pharmacokinetic modeling. Further dose escalation of subQ epcoritamab is ongoing and new clinical studies will be initiated once the recommended Phase II dose is established.

DuoBody-PD-L1x4-1BB

DuoBody-PD-L1x4-1BB is a bispecific antibody designed to target PD-L1 and 4-1BB to block the inhibitory PD-1/PD-L1 axis and simultaneously activate essential co-stimulatory activity via 4-1BB using an inert Fc backbone. PD-L1 is a validated target that is expressed on tumor cells. 4-1BB is a trans-membrane receptor belonging to the TNF receptor super-family and is expressed predominantly on activated T-cells. In pre-clinical settings, DuoBody-PD-L1x4-1BB promoted conditional T-cell activation in a tumor-specific manner by simultaneous activation and release of the tumor inhibitory brake. Pre-clinical studies also indicated a release of T-cell inhibitory activity through the PD-L1/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. We submitted a CTA for this product candidate in 2019 and dosed the first patient for a Phase I/II study of DuoBody-PD-L1x4-1BB for the treatment of malignant solid tumors in May 2019.

DuoBody-CD40x4-1BB

DuoBody-CD40x4-1BB is a bispecific antibody designed to conditionally activate both CD40-expressing antigen-presenting cells (APC) and 4-1BB-expressing T-cells using an inert DuoBody format. In preclinical settings, as presented at European Association for Cancer Immunotherapy Annual meeting in May 2019, the CD40- and 4-1BB-specific Fab arms of DuoBody-CD40x4-1BB bound to primary human CD40-expressing CD20+ B cells and activated 4-1BB-expressing CD3+ T cells. DuoBody-CD40x4-1BB dose-dependently induced CD40 signaling only upon CD40 binding and simultaneous binding to 4-1BB expressing cells and induced 4-1BB signaling only upon 4-1BB binding and simultaneous binding to CD40-expressing cells. DuoBody-CD40x4-1BB was also shown to conditionally increase proliferation of activated T cells in the presence of CD40-expressing cells in vitro. DuoBody-CD40x4-1BB induced T-cell proliferation upon crosslinking of CD40- and 4-1BB-expressing cells and the binding of only the CD40 arm or the 4-1BB arm had no effect on T-cell proliferation. In addition, DuoBody-CD40x4-1BB did not induce proliferation of T cells that had not been activate 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 in solid tumors. We are developing DuoBody-CD40x4-1BB for the treatment of solid cancers in collaboration with BioNTech using Gennmab’s proprietary DuoBody
technology platform and BioNTech’s CD40 and 4-1BB antibodies. We submitted a CTA for this product candidate in 2019 and the first patient was dosed in the first-in-human Phase I/II study of DuoBody-CD40x4-1BB for the treatment of malignant solid tumors in September 2019.

**DuoHexaBody-CD37**

DuoHexaBody-CD37 is a bispecific IgG1, created with our propriety DuoHexaBody technology platform. 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. Complement-dependent cytotoxicity (CDC) is an efficient effector mechanism employed by multiple existing antibody therapeutics, but CD37 antibody-based therapeutics currently in clinical development are poor inducers of CDC. With DuoHexaBody-CD37 we aimed to generate CD37-specific antibodies with superior CDC activity. In preclinical settings DuoHexaBody-CD37 has been shown to induce potent *in vivo* and *in vitro* anti-tumor activity. As presented at ASH in December 2018, DuoHexaBody-CD37 induced superior CDC activity compared to single HexaBody molecules or the combination thereof in CLL cells *ex vivo*. In addition, the potency of DuoHexaBody-CD37 was superior to standard-of-care CD20 antibodies. The encouraging preclinical models suggest DuoHexaBody-CD37 is a promising candidate for clinical development in B-cell malignancies and an IND was submitted to the FDA in November 2019. The first patient was dosed with DuoHexaBody-CD37 in March 2020.

**Pre-clinical Programs**

In addition to our marketed products and clinical product candidates, we have approximately 20 active in-house and partnered preclinical programs. Our two most advanced proprietary preclinical programs are (i) DuoBody-CD3x5T4 and (ii) HexaBody-CD38.

**DuoBody-CD3x5T4**

DuoBody-CD3x5T4 is a CD3 bispecific, Fc-silenced IgG1 antibody with the capacity to crosslink T cells with 5T4-expressing tumor cells. In preclinical models DuoBody-CD3x5T4 shows potent antitumor activity *in vitro* and *in vivo* in a range of cancer indications. Initial preclinical data for DuoBody-CD3x5T4 was presented at the 34th Society for Immunotherapy of Cancer Annual Meeting in November 2019. Key findings were that DuoBody-CD3x5T4 induced CD4+ and CD8+ T-cell mediated cytotoxicity in 5T4-expressing tumor cell lines derived from a variety of solid cancers. T-cell mediated cytotoxicity was associated with T-cell activation, release of perforin and granzyme B and production of inflammatory cytokines. DuoBody-CD3x5T4 showed anti-tumor activity in breast cancer CDX and lung cancer PDX models in humanized mice, which was associated with peripheral T-cell activation and cytokine production *in vivo*. The broad expression of 5T4 across cancer indications and limited expression in normal cells makes DuoBody-CD3x5T4 a promising novel drug candidate with potential anti-tumor effect across different solid tumor indications. The first CTAs for DuoBody-CD3x5T4 were submitted to authorities in Denmark and Spain in January 2020, followed by the IND, which was submitted to the FDA in February 2020.

**HexaBody-CD38**

HexaBody-CD38 is a novel human CD38 monoclonal antibody product incorporating our HexaBody technology. In preclinical models of hematological malignancies, as presented at ASH in December 2019, HexaBody-CD38 demonstrates enhanced CDC and shows potent anti-tumor activity. HexaBody-CD38 carries the E430G mutation that facilitates the natural process of antibody hexamer formation through intermolecular Fc-Fc interactions after antigen binding at the cell surface. Enhanced IgG hexamer formation increases binding of the hexavalent complement component C1q, thereby potentiating or unlocking antibody-mediated CDC. HexaBody-CD38 induced highly potent CDC *in vitro* in cell lines derived from hematological malignancies including MM, BCL and AML, inducing CDC in seventeen out of twenty-eight tumor cell lines that were not sensitive to daratumumab (<50% tumor cell lysis), including cell lines with low expression of CD38 or high expression of the complement inhibitory protein CD59. HexaBody-CD38 did not induce lysis of normal human B cells, T cells or erythrocytes, and induced minimal lysis of normal human NK cells. In addition, HexaBody-CD38 was consistently more potent than daratumumab in samples from daratumumab-naïve patients (newly diagnosed or relapsed/refractory to standard-of-care, including chemotherapy or high dose chemotherapy followed by ASCT, immunomodulatory drugs and proteasome inhibitors). In June 2019, Genmab entered
into an exclusive worldwide license and option agreement with Janssen to develop and commercialize HexaBody-CD38. See below for additional details about this agreement. We intend to submit an IND to the FDA and/or a CTA to the EMA for HexaBody-CD38 in 2020.

Partnered Candidates

As of December 31, 2019, our partners have ten additional product candidates in clinical development through collaboration agreements with us. These include several antibodies being developed by Janssen using our proprietary DuoBody technology, which are being tested to treat NSCLC, AML, R/R AML or MDS, solid tumors and certain MM indications. Additional products are being developed in partnership with BMS, ADC Therapeutics, Lundbeck, Amgen and Novo Nordisk. In December 2019 the first clinical trial for Mim8, a DuoBody product candidate for hemophilia being developed by Novo Nordisk under our DuoBody collaboration with them, was published on www.clinicaltrials.gov.

Our Technology Platforms

DuoBody Platform

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

Epcoritamab (DuoBody-CD3xCD20), DuoBody-PD-L1x4-1BB and DuoBody-CD40x4-1BB are our first proprietary bispecific antibodies created with DuoBody technology to reach clinical development. In addition, Janssen has progressed a number of product candidates into clinical development through our DuoBody partnership.

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 (e.g. in the case of our HexaBody-DR5/DR5 product leading to cell death). 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 our DuoBody platform as well as other antibody technologies. The technology has the potential to enhance antibody therapeutics for a broad range of applications in cancer and infectious diseases.
HexaBody-DR5/DR5 is our first proprietary antibody created with HexaBody technology to reach clinical development. In addition, in June 2019, we entered into an exclusive license and option agreement with Janssen to collaborate exclusively on a next-generation CD38 antibody product incorporating our proprietary HexaBody technology. We actively seek new partners interested in developing antibody therapeutics using our HexaBody technology.

**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. We actively seek partners interested in developing antibody therapeutics using our DuoHexaBody technology.

**HexElect Platform**

The HexElect platform is a novel proprietary technology that combines two 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. We actively seek partners interested in developing antibody therapeutics using our HexElect technology.

**Manufacturing**

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

We have no involvement with the manufacturing process for our partnered approved products, DARZALEX, Arzerra and TEPEZZA, which are handled by Janssen, Novartis and Horizon, respectively, under the applicable agreements. Currently, the majority of the drug products required for our clinical trials and pre-clinical studies are manufactured by Lonza. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including fill and finish, shipping and storage of drug products and our product candidates. To meet our expected needs for commercial manufacturing in connection with the anticipated commercial launch of tisotumab vedotin, we are currently in negotiations with a CMO to manufacture commercial quantities of tisotumab vedotin, subject to regulatory approval. 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.

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

Our partnered approved products, DARZALEX, Arzerra and TEPEZZA, are marketed by Janssen, Novartis and Horizon, respectively, 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, Arzerra and TEPEZZA, but we are not involved with commercialization activities or strategy. We are currently in the early stages of building and expanding our commercial capabilities to allow us to market our own products in the future for the indications and in the geographies we determine would be most effective to create value for our shareholders. Our goal is to become a commercial-stage company with an initial focus on achieving commercial launch readiness to support the potential launch of tisotumab vedotin for the treatment of cervical cancer, subject to obtaining regulatory approval and, where applicable, reimbursement approval. We are developing tisotumab vedotin in collaboration with Seattle Genetics. Under our agreement, Seattle Genetics and Genmab will each be responsible for leading tisotumab vedotin commercialization activities in certain territories. We are currently in discussions with Seattle Genetics regarding the detailed terms on which we will work together to commercialize tisotumab vedotin under this agreement. We view Japan as a promising commercial opportunity where a modest commercial and medical affairs infrastructure has the potential to become a high-value investment. Given the low rate of cancer screening and HPV vaccinations in Japan, we believe that cervical cancer presents a significant unmet need in the Japanese medical market.

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

Competition

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

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

With respect to daratumumab, there are numerous other FDA-approved drugs for the treatment of MM, including immunomodulating agents such as Celgene’s Revlimid and Pomalyst®, PIs such as Janssen and Takeda’s Velcade®, Amgen’s Kyprolis®, and Takeda’s Ninlaro®, histone deacetylase inhibitors such as Novartis’ Farydak® and mAbs such as BMS’ Empliciti®. Several of these drugs are used in combination with chemotherapy and corticosteroids. The competition daratumumab faces from these and other therapies is intensifying. Additionally, isatuximab, a CD38 antibody developed by Sanofi, was approved as SARCLISA by the FDA in March 2020 for the treatment of adult patients with MM who have received at least two prior therapies including lenalidomide and a PI. In January 2020, GlaxoSmithKline announced a head-to-head trial of belantamab mafodotin, a humanized BCMA ADC, in combination
with bortezomib and dexamethasone versus daratumumab in combination with bortezomib and dexamethasone in patients with relapsed/refractory multiple myeloma. We are also aware of numerous additional investigational agents that are currently being studied. If any of these investigational agents are successful, they may compete with daratumumab in the future. Data have also been presented on several developing technologies and related potential products, including bispecific antibodies, ADCs and CAR-Ts that may compete with daratumumab in the future.

In December 2019 Novartis initiated the submission of an sBLA to the FDA for subQ ofatumumab for the treatment of RMS in adults. There are numerous FDA-approved drugs for the treatment of the various forms of MS, including Biogen Inc.’s Tecfidera®, Novartis’ GILENYA®, Sanofi’s AUBAGIO® and several mAbs such as Genentech’s OCREVUS® (a CD20 antibody), Sanofi’s LETRADA® and Biogen’s TYSABRI®; glatiramer acetate-based therapies such as Teva Pharmaceutical Industries Limited’s COPAXONE® and Sandoz’s Glatopa®; and interferon-beta-based therapies such as Biogen’s AVONEX® and PLEGRIDY®, Bayer AG’s BETAFERON®, Novartis’ EXTAVIA®, and Merck KGaA’s Rebi². A number of companies are also working to develop additional potential treatments for MS that may in the future further intensify the competition in the MS market, such as Celgene’s Ozanimod and Novartis’ Siponimod, which are currently being evaluated in Phase III clinical trials. Potential future sales may also be negatively impacted by the introduction of generics, prodrugs of existing therapeutics or biosimilars of existing products and other technologies.

With respect to tisotumab vedotin, we are aware of other companies that currently have products in development for the treatment of late-stage cervical cancer, which could be competitive with tisotumab vedotin, including checkpoint inhibitors from Agenus Inc., Regeneron Pharmaceuticals Inc., BMS, Merck, Roche, and Innovoat Biologics, Inc. as well as other drugs in development from companies such as Immunomedics. Additionally AXAL (axalimogene filolisibac, a targeted Listeria monocytogenes-based immunotherapy), developed by Advaxis, is in clinical trials for HPV-related cancers, including cervical cancer and LN-145 (autologous tumor infiltrating lymphocytes (TIL) therapy) from Iovance is in a Phase II study for recurrent, metastatic or persistent cervical carcinoma.

We are similarly aware, with respect to epcoritamab, of a number of other companies that have bispecific CD3xCD20-targeted products in development for the treatment of B-cell malignancies, which could be competitive with epcoritamab including Regeneron’s odronextamab, Roche’s mosunetuzumab and RG6026, Xencor’s Xmab13676 and IGM biosciences IGM 2323. We are also aware that there are a number of various CD20 and CD19 antibodies, immunomodulators, ADCs, tyrosine kinase inhibitors and CAR-T therapies that are either approved or in development for non-Hodgkin’s lymphomas.

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

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

In addition, in the United States, the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biological products that are demonstrated to be “highly similar” or “biosimilar” to or “interchangeable” with an FDA-approved biological product. This pathway allows competitors to reference the FDA’s prior approvals regarding innovative biological products and data submitted with a BLA to obtain approval of a biosimilar application 12 years after the time of approval of the innovative biological product. The 12-year exclusivity period runs from the initial approval of the innovator product and not from approval of a new indication. In addition, the 12-year exclusivity period does not prevent another company from independently developing a product that is highly similar to the innovative product, generating all the data necessary for a full BLA and seeking approval. Data exclusivity only assures that another company cannot rely on the FDA’s prior approvals in approving a BLA for an innovator’s
biological product to support the biosimilar product’s approval. Further, under the FDA’s current interpretation, it is possible that a biosimilar applicant could obtain approval for one or more of the indications approved for the innovator product by extrapolating clinical data from one indication to support approval for other indications. In the European Union, the European Commission has granted 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 additional technology;
- complete clinical trials which position our products for regulatory and commercial success;
- maintain a proprietary position in our technologies and products;
- obtain required government and other public and private approvals on a timely basis;
- attract and retain key personnel;
- commercialize effectively;
- obtain reimbursement for our products in approved indications;
- establish efficient manufacturing processes and supply chain;
- comply with applicable laws, regulations and regulatory requirements and restrictions with respect to our business, including the commercialization of our products, including with respect to any changed or increased regulatory restrictions; and
- enter into additional collaborations to advance the development and commercialization of our product candidates.

**Product and Technology Collaborations**

**Collaborations for our Marketed Products**

**Janssen Daratumumab License and Development Agreement**

In August 2012, we entered into a global license, development and commercialization agreement, or the Janssen Agreement, with Janssen Biotech Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, or 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, or JJDC, 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, 2019, Genmab has recorded $835 million in milestone payments from Janssen and could be entitled to receive up to $180 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, as calculated on the basis of the license agreement terms, were achieved. No further sales volume 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 $750 million; 13% on net sales between $750 million and $1.5 billion; 16% on net sales between $1.5 billion and $2.0 billion; 18% on net sales between $2.0 billion and $3.0 billion; and 20% on net sales exceeding $3.0 billion. The royalties payable by Janssen are limited in time and subject to reduction on a country-by-country basis for customary reduction events, including upon patent expiration or invalidation in the relevant country and upon the first commercial sale of a biosimilar product in the relevant country (for as long as the biosimilar product remains for sale in that country). Pursuant to the terms of the agreement, Janssen’s obligation to pay royalties under this agreement will expire on a country-by-country basis on the later of the date that is 13 years after the first sale of daratumumab in such country or upon the expiration of the last-to-expire relevant product patent (as defined in the agreement) covering daratumumab in such country. Janssen may fully or partially terminate the agreement at any time upon 150 days’ prior written notice to us. Our issued U.S., European and Japanese patents covering the composition of matter for daratumumab do not begin to expire until March 2026. 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.

**Novartis Ofatumumab Collaboration**

In December 2006, we entered into a co-development and collaboration agreement with 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. Ofatumumab is approved and marketed under the name Arzerra for the treatment of certain CLL cancer indications, where ofatumumab is being administered intravenously. In addition, Novartis is currently investigating a subQ formulation of ofatumumab for the treatment of RMS. 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 January 2018, due to low and decreasing global demand for Arzerra primarily related to increased competition from new entrants to the CLL treatment space, Novartis announced that it intends to transition the commercial availability of Arzerra to limited availability through managed access programs or alternative solutions for the treatment of approved CLL indications in non-U.S. markets where applicable and allowed by local regulations. In 2019, marketing authorizations for Arzerra were
withdrawn in the European Union and certain other territories. We expect Arzerra to remain commercially available for approved CLL indications in the United States and Japan. We recorded a one-time payment of $50 million from Novartis in 2018 as payment for lost potential milestones and royalties.

Certain Collaborations for our Proprietary Product Candidates

Seattle Genetics Tisotumab Vedotin Collaboration

In October 2011, we entered into a license and collaboration agreement with Seattle Genetics granting us an exclusive right to utilize Seattle Genetics’ ADC technology with our HuMax-TF antibody in return for milestone payments and royalties. We also granted Seattle Genetics 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, Seattle Genetics exercised this option to co-develop and co-commercialize tisotumab vedotin with us. Under our collaboration agreement, Seattle Genetics and Genmab will each be responsible for leading commercialization activities in certain territories. We are currently in discussions with Seattle Genetics regarding the detailed terms on which we will work together to commercialize tisotumab vedotin under this agreement. All costs and profits for tisotumab vedotin will be shared on a 50:50 basis. However, either party may opt out of co-development and profit-sharing in return for receiving milestone payments and royalties from the continuing party.

Seattle Genetics ADC Technology License

In September 2014, we entered into an ADC license agreement with Seattle Genetics. Under this agreement, we paid an upfront fee of $11 million for exclusive rights to utilize Seattle Genetics’ ADC technology with our HuMax-AXL antibody. Pursuant to this agreement, Seattle Genetics is also entitled to receive more than $200 million in potential milestone payments and mid-to-high single digit royalties on worldwide net sales of any resulting products. In addition, prior to our initiation of a Phase III study for any resulting products, Seattle Genetics has the right to exercise an option to increase the royalties to the low tens in exchange for a reduction of the milestone payments owed by us. Irrespective of any exercise of this option, we remain in full control of the development and commercialization of any resulting products.

BioNTech DuoBody Collaboration

In May 2015, we entered into an agreement with BioNTech SE, or BioNTech to jointly research, develop and commercialize bispecific antibody products using our DuoBody technology platform and antibodies. Under the terms of the agreement, BioNTech provides proprietary antibodies against key immunomodulatory targets, while we provide access to our DuoBody technology platform. We paid an upfront fee of $10 million to BioNTech and an additional $2 million as certain BioNTech assets were selected for further development. If the companies jointly select any product candidates for clinical development, development costs and product ownership will be shared equally going forward. If one of the companies does not wish to move a product candidate forward, the other company is entitled to continue developing the product on predetermined licensing terms. The agreement also includes provisions which will allow the parties to opt out of joint development at key points. Two product candidates are currently in development in connection with this agreement, DuoBody-PD-L1x4-1BB and DuoBody-CD40x4-1BB. We submitted CTAs for these product candidates in 2019 and dosed the first patient in a Phase I/II study of DuoBody-PD-L1x4-1BB in May 2019 and dosed the first patient in a Phase I/II study of DuoBody-CD40x4-1BB in September 2019.

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 16 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, enapotamab, forming part of enapotamab 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, enapotamab vedotin, epcoritamab (DuoBody-CD3-CD20), 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. Aggregate milestones for the product candidates subject to payment obligations range from $1.5 million to $6 million per product, of which a total of approximately $17.4 million remains payable by us or our partners across all such product candidates currently in development. Royalties are in the low single digits of net sales.

Janssen HexaBody-CD38 Collaboration

In June 2019, we entered into an exclusive worldwide license and option agreement with Janssen to develop and commercialize HexaBody-CD38, a next-generation human CD38 mAb product incorporating our proprietary HexaBody technology. Under the terms of the agreement, we have agreed to collaborate exclusively with Janssen on HexaBody-CD38 and to fund research and development activities until completion of clinical proof of concept studies in MM and diffuse large B-cell lymphoma. Based on the data from these studies, Janssen may exercise its option and receive a worldwide exclusive license to certain of our intellectual property and an exclusive sublicense to certain intellectual property that we license from third parties, in each case, to develop, manufacture and commercialize HexaBody-CD38. If Janssen exercises this option, we will be entitled to a $150 million option exercise fee and up to $125 million in development milestones, as well as a flat royalty rate of 20% on sales of HexaBody-CD38 until a specified time in 2031, followed by 13-20% tiered royalties on 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.

Immatics Collaboration

In July 2018, we entered into a research collaboration and exclusive license agreement with Immatics to discover and develop next-generation bispecific immunotherapies to target multiple cancer indications. We received an exclusive license to three proprietary targets disclosed and developed from Immatics’ XPRESIDENT targets and T-cell receptor technology, with an option to license up to two additional targets at predetermined economics. We and Immatics will conduct joint research, funded by us, on multiple antibody and/or T-cell receptor-based bispecific therapeutic product concepts. We may elect to progress any resulting product candidates, and will be responsible for development, manufacturing and worldwide commercialization. For any products that are commercialized by us, Immatics will have an option to limited co-promotion efforts in selected countries in the European Union. Under the terms of the agreement, we paid Immatics an upfront fee of $54 million in July 2018 and Immatics is eligible to receive up to $550 million in development, regulatory and commercial milestone payments for each product, as well as tiered royalties in the high-single digits to low tens on net sales.

CureVac Collaboration

During December 2019, Genmab entered into a research collaboration and license agreement with CureVac AG. The strategic partnership will focus on the research and development of differentiated mRNA-based antibody products by combining CureVac’s mRNA technology and know-how with Genmab’s proprietary antibody technologies and expertise. Under the terms of the agreement Genmab will provide CureVac with a $10 million upfront payment. The companies will collaborate on research to identify an initial product candidate and CureVac will contribute a portion of
the overall costs for the development of this product candidate, up to the time of an Investigational New Drug Application. Genmab would thereafter be fully responsible for the development and commercialization of the potential product, in exchange for $280 million in development, regulatory and commercial milestones and tiered royalties in the range from mid-single digits up to low-double digits to CureVac. The agreement also includes three additional options for Genmab to obtain commercial licenses to CureVac’s mRNA technology at pre-defined terms, exercisable within a five-year period. If Genmab exercises any of these options, it would fund all research and would develop and commercialize any resulting product candidates with CureVac eligible to receive between $275 million and $368 million in development, regulatory and commercial milestone payments for each product, dependent on the specific product concept. In addition, CureVac is eligible to receive tiered royalties in the range from mid-single digits up to low double digits per product. CureVac would retain an option to participate in development and/or commercialization of one of the potential additional programs under predefined terms and conditions. Further, Genmab made a €20 million equity investment in CureVac. The investment in CureVac AG is recorded at fair value through profit and loss. This investment represents 2.2% ownership of CureVac AG and is recorded at a fair value of DKK 149 million as of December 31, 2019.

Other Collaborations and Agreements

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

We also license technologies from a number of other companies that we use or have used to contribute to the antibody products in our pipeline. Key technologies include Seattle Genetics’ ADC technologies, the OmniAb transgenic mouse and rat platforms from OMT, certain transgenic mouse technologies from Medarex, the rabbit antibody platform from MAB Discovery GmbH and certain expression systems used by Lonza for production of our product candidates. Pursuant to certain of these licenses, we or our partners are or may be obligated to pay small royalties for certain products generated or produced using these technologies upon commercialization of such products or product candidates. We also license certain targets disclosed and developed from Immatics’ XPRESIDENT targets and T-cell receptor technology as part 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 May 24, 2019, we held more than 1,100 patents and patent applications, including more than 35 issued U.S. patents and more than 50 U.S. patent applications. All of our current issued patents and patent applications are projected to expire between 2019 and 2039.

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

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

The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage as determined by the patent office or courts in the country, and the availability of legal remedies in the country. This list above does not identify all patents that may be related to daratumumab, ofatumumab 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, that may confer additional patent protection. We also have pending patent applications that may give rise to new patents related to one or more of these product candidates, technologies, formulations and uses.

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

Patents expire, on a country-by-country basis, at various times depending on various factors, including the filing date of the corresponding patent application(s), the availability of patent term adjustment, patent term extension and supplemental protection certificates and requirements for terminal disclaimers. Although we believe our owned and licensed patents and patent applications provide us with a competitive advantage, the patent positions of biotechnology and pharmaceutical companies can be uncertain and involve complex legal and factual questions. We and our partners may not be able to develop patentable products or processes or obtain patents from pending patent applications. In the event of patent issuance, the patents may not be sufficient to protect the proprietary technology owned by or licensed to us or our partners. Our or our partners’ current patents, or patents that issue on pending applications, may be challenged, invalidated, infringed or circumvented. In addition, changes to patent laws in the United States or in other countries may limit our ability to defend or enforce our patents, or may apply retroactively to affect the term and/or scope of our patents. Our patents have been and may in the future be challenged by third parties in post-issuance administrative proceedings or in litigation as invalid, not infringed or unenforceable under U.S. or foreign laws, or they may be infringed by third parties. As a result, we are or may be from time to time involved in the defense and enforcement of our patent or other intellectual property rights in a court of law and administrative tribunals, such as in USPTO inter partes review or reexamination proceedings, foreign opposition proceedings or related legal and administrative proceedings in the United States and elsewhere. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings or litigation may be substantial and the outcome can be uncertain. An adverse outcome may allow third parties to use our proprietary technologies without a license from us or our partners. Our
partners’ patents may also be circumvented, which may allow third parties to use similar technologies without a license from us or our partners.

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

**Trademarks**

As of April 17, 2019, we and/or our subsidiaries own approximately 285 international trademark registrations and applications, and 12 U.S. trademark registrations, including: Genmab®; the Y-shaped Genmab logo®; Genmab in combination with the Y-shaped Genmab logo®; HuMax®; DuoBody®; DuoBody in combination with the DuoBody logo®; HexaBody®; HexaBody in combination with the HexaBody logo®; DuoHexaBody®; HexElect®; and UniBody®. Arzerra® is a trademark of Novartis Pharma AG or its affiliates. DARZALEX® is a trademark of Janssen Pharmaceutica NV. TEPEZZA™ is a trademark of Horizon Therapeutics plc. Other than the registered trademarks listed above, we currently rely on our unregistered trademarks, trade names and service marks, as well as our domain names and logos, as appropriate, to market our brands and to build and maintain brand recognition. We are seeking to register and will continue to seek to register and renew, or secure by contract where appropriate, trademarks, trade names and service marks as they are developed and used, and reserve, register and renew domain names as appropriate. If we do not secure trademark registration successfully for our trademarks, we may encounter difficulty in enforcing, or be unable to enforce, our rights in our trademarks, trade names and service marks against third parties.

**Trade Secrets**

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

**Government Regulation**

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

**Review and Approval of Biologic Products in the United States**

Biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, and the Public Health Service Act, or PHS 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 studies performed in accordance with the FDA's current Good Laboratory Practices, or cGLP, 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, or 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, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a Biologics License Application, or BLA, after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to file 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 Good Clinical Practices, or 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 annually when significant changes are made.

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

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

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

- **Phase 1**—The investigational product is initially introduced into human patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- **Phase 2**—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 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- **Phase 3**—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 4 studies may be made a condition to approval of the BLA.

Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within a specified period, if at all, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.
Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, non-clinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent pre-clinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product’s chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators. The submission of a BLA requires payment of a substantial user fee to the FDA, and the sponsor of an approved BLA is also subject to annual program fees. These fees are typically increased annually. A waiver of user fees may be obtained under certain limited circumstances.

In addition, under the Pediatric Research Equity Act, or 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. The Food and Drug Administration Safety and Innovation Act, or FDASIA, requires that 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 submit an initial Pediatric Study Plan, or PSP, within sixty days after an end-of-Phase 2 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. The review process may be extended by the FDA’s requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product’s continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

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

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or 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 4 post-market studies and surveillance to further assess and monitor the product’s safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA’s policies may change, which could delay or prevent regulatory approval of our products under development.

**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. If criteria are not met for priority review, the application is subject to the standard FDA review period of 10 months after FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the accelerated approval program, the FDA may approve a BLA on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical objective that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing studies or completion of ongoing studies after marketing approval are generally required to verify the biologic’s clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. In addition, a sponsor may seek FDA breakthrough therapy designation, or BTD, of its product candidate if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant objectives, such as substantial treatment effects observed early in clinical development. Sponsors may request the FDA to designate a breakthrough therapy at the time of or any time after the submission of an IND, but ideally before an end-of-Phase 2 meeting with the FDA. 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.

The FDA is also exploring other options to expedite processing of certain applications. For example, in 2018 the FDA started using real-time review of drug applications to evaluate clinical data as soon as the trial results become available. This means that the FDA can approve a new indication soon after an applicant files a marketing application. Currently, this approach is only being implemented by the FDA’s Oncology Center of Excellence through two pilot programs, including the FDA’s Real-Time Oncology Review, or RTOR, Pilot Program, which is currently available for certain supplemental applications for already-approved cancer drugs.
FTD, priority review, BTD, and pilot review programs do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

**Review and Approval of Combination Products**

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

**Post-Approval Requirements**

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

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

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

**Biosimilars and Exclusivity**

The Affordable Care Act, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or diminishing efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant’s own pre-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed “interchangeable” by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA
exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact of the BPCIA is subject to significant uncertainty.

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

**Regulation of Diagnostic Tests**

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

PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, pre-clinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA application typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. FDA review of an initial PMA may require several years to complete. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA’s evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

On August 6, 2014, the FDA issued a final guidance document addressing the development and approval process for “In Vitro Companion Diagnostic Devices.” According to the guidance, 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, or IDE, regulations. Thus, the sponsor of the diagnostic device will be required to comply with the IDE regulations. According to the guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets both the requirements of the IDE regulations and the IND regulations.

In the EEA, in vitro diagnostics medical devices are required to conform with the essential requirements of the EU Directive on in vitro diagnostic medical devices (Directive No 98/79/EC, as amended). To demonstrate compliance with the essential requirements, the manufacturer must undergo a conformity assessment procedure. The conformity assessment varies according to the type of in vitro diagnostics medical device and its classification. The conformity assessment of in vitro diagnostics medical devices can require the intervention of an accredited EEA Notified Body. If successful, the conformity assessment concludes with the drawing up by the manufacturer of an EC Declaration of Conformity entitling the manufacturer to affix the CE mark to its products and to sell them throughout the EEA.
On April 5, 2017, the European Parliament passed the In Vitro Device Regulation, or IVDR, which repeals and replaces Directive No 98/79/EC. Unlike directives, which must be implemented into the national laws of the EU member states, a regulation is directly applicable, i.e., without the need for adoption of EU member state laws implementing them, in all EEA member states. The IVDR, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EU for in vitro diagnostic medical devices and ensure a high level of safety and health while supporting innovation. The IVDR will not become fully applicable until five years following its entry into force.

Other Healthcare Laws and Compliance Requirements

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

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

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

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willingly executing, or attempting to execute, a scheme or making false statements in connection with the delivery of or payment for health care benefits, items, or services;

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

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

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

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

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

**Healthcare Reform**

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

In March 2010, the U.S. Congress enacted the ACA, which, among other things, includes changes to the coverage and payment for drug products under government health care programs. Among the provisions of the ACA of importance to our potential product candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer’s Medicaid rebate liability; and

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.
Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, 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 went into effect in April 2013 and will remain in effect through 2027 unless additional Congressional action is taken.

Since its enactment, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the ACA. Some of the provisions of the ACA have yet to be implemented, and there have been legal and political challenges to certain aspects of the ACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Moreover, the Tax Reform Bill was enacted on December 22, 2017, and includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Congress may consider other legislation to repeal or replace additional elements of the ACA. We continue to evaluate the effect that the ACA, the repeal of the individual mandate, and any additional 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 that we successfully commercialize or to successfully commercialize our product candidates, if approved. In addition to the ACA, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payers to keep healthcare costs down while expanding individual healthcare benefits.

**Coverage and Reimbursement**

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

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

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

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

**Review and Approval of Medicinal Products in the European Union**

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

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on Good Clinical Practice, or GCP, and the related national implementing provisions of the individual EU member states, or EU Member States, govern the system for the approval of clinical trials in the European Union. Under this system, an applicant must obtain prior approval from the competent national authority of the EU Member States in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by, among other documents, an investigational medicinal product dossier, or the Common Technical Document, with supporting information prescribed by Directive 2001/20/EC, Directive 2005/28/EC, where relevant the implementing national provisions of the individual EU Member States and further detailed in applicable guidance documents.

In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014, or the Clinical Trials Regulation, was adopted, and is anticipated to enter into force in 2019. The Clinical Trials Regulation will be directly applicable in all of the EU Member States, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the European Union will continue to be bound by currently applicable provisions until the new Clinical Trials Regulation becomes applicable. The extent to which on-going clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable, the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

The Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: 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; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (EU Member States concerned). Part II is assessed separately by each EU Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation.

To obtain a marketing authorization for a product under European Union regulatory systems, an applicant must submit an MAA either under a centralized procedure administered by the EMA, or one of the procedures administered by competent authorities in the EU Member States (decentralized procedure, national procedure or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the European Union. Regulation (EC) No 1901/2006 provides that prior to obtaining a marketing authorization in the European Union, applicants have to demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted (1) a product-specific waiver, (2) a class waiver or (3) a deferral for one or more of the measures included in the PIP.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all EU Member States and three of the four European Free Trade Association, or EFTA, States, Iceland, Liechtenstein and Norway. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA is responsible for conducting the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. If the CHMP accepts such request, the time limit of 210 days will be reduced to 150 days but it is possible that the CHMP can revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. At the end of this period, the CHMP provides a scientific opinion on whether or not a marketing authorization should be granted in relation to a medicinal product. Within 15 calendar days of receipt of a final opinion from the CHMP, the European Commission must prepare a draft decision concerning an application for marketing authorization. This draft decision must take the opinion and any relevant provisions of EU law into account. Before arriving at a final decision on an application for centralized authorization of a medicinal product the European Commission must consult the Standing Committee on Medicinal Products for Human Use. The Standing Committee is composed of representatives of the EU Member States and chaired by a non-voting European Commission representative. The European Parliament also has a related "droit de regard". The European Parliament’s role is to ensure that the European Commission has not exceeded its powers in deciding to grant or refuse to grant a marketing authorization.

Unlike the centralized authorization procedure, the decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials
due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the European Commission, whose decision is binding on all EU Member States.

The mutual recognition procedure similarly is based on the acceptance by the competent authorities of the EU Member States of the marketing authorization of a medicinal product by the competent authorities of other EU Member States. The holder of a national marketing authorization may submit an application to the competent authority of an EU Member State requesting that this authority recognize the marketing authorization delivered by the competent authority of another EU Member State.

In the European Union, innovative medicinal products approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity pursuant to Directive 2001/83/EC. Regulation (EC) No 726/2004 repeats this entitlement for medicinal products authorized in accordance with the centralized authorization procedure. Data exclusivity prevents applicants for authorization of generics of these innovative products from referencing the innovator’s data to assess a generic (abbreviated) application for a period of eight years. During an additional two-year period of market exclusivity, a generic marketing authorization application can be submitted and authorized, and the innovator’s data may be referenced, but no generic medicinal product can be placed on the European Union market until the expiration of the market exclusivity. The overall 10-year period will be extended to a maximum of 11 years if, during the first eight years of those 10 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. Even if a compound is considered to be a new chemical entity so that the innovator gains the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical tests, pre-clinical tests and clinical trials.

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

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

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

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

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

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

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

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union (commonly referred to as “Brexit”). Thereafter, on March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Treaty of Lisbon Amending the Treaty on European Union and the Treaty Establishing the European Community. The withdrawal of the United Kingdom from the European Union will take effect either on the effective date of the withdrawal agreement or, in the absence of agreement, two years after the United Kingdom provided its notice of withdrawal pursuant to the Treaty on European Union. Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the United Kingdom. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the United Kingdom.

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 & development, general & administrative, and management activities on behalf of Genmab A/S.

D. PROPERTY, PLANT AND EQUIPMENT

Our corporate headquarters are located in Copenhagen, Denmark, where we currently lease approximately 56,500 square feet, pursuant to a lease agreement dated as of February 15, 2017, by and between us and Castellum 2 i København ApS, or Castellum, as amended. On December 14, 2018, we entered into an agreement with Castellum for additional lease space in Copenhagen, Denmark, to lease approximately 14,929 square feet. The leases are perpetual, but can be terminated with six months’ prior notice, which can be made effective no earlier than December 1, 2022 in the case of termination by us, and no earlier than December 1, 2027 in the case of termination by Castellum.
Our indirectly wholly-owned subsidiary, Genmab B.V., leases approximately 90,094 square feet of office, laboratory and pre-clinical development space in Utrecht, the Netherlands pursuant to a lease agreement dated June 17, 2015. The start date of the lease term is May 22, 2017 and the lease term is 15 years with a cost-free break option at 10 years.

In addition, our wholly-owned subsidiary, Genmab US, Inc., leases approximate 24,771 square feet of office space with a termination date of December 31, 2022.

During 2019, Genmab A/S’s subsidiaries including Genmab US, Inc. and Genmab B.V. entered into lease agreements with respect to office and laboratory space. See Note 3.3 of the Audited Financial Statements for additional details regarding the leases.

We believe that suitable additional or alternative space for each of our locations would be available as required in the future on commercially reasonable terms. However, the unexpected loss of our Utrecht laboratory facility or termination of the lease could result in delays in development of certain products and technology while we transition our research operations to an alternate facility.

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 specializing in antibody therapeutics for the treatment of cancer and other diseases. Our core purpose is to improve the lives of patients by creating and developing innovative antibody products. Our vision is to transform cancer treatment by launching our own proprietary product by 2025 and advancing our pipeline of differentiated and well-tolerated antibodies. We are building and expanding our late-stage development and commercial capabilities to allow us to bring our proprietary products to market in the future. We are continuing to build a well-diversified portfolio of products, product candidates and technologies. Our portfolio includes three approved partnered products, daratumumab, marketed by Janssen Biotech, Inc. as DARZALEX for the treatment of certain MM indications, ofatumumab, marketed as Arzerra by Novartis AG for the treatment of certain CLL indications and teprotumumab, approved as TEPEZZA, developed by Horizon Therapeutics plc for the treatment of thyroid eye disease, in addition to a broad pipeline of differentiated product candidates. Our pipeline includes seven proprietary product candidates in clinical development and approximately 20 proprietary and partnered pre-clinical programs, including two proprietary candidates for which we have submitted or intend to submit INDs to the FDA and/or CTAs to the EMA in 2020. In addition to our proprietary clinical product candidates and our partners’ ongoing label expansion studies for daratumumab and ofatumumab, our partners have ten additional product candidates in clinical development through collaboration agreements with us. Our portfolio also includes four proprietary antibody technologies that play a key role in building our product pipeline, enhancing our partnerships and generating revenue. We selectively enter into strategic alliances 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.

In addition to our partnered approved products, we are currently in the early stages of building and expanding our commercial capabilities to allow us to market our own products in the future for the indications and in the geographies we determine would be most effective to create value for our shareholders. Our goal is to become a commercial-stage company. Our initial focus will be on achieving commercial launch readiness to support the potential launch of tisotumab vedotin for the treatment of cervical cancer, subject to obtaining regulatory approval and, where applicable, reimbursement approval. We are developing tisotumab vedotin in collaboration with Seattle Genetics. Under our agreement, Seattle Genetics and Genmab will each be responsible for leading tisotumab vedotin commercialization
activities in certain territories. We are currently in discussions with Seattle Genetics regarding the detailed terms on which we will work together to commercialize tisotumab vedotin under this agreement.

In 2019, we generated revenue of DKK 5,366 million and recorded operating income of DKK 2,638 million and net income of DKK 2,166 million, as compared to revenue of DKK 3,025 million, operating income of DKK 1,380 million and net income of DKK 1,472 million in 2018. Our results of operations have been, and we expect them to continue to be, affected by our collaboration with Janssen for the development and commercialization of daratumumab. Since inception, we have funded our operating requirements primarily through proceeds from equity financings and milestone payments and royalties from our partners. We expect to continue to fund a significant portion of our development costs for our proprietary product candidates as well as our planned commercialization activities with funds received from royalties and milestone payments from our partners.

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—Product and Technology Collaborations” in this Annual Report.

Key Components of Our Results and Related Trends

Revenues

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

In 2019, DKK 4,983 million, or 93% of our total revenues, related to our various collaborations with Janssen, as compared to DKK 2,390 million, or 79% of our total revenues, in 2018. In 2019, DKK 4,910 million, or 99% of our revenues received under our various collaborations with Janssen were related to royalties and milestone payments with respect to DARZALEX, as compared to DKK 2,294 million, or 96% of revenues, in 2018.

Of revenue for 2019, royalties, milestone payments, license fees and reimbursement income represented 59%, 35%, nil, and 6%, respectively. The corresponding percentages were 58%, 23%, 11% and 8% in 2018. At this time, all of our revenues come from payments made to us by our partners under our collaboration agreements. We do not earn any revenue from direct sales of our own products, and we will not earn such revenue unless and until we obtain regulatory approvals for any candidates in our proprietary pipeline and successfully commercialize such candidates. Our reported revenue is affected by the translation of royalties and other income denominated in foreign currencies—primarily U.S. dollars—into Danish kroner as our reporting currency.

In addition to existing approvals of DARZALEX for the treatment of certain MM indications in the United States, the European Union, Japan and certain other countries, applications for the subcutaneous formulation of daratumumab are currently pending with United States and European regulators. Clinical studies are ongoing to expand daratumumab to new indications of MM. In addition to the ongoing studies of daratumumab for the treatment of MM, Janssen is conducting a number of studies to assess the use of daratumumab in the treatment of other malignant and pre-malignant diseases in which the CD38 is expressed, including amyloidosis, acute lymphocytic leukemia and NKT-cell lymphoma. Our ability to generate revenue will significantly depend on the success of Janssen’s continued ability to effectively maintain and grow sales of DARZALEX for its approved indications, expand its indications, and successfully compete with existing and additional investigational agents and technologies that are currently being marketed or studied for the same indications as DARZALEX.

Our historical revenue also reflects milestone payments and royalties related to our collaboration with Novartis for ofatumumab, marketed as Arzerra for the treatment of certain indications of CLL, and milestone and other payments relating to our other collaborations. We expect competitive pressures in the CLL treatment space to remain or intensify,
which may cause sales of Arzerra to further decline, particularly as Novartis continues to transition Arzerra to
compasionate use in most jurisdictions. For these and other reasons, we believe that our future prospects for material
revenues from ofatumumab depend on Novartis’ ability to expand the labeled indications of use for ofatumumab and to
successfully commercialize it for such indications. Novartis is currently investigating a subQ formulation of ofatumumab in
two Phase III clinical studies, ASCLEPIOS I and II, in RMS. Novartis reported positive data from these studies in August
2019 and based on this data, submitted an sBLA to the FDA in December 2019 and an MAA to the EMA in January 2020.

In addition to the key studies ongoing for daratumumab and ofatumumab outlined above, we anticipate that our
partners under our collaboration agreements will report results or preliminary data for a number of additional clinical
studies in 2020. However, there can be no assurance that any of the studies conducted by Janssen or Novartis or by us or
our other partners will be completed on the expected timeline or at all, or that the final results will be positive. Our ability
to generate revenue from our partnered product candidates depends on our and our partners’ ability to successfully
complete clinical trials for our product candidates and receive regulatory approvals, which could impact the commercial
potential of such products and our potential to receive milestone payments and royalties for these products in the future.

Operating Expenses

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

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

Major components of the external costs are fees and other costs paid to CROs in conjunction with pre-clinical studies
and the performance of clinical trials, milestone payments for in-licensed technology, as well as fees paid to contract
manufacturers in conjunction with the production of clinical compounds, drug substances and drugs. This includes
(i) antibody clinical material for use in clinical trials and (ii) preparation for production of process validation batches for
potential future regulatory submissions and related activities. These costs are expensed as incurred, because they do not
qualify to be capitalized as inventory under IFRS since the technical feasibility of the materials is not proven and no
alternative use for them exists in the absence of marketing approval. Research and development expenses include
amortization of intangible assets only in connection with licenses and rights we have acquired and capitalized. We do not
capitalize intellectual property generated through our internal development activities. We expect to incur higher research
and development costs in future periods, including increasing costs for clinical trials and manufacturing as our proprietary
product candidates advance in clinical development and we increase the number of product candidates under active clinical
development. Our research and development expenses may vary substantially from period to period based on the timing of
our research and development activities, including timing due to regulatory approvals and enrollment of patients in clinical
trials. See “—Liquidity and Capital Resources” below.

Our 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 depreciation, amortization and impairment of intangible assets and
property, plant and equipment, to the extent such expenses are related to the administrative functions.

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

Our ongoing research and development and, increasingly, pre-launch 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 into commercially viable products, if they are approved and commercialized at all. Our commitment of resources to the research and continued development of our product candidates and expansion of our proprietary pipeline will likely result in our operating expenses increasing and/or fluctuating as a result of such activities in future periods. We may also incur significant milestone payment obligations to certain of our licensors as our product candidates progress through clinical trials towards potential commercialization.

Potential Impact of COVID-19

The full extent and nature of the impact of the COVID-19 pandemic and related containment measures on our business and financial performance is uncertain as the situation continues to develop. See “Item 3.D—Risk Factors—Risks Related to Our Business—The COVID-19 pandemic could materially adversely impact our business and financial performance, including our clinical trials, projected regulatory approval timelines, supply chain and revenues.”

Results of Operations

Financial Results for the Year Ended December 31, 2019 Compared to the Year Ended December 31, 2018

The following table provides information regarding our revenue by source and split by collaboration partner for the year ended December 31, 2019, as compared to the year ended December 31, 2018.

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>Year Ended December 31</th>
<th>Percentage Change 2019/2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenue by source:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Royalties</td>
<td>3,155</td>
<td>1,741</td>
</tr>
<tr>
<td>Milestone payments</td>
<td>1,869</td>
<td>687</td>
</tr>
<tr>
<td>License fees</td>
<td>—</td>
<td>348</td>
</tr>
<tr>
<td>Reimbursement income</td>
<td>342</td>
<td>249</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>5,366</td>
<td>3,025</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Revenue split by collaboration partner:</strong></th>
<th>Year Ended December 31</th>
<th>Percentage Change 2019/2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Janssen (DARZALEX/Daratumumab &amp; DuoBody)</td>
<td>4,983</td>
<td>2,390</td>
</tr>
<tr>
<td>Novartis (Arzerra/Ofatumumab)</td>
<td>23</td>
<td>338</td>
</tr>
<tr>
<td>Other collaboration partners</td>
<td>360</td>
<td>297</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>5,366</td>
<td>3,025</td>
</tr>
</tbody>
</table>

Revenue for the year ended December 31, 2019 was DKK 5,366 million, as compared to DKK 3,025 million for the year ended December 31, 2018. The increase of DKK 2,341 million, or 77%, was mainly driven by higher DARZALEX royalties under our daratumumab collaboration with Janssen.

Of the revenue for 2019, DKK 3,155 million, or 59%, was attributable to royalties, DKK 1,869 million, or 35% to milestone payments and DKK 342 million, or 6%, to reimbursement income. This is compared to DKK 1,741 million, or 58%, attributable to royalties, DKK 687 million, or 23%, to milestone payments, DKK 348 million, or 11%, to license fees and DKK 249 million, or 8%, to reimbursement income in 2018.
Net sales of DARZALEX by Janssen were $2,998 million in 2019 compared to $2,025 million in 2018. The increase of $973 million, or 48%, was driven by the continued strong uptake of DARZALEX. The resulting royalty income on net sales of DARZALEX was DKK 3,132 million in 2019 compared to DKK 1,708 million in 2018, an increase of DKK 1,424 million. The increase in royalties of 83% is higher than the increase in the underlying sales due to a combination of the change in royalty tiers in 2019 and positive currency fluctuations between the USD and DKK.

Novartis’ net sales of Arzerra were $17 million in 2019 compared to $26 million in 2018, a decrease of $9 million, or 35%. The resulting royalty income on net sales of Arzerra was DKK 23 million in 2019 compared to DKK 33 million in 2018, a decrease of DKK 10 million, or 30%. The decrease in Arzerra net sales and resulting royalties was due to Novartis’ ongoing transition of Arzerra to limited availability in most jurisdictions.

Milestone income was DKK 1,869 million in 2019 compared to DKK 687 million in 2018. The increase of DKK 1,182 million was mainly driven by higher DARZALEX milestone payments achieved in 2019, as compared to 2018. In 2019, we recorded DKK 1,778 million ($264 million) in DARZALEX milestone payments from Janssen, including (i) a $150 million milestone payment related to the achievement of $3.0 billion in net sales (as calculated on the basis of the license agreement terms) of DARZALEX in calendar year 2019, (ii) a $100 million milestone payment related to the achievement of $2.5 billion in net sales of DARZALEX in calendar year 2019, and (iii) $14 million of milestone payments related to the first commercial sales of DARZALEX in Japan in the third and fourth indications under the expanded labels. No further sales volume milestones are due under the agreement with Janssen. The remaining DKK 91 million included milestone payments related to pre-clinical and clinical progress under our DuoBody collaboration with Janssen and other collaborations. By comparison, in 2018, we recorded DKK 586 million ($90 million) in DARZALEX milestone payments from Janssen, including (i) a $75 million payment related to achievement of $2.0 billion in net sales of DARZALEX in the fourth quarter of 2018 and (ii) a $13 million milestone payment related to the first sale of DARZALEX in combination with VMP in patients with newly diagnosed multiple myeloma. The remaining DKK 101 million included milestone payments related to pre-clinical and clinical progress under our DuoBody collaboration with Janssen and other collaborations. Milestone income may fluctuate significantly from period to period due to both the timing of achievements and the varying amount of each individual milestone under our license and collaboration agreements.

There was no license fee income during 2019. License fee income was DKK 348 million in 2018 which was driven by (i) the $50 million one-time payment from Novartis related to lost potential Arzerra milestones and royalties due to the transition of Arzerra to limited availability in most jurisdictions, under the Novartis ofatumumab collaboration, (ii) payment from Janssen for additional DuoBody target pairs under the Janssen DuoBody collaboration and (iii) the payment from Novo Nordisk for extending exclusivity of the commercial license for a DuoBody target pair under the Novo Nordisk DuoBody collaboration.

Reimbursement income, mainly comprised of the reimbursement of certain research and development costs related to the development work under Genmab’s collaboration agreements, amounted to DKK 342 million in 2019 compared to DKK 249 million in 2018. The increase of DKK 93 million, or 37%, was driven by reimbursement payments associated with our development activities relating to tisotumab vedotin under our collaboration with Seattle Genetics and the continued advancement of product candidates under our collaboration with BioNTech.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2019 were DKK 2,386 million, or 87% of our total operating expenses for 2019, as compared to DKK 1,431 million, or 87% of our total operating expenses for 2018. The increase of DKK 955 million, or 67%, was driven by was driven by the advancement of tisotumab vedotin and enapotamab vedotin, the additional investment in our product pipeline, and the increase in research and development employees.
The following table provides information regarding our research and development expenses for the year ended December 31, 2019, as compared to the year ended December 31, 2018.

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>Year ended December 31</th>
<th>Percentage Change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2019</td>
<td>2018</td>
</tr>
<tr>
<td>Research(1)</td>
<td>576</td>
<td>356</td>
</tr>
<tr>
<td>Development and contract manufacturing(2)</td>
<td>786</td>
<td>509</td>
</tr>
<tr>
<td>Clinical(3)</td>
<td>790</td>
<td>424</td>
</tr>
<tr>
<td>Other(4)</td>
<td>234</td>
<td>142</td>
</tr>
<tr>
<td><strong>Total research and development expenses</strong></td>
<td><strong>2,386</strong></td>
<td><strong>1,431</strong></td>
</tr>
</tbody>
</table>

(1) Research expenses include, among other things, personnel, occupancy and laboratory expenses, technology access fees associated with identification of new mAbs, expenses associated with the development of new proprietary technologies and research activities associated with our product candidates, such as in vitro and in vivo studies, translational research, and IND enabling toxicology studies.

(2) Development and contract manufacturing expenses include personnel and occupancy expenses, external contract manufacturing costs for the scale-up and pre-approval manufacturing of drug product used in research and our clinical trials, costs for drug product supplied to our collaborators, costs related to preparation for the production of process validation batches to be used in potential future regulatory submissions, quality control and assurance activities, and storage and shipment of our product candidates.

(3) Clinical expenses include personnel, travel, occupancy costs, and external clinical trial costs including costs for clinical sites, CROs, contractors and regulatory activities associated with conducting human clinical trials.

(4) Other research and development expenses primarily include share-based compensation, depreciation and amortization expenses.

The following table shows third-party costs incurred for research, contract manufacturing of our product candidates and clinical and regulatory services for the year ended December 31, 2019, as compared to the year ended December 31, 2018. The table also presents unallocated costs and overhead consisting of third-party costs for our pre-clinical stage programs, personnel, facilities and other indirect costs not directly charged to development programs.

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>Year ended December 31</th>
<th>Percentage Change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2019</td>
<td>2018</td>
</tr>
<tr>
<td>Tisotumab vedotin</td>
<td>436</td>
<td>292</td>
</tr>
<tr>
<td>Enapotamab</td>
<td>268</td>
<td>126</td>
</tr>
<tr>
<td>Other clinical stage programs</td>
<td>379</td>
<td>102</td>
</tr>
<tr>
<td><strong>Total third-party costs for clinical stage programs</strong></td>
<td><strong>1,083</strong></td>
<td><strong>520</strong></td>
</tr>
<tr>
<td>Pre-clinical projects</td>
<td>423</td>
<td>405</td>
</tr>
<tr>
<td>Unallocated costs and overhead</td>
<td>880</td>
<td>506</td>
</tr>
<tr>
<td><strong>Total research and development expenses</strong></td>
<td><strong>2,386</strong></td>
<td><strong>1,431</strong></td>
</tr>
</tbody>
</table>

Third-party costs for tisotumab vedotin increased by DKK 144 million, or 49%, in 2019 as compared to 2018, primarily due to the advancement of clinical trials.

Third-party costs for enapotamab vedotin increased by DKK 142 million, or 113%, in 2019 as compared to 2018, primarily due to increases in clinical trial and contract manufacturing costs related to the progression of the program.

Third-party costs for our other clinical-stage programs increased by DKK 277 million, or 272%, in 2019 as compared to 2018, primarily related to the timing of multiple earlier-stage development programs including DuoBody-PD-L1x4-1BB and DuoBody-CD40x4-1BB moving into the clinical stage in 2019. Refer to the Business Overview section within Item 4 in this Annual Report for additional information related to our clinical-stage programs.

Research and development expenses related to our pre-clinical projects increased by DKK 18 million, or 4%, in 2019 as compared to 2018 driven by the continued investment in our pre-clinical programs. Refer to the Business Overview section within Item 4 in this Annual Report for additional information related to our pre-clinical programs.
Unallocated costs and overhead increased by DKK 374 million, or 74%, in 2019 as compared to 2018, primarily due to an increase in staffing levels and the expansion of our facilities to accommodate our growth. Our research and development FTEs (full-time equivalents) increased from 323 at the end of 2018 to 468 at the end of 2019.

**General and Administrative Expenses**

General and administrative expenses for the year ended December 31, 2019 were DKK 342 million, or 13% of our total operating expenses for 2019, as compared to DKK 214 million for the year ended December 31, 2018, or 13% of our total operating expenses for 2018. The increase of DKK 128 million, or 60%, was driven by growth across all support areas including enhanced technology and systems, early investment in commercial, and other areas due to the expansion of our product pipeline. DKK 175 million, or 51% of general and administrative expenses in 2019, was related to remuneration of employees and senior management involved in general and administrative activities, as compared to DKK 122 million, or 57% of general and administrative expenses in 2018.

**Net Financial Items**

The net financial items reflect a combination of interest income, unrealized and realized fair market value adjustments on our portfolio of marketable securities, as well as realized and unrealized foreign exchange adjustments.

Financial income for the year ended December 31, 2019 was DKK 228 million, reflecting interest and other financial income of DKK 120 million, net realized and unrealized gains on marketable securities of DKK 9 million and net realized and unrealized exchange rate gains of DKK 99 million. This compares to DKK 243 million for the year ended December 31, 2018, reflecting interest and other financial income of DKK 63 million, net realized and unrealized gains on fair value hedges of DKK 2 million and net realized and unrealized exchange rate gains of DKK 178 million.

Financial expenses for the year ended December 31, 2019 were DKK 7 million related to interest and other financial expenses, as compared to DKK 11 million for the year ended December 31, 2018 related to realized and unrealized losses on marketable securities.

As a result of the above, net financial items for the year ended December 31, 2019 were a net gain of DKK 221 million, as compared to a net gain of DKK 232 million for the year ended December 31, 2018. The decrease in net financial items was driven primarily by a decrease in net realized and unrealized exchange rate gains driven by foreign exchange movements which positively impacted our U.S. dollar-denominated portfolio and cash holdings to a greater extent in 2018 than 2019, partly offset by an increase in interest income due to the combination of higher yield and level of investments in marketable securities in 2019 as compared to 2018.

**Income Tax**

Corporate tax expense was DKK 693 million for the year ended December 31, 2019 compared to DKK 140 million in for the year ended December 31, 2018, corresponding to an effective tax rate of 24% for the year ended December 31, 2019 and 9% for the year ended December 31, 2018. The effective tax rate increased in 2019 as the discrete tax benefit related to the reversal of valuation allowances on deferred tax assets for future taxable income was significantly higher in 2018 than 2019. In 2018, the discrete tax benefit was DKK 268 million as compared to DKK 29 million in 2019.

**Financial Results for the Year Ended December 31, 2018 Compared to the Year Ended December 31, 2017**

A discussion of the financial results for the year ended December 31, 2018 as compared to the year ended December 31, 2017 can be found in section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations—Financial Results for the Year Ended December 31, 2018 Compared to the Year Ended December 31, 2017” in the Company’s prospectus, filed with the SEC on July 19, 2019.

101
**Significant Accounting Policies**

Our consolidated financial statements have been prepared in accordance with IFRS, as issued by the IASB. A description of our significant accounting policies is provided in Note 1.1 to our Audited Financial Statements.

**Implementation of New and Revised Standards and Interpretations**

Effective January 1, 2019, we adopted IFRS 16 using the modified retrospective transition method. Under this method, all leases are recognized in the balance sheet as a right-of-use, or ROU, asset with a corresponding lease liability, except for short term assets in which the lease term is 12 months or less, or low-value assets. ROU assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. The ROU asset is depreciated over the shorter of the asset’s useful life and the lease term on a straight-line basis over the lease term. In the income statement, the lease costs are replaced by the depreciation of the ROU asset recognized over the lease term in operating expenses, and interest expenses related to the lease liability are classified in financial items. The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods.

Genmab determines if an arrangement is a lease at inception. Genmab leases various properties and information technology, or IT, equipment. Rental contracts are typically made for fixed periods. Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of fixed payments, less any lease incentives. As our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. In determining the lease term, management considers all facts and circumstances that create an economic incentive to exercise an extension option, or not exercise a termination option. Extension options (or periods after termination options) are only included in the lease term if the lease is reasonably certain to be extended (or not terminated).

ROU assets are measured at cost and include the amount of the initial measurement of lease liability, any lease payments made at or before the commencement date less any lease incentives received, any initial direct costs, and restoration costs.

Payments associated with short-term leases and leases of low-value assets are recognized on a straight-line basis as an expense in the income statement. Short-term leases are leases with a lease term of 12 months or less and low-value assets comprise IT equipment and small items of office furniture.

On adoption of IFRS 16, the group recognized lease liabilities in relation to leases that had previously been classified as ‘operating leases’ under the principles of IAS 17 Leases. These liabilities were measured at the present value of the remaining lease payments, discounted using the lessee’s incremental borrowing rate as of January 1, 2019. The weighted average lessee’s incremental borrowing rate applied to the lease liabilities on January 1, 2019 was 3.7%.
The impact of the adoption of IFRS 16 on the financial statements as of January 1, 2019 is shown in the table and further described below:

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>January 1, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating lease commitments disclosed as at December 31, 2018</td>
<td>184</td>
</tr>
<tr>
<td>Discounted using the incremental borrowing rate of 3.7%</td>
<td>(42)</td>
</tr>
<tr>
<td>(Less): short-term leases recognized on a straight-line basis as expense</td>
<td>(3)</td>
</tr>
<tr>
<td>Add/(less): adjustments as a result of a different treatment of extension and</td>
<td>66</td>
</tr>
<tr>
<td>termination options</td>
<td></td>
</tr>
<tr>
<td><strong>Lease liability recognized at January 1, 2019</strong></td>
<td><strong>205</strong></td>
</tr>
</tbody>
</table>

The ROU assets established on the balance sheet at January 1, 2019 were DKK 205 million. Net result decreased by DKK 4 million as a result of adopting IFRS 16 2019. Cash flows from operating activities increased by DKK 35 million and cash flows from financing activities decreased by DKK 31 million as a result of adopting IFRS 16 in 2019.

For purposes of applying the modified retrospective approach in adoption of IFRS 16, we used the following practical expedients permitted by the standard:

- applied the exemption not to recognize ROU assets and liabilities for leases with less than 12 months of lease term from January 1, 2019; and
- excluded initial direct costs for the measurement of the ROU assets at the date of initial application.

There are no ROU assets that meet the definition of investment property.

**Standards and Interpretations Not Yet in Effect**

At the date of the approval of the audited consolidated financial statements for the year ended December 31, 2019, the IASB has issued a number of new standards and updated some existing standards, the majority of which are effective for accounting periods beginning on January 1, 2020 or later. Therefore, they are not incorporated in the audited consolidated financial statements. There are no standards that are not yet effective and that would be expected to have a material impact on the entity in the current or future reporting periods and on foreseeable future transactions.

**Significant Accounting Estimates, Assumptions and Uncertainties**

In the preparation of the consolidated financial statements, we make a number of accounting estimates which form the basis for the presentation, recognition and measurement of our assets and liabilities.

In the application of our accounting policies, we are required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates. The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

The used estimates are based on assumptions assessed to be reasonable by management. However, estimates are inherently uncertain and unpredictable. The assumptions can be incomplete or inaccurate and unexpected events or circumstances might occur. Furthermore, we are subject to risks and uncertainties that might result in deviations in actual results compared to estimates.

In connection with the preparation of the consolidated financial statements, we have made a number of estimates and assumptions concerning carrying amounts.
Revenue recognition is one of the most significant accounting estimates and assessments applied by us in our consolidated financial statements. Royalty income under license and collaboration agreements includes sales-based royalties and is recognized when the related sales occur. Milestone payments related to the achievement of certain sales levels are recognized when such sales levels are achieved.

The estimated value of milestone payments not related to achievement of sales levels is included in the transaction price of each arrangement that includes such payments if (i) the achievement of the milestones is within our control or the control of our partner, (ii) the achievement of the milestones is considered highly probable at the inception of the arrangement, and (iii) it is highly probable that a significant revenue reversal would not occur. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraints and, if necessary, adjust the estimate of the overall transaction price. Revenue from non-refundable upfront fees allocated to a license to our functional intellectual property is recognized as license fees revenue at the point in time the license is transferred to the licensee and the licensee is able to use and benefit from the license, if the license is determined to be distinct from the other performance obligations identified in the arrangement. If the license is bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether it is satisfied over time or at a point in time. If the performance obligation is satisfied over time, we utilize judgment to determine the appropriate method of measuring progress for purposes of recognizing revenue. Under all of our existing license and collaboration agreements, the license to functional intellectual property has been determined to be distinct from other performance obligations identified in the agreement.

Evaluating the criteria for revenue recognition requires management’s judgment to assess and determine: (i) the nature of performance obligations and whether they are distinct or should be combined with other performance obligations to determine whether the performance obligations are satisfied over time or at a point in time, (ii) an assessment of whether the achievement of milestone payments is highly probable, and (iii) the stand-alone selling price of each performance obligation identified in the contract using key assumptions which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

Realization of our deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. We recognize deferred tax assets only to the extent that it is probable that future taxable profit will be available against which the deferred tax assets can be utilized. Such assessment is required on a jurisdiction by jurisdiction basis. Changes in future taxable income impact the utilization of recognized as well as unrecognized deferred tax assets. The recognition of deferred tax assets requires judgment and estimation by us and involves estimates based on certain assumptions in relation to future taxable income.

Please refer to the notes to the Audited Financial Statements for a further description of other significant accounting estimates and assumptions used with respect to share-based compensation and research and development costs.

B. Liquidity and Capital Resources

As of December 31, 2019, Genmab’s cash, cash equivalents, and marketable securities (cash position) amounted to DKK 10,971 million. This represents a net increase of DKK 4,865 million, or 80%, from the beginning of 2019, which was mainly driven by net proceeds from the issuance of new shares in connection with the public offering and listing of ADSs on the Nasdaq Global Select Market of DKK 3,635 million and our operating income of DKK 2,638 million, which were partly offset by negative working capital adjustments of DKK 1,218 million primarily related to royalties and milestones achieved in the fourth quarter of 2019, which were receivables as of December 31, 2019.

As of December 31, 2019, DKK 3,552 million, as compared to DKK 533 million as of December 31, 2018, was held as cash and cash equivalents, and DKK 7,419 million, as compared to DKK 5,573 million as of December 31, 2018, was held as liquid investments in short-term government and other debt instruments.
We require cash to meet our operating expenses and capital expenditures. We have funded our cash requirements since our inception, including through December 31, 2019, primarily with equity financing, upfront payments and royalty and milestone payments from our partners.

Cash and cash equivalents included short-term marketable securities of DKK 668 million at the end of December 2019. There were no short-term marketable securities included in cash and cash equivalents at the end of December 2018. In accordance with our accounting policy, securities purchased with a maturity of less than three months at the date of acquisition are classified as cash and cash equivalents.

We expect to continue to fund a significant portion of our development costs for our proprietary product candidates as well as our planned commercialization activities with funds received from royalties and milestone payments from our partners.

However, because our product candidates are in various stages of development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and to obtain regulatory approval of, and ultimately commercialize, our product candidates.

Our expenditures on our current and future pre-clinical and clinical development programs are subject to numerous uncertainties in timing and cost to completion. In order to advance our product candidates toward commercialization, the product candidates are tested in numerous pre-clinical safety, toxicology and efficacy studies. We then conduct clinical trials for those product candidates that take several years or more to complete. The length of time varies substantially based upon the type, complexity, novelty and intended use of a product candidate. The cost of clinical trials may vary significantly over the life of a project as a result of a variety of factors, including: the number of patients required in our clinical trials; the length of time required to enroll trial participants; the number and location of sites included in the trials; the costs of producing supplies of the product candidates needed for clinical trials and regulatory submissions; the safety and efficacy profile of the product candidate; the use of CROs to assist with the management of the trials; and the costs and timing of, and the ability to secure, regulatory approvals.

Our expenses also fluctuate from period to period based on the degree of collaborative activities, timing of manufacturing campaigns, numbers of patients enrolled in our clinical trials and the outcome of each clinical trial event. As a result, we are unable to determine with any degree of certainty the anticipated completion dates, duration and completion costs of our research and development projects, or when and to what extent we will receive cash inflows from the commercialization and sale of any of our product candidates. We also cannot predict the actual amount or timing of future royalties and milestone payments to us, and these may differ from our estimates.

We expect to make additional capital outlays and to increase operating expenditures over the next several years as we hire additional employees, support our pre-clinical development, manufacturing and clinical trial activities for tisotumab vedotin and our other proprietary product candidates, and expand internationally, as well as commercialize tisotumab vedotin, if we receive regulatory approval. We are developing tisotumab vedotin in collaboration with Seattle Genetics. Under our agreement, Seattle Genetics and Genmab will each be responsible for leading tisotumab vedotin commercialization activities in certain territories. We are currently in discussions with Seattle Genetics regarding the detailed terms on which we will work together to commercialize tisotumab vedotin under this agreement. As we increase our spending on research and development related to our product collaborations, we may be required to make certain capital outlays against which we expect to receive reimbursement income to the extent the outlay exceeds our share under the applicable collaboration agreement. We expect that the time-lag between the expenditure by us, on the one hand, and the reimbursement by our partner of its relevant share, on the other hand, will increase our working capital needs. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our operating requirements and cash needs through public or private equity offerings, debt financings, or additional corporate collaboration and licensing arrangements.
Cash flows

The following table provides information regarding our cash flows for the years ended December 31, 2019 and December 31, 2018.

<table>
<thead>
<tr>
<th>Cash Flow (DKK million)</th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash provided by (used in) operating activities</td>
<td>1,326</td>
<td>1,015</td>
</tr>
<tr>
<td>Cash provided by (used in) investing activities</td>
<td>(1,983)</td>
<td>(1,778)</td>
</tr>
<tr>
<td>Cash provided by (used in) financing activities</td>
<td>3,660</td>
<td>(71)</td>
</tr>
<tr>
<td>Increase (decrease) in cash and cash equivalents</td>
<td>3,003</td>
<td>(834)</td>
</tr>
</tbody>
</table>

Cash inflow from operating activities for the year ended December 31, 2019 was DKK 1,326 million, as compared to DKK 1,015 million for the year ended December 31, 2018. The increase of DKK 311 million, or 31%, was primarily driven by higher operating income for the year ended December 31, 2019 compared to the year ended December 31, 2018. Working capital fluctuations, reversal of net financial items and adjustments related to non-cash expenses, all of which may be highly variable period to period, also contributed to the variation.

Cash outflow from investing activities for the year ended December 31, 2019 was DKK 1,983 million, as compared to DKK 1,778 million for the year ended December 31, 2018. The increase of DKK 205 million, or 12%, primarily reflects differences between the proceeds received from sale and maturity of our investments and amounts invested. Purchases of marketable securities exceeded sales and maturities in both 2019 and 2018, which has resulted in significant growth in the marketable securities portion of the cash position.

Cash inflow from financing activities for the year ended December 31, 2019 was DKK 3,660 million, as compared to an outflow of DKK 71 million for the year ended December 31, 2018. The increase of DKK 3,731 million was primarily related to net proceeds from the issuance of new shares in connection with the public offering and listing of ADSs on the Nasdaq Global Select Market of DKK 3,635 million, and purchase of treasury shares during 2018 of DKK 146 million. There were no purchases of treasury shares during 2019.

 Marketable securities are invested in highly secure, liquid and conservative investments with short effective maturity. As of December 31, 2019, 91% of our marketable securities had a triple A- rating, compared to 90% at December 31, 2018. The weighted average effective duration was approximately 1.1 years as of December 31, 2019 (2018: 1.4 years).

The discussion of cash flows for the year ended December 31, 2018 as compared to cash flows for the year ended December 31, 2017, can be found in the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Cash Flows” in the Company’s prospectus, filed with the SEC on July 19, 2019.

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. Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements.
F. Tabular Disclosure of Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2019.

<table>
<thead>
<tr>
<th></th>
<th>Less than 1 year</th>
<th>1 - 3 years</th>
<th>More than 3 years but less than 5 years</th>
<th>More than 5 years</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leases</td>
<td>32</td>
<td>64</td>
<td>27</td>
<td>93</td>
<td>216</td>
</tr>
<tr>
<td>Contractual obligations related to agreements for research and development activities</td>
<td>546</td>
<td>18</td>
<td>—</td>
<td>—</td>
<td>564</td>
</tr>
<tr>
<td><strong>Total Contractual Obligations</strong></td>
<td><strong>578</strong></td>
<td><strong>82</strong></td>
<td><strong>27</strong></td>
<td><strong>93</strong></td>
<td><strong>780</strong></td>
</tr>
</tbody>
</table>

Our lease obligations in the table above relate to leases for office space and office equipment recognized in the balance sheet as of December 31, 2019. The leases are non-cancelable for various periods up to 2032.

During 2019, Genmab A/S’s subsidiaries including Genmab US, Inc. and Genmab B.V. entered into lease agreements with respect to office and laboratory space which are obligations not recognized in the balance sheet or in the table above as of December 31, 2019 as the leases will not commence until 2020. See Note 3.3 of the Audited Financial Statements for additional details regarding these leases.

In addition to our leases, we have also entered into a number of agreements primarily related to research and development activities.

We also have certain contingent commitments under our license and collaboration agreements that may become due for future payments. These contingent commitments relate to potential future development, regulatory and commercial milestone payments to third parties under license and collaboration agreements for our pre-clinical and clinical-stage development programs. These milestone payments generally become due and payable only upon the achievement of certain development, clinical, regulatory or commercial milestones. The events triggering such payments or obligations have not yet occurred. As of December 31, 2019, these contingent commitments amounted to approximately DKK 9,520 million, of which DKK 8,440 million relate to regulatory and commercial sales based milestones which are not expected to be triggered 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.

G. Safe Harbor

Forward-looking information discussed in this Item 5 includes assumptions, expectations, projections, intentions and beliefs about future events. These statements are intended as “forward-looking statements”. We caution that assumptions, expectations, projections, intentions and beliefs about future events may and often do vary from actual results and the differences can be material. Please see the section entitled "Forward-Looking Statements" at the beginning of this Annual Report.

ITEM 6 DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table sets forth the name, age and position of each of our Board members as of the date of this Annual Report. Our Board consists of six members elected by our shareholders at the general meeting, or Shareholder Elected Members (and each, a Shareholder Elected Member), and three members elected by our employees, or
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 2020 and the terms of office of the Employee Elected Members expire in 2022. All members of the Board, however elected, are eligible for re-election.

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

<table>
<thead>
<tr>
<th>Name of Board Member</th>
<th>Age</th>
<th>Position(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deirdre P. Connelly</td>
<td>59</td>
<td>Chairman (independent, Shareholder Elected)</td>
</tr>
<tr>
<td>Pernille Erenbjerg</td>
<td>52</td>
<td>Deputy Chairman (independent, Shareholder Elected)</td>
</tr>
<tr>
<td>Anders Gersel Pedersen</td>
<td>68</td>
<td>Board member (non-independent, Shareholder Elected)</td>
</tr>
<tr>
<td>Paolo Paoletti</td>
<td>69</td>
<td>Board member (independent, Shareholder Elected)</td>
</tr>
<tr>
<td>Rolf Hoffmann</td>
<td>60</td>
<td>Board member (independent, Shareholder Elected)</td>
</tr>
<tr>
<td>Jonathan Peacock</td>
<td>62</td>
<td>Board member (independent, Shareholder Elected)</td>
</tr>
<tr>
<td>Peter Storm Kristensen</td>
<td>45</td>
<td>Board member (non-independent, Employee Elected)</td>
</tr>
<tr>
<td>Mijke Zachariasse</td>
<td>46</td>
<td>Board member (non-independent, Employee Elected)</td>
</tr>
<tr>
<td>Daniel J. Bruno</td>
<td>40</td>
<td>Board member (non-independent, Employee Elected)</td>
</tr>
</tbody>
</table>

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 Chairman of the Board and as the Chairman of the Compensation Committee. She is a member of the Audit and Finance Committee and the Nominating and Corporate Governance 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 Macy’s, Inc. and of the Lincoln National Corporation. 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 Vice President of Human Resources for Pharmaceutical Operations. 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 Chairman of the Board and as the Chairman of the Audit and Finance Committee and as a member of the Nominating and Corporate Governance Committee. Ms. Erenbjerg is a Certified Public Accountant, (CPA) in 1994, but is no longer practicing as such. 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 is a non-executive board member, Audit Committee member and member of the Operations and Sustainability Committee of Nordea AB. She is a non-executive board member, Deputy Chair, Chair of the Remuneration Committee and member of the Audit Committee of Millicom SA. She was formerly a non-executive member of the board and chairman of the audit committee of DFDS A/S from 2014 to 2018 and a non-executive board member of the Royal Danish Theatre from 2011 to 2015. She is formerly a partner at Deloitte Touche Tohmatsu Limited and spent 14 years as a CPA at Arthur Anderson LLP from 1987 to 2002. Ms. Erenbjerg holds a B.S. and a M.Sc. in Economics from Copenhagen Business School.

**Anders Gersel Pedersen** was elected to the Board in 2003 and currently serves as the Chairman of the Nominating and Corporate Governance Committee and is a member of the Scientific Committee and the Compensation Committee. Dr. Pedersen currently serves as the Chairman of the board of Aelis Farma, Deputy Chairman of the board of Bavarian Nordic A/S and as a member of the board of Hansa Medical AB and of Bond 2 development ZGP 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 Chairman of the Scientific Committee and is a member of the Compensation Committee. Dr. Paoletti served as President of Oncology at GlaxoSmithKline plc and in various roles at Eli Lilly and Company, including Vice President of Oncology Research. Dr. Paoletti is the CEO of GammaDelta Therapeutics Limited and is a member of the board of PsiOxus Therapeutics Limited and a member of the board of FORMA Therapeutics, Inc. 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 2012. Mr. Hoffmann is currently an adjunct professor of Strategy and Entrepreneurship at the University of North Carolina Business School and serves as Chairman of the board of directors at Biotest AG and as a board member at Trizell Ltd., EUSA Pharma, Inc., Paratek Pharmaceuticals, Inc. and Shield Therapeutics plc. He holds an M.A. in English from the University of Cologne, an MA in Kinesiology from Deutsche Sporthochschule Köln in Cologne, Germany and an M.B.A. from the University of North Carolina at Chapel Hill.

Jonathan Peacock was elected to the Board in 2020 and is a member of the Audit and Finance Committee and the Compensation Committee. Mr. Peacock has extensive experience in corporate finance, strategy and international expansion in the pharmaceutical industry. He was involved in several large and small acquisitions and partnerships of commercial, pipeline and research assets covering diverse global markets as CFO at Novartis Pharma and CFO at Amgen. He serves as Chairman of the board of directors at Arix Bioscience plc and at Bellerophon Therapeutics Inc. and as a board member at Avantor Inc., W20 Group, Socati Corporation and the Natural History Museum of Los Angeles. Mr. Peacock holds a degree in Economics, is a chartered accountant and has a background as a partner at McKinsey and Price Waterhouse.

Mats Pettersson was elected to the Board in 2013 and acted as Chairman of the Board and as a member of the Audit and Finance Committee until he stepped down at our Annual General Meeting on March 26, 2020 when his election period was set to expire. Mr. Pettersson served as a member of the board of NsGene A/S from 2008 to 2012, Ahlynx NV from 2007 to 2013, and as member of the board of H. Lundbeck A/S from 2003 to 2013, serving as Chairman from 2011 to 2013, BBB NV from 2008 to 2015, Photocure ASA from 2008 to 2015 and Moberg Pharma AB from 2010 to 2016. He was a member of various executive management committees at Pharmacia Corporation (acquired by Pfizer Inc.). Mr. Pettersson is the founder and former Chief Executive Officer of SOBI AB, an international biotechnology company headquartered in Stockholm, Sweden. Mr. Pettersson is a current board member of Magle Chemoswed AB. He holds a bachelor’s degree and an M.B.A. from Handelshögskolan vid Göteborgs Universitet in Gothenburg, Sweden.

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

Mijke Zachariasse was elected to the Board in 2019. Dr. Zachariasse joined us in 2017 and currently serves as our Director of Protein Production and Chemistry. 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.

Daniel J. Bruno was elected to the Board in 2016. Mr. Bruno currently serves as our Vice President and Corporate Controller. Prior to joining Genmab, he worked at PricewaterhouseCoopers in the Assurance and Business Advisory Services division. He holds an MS degree in accounting from Fairleigh Dickinson University and is a CPA.
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. The business address of these members of our senior management is our registered office address at c/o Genmab A/S, Kalvebod Brygge 43, 1560 Copenhagen V, Denmark. We note that only

Jan G. J. van de Winkel, Anthony Pagano, Judith Klimovsky and Anthony Mancini are registered with the Danish Business Authority as members of executive management, or registered managers, within the meaning of the DCA.

<table>
<thead>
<tr>
<th>Name of Member of Senior Management</th>
<th>Age</th>
<th>Position(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan G. J. van de Winkel</td>
<td>59</td>
<td>President and Chief Executive Officer</td>
</tr>
<tr>
<td>Anthony Pagano</td>
<td>42</td>
<td>Executive Vice President and Chief Financial Officer</td>
</tr>
<tr>
<td>Judith Klimovsky</td>
<td>63</td>
<td>Executive Vice President and Chief Development Officer</td>
</tr>
<tr>
<td>Anthony Mancini</td>
<td>49</td>
<td>Executive Vice President and Chief Operating Officer</td>
</tr>
<tr>
<td>Birgitte Stephensen</td>
<td>59</td>
<td>Senior Vice President, IPR &amp; Legal</td>
</tr>
<tr>
<td>Michael K. Bauer</td>
<td>56</td>
<td>Senior Vice President, Head of R&amp;D Operations</td>
</tr>
<tr>
<td>Tahamtan Ahmadi</td>
<td>47</td>
<td>Senior Vice President, Head of Oncology</td>
</tr>
<tr>
<td>Martine J. van Vugt</td>
<td>50</td>
<td>Senior Vice President, Chief of Staff</td>
</tr>
</tbody>
</table>

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

Jan G. J. van de Winkel is our co-founder and served as President, Research & Development and Chief Scientific Officer of the Company until his appointment as President & Chief Executive Officer in 2010. Dr. van de Winkel served as Vice President and Scientific Director of Medarex Europe prior to founding Genmab. Dr. van de Winkel holds a professorship of immunotherapy at Utrecht University. He is Chairman of the board of directors of Hookipa Pharma Inc. and a member of the board of directors of Celdara Medical, LLC and LEO Pharma A/S, and a member of the scientific advisory board of Thuja Capital Healthcare Fund and the advisory board of Capricorn Health-tech Fund. 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, following the retirement of David A. Eatwell from his position on February 29, 2020. Prior to joining us, Mr. Pagano was Corporate Controller and Senior Director of Business Planning at NovaDel Pharma, Inc. from 2005 to 2007, a publicly-traded specialty pharmaceutical company. He previously worked as a Manager at KPMG LLP from 1999 to 2005. He is a Certified Public Accountant and received a B.S. in Accounting from The College of New Jersey, as well as an M.B.A. from the Stern School of Business at New York University.

Judith Klimovsky joined us in 2017 and currently serves as the Executive Vice President and Chief Development Officer. She worked previously as a drug developer and has more than 10 years of experience in research and development leadership roles at Bristol-Myers Squibb Company and Novartis Pharma AG. Dr. Klimovsky is also a medical doctor who has worked as a clinician in hospital environments. Prior to joining us, she held various positions at Novartis Pharma AG from 2009 to 2017, including Senior Vice President, Head of Clinical Development. Dr. Klimovsky is a member of the board of directors of Bellicum Pharmaceuticals. She holds a medical degree from the Universidad de Buenos Aires in Argentina.

Anthony Mancini joined Genmab in March 2020 as Executive Vice President and Chief Operating Officer. Prior to joining Genmab, Mr. Mancini served in a variety of strategic and operational leadership roles over a nearly 24-year career at Bristol-Myers Squibb (BMS). Most recently, he led BMS’ US Innovative Medicines Unit, a team of over 1100 people focused on Immunology & Cardiovascular diseases. He holds a Bachelor of Science in Biochemistry from the University of Ottawa, Canada, an MBA from Clemson University, South Carolina, USA, and participated in the General Management Program, CEDEP at INSEAD, Fontainebleau, France.
Birgitte Stephensen joined us in 2002 and was appointed Senior Vice President in 2010. Ms. Stephensen has experience in both private practice and industry working with legal and intellectual property matters within the pharmaceutical and biotechnology fields. Prior to joining us, Ms. Stephensen worked in a patent law firm from 1988 to 1997, and was with the patent department of Novo Nordisk A/S from 1997 to 2002. Ms. Stephensen qualified as a European patent attorney in 1994. She earned an M.Sc. from the School of Pharmaceutical Sciences at the University of Copenhagen.

Michael K. Bauer joined us in 2006 and was appointed Senior Vice President in 2010. Before joining us, Dr. Bauer held various positions in academia, the pharmaceutical industry and the venture finance sector in Germany, New Zealand, the United States and Denmark, including at the University of Auckland from 1992 to 1998, Novo Nordisk A/S from 1998 to 2005 and BankInvest Group from 2005 to 2006. Dr. Bauer earned an M.Sc. from the University of Stuttgart-Hohenheim and a Ph.D. from the University of Göttingen, both in Germany.

Tahamtan Ahmadi joined us in 2017 and currently serves as the Senior Vice President, Head of Oncology. 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.

Martine J. van Vugt started her professional career with us in 2001 and was appointed Senior Vice President, Chief of Staff in January 2019. Previously, she was responsible for our Project and Alliance Management as well as Strategic Initiatives and continues to oversee these areas. She has been active in our business development 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.

David A. Eatwell joined us in 2008 and served as our Executive Vice President and Chief Financial Officer until his retirement from this position on February 29, 2020. Mr. Eatwell has experience in leading international life science businesses, having spent 15 years working in Europe and ten years in the United States. Most recently, prior to joining Genmab, he served as Chief Financial Officer of Catalent Pharma Solutions, Inc., a leading provider of manufacturing and packaging services for the pharmaceutical and biotech industry. Prior to Catalent Pharma Solutions, Inc., Mr. Eatwell served as a divisional CFO of Cardinal Health, Inc. Mr. Eatwell is a member of the Association of Chartered Certified Accountants. Mr. Eatwell holds a degree in Business Administration from Swindon College in the United Kingdom.

### B. Compensation

In 2019, the aggregate remuneration paid to the Board was DKK 11.9 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 2019, the aggregate remuneration to our senior management was DKK 101.7 million, all of which was fully accrued at December 31, 2019. This amount includes base salary, defined contribution plans, other benefits, share-based compensation expenses and annual cash bonuses. Compensation paid for the financial year ended December 31, 2019 to each of Dr. Jan van de Winkel, David A. Eatwell and Judith Klimovsky is disclosed below, as such disclosure is included in our Audited Financial Statements. See Note 5.1 to the Audited Financial Statements for details on compensation of these individuals.

The Board has adopted a remuneration policy for the Board and registered managers, including general guidelines for incentive remuneration.
Compensation of Members of Our Board of Directors and Certain Members of Senior Management

See Note 5.1 to the Audited Financial Statements for warrants and RSUs granted to members of our Board and certain members of our senior management, as well as compensation in connection with their membership to the Board and our registered managers 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 and our Executive Vice President and COO, Anthony Mancini in accordance with their service agreements consists of a base salary, a cash bonus, RSUs and warrants. The cash bonus for Dr. van de Winkel is in accordance with the remuneration policy and as determined by the Compensation Committee and approved by the Board in a range of 0 to 100 percent of his annual base salary. The cash bonuses for Mr. Pagano, Dr. Klimovsky and Mr. Mancini are conditional upon the recommendation of the CEO, in an amount between 0 and 60 percent of the individual’s annual base salary, in accordance with the remuneration policy and as determined by the Compensation Committee and approved by the Board. For 2019, RSUs have been granted to Dr. van de Winkel, Mr. Pagano and Dr. Klimovsky under our RSU program, which is further described below. The above-named individuals qualify for all of our benefit programs, including pension plans.

Remuneration was also given to Genmab’s former Executive Vice President and CFO, David Eatwell, in accordance with his service agreement, consisting of base salary, cash bonus, RSUs and warrants. The cash bonus for Mr. Eatwell was conditional upon the recommendation of the CEO, in an amount between 0 and 60 percent of his annual base salary, in accordance with the remuneration policy and as determined by the Compensation Committee and approved by the Board. During his employment at Genmab, Mr. Eatwell qualified for all of our benefit programs, including pension plans. Mr. Eatwell retired from Genmab on February 29, 2020.

The Dr. van de Winkel, Dr. Klimovsky, Mr. Pagano and Mr. Mancini 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 Dr. Klimovsky, Mr. Pagano and Mr. Mancini 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 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 Dr. Klimovsky, Mr. Pagano and Mr. Mancini. Dr. van de Winkel will also receive an amount equal to two times the highest total bonus awarded to him, and Dr. Klimovsky, Mr. Pagano and Mr. Mancini 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 and Mr. Mancini 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, or the 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 the incentive guidelines adopted by the shareholders at the general meeting, or the remuneration principles. Under the terms of the Warrant Program, (i) warrants are granted at an exercise price equal to the share price on the grant date, (ii) the exercise price cannot be fixed at a lower price than the market price at the grant date and (iii) in connection with exercise, the warrants are to be settled with the delivery of our shares. The Warrant Program contains anti-dilution provisions if changes occur in our share capital prior to the warrants being exercised.

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

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

The terms of the warrants issued under the Warrant Program were amended in August 2004, April 2012 and March 2017. Warrants granted on terms as amended in August 2004 can be exercised starting from one year after the grant date and lapse on the tenth anniversary of the grant date. As a general rule, the warrant holder may only exercise 25% of the warrants granted per full year of employment or affiliation with us after the grant date. However, the warrant holder will be entitled to continue to be able to exercise all warrants on a regular schedule in instances where the employment relationship is terminated by us without cause.

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

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

In addition, in March 2019, our shareholders authorized the Board to issue additional warrants to subscribe for our shares up to a nominal value of DKK 500,000 (500,000 shares), on one or more occasions, to our employees, as well as employees of our directly and indirectly owned subsidiaries, but not to our registered managers. The terms of these warrants are identical to those issued pursuant to the March 2017 amendment.

See Note 4.6 to our Audited Financial Statements for our outstanding warrants and a summary of the holders of such warrants as of December 31, 2019.

**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 decided by the Board in its sole discretion. Under the terms of the RSU program, RSUs are subject to a cliff vesting period and become fully vested on the first banking day of the month following a period of three years from the date of grant. If an employee, member of senior management, or member of the Board ceases his or her employment or Board membership prior to the vesting date, all RSUs that are granted but not yet vested will lapse automatically. However, if an employee, a member of senior management or a member of the Board ceases employment or Board membership due to retirement or age limitation in our articles of association, death, serious sickness or serious injury then all RSUs that are granted, but not yet vested will remain outstanding and will be settled in accordance with their terms. In addition, for an employee or a member of senior management, RSUs that are granted but not yet vested will remain outstanding and will be settled in accordance with their terms in instances where the employment relationship is terminated by us without cause. Within 30 days of the vesting date, the holder of an RSU receives one share in the Company for each RSU. We may, at our sole discretion in extraordinary circumstances, choose to make a cash settlement instead of delivering shares.

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

We intend to purchase our own shares in order to cover our obligations in relation to the RSUs. Authorization to purchase our own shares up to a nominal value of DKK 500,000 (500,000 shares) was given by the shareholders at the annual general meeting in March 2016. Pursuant to this authorization and to cover our obligations under the RSU program, in 2018, we acquired 125,000 of our treasury shares, representing approximately 0.2% of share capital, for DKK 146.2 million, including directly attributable costs. Additionally, in March 2019, our shareholders authorized us to repurchase up to an additional nominal value of DKK 500,000 (500,000 shares). A portion of the shares that may be repurchased under this authorization may be used to cover our obligations in relation to the RSUs. The weighted average fair value of RSUs granted in 2019 was DKK 1,511.70.

See Note 4.6 to our Audited Financial Statements for our outstanding RSUs and a summary of the holders of such RSUs as of December 31, 2019.

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 of 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 warrants to, our senior management. See “—Compensation—Certain Senior Management Agreements” and “—Compensation—Warrant 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 or telephonic meetings during the year. During 2019, the Board held eight 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. Currently, the Board has three Employee Elected Members, Peter Storm Kristensen, Mijke Zachariasse and Daniel J. Bruno. In total, our Board currently consists of nine Board members (including six Shareholder Elected Members and three Employee Elected Members). The Board elects a chairman from among its members. The majority of our Board members are considered to be independent under the corporate governance standards of the Nasdaq Stock Market and Nasdaq Copenhagen.

Senior Management

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

Committees of the Board of Directors

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

Audit and Finance Committee

According to the Audit and Finance Committee charter, the Audit and Finance Committee must consist of at least three non-executive Board members, all of whom must be independent. Furthermore, the Chairman of the Board shall not be Chairman of the Audit and Finance Committee. As of the date of this Annual Report, the Audit and Finance Committee consists of members Jonathan Peacock, Rolf Hoffmann and Deirdre P. Connelly and is chaired by Pernille Erenbjerg. The Audit and Finance Committee assists the Board with the oversight of the financial reporting process, the effectiveness of internal controls over financial reporting and risk management, the independent audit process and compliance with legal and regulatory requirements, in accordance with the Audit and Finance Committee charter. Each member of the Audit and Finance Committee satisfies the independence requirements of the corporate governance standards of the Nasdaq Stock Market, and Pernille Erenbjerg qualifies as an “Audit Committee financial expert,” as defined in Nasdaq Rule 5605(c)(2)(A) and as determined by our Board.
Our Audit and Finance Committee oversees our accounting and financial reporting processes and the audits of our consolidated financial statements. Our Audit and Finance Committee has the following principal responsibilities:

- overseeing the accounting and financial reporting principles and process to ensure compliance with legal and regulatory requirements and the quality, transparency and integrity of the published financial information;
- overseeing the appropriateness and effectiveness of our internal controls over financial reporting and risk management system and evaluating the need for an internal audit;
- overseeing our audits and the independent auditor process, including recommending the appointment of the independent auditors and overseeing the annual assessment of their performance and qualifications, overseeing non-audit services and, to the extent permitted by applicable law, being directly responsible for the appointment, retention and compensation of the independent auditors in connection with audit, review or attestation services;
- considering the independence of the independent auditors and any potential conflicts of interest, including by (i) ensuring receipt from the independent auditors of a formal written statement delineating all relationships with the Company, (ii) actively engaging in dialogue with the independent auditors with respect to factors that may impact the independent auditors’ objectivity and independence, and (iii) taking, or recommending that the Board takes, appropriate action to oversee auditor independence;
- ensuring that significant adjustments, unadjusted differences, disagreements between management and the independent auditors and management responses thereto are discussed with the independent auditors and resolving disagreements between management and the independent auditors;
- assessing transactions between the Company and the Company’s related parties and, in respect of material related party transactions, submitting a recommendation for approval or non-approval of such transactions to the Board prior to their completion;
- overseeing compliance with legal and regulatory requirements in relation to financial reporting and auditing regulation;
- authority to obtain advice and assistance from independent counsel and other advisors;
- obtaining appropriate funding, as determined by the Audit and Finance Committee, for compensation to the independent auditor and to any advisors that the Audit and Finance Committee chooses to engage;
- undertaking 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, the Compensation Committee consists of members Jonathan Peacock, Paolo Paoletti and Anders Gersel Pedersen and is chaired by Deirdre P. Connelly. Jonathan Peacock, Paolo Paoletti and Deirdre P. Connelly satisfy the independence requirements of the corporate governance standards of the Nasdaq Stock Market. 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 principles, if adopted by the Board, are subject to the approval of our shareholders at the annual general meeting. The Compensation Committee’s primary responsibilities are as follows:

- reviewing trends in compensation and the competitiveness of our executive compensation programs to ensure (a) the attraction and retention of registered managers, (b) the motivation of registered managers to achieve our business objectives, and (c) the alignment of the interests of key leadership with the long-term interests of our shareholders;
- making proposals for the approval of the Board prior to approval by shareholders at the general meeting, on the compensation policy for members of the Board and the registered managers, including the overall principles of incentive pay schemes, compensation structure and long-term incentive compensation plans and a remuneration policy applicable to the Company in general;
- reviewing goals and objectives of our CEO and evaluating his performance to make recommendations concerning CEO compensation upon deliberations or voting in the CEO’s absence;
- overseeing the evaluation of the performance of the Company’s registered managers, and discussing their annual compensation, including salary, bonus, incentive and equity compensation;
- reviewing plans for registered managers’ development and corporate succession plans for registered management;
- reviewing termination and compensation packages for new registered managers as requested by management;
- in its sole discretion, retaining, terminating and receiving advice from outside counsel, compensation consultants or other advisers, upon consideration of (i) whether such counsel, consultant or adviser provides other services to the Company and the amount of fees they receive from the Company as a percentage of their total revenue, (ii) the policies of such counsel, consultant or adviser designed to prevent conflicts of interest, (iii) any business or personal relationship of the consultant, counsel or adviser with a member of the Compensation Committee or a member of senior management of the Company, and (iv) any ownership of shares in the Company by the consultant, legal counsel or adviser;
- approving the fees of outside counsel, compensation consultants or other advisers, to be appropriately funded by the Company and directly overseeing the work of such counsel, consultants or advisers; and
- overseeing that the information in the annual report on the compensation of the Board and registered managers is correct, true and sufficient.

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

According to its charter, our Nominating and Corporate Governance Committee must include at least two non-executive directors, appointed by the Board. A majority of members must be independent. As of the date of this Annual Report, the Nominating and Corporate Governance Committee consists of members Pernille Erenbjerg and Deirdre P. Connelly and is chaired by Anders Gersel Pedersen. Pernille Erenbjerg and Deirdre P. Connelly satisfy the independence requirements of the corporate governance standards of the Nasdaq Global Select Market. 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 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 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, 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 extent 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, 2019, we had 548 employees. Of these employees, 468 were engaged in or support research and development and 80 were in administrative and business related positions. Each of our employees has signed confidentiality and inventions assignment agreements, or have signed employment agreements containing confidentiality and inventions assignment provisions, and none are covered by a collective bargaining agreement. We have never experienced employment-related work stoppages and consider our employee relations to be good.

E. Share Ownership

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

ITEM 7 MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth information relating to the beneficial ownership of our shares as of March 26, 2020 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
<table>
<thead>
<tr>
<th>Name of Beneficial Owner</th>
<th>Number of Shares Beneficially Owned</th>
<th>Number of Warrants Exercisable and RSUs to be Settled Within 60 days</th>
<th>Fully Diluted Number of Shares Beneficially Owned</th>
<th>Fully Diluted Percentage of Beneficial Ownership</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5% Shareholders</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Artisan Partners Limited Partnership (1)</td>
<td>3,081,731</td>
<td>—</td>
<td>3,081,731</td>
<td>5 %</td>
</tr>
<tr>
<td>BlackRock, Inc. (2)</td>
<td>4,611,434</td>
<td>—</td>
<td>4,611,434</td>
<td>7 %</td>
</tr>
<tr>
<td><strong>Board Members and Senior Management</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anders Gersel Pedersen</td>
<td>9,307</td>
<td>10,000</td>
<td>19,307</td>
<td>0.03 %</td>
</tr>
<tr>
<td>Pernille Erenbjerg</td>
<td>3,571</td>
<td>—</td>
<td>3,571</td>
<td>0.01 %</td>
</tr>
<tr>
<td>Paolo Paoletti</td>
<td>1,030</td>
<td>—</td>
<td>1,030</td>
<td>0.00 %</td>
</tr>
<tr>
<td>Rolf Hoffmann</td>
<td>1,050</td>
<td>1,121</td>
<td>2,171</td>
<td>0.00 %</td>
</tr>
<tr>
<td>Deirdre P. Connelly</td>
<td>2,200</td>
<td>1,121</td>
<td>3,321</td>
<td>0.01 %</td>
</tr>
<tr>
<td>Jonathan Peacock</td>
<td>—</td>
<td>315</td>
<td>315</td>
<td>0.00 %</td>
</tr>
<tr>
<td>Mijke Zachariasse</td>
<td>300</td>
<td>766</td>
<td>1,066</td>
<td>0.00 %</td>
</tr>
<tr>
<td>Daniel J. Bruno</td>
<td>1,080</td>
<td>2,523</td>
<td>3,603</td>
<td>0.01 %</td>
</tr>
<tr>
<td>Jan G. J. van de Winkel</td>
<td>671,423</td>
<td>13,456</td>
<td>684,879</td>
<td>1.05 %</td>
</tr>
<tr>
<td>Anthony Pagano</td>
<td>863</td>
<td>12,594</td>
<td>13,457</td>
<td>0.02 %</td>
</tr>
<tr>
<td>Judith Klimovsky</td>
<td>—</td>
<td>11,200</td>
<td>11,200</td>
<td>0.02 %</td>
</tr>
<tr>
<td>Anthony Mancini</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Birgitte Stephenson</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Michael K. Bauer</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Tahamant Ahmadi</td>
<td>—</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Martine J. van Vugt</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td><strong>All board members and senior management as a group (17 persons)</strong></td>
<td>697,683</td>
<td>121,059</td>
<td>818,742</td>
<td>1.26 %</td>
</tr>
</tbody>
</table>

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

(1) This information is based solely on a notification provided by Artisan Partners Limited Partnership pursuant to Section 38 of the Danish Capital Markets Act. Genmab issued a major shareholder announcement on January 9, 2018. Artisan Partners Limited Partnership does not have different voting rights from other shareholders.

(2) This information is based solely on the Schedule 13G filed by BlackRock, Inc. on February 7, 2020 with the SEC. BlackRock, Inc. does not have different voting rights from other shareholders.

The number of shares beneficially owned by each entity, person or member of our board of directors or senior management is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares for which the individual has the right to subscribe within 60 days of March 26, 2020 through the exercise of any options, warrants or other rights. There are 121,059 shares for which our board members and senior management as a group have the right to subscribe within 60 days of March 26, 2020 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 65,156,578 shares outstanding as of March 26, 2020. Shares for which a person has the right to subscribe within 60 days of March 26, 2020 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. As of March 26, 2020, we estimate that approximately 40%, or 26.1 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**

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.
We have entered into employment agreements with, and issued warrants and RSUs to, our senior management.

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.

For example, in April 2016, MorphoSys filed a complaint at the U.S. District Court of Delaware against Genmab and Janssen Biotech, Inc. for patent infringement based on activities relating to the manufacture, use and sale of DARZALEX in the United States, which was subsequently amended to include two additional MorphoSys patents. In addition, a further claim by Janssen and us that the three MorphoSys patents were unenforceable due to inequitable conduct by MorphoSys was included in the case. On January 25, 2019, the District Court ruled on summary judgment that the three MorphoSys patents were invalid for lack of enablement. MorphoSys had the opportunity to appeal the District Court’s decision. On January 31, 2019, MorphoSys dismissed its infringement claims against us and Janssen with prejudice, and we and Janssen, in turn, dismissed our inequitable conduct claims against MorphoSys. As such, there will be no further proceedings in the case.

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

DARZALEX Approved in Combination with VTd in Europe

On January 20, 2020, the European Commission granted marketing authorization for DARZALEX in combination with VTd for the treatment of adult patients with newly diagnosed MM who are eligible for ASCT. The approval was based on the Phase III CASSIOPEIA data.

Genmab Board of Directors Chairman to Step Down

On February 21, 2020, we announced that the Chairman of the Board of Directors, Mr. Mats Pettersson, B.Sc., has decided to step down from the Board at Genmab A/S’ Annual General Meeting on March 26, 2020, when his election
period is set to expire. Subject to re-election at the 2020 Annual General Meeting, it is the Board of Director’s intention to appoint Ms. Deirdre P. Connelly as the new Chairman of the Board.

David Eatwell Retires, and Anthony Pagano Appointed Chief Financial Officer

On February 29, 2020, David Eatwell retired from his position as Executive Vice President and Chief Financial Officer of Genmab. On March 1, 2020, Anthony Pagano, previously Senior Vice President Finance and Corporate Development of Genmab, assumed the role of Executive Vice President and Chief Financial Officer of Genmab.

Anthony Mancini Joins Genmab in Newly Created Position of Chief Operating Officer

On March 23, 2020 Anthony Mancini joined Genmab as Executive Vice President and Chief Operating Officer. Mr. Mancini will be responsible for overseeing Genmab’s Commercial, Corporate Development, Business Development and Information Technology functions.

Constitution of the Board of Directors in Genmab A/S

On March 26, 2020 at Genmab’s Annual General meeting Mr. Jonathan Peacock was elected to the Board of Directors for a one-year period. Ms. Deirdre P. Connelly, Ms. Pernille Erenbjerg, Mr. Rolf Hoffmann, Dr. Paolo Paoletti and Dr. Anders Gersel Pedersen were re-elected to the Board of Directors for a one-year period, while Mr. Mats Pettersson, the Chairman of Genmab’s Board of Directors, stepped down from the Board and did not stand for re-election. Immediately following the Annual General Meeting, Genmab’s Board of Directors met to constitute itself with Ms. Deirdre P. Connelly appointed Chairman and Ms. Pernille Erenbjerg appointed Deputy Chairman.

ITEM 9 THE OFFER AND LISTING

A. Offer and Listing Details

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

B. Plan of Distribution

Not applicable.

C. Markets

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

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

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

122
F. Expenses of the Issue

Not applicable.

ITEM 10 ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

The sections entitled “Description of Share Capital and Certain Corporate Matters—Shareholders’ Register,” “Description of Share Capital and Certain Corporate Matters—Articles of Association and Danish Corporate Law” and “Description of Share Capital and Certain Corporate Matters—Comparison of Danish Corporate Law and our Articles of Association and Delaware Corporate Law” in the Company’s prospectus, filed with the SEC on July 19, 2019 are incorporated herein by reference.

C. Material Contracts

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

D. Exchange Controls

There are no governmental laws, decrees, or regulations in Denmark (including, but not limited to, foreign exchange controls) that restrict the export or import of capital, or that affect the remittance of dividends, interest or other payments to non-resident holders of the shares or the ADSs (please see below under “Item 7—Taxation” in respect of Danish withholding tax on dividends). There are no limitations on the right of non-resident or foreign owners to hold or vote the shares or the ADSs imposed by the laws of Denmark or the Articles of Association of the Company solely due to the fact that such holders are non-residents or foreign owners.

E. Taxation

Payment of Taxes

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

General

The following discussion is a summary of the material U.S. federal income tax consequences relating to the acquisition, ownership and disposition of the ADSs. This summary does not purport to be a comprehensive description of all of the U.S. federal income tax considerations that may be relevant to a particular person's decision to acquire the ADSs. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, and U.S. Treasury regulations promulgated thereunder, or the Treasury Regulations, as well as judicial and administrative interpretations thereof as in effect as of the date of this Annual Report. 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, or the 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 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.


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 passive foreign investment company, or 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 American Depository Shares 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, as our ADSs are expected to be. 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, will be 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**

126
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, 2020, or in the foreseeable future. However, the determination of PFIC status is based on an annual determination that cannot be made until the close of a taxable year, involves extensive factual investigation, including ascertaining the fair market value of all of our assets on a quarterly basis and the active or passive character of each item of income that we earn, and is subject to uncertainty in several respects. Changes in the nature or composition of our income or assets, the structure of our operation or the value of our assets may cause us to become a PFIC. The determination of the value of our assets may depend in part upon the value of our goodwill not reflected on our balance sheet (which may depend upon the market value of the ADSs from time to time, which may be volatile). Accordingly, we cannot assure you that we will not be a PFIC for our current taxable year ending December 31, 2020, 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.

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. 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. This summary assumes that 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, and that the ADS holder is deemed the beneficial owner of any dividend distributed on the underlying shares for Danish domestic tax law purposes as well as under any applicable tax treaty. Accordingly, the following deals with material Danish tax considerations relating to the ownership and disposition of listed 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 55,300 (for cohabiting spouses, a total of DKK 110,600) and at a rate of 42% on share income exceeding DKK 55,300 (for cohabiting spouses over DKK 110,600) (all 2020 amounts and thresholds). The threshold is subject to annual adjustments and include all share income included in the calculation (i.e., all capital gains on shares and dividends derived by the individual or cohabiting spouses, respectively).
Gains and losses on the sale of shares are calculated as the difference between the purchase price and the sales price. The purchase price is based on the average purchase price paid for the shares in the company (i.e., not the purchase price paid for each share).

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

Dividends

Dividends paid to Danish tax resident individuals 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 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.

In the event that the shareholder 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 shareholder 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, Danish domestic tax law provides for a 15% tax rate, if the shareholder 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 shareholder is tax resident outside the EU, it is an additional requirement for application of the 15% tax rate that the shareholder together with related shareholders holds less than 10% of the share capital of the company.

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

As a general rule, the refund shall be paid within six months following the Danish Tax Agency's receipt of the refund claim. If the refund is paid later than six months after the receipt of the claim, interest will in general be calculated on the amount of refund. For 2016 and subsequent years, the rate per month will be 0.4% plus a premium fixed annually. The six-month deadline is suspended by the Danish Tax Agency, if the Tax Agency is unable to determine whether the taxpayer is entitled to a refund based on the taxpayer's affairs. If the deadline is suspended accordingly, computation of interest is also suspended.
The Danish Tax Agency has recently published new 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. 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**

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 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 on or after July 1, 2016. However, the withholding rate is 27%, meaning that all foreign corporate shareholders receiving taxable dividends distributed from Danish companies on or after July 1, 2016 will be able to ask for a refund of at least 5% of the total dividend.

Further, in the event that the shareholder 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 shareholder 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, Danish domestic tax law provides for an applicable 15% tax rate, if the shareholder 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 shareholder is tax resident outside the EU, it is an additional requirement for eligibility for the 15% tax rate that the shareholder together with related shareholders holds less than 10% of the nominal share capital of the company.

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. For 2016 and subsequent years, the rate per month will be 0.4% plus a premium fixed annually. The six-month deadline can be suspended by the Danish Tax Agency, if the Tax Agency is unable to determine whether the taxpayer is entitled to a refund based on the taxpayer’s affairs. If the deadline is suspended accordingly, computation of interest is also suspended.

The Danish Tax Agency has recently published new 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. We have included such website address as an inactive textual reference only.

Danish Anti-Avoidance Rules

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

Further, Danish law has certain general anti-avoidance rules, or the 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, i.e., the ADS, at the time of the general meeting where the decision to distribute dividend is passed who is 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 2019, can be downloaded from the “Investors” page at www.genmab.com. The contents of our website are not incorporated by reference into this Annual Report on Form 20-F. This Annual Report on Form 20-F is also filed and can be viewed via EDGAR on www.sec.gov.

I. Subsidiary Information

Not applicable.

ITEM 11 QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISKS

For qualitative and quantitative disclosures about market risks including foreign currency risk interest rate risk, and credit risk, see Note 4.2 to the Audited Financial Statements.

ITEM 12 DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

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

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

<table>
<thead>
<tr>
<th>Service</th>
<th>Fees</th>
</tr>
</thead>
<tbody>
<tr>
<td>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)</td>
<td>Up to $0.05 per ADS issued</td>
</tr>
<tr>
<td>Cancellation of ADSs, including the case of termination of the deposit agreement</td>
<td>Up to $0.05 per ADS cancelled</td>
</tr>
<tr>
<td>Distribution of cash dividends</td>
<td>Up to $0.05 per ADS held</td>
</tr>
<tr>
<td>Distribution of cash entitlements (other than cash dividends) and/or cash proceeds from the sale of rights, securities and other entitlements</td>
<td>Up to $0.05 per ADS held</td>
</tr>
<tr>
<td>Distribution of ADSs pursuant to exercise of rights.</td>
<td>Up to $0.05 per ADS held</td>
</tr>
<tr>
<td>Distribution of securities other than ADSs or rights to purchase additional ADSs</td>
<td>Up to $0.05 per ADS held</td>
</tr>
<tr>
<td>Depositary services</td>
<td>Up to $0.05 per ADS held on the applicable record date(s) established by the depositary bank</td>
</tr>
</tbody>
</table>

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 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**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended), as of the end of the period covered by this Annual Report on Form 20-F. Based on such evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective as of December 31, 2019.

This Annual Report does not include a report of management’s assessment regarding internal control over financial reporting or an attestation report of the Company’s registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

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

**ITEM 16A  AUDIT COMMITTEE FINANCIAL EXPERTS**

Our Audit and Finance Committee consists of members Jonathan Peacock, Rolf Hoffmann and Deirdre P. Connelly and is chaired by Pernille Erenbjerg. Each member of the Audit and Finance Committee satisfies the independence requirements of the corporate governance standards of the Nasdaq Stock Market, and Pernille Erenbjerg qualifies as an “audit committee financial expert,” as defined in Nasdaq Rule 5605(c)(2)(A) and as determined by our Board of Directors.
ITEM 16B  CODE OF ETHICS

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

During 2019, the Company did not significantly 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 Code of Conduct, or any waivers of its requirements, will be disclosed on our website.

ITEM 16C  PRINCIPAL ACCOUNTANT FEES AND SERVICES

For principal accountant fees and services, see Note 5.6 to the Audited Financial Statements.

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

None.
ITEM 16F CHANGE IN REGISTRANT’S CERTIFYING ACCOUNTANT

None.

ITEM 16G CORPORATE GOVERNANCE

The Nasdaq Listing Rules provide that foreign private issuers may follow home country practice in lieu of Nasdaq Global Select Market corporate governance standards, subject to certain exceptions and except to the extent that such exemptions would be contrary to U.S. federal securities laws. The home country practices we follow in lieu of the Nasdaq Listing Rules are described below.

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

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

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

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

- We do not follow the requirement of the Nasdaq Stock Market that we have independent director oversight of director nominations as prescribed by Nasdaq Listing Rule 5605(e)(1). No such requirement exists pursuant to Danish law. We do not have independent oversight of director nominations because we consider Anders Gersel Pedersen, Chairman of the Nominating and Corporate Governance 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 Chairman 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.

PART III

ITEM 17  FINANCIAL STATEMENTS

See “Item 18—Financial Statements.”

ITEM 18  FINANCIAL STATEMENTS

The financial statements filed as part of this Annual Report begin on page F-1.

ITEM 19  EXHIBITS

Exhibit Index

<table>
<thead>
<tr>
<th>Exhibit No.</th>
<th>Description</th>
<th>Method of filing</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Amended and Restated Deposit Agreement</td>
<td>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.</td>
</tr>
<tr>
<td>2.2</td>
<td>Form of American Depositary Receipt</td>
<td>Filed together with this Annual Report on Form 20-F for the year ended December 31, 2019</td>
</tr>
<tr>
<td>2.3</td>
<td>Description of Securities Registered under Section 12 of the Exchange Act</td>
<td></td>
</tr>
<tr>
<td>4.1†</td>
<td>License Agreement, dated as of August 30, 2012, by and between Janssen Biotech, Inc. and Genmab A/S</td>
<td>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</td>
</tr>
<tr>
<td>4.2†</td>
<td>Amendment Number 1 to the License Agreement, dated as of January 31, 2013, by and between Janssen Biotech, Inc. and Genmab A/S</td>
<td>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</td>
</tr>
<tr>
<td>4.3†</td>
<td>Amendment Number 2 to the License Agreement, dated as of October 10, 2013, by and between Janssen Biotech, Inc. and Genmab A/S</td>
<td>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</td>
</tr>
<tr>
<td>4.4†</td>
<td>License and Collaboration Agreement, dated as of October 7, 2011, by and between Seattle Genetics, Inc. and Genmab A/S</td>
<td>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</td>
</tr>
<tr>
<td>4.5†</td>
<td>Co-development and Collaboration Agreement, dated as of December 19, 2006, by and between Glaxo Group Limited and Genmab A/S</td>
<td>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</td>
</tr>
<tr>
<td>4.6†</td>
<td>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</td>
<td>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</td>
</tr>
<tr>
<td>4.7†</td>
<td>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</td>
<td>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</td>
</tr>
<tr>
<td>Exhibit No.</td>
<td>Description</td>
<td>Method of filing</td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>4.8</td>
<td>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</td>
<td>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</td>
</tr>
<tr>
<td>4.9</td>
<td>Amendment Number 4 to the Co-development and Collaboration Agreement, dated as of December 22, 2010, by and between Glaxo Group Limited and Genmab A/S</td>
<td>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</td>
</tr>
<tr>
<td>4.10</td>
<td>Novation Agreement, dated as of November 3, 2014, by and among Glaxo Group Limited, Novartis Pharma AG and Genmab A/S</td>
<td>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</td>
</tr>
<tr>
<td>4.11</td>
<td>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</td>
<td>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</td>
</tr>
<tr>
<td>4.12</td>
<td>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</td>
<td>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</td>
</tr>
<tr>
<td>8.1</td>
<td>List of Subsidiaries</td>
<td>Filed together with this Annual Report on Form 20-F for the year ended December 31, 2019</td>
</tr>
<tr>
<td>12.1</td>
<td>Certification of the Principal Executive Officer</td>
<td>Filed together with this Annual Report on Form 20-F for the year ended December 31, 2019</td>
</tr>
<tr>
<td>12.2</td>
<td>Certification of the Principal Financial Officer</td>
<td>Filed together with this Annual Report on Form 20-F for the year ended December 31, 2019</td>
</tr>
<tr>
<td>13.1</td>
<td>Certification of the Principal Executive Officer pursuant to 18 U.S.C. section 1350</td>
<td>Furnished together with this Annual Report on Form 20-F for the year ended December 31, 2019</td>
</tr>
<tr>
<td>13.2</td>
<td>Certification of the Principal Financial Officer pursuant to 18 U.S.C. section 1350</td>
<td>Furnished together with this Annual Report on Form 20-F for the year ended December 31, 2019</td>
</tr>
<tr>
<td>15.1</td>
<td>Consent of Independent Registered Public Accounting Firm</td>
<td>Filed together with this Annual Report on Form 20 F for the year ended December 31, 2019</td>
</tr>
<tr>
<td>EX-101.INS</td>
<td>XBRL Instance Document</td>
<td>Filed together with this Annual Report on Form 20 F for the year ended December 31, 2019</td>
</tr>
<tr>
<td>EX-101.SCH</td>
<td>XBRL Taxonomy Extension Schema Document</td>
<td>Filed together with this Annual Report on Form 20 F for the year ended December 31, 2019</td>
</tr>
<tr>
<td>EX-101.CAL</td>
<td>XBRL Taxonomy Extension Calculation Linkbase Document</td>
<td>Filed together with this Annual Report on Form 20 F for the year ended December 31, 2019</td>
</tr>
<tr>
<td>EX-101.DEF</td>
<td>XBRL Taxonomy Extension Definition Linkbase Document</td>
<td>Filed together with this Annual Report on Form 20 F for the year ended December 31, 2019</td>
</tr>
<tr>
<td>EX-101.LAB</td>
<td>XBRL Taxonomy Extension Labels Linkbase Document</td>
<td>Filed together with this Annual Report on Form 20 F for the year ended December 31, 2019</td>
</tr>
<tr>
<td>EX-101.PRE</td>
<td>XBRL Taxonomy Extension Presentation Linkbase Document</td>
<td>Filed together with this Annual Report on Form 20 F for the year ended December 31, 2019</td>
</tr>
</tbody>
</table>

† 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) would likely cause competitive harm to the registrant if publicly disclosed.
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: March 30, 2020
# INDEX TO FINANCIAL STATEMENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report of Independent Registered Public Accounting Firm</td>
<td>F-2</td>
</tr>
<tr>
<td>Consolidated Statements of Comprehensive Income for the Years Ended</td>
<td>F-4</td>
</tr>
<tr>
<td>December 31, 2019, 2018 and 2017</td>
<td></td>
</tr>
<tr>
<td>Consolidated Balance Sheets as of December 31, 2019 and 2018</td>
<td>F-5</td>
</tr>
<tr>
<td>Consolidated Statements of Cash Flows for the Years Ended December</td>
<td>F-6</td>
</tr>
<tr>
<td>31, 2019, 2018 and 2017</td>
<td></td>
</tr>
<tr>
<td>Consolidated Statements of Changes in Equity at December 31, 2019, 2018</td>
<td>F-7</td>
</tr>
<tr>
<td>F-8</td>
<td></td>
</tr>
<tr>
<td>Notes to the Consolidated Financial Statements</td>
<td>F-8</td>
</tr>
</tbody>
</table>
Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Genmab A/S and its subsidiaries (the “Company”) as of December 31, 2019 and 2018 and the related consolidated statements of comprehensive income, consolidated statements of cash flows and consolidated statements of changes in equity for each of the three years in the period ended December 31, 2019, including the related notes (collectively referred to as the “consolidated financial statements”). In our opinion the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements 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 of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits 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. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers
Statsautoriseret Revisionspartnerselskab
Hellerup, Denmark
March 30, 2020

We have served as the Company’s auditor since 2000.
### Consolidated Statements of Comprehensive Income

(DKK million)

<table>
<thead>
<tr>
<th></th>
<th>Note</th>
<th>2019</th>
<th>2018</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenue</strong></td>
<td></td>
<td>5,366</td>
<td>3,025</td>
<td>2,365</td>
</tr>
<tr>
<td>Research and development expenses</td>
<td>2.3, 3.1, 3.2</td>
<td>(2,386)</td>
<td>(1,431)</td>
<td>(874)</td>
</tr>
<tr>
<td>General and administrative expenses</td>
<td>2.3, 3.2</td>
<td>(342)</td>
<td>(214)</td>
<td>(147)</td>
</tr>
<tr>
<td><strong>Operating expenses</strong></td>
<td></td>
<td>(2,728)</td>
<td>(1,645)</td>
<td>(1,021)</td>
</tr>
<tr>
<td><strong>Operating result</strong></td>
<td></td>
<td>2,636</td>
<td>1,380</td>
<td>1,344</td>
</tr>
<tr>
<td>Financial income</td>
<td>4.5</td>
<td>228</td>
<td>243</td>
<td>72</td>
</tr>
<tr>
<td>Financial expenses</td>
<td>4.5</td>
<td>(7)</td>
<td>(11)</td>
<td>(352)</td>
</tr>
<tr>
<td><strong>Net result before tax</strong></td>
<td></td>
<td>2,859</td>
<td>1,612</td>
<td>1,064</td>
</tr>
<tr>
<td>Corporate tax</td>
<td>2.4</td>
<td>(693)</td>
<td>(140)</td>
<td>40</td>
</tr>
<tr>
<td><strong>Net result</strong></td>
<td></td>
<td>2,166</td>
<td>1,472</td>
<td>1,104</td>
</tr>
<tr>
<td>Basic net result per share</td>
<td>2.5</td>
<td>34.40</td>
<td>24.03</td>
<td>18.14</td>
</tr>
<tr>
<td>Diluted net result per share</td>
<td>2.5</td>
<td>34.03</td>
<td>23.73</td>
<td>17.77</td>
</tr>
</tbody>
</table>

#### Statement of Comprehensive Income

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>2019</th>
<th>2018</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Net result</strong></td>
<td></td>
<td>2,166</td>
<td>1,472</td>
<td>1,104</td>
</tr>
<tr>
<td><strong>Other comprehensive income:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amounts which may be re-classified to the income statement:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adjustment of foreign currency fluctuations on subsidiaries</td>
<td>6</td>
<td>10</td>
<td>(17)</td>
<td></td>
</tr>
<tr>
<td><strong>Fair value adjustments of cash flow hedges:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fair value adjustments during the period</td>
<td>—</td>
<td>—</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>Fair value adjustments reclassified to the income statement to financial income</td>
<td>—</td>
<td>—</td>
<td>(20)</td>
<td></td>
</tr>
<tr>
<td><strong>Total comprehensive income</strong></td>
<td></td>
<td>2,172</td>
<td>1,482</td>
<td>1,083</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these consolidated financial statements.
# Consolidated Balance Sheets

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>Note</th>
<th>December 31, 2019</th>
<th>December 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASSETS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intangible assets</td>
<td>2.2, 3.1</td>
<td>470</td>
<td>470</td>
</tr>
<tr>
<td>Property, plant and equipment</td>
<td>2.2, 3.2</td>
<td>237</td>
<td>162</td>
</tr>
<tr>
<td>Right-of-use assets</td>
<td>3.3</td>
<td>177</td>
<td>—</td>
</tr>
<tr>
<td>Receivables</td>
<td>3.5</td>
<td>11</td>
<td>10</td>
</tr>
<tr>
<td>Deferred tax assets</td>
<td>2.4</td>
<td>139</td>
<td>386</td>
</tr>
<tr>
<td>Other investments</td>
<td>3.4</td>
<td>149</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total non-current assets</strong></td>
<td></td>
<td>1,183</td>
<td>1,028</td>
</tr>
<tr>
<td>Receivables</td>
<td>3.5</td>
<td>2,990</td>
<td>1,327</td>
</tr>
<tr>
<td>Marketable securities</td>
<td>4.4</td>
<td>7,419</td>
<td>5,573</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td></td>
<td>3,552</td>
<td>533</td>
</tr>
<tr>
<td><strong>Total current assets</strong></td>
<td></td>
<td>13,961</td>
<td>7,433</td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td></td>
<td>15,144</td>
<td>8,461</td>
</tr>
</tbody>
</table>

| **SHAREHOLDERS’ EQUITY AND LIABILITIES** |       |                   |                   |
| Share capital | 4.7 | 65               | 61                |
| Share premium | 4.7 | 11,755           | 8,059             |
| Other reserves | | 98              | 92                |
| Retained Earnings | | 2,130            | (198)             |
| **Total shareholders’ equity** | | 14,048           | 8,014             |
| Provisions | 3.6 | 2               | 1                 |
| Lease liabilities | 3.3 | 155             | —                 |
| Other payables | 3.7 | 1               | 2                 |
| **Total non-current liabilities** | | 158             | 3                 |
| Provisions | |                   |                   |
| Corporate tax payable | 2.4 | 73              | 128               |
| Lease liabilities | 3.3 | 26               | —                 |
| Other payables | 3.7 | 839            | 316               |
| **Total current liabilities** | | 938             | 444               |
| **Total liabilities** | | 1,096           | 447               |
| **Total shareholders’ equity and liabilities** | | 15,144          | 8,461             |

The accompanying notes are an integral part of these consolidated financial statements.
### Consolidated Statements of Cash Flows

(DKK million)

<table>
<thead>
<tr>
<th>Note</th>
<th>2019</th>
<th>2018</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cash flows from operating activities:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net result before tax</td>
<td>2,859</td>
<td>1,612</td>
<td>1,064</td>
</tr>
<tr>
<td>Reversal of financial items, net</td>
<td>4.5</td>
<td>(221)</td>
<td>(232)</td>
</tr>
<tr>
<td>Adjustment for non-cash transactions</td>
<td>5.7</td>
<td>291</td>
<td>179</td>
</tr>
<tr>
<td>Change in working capital</td>
<td>5.7</td>
<td>(1,218)</td>
<td>(634)</td>
</tr>
<tr>
<td><strong>Cash generated by operating activities before financial items</strong></td>
<td>1,711</td>
<td>925</td>
<td>1,730</td>
</tr>
<tr>
<td>Interest received</td>
<td>111</td>
<td>44</td>
<td>43</td>
</tr>
<tr>
<td>Interest elements of lease payments</td>
<td>3.3</td>
<td>(7)</td>
<td>—</td>
</tr>
<tr>
<td>Interest paid</td>
<td>(13)</td>
<td>—</td>
<td>(3)</td>
</tr>
<tr>
<td>Corporate taxes (paid)/received</td>
<td>(476)</td>
<td>46</td>
<td>(181)</td>
</tr>
<tr>
<td><strong>Net cash generated by operating activities</strong></td>
<td>1,326</td>
<td>1,015</td>
<td>1,589</td>
</tr>
<tr>
<td><strong>Cash flows from investing activities:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Investment in intangible assets</td>
<td>3.1</td>
<td>(32)</td>
<td>(406)</td>
</tr>
<tr>
<td>Investment in tangible assets</td>
<td>3.2</td>
<td>(79)</td>
<td>(72)</td>
</tr>
<tr>
<td>Transactions with subsidiaries</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Marketable securities bought</td>
<td>4.4</td>
<td>(5,812)</td>
<td>(3,521)</td>
</tr>
<tr>
<td>Marketable securities sold</td>
<td>3,940</td>
<td>2,221</td>
<td>2,846</td>
</tr>
<tr>
<td><strong>Net cash used in investing activities</strong></td>
<td>(1,983)</td>
<td>(1,778)</td>
<td>(668)</td>
</tr>
<tr>
<td><strong>Cash flows from financing activities:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warrants exercised</td>
<td>65</td>
<td>75</td>
<td>215</td>
</tr>
<tr>
<td>Shares issued for cash</td>
<td>3,873</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Costs related to issuance of shares</td>
<td>(238)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Principal elements of lease payments</td>
<td>3.3</td>
<td>(31)</td>
<td>—</td>
</tr>
<tr>
<td>Purchase of treasury shares</td>
<td>—</td>
<td>(146)</td>
<td>—</td>
</tr>
<tr>
<td>Payment of withholding taxes on behalf of employees on net settled RSUs</td>
<td>(9)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Net cash from financing activities</strong></td>
<td>3,660</td>
<td>(71)</td>
<td>215</td>
</tr>
<tr>
<td><strong>Changes in cash and cash equivalents</strong></td>
<td>3,003</td>
<td>(834)</td>
<td>1,136</td>
</tr>
<tr>
<td>Cash and cash equivalents at the beginning of the period</td>
<td>533</td>
<td>1,348</td>
<td>307</td>
</tr>
<tr>
<td>Exchange rate adjustments</td>
<td>16</td>
<td>19</td>
<td>(95)</td>
</tr>
<tr>
<td><strong>Cash and cash equivalents at the end of the period</strong></td>
<td>3,552</td>
<td>533</td>
<td>1,348</td>
</tr>
</tbody>
</table>

**Cash and cash equivalents include:**

- Bank deposits and petty cash: 2,884, 533, 1,348
- Short-term marketable securities: 668, —, —

**Cash and cash equivalents at the end of the period:** 3,552, 533, 1,348

The accompanying notes are an integral part of these consolidated financial statements.

F-6
### Consolidated Statements of Changes in Equity

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>Share capital</th>
<th>Share premium</th>
<th>Translation reserves</th>
<th>Cash flow hedges</th>
<th>Retained Earnings/(Accumulated Deficit)</th>
<th>Shareholders' equity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Balance at December 31, 2016</strong></td>
<td>60</td>
<td>7,770</td>
<td>99</td>
<td>4</td>
<td>(3,107)</td>
<td>4,826</td>
</tr>
<tr>
<td><strong>Net result</strong></td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>1,104</td>
<td>1,104</td>
</tr>
<tr>
<td><strong>Other comprehensive income</strong></td>
<td>—</td>
<td>—</td>
<td>(17)</td>
<td>(4)</td>
<td>—</td>
<td>(21)</td>
</tr>
<tr>
<td><strong>Total comprehensive income</strong></td>
<td>—</td>
<td>—</td>
<td>(17)</td>
<td>(4)</td>
<td>1,104</td>
<td>1,083</td>
</tr>
<tr>
<td><strong>Transactions with owners:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercise of warrants</td>
<td>1</td>
<td>214</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>215</td>
</tr>
<tr>
<td>Share-based compensation expenses</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>76</td>
<td>76</td>
</tr>
<tr>
<td>Tax on items recognized directly in equity</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>72</td>
<td>72</td>
</tr>
<tr>
<td><strong>Balance at December 31, 2017</strong></td>
<td>61</td>
<td>7,984</td>
<td>82</td>
<td>—</td>
<td>(1,855)</td>
<td>6,272</td>
</tr>
<tr>
<td><strong>Change in accounting policy: Adoption of IFRS</strong></td>
<td>15</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>151</td>
</tr>
<tr>
<td><strong>Adjusted total equity at January 1, 2018</strong></td>
<td>61</td>
<td>7,984</td>
<td>82</td>
<td>—</td>
<td>(1,704)</td>
<td>6,423</td>
</tr>
<tr>
<td><strong>Net result</strong></td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>1,472</td>
<td>1,472</td>
</tr>
<tr>
<td><strong>Other comprehensive income</strong></td>
<td>—</td>
<td>—</td>
<td>10</td>
<td>—</td>
<td>—</td>
<td>10</td>
</tr>
<tr>
<td><strong>Total comprehensive income</strong></td>
<td>—</td>
<td>—</td>
<td>10</td>
<td>—</td>
<td>1,472</td>
<td>1,482</td>
</tr>
<tr>
<td><strong>Transactions with owners:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercise of warrants</td>
<td>—</td>
<td>75</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>75</td>
</tr>
<tr>
<td>Purchase of treasury shares</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(146)</td>
<td>(146)</td>
</tr>
<tr>
<td>Share-based compensation expenses</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>91</td>
<td>91</td>
</tr>
<tr>
<td>Tax on items recognized directly in equity</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>89</td>
<td>89</td>
</tr>
<tr>
<td><strong>Balance at December 31, 2018</strong></td>
<td>61</td>
<td>8,059</td>
<td>92</td>
<td>—</td>
<td>(198)</td>
<td>8,014</td>
</tr>
<tr>
<td><strong>Net result</strong></td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>2,166</td>
<td>2,166</td>
</tr>
<tr>
<td><strong>Other comprehensive income, net</strong></td>
<td>—</td>
<td>—</td>
<td>6</td>
<td>—</td>
<td>—</td>
<td>6</td>
</tr>
<tr>
<td><strong>Total comprehensive income</strong></td>
<td>—</td>
<td>—</td>
<td>6</td>
<td>—</td>
<td>2,166</td>
<td>2,172</td>
</tr>
<tr>
<td><strong>Transactions with owners:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercise of warrants</td>
<td>1</td>
<td>64</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>65</td>
</tr>
<tr>
<td>Shares issued for cash</td>
<td>3</td>
<td>3,870</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>3,873</td>
</tr>
<tr>
<td>Expenses related to capital increases</td>
<td>—</td>
<td>(238)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(238)</td>
</tr>
<tr>
<td>Share-based compensation expenses</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>147</td>
<td>147</td>
</tr>
<tr>
<td>Net settlement of RSUs</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(9)</td>
<td>(9)</td>
</tr>
<tr>
<td>Tax on items recognized directly in equity</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>24</td>
<td>24</td>
</tr>
<tr>
<td><strong>Balance at December 31, 2019</strong></td>
<td>65</td>
<td>11,755</td>
<td>98</td>
<td>—</td>
<td>2,130</td>
<td>14,048</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these consolidated financial statements.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

SECTION 1—BASIS OF PRESENTATION

1.1—Nature of the Business and Accounting Policies

Genmab A/S is a publicly traded, international biotechnology company specializing in the creation and development of differentiated antibody therapeutics for the treatment of cancer and other diseases. Founded in 1999, the company has two approved antibodies, a broad clinical and pre-clinical product pipeline and proprietary next generation antibody technologies.

The financial statements have been prepared in accordance with IFRS as issued by the International Accounting Standards Board (IASB). Except as outlined in note 1.2, the financial statements have been prepared using the same accounting policies as 2018. These consolidated financial statements were approved by our Board of Directors on March 26, 2020.

Section 2—Results for the Year

2.1 Revenue
2.2 Information about Geographical Areas
2.3 Staff Costs
2.4 Corporate and Deferred Tax
2.5 Result per Share

Section 3—Operating Assets and Liabilities

3.1 Intangible Assets
3.2 Property, Plant and Equipment
3.3 Leases
3.4 Other Investments
3.5 Receivables
3.6 Provisions
3.7 Other Payables

Section 4—Capital Structure, Financial Risk and Related Items

4.3 Financial Assets and Liabilities
4.4 Marketable Securities
4.5 Financial Income and Expenses

Section 5—Other Disclosures

5.3 Contingent Assets, Contingent Liabilities and Subsequent Events

Materiality

The group’s annual report is based on the concept of materiality and the group focuses on information that is considered material and relevant to the users of the consolidated financial statements. The consolidated financial statements consist of a large number of transactions. These transactions are aggregated into classes according to their nature or function and presented in classes of similar items in the consolidated financial statements as required by IFRS and Danish disclosure requirements for listed companies. If items are individually immaterial, they are aggregated with other items of similar nature in the financial statements or in the notes.
The disclosure requirements are substantial in IFRS. The group provides these specific required disclosures unless the information is considered immaterial to the economic decision-making of the readers of the financial statements or not applicable.

**Consolidated Financial Statements**

The consolidated financial statements include Genmab A/S (the parent company) and subsidiaries over which the parent company has control. The parent controls a subsidiary when the parent is exposed to, or has rights to, variable returns from its involvement with the subsidiary and has the ability to affect those returns through its power to direct the activities of the subsidiary. A company overview is included in note 5.3.

The group’s consolidated financial statements have been prepared on the basis of the financial statements of the parent company and subsidiaries—prepared under the group’s accounting policies—by combining similar accounting items on a line-by-line basis. On consolidation, intercompany income and expenses, intercompany receivables and payables, and unrealized gains and losses on transactions between the consolidated companies are eliminated.

The recorded value of the equity interests in the consolidated subsidiaries is eliminated with the proportionate share of the subsidiaries’ equity. Subsidiaries are consolidated from the date when control is transferred to the group.

The income statements for subsidiaries with a different functional currency than the group presentation currency are translated into the group’s presentation currency at the year’s weighted average exchange rate, and the balance sheets are translated at the exchange rate in effect at the balance sheet date.

Exchange rate differences arising from the translation of foreign subsidiaries shareholders’ equity at the beginning of the year and exchange rate differences arising as a result of foreign subsidiaries’ income statements being translated at average exchange rates are recorded in translation reserves in shareholders’ equity.

**Functional and Presentation Currency**

The financial statements have been prepared in Danish Krone (DKK), which is the functional and presentation currency of the parent company.

**Foreign Currency**

Transactions in foreign currencies are translated at the exchange rates in effect at the date of the transaction.

Exchange rate gains and losses arising between the transaction date and the settlement date are recognized in the income statement as financial items.

Unsettled monetary assets and liabilities in foreign currencies are translated at the exchange rates in effect at the balance sheet date. Exchange rate gains and losses arising between the transaction date and the balance sheet date are recognized in the income statement as financial items.

**Classification of Operating Expenses in the Income Statement**

**Research and Development Expense**

Research and development expenses primarily include salaries, benefits and other employee related costs of our research and development staff, license costs, manufacturing costs, pre-clinical costs, clinical trials, contractors and outside service fees, amortization of licenses and rights, and depreciation and impairment of intangible assets and property, plant and equipment, to the extent that such costs are related to the group’s research and development activities. Please see note 3.1 for a more detailed description on the treatment of Genmab’s research and development expenses.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

General and Administrative Expense

General and administrative expenses relate to the management and administration of the group. This includes salaries, benefits and other headcount costs related to management and support functions including human resources, information technology and the finance departments. In addition, depreciation and impairment of intangible assets and property, plant and equipment, to the extent such expenses are related to administrative functions are also included. General and administrative expenses are recognized in the income statement in the period to which they relate.

Statement of Cash Flow

The cash flow statement is presented using the indirect method with basis in the net result before tax.

Cash flow from operating activities is stated as the net result adjusted for net financial items, non-cash operating items such as depreciation, amortization, impairment losses, share-based compensation expenses, provisions, and for changes in working capital, interest paid and received, and corporate taxes paid. Working capital mainly comprises changes in receivables, provisions paid and other payables excluding the items included in cash and cash equivalents. Changes in non-current assets and liabilities are included in working capital, if related to the main revenue-producing activities of Genmab.

Cash flow from investing activities is comprised of cash flow from the purchase and sale of intangible assets and property, plant and equipment and financial assets as well as purchase and sale of marketable securities.

Cash flow from financing activities is comprised of cash flow from the issuance of shares, if any, and payment of long-term loans including installments on lease liabilities. Finance lease transactions are considered non-cash transactions.

Cash and cash equivalents comprise cash, bank deposits, and marketable securities with a maturity of three months or less on the date of acquisition. The cash flow statement cannot be derived solely from the financial statements.

Derivative Financial Instruments and Hedging Activities

Derivatives are initially recognized at fair value on the date a derivative contract is entered into and are subsequently re-measured at their fair value. The method of recognizing the resulting gain or loss depends on whether the derivative is designated as a hedging instrument, and if so, the nature of the item being hedged. Genmab designates certain derivatives as either:

1. Fair value hedge (hedges of the fair value of recognized assets or liabilities or a firm commitment); or
2. Cash flow hedge (hedges of a particular risk associated with a recognized asset or liability or a highly probable forecast transaction).

At the inception of a transaction, Genmab documents the relationship between hedging instruments and hedged items, as well as its risk management objectives and strategy for undertaking various hedging transactions. Genmab also documents its assessment, both at hedge inception and on an ongoing basis, of whether the derivatives that are used in hedging transactions are highly effective in offsetting changes in fair values or cash flows of hedged items.

Movements on the hedging reserve in other comprehensive income are shown as part of the statement of shareholders’ equity. The full fair value of a hedging derivative is classified as a non-current asset or liability when the remaining maturity of the hedged item is more than 12 months and as a current asset or liability when the remaining maturity of the hedged item is less than 12 months.
Cash Flow Hedge

The effective portion of changes in the fair value of derivatives that are designated and qualify as cash flow hedges is recognized in other comprehensive income. The gain or loss relating to the ineffective portion and changes in time value of the derivative instrument is recognized immediately in the income statement within financial income or expenses.

When forward contracts are used to hedge forecast transactions, Genmab generally designates the full change in fair value of the forward contract (including forward points) as the hedging instrument. In such cases, the gains or losses relating to the effective portion of the change in fair value of the entire forward contract are recognized in the cash flow hedge reserve within equity.

Fair Value Hedge

Changes in the fair value of derivatives that are designated and qualify as fair value hedges are recorded in the income statement, together with any changes in the fair value of the hedged asset or liability that is attributable to the hedged risk.

Treasury Shares

The total amount paid to acquire treasury shares including directly attributable costs and the proceeds from the sale of treasury shares are recognized in retained earnings.

Collaboration Agreements

The group has entered into various collaboration agreements, primarily in connection with the group’s research and development projects and the clinical testing of product candidates. The collaboration agreements are structured such that each party contributes its respective skills in the various phases of the development project and contain contractual terms regarding sharing of control over the relevant activities under the agreement. No joint control exists for the group’s collaborations with Janssen and Novartis as they retain final decision making authority over the relevant activities.

The group’s collaboration agreements with BioNTech may become subject to joint control if product candidates under the agreements are selected for joint clinical development as this would require unanimous consent of both parties on decisions related to the relevant activities. Under these agreements, joint clinical development may be selected on a product by product basis and would result in development cost and product ownership being shared equally going forward. These agreements also include provisions which will allow the parties to opt out of joint development at key points along the development timeline. An opt out by one of the parties would result in loss of joint control by the opt out party and the other party is entitled to continue developing the product on predetermined licensing terms.

During 2017 Seattle Genetics exercised its option to co-develop and co-commercialize tisotumab vedotin. All costs and profits for tisotumab vedotin will be shared on a 50:50 basis and joint control exists over the relevant activities.

During December 2019, Genmab entered into a research collaboration and license agreement with CureVac AG. The strategic partnership will focus on the research and development of differentiated mRNA-based antibody products by combining CureVac’s mRNA technology and know-how with Genmab’s proprietary antibody technologies and expertise. Under the terms of the agreement Genmab will provide CureVac with a $10 million upfront payment. The companies will collaborate on research to identify an initial product candidate and CureVac will contribute a portion of the overall costs for the development of this product candidate, up to the time of an Investigational New Drug
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Application. Genmab would thereafter be fully responsible for the development and commercialization of the potential product, in exchange for $280 million in development, regulatory and commercial milestones and tiered royalties in the range from mid-single digits up to low-double digits to CureVac. The agreement also includes three additional options for Genmab to obtain commercial licenses to CureVac’s mRNA technology at pre-defined terms, exercisable within a five-year period. If Genmab exercises any of these options, it would fund all research and would develop and commercialize any resulting product candidates with CureVac eligible to receive between $275 million and $368 million in development, regulatory and commercial milestone payments for each product, dependent on the specific product concept. In addition, CureVac is eligible to receive tiered royalties in the range from mid-single digits up to low double digits per product. CureVac would retain an option to participate in development and/or commercialization of one of the potential additional programs under pre-defined terms and conditions. Further, Genmab made a €20 million equity investment in CureVac. Refer to note 3.4 for additional information regarding Genmab’s equity investment in CureVac.

1.2—New Accounting Policies and Disclosures

New Accounting Policies and Disclosures

Genmab has, with effect from January 1, 2019, implemented the amendments to IFRS 9, IAS 19, IAS 28, IFRIC 23 and annual improvements to IFRSs 2015-2017. The implementation of these standards has not had a material impact on the entity in the current reporting period.

Genmab has, with effect from January 1, 2019, implemented IFRS 16. The impact of the adoption of the standard is described below.

Effective January 1, 2019, we adopted IFRS 16 using the modified retrospective transition method. Under this method, all leases are recognized in the balance sheet as a right-of-use (“ROU”) asset with a corresponding lease liability, except for short term assets in which the lease term is 12 months or less, or low value assets. ROU assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. The ROU asset is depreciated over the shorter of the asset’s useful life and the lease term on a straight-line basis over the lease term. In the income statement, lease costs are replaced by depreciation of the ROU asset recognized over the lease term in operating expenses, and interest expenses related to the lease liability are classified in financial items. The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods.

Genmab determines if an arrangement is a lease at inception. Genmab leases various properties and IT equipment. Rental contracts are typically made for fixed periods. Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of fixed payments, less any lease incentives. As our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. In determining the lease term, management considers all facts and circumstances that create an economic incentive to exercise an extension option, or not exercise a termination option. Extension options (or periods after termination options) are only included in the lease term if the lease is reasonably certain to be extended (or not terminated).

ROU assets are measured at cost and include the amount of the initial measurement of lease liability, any lease payments made at or before the commencement date less any lease incentives received, any initial direct costs, and restoration costs.

Payments associated with short-term leases and leases of low-value assets are recognized on a straight-line basis as an expense in the income statement. Short-term leases are leases with a lease term of 12 months or less and low-value assets comprise IT equipment and small items of office furniture.
On adoption of IFRS 16, the group recognized lease liabilities in relation to leases that had previously been classified as ‘operating leases’ under the principles of IAS 17 Leases. These liabilities were measured at the present value of the remaining lease payments, discounted using the lessee’s incremental borrowing rate as of January 1, 2019. The weighted average lessee’s incremental borrowing rate applied to the lease liabilities on January 1, 2019 was 3.7%.

The impact of the adoption of IFRS 16 on the financial statements as of January 1, 2019 is shown in the table and further described below:

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>January 1, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating lease commitments disclosed as at December 31, 2018</td>
<td>184</td>
</tr>
<tr>
<td>Discounted using the incremental borrowing rate of 3.7%</td>
<td>(42)</td>
</tr>
<tr>
<td>(Less): short-term leases recognized on a straight-line basis as expense</td>
<td>(3)</td>
</tr>
<tr>
<td>Add/(less): adjustments as a result of a different treatment of extension and termination options</td>
<td>66</td>
</tr>
<tr>
<td><strong>Lease liability recognized at January 1, 2019</strong></td>
<td><strong>205</strong></td>
</tr>
</tbody>
</table>

The ROU assets established at January 1, 2019 on the balance sheet was DKK 205 million. Net result decreased by DKK 4 million as a result of adopting IFRS 16 in 2019. Cash flows from operating activities increased by DKK 35 million and cash flows from financing activities decreased by DKK 31 million as a result of adopting IFRS 16 in 2019.

For purposes of applying the modified retrospective approach in adoption of IFRS 16, Genmab has used the following practical expedients permitted by the standard:

- applied the exemption not to recognize ROU assets and liabilities for leases with less than 12 months of lease term from January 1, 2019, and
- excluded initial direct costs for the measurement of the ROU assets at the date of initial application

There are no ROU assets that meet the definition of investment property.

**New Accounting Policies and Disclosures Effective in 2020 or Later**

The IASB has issued, a number of new standards and updated some existing standards, the majority of which are effective for accounting periods beginning on January 1, 2020 or later. Therefore, they are not incorporated in the consolidated financial statements. There are no standards that are not yet effective and that would be expected to have a material impact on the entity in the current or future reporting periods and on foreseeable future transactions.

**1.3—Management’s Judgments and Estimates under IFRS**

In preparing financial statements under IFRS, certain provisions in the standards require management’s judgments, including various accounting estimates and assumptions. These affect the application of accounting policies, as well as reported amounts within the financial statements and disclosures.

Determining the carrying amount of some assets and liabilities requires judgments, estimates and assumptions concerning future events that are based on historical experience and other factors, which by their very nature are associated with uncertainty and unpredictability.

Accounting estimates are based on historical experience and various other factors relative to the circumstances in which they are applied. Estimates are generally made based on information available at the time. An example would include management’s estimation of deferred income tax assets.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Accounting judgments are made in the process of applying Genmab’s accounting policies. These judgements are typically made based on the guidance and information available at the time of application. Examples would include management’s judgements utilized in determining revenue recognition.

These estimates and judgments may prove incomplete or incorrect, and unexpected events or circumstances may arise. The Genmab group is also subject to risks and uncertainties which may lead actual results to differ from these estimates, both positively and negatively. Specific risks for the Genmab group are discussed in the relevant section of the management’s review and in the notes to the financial statements.

The areas involving a high degree of judgment and estimation that are significant to the financial statements are summarized below. Refer to the identified notes for further information on the key accounting estimates and judgements utilized in the preparation of the consolidated financial statements.

- Recognition of revenue – Note 2.1
- Valuation assumptions in Black-Scholes pricing model – Note 2.3
- Estimation of current and deferred income taxes – Note 2.4
- Estimated useful life of intangible assets – Note 3.1
- Capitalization of research and development costs – Note 3.1

SECTION 2 – RESULTS FOR THE YEAR

2.1 – Revenue

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>2019</th>
<th>2018</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenue:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Royalties</td>
<td>3,155</td>
<td>1,741</td>
<td>1,061</td>
</tr>
<tr>
<td>Milestone payments</td>
<td>1,869</td>
<td>687</td>
<td>1,133</td>
</tr>
<tr>
<td>License fees</td>
<td>342</td>
<td>348</td>
<td>90</td>
</tr>
<tr>
<td>Reimbursement income</td>
<td>342</td>
<td>348</td>
<td>90</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>5,366</td>
<td>3,025</td>
<td>2,365</td>
</tr>
</tbody>
</table>

Revenue split by collaboration partner:

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Janssen (DARZALEX/Daratumumab &amp; DuoBody)</td>
<td>4,983</td>
<td>2,390</td>
<td>2,214</td>
</tr>
<tr>
<td>Novartis (Arzerra/Ofatumumab)</td>
<td>23</td>
<td>338</td>
<td>48</td>
</tr>
<tr>
<td>Other collaboration partners</td>
<td>360</td>
<td>297</td>
<td>103</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>5,366</td>
<td>3,025</td>
<td>2,365</td>
</tr>
</tbody>
</table>

Accounting Policies

Genmab recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that Genmab determines are within the scope of IFRS 15, Genmab performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of IFRS 15, we assess the goods or services promised within each contract and identify, as a performance obligation, and

F-14
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price
that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Royalties: License and collaboration agreements include sales-based royalties, including commercial milestone
payments based on the level of sales. The license has been deemed to be the predominant item to which the royalties relate
under our license and collaboration agreements. As a result, Genmab recognizes revenue when the related sales occur.

Accounting Policies

Royalties: License and collaboration agreements include sales-based royalties, including commercial milestone
payments based on the level of sales. The license has been deemed to be the predominant item to which the royalties relate
under our license and collaboration agreements. As a result, Genmab recognizes revenue when the related sales occur.

Milestone Payments: At the inception of each arrangement that includes milestone payments, Genmab evaluates
whether the achievement of milestones are considered highly probable and estimates the amount to be included in the
transaction price using the most likely amount method. If it is highly probable that a significant revenue reversal would not
occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control
of Genmab or the license and collaboration partner, such as regulatory approvals, are not considered probable of being
achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a
relative stand-alone selling price basis, for which Genmab recognizes revenue as or when the performance obligations
under the contract are satisfied. At the end of each subsequent reporting period, Genmab re-evaluates the probability of
achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall
transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and
earnings in the period of adjustment. Under all of Genmab’s existing license and collaboration agreements, milestone
payments have been allocated to the license transfer performance obligation.

License Fees for Intellectual Property: If the license to Genmab’s functional intellectual property is determined to be
distinct from the other performance obligations identified in the arrangement, Genmab recognizes revenues from non-
refundable upfront fees allocated to the license at the point in time the license is transferred to the licensee and the licensee
is able to use and benefit from the license. For licenses that are bundled with other promises, Genmab utilizes judgment to
assess the nature of the combined performance obligation to determine whether the combined performance obligation is
satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of
recognizing revenue from non-refundable, upfront fees. Under all of Genmab’s existing license and collaboration
agreements the license to functional intellectual property has been determined to be distinct from other performance
obligations identified in the agreement.

Reimbursement Income for R&D Services: License and collaboration agreements include the reimbursement or cost
sharing for research and development services and payment for FTEs at contractual rates. R&D services are performed and
satisfied over time given that the customer simultaneously receives and consumes the benefits provided by Genmab and
revenue for R&D services is recognized over time rather than a point in time.

Management’s Judgments and Estimates

Evaluating the criteria for revenue recognition under license and collaboration agreements requires management’s
judgement to assess and determine the following:

· The nature of performance obligations and whether they are distinct or should be combined with other
  performance obligations to determine whether the performance obligations are satisfied over time or at a
  point in time.

· An assessment of whether the achievement of milestone payments is highly probable.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

· The stand-alone selling price of each performance obligation identified in the contract using key assumptions which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

2.2—Information about Geographical Areas

The Genmab group is managed and operated as one business unit, which is reflected in the organizational structure and internal reporting. No separate lines of business or separate business entities have been identified with respect to any of the product candidates or geographical markets and no segment information is currently disclosed in the internal reporting.

Accordingly, it has been concluded that it is not relevant to include segment disclosures in the financial statements as the group’s business activities are not organized on the basis of differences in related product and geographical areas.

<table>
<thead>
<tr>
<th></th>
<th>2019 Revenue (DKK million)</th>
<th>2018 Revenue (DKK million)</th>
<th>2017 Revenue (DKK million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-current assets</td>
<td>3,025</td>
<td>454</td>
<td>2,365</td>
</tr>
<tr>
<td>Non-current assets</td>
<td>5,366</td>
<td>387</td>
<td>105</td>
</tr>
<tr>
<td>Total</td>
<td>5,366</td>
<td>707</td>
<td>3,025</td>
</tr>
</tbody>
</table>

Accounting Policies

Geographical information is presented for the Genmab group’s revenue and non-current assets. Revenue is attributed to countries on the basis of the location of the legal entity holding the contract with the counterparty and operations. Non-current assets comprise intangible assets and property, plant and equipment.

2.3—Staff Costs

<table>
<thead>
<tr>
<th></th>
<th>2019 (DKK million)</th>
<th>2018 (DKK million)</th>
<th>2017 (DKK million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wages and salaries</td>
<td>489</td>
<td>308</td>
<td>230</td>
</tr>
<tr>
<td>Share-based compensation</td>
<td>147</td>
<td>91</td>
<td>76</td>
</tr>
<tr>
<td>Defined contribution plans</td>
<td>39</td>
<td>24</td>
<td>19</td>
</tr>
<tr>
<td>Other social security costs</td>
<td>72</td>
<td>23</td>
<td>18</td>
</tr>
<tr>
<td>Government grants</td>
<td>(96)</td>
<td>(86)</td>
<td>(64)</td>
</tr>
<tr>
<td>Total</td>
<td>651</td>
<td>360</td>
<td>279</td>
</tr>
</tbody>
</table>

Staff costs are included in the income statement as follows:

<table>
<thead>
<tr>
<th></th>
<th>2019 (DKK million)</th>
<th>2018 (DKK million)</th>
<th>2017 (DKK million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and development expenses</td>
<td>572</td>
<td>324</td>
<td>249</td>
</tr>
<tr>
<td>General and administrative expenses</td>
<td>175</td>
<td>122</td>
<td>94</td>
</tr>
<tr>
<td>Government grants related to research and development expenses</td>
<td>(96)</td>
<td>(86)</td>
<td>(64)</td>
</tr>
<tr>
<td>Total</td>
<td>651</td>
<td>360</td>
<td>279</td>
</tr>
</tbody>
</table>

Average number of FTE

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of FTE at year-end</td>
<td>548</td>
<td>377</td>
<td>257</td>
</tr>
</tbody>
</table>

Please refer to note 5.1 for additional information regarding the remuneration of the Board of Directors and Executive Management. Government grants, which are a reduction of payroll taxes in the Netherlands, amounted to DKK 96 million in 2019, 86 million in 2018 and DKK 64 million in 2017. These amounts are an offset to wages and salaries and research and development costs in the table above. The increases in 2019, 2018 and 2017 were primarily due
to increased research activities in the Netherlands combined with a higher level of grants provided by the Dutch government.

**Accounting Policies**

*Share-Based Compensation Expenses*

Genmab has granted restricted stock units (RSUs) and warrants to the Board of Directors, Executive Management and employees under various share-based compensation programs. The group applies IFRS 2, according to which the fair value of the warrants and RSUs at grant date is recognized as an expense in the income statement over the vesting period. Such compensation expenses represent calculated values of warrants and RSUs granted and do not represent actual cash expenditures. A corresponding amount is recognized in shareholders’ equity as both the warrant and RSU programs are designated as equity-settled share-based payment transactions.

*Government Grants*

The Dutch Research and Development Act “WBSO” provides compensation for a part of research and development wages and other costs through a reduction in payroll taxes. WBSO grant amounts are offset against wages and salaries and research and development costs.

*Management’s Judgments and Estimates*

*Share-Based Compensation Expenses*

In accordance with IFRS 2 “Share-based Payment,” the fair value of the warrants and RSUs at grant date is recognized as an expense in the income statement over the vesting period, the period of delivery of work. Subsequently, the fair value is not remeasured.

The fair value of each warrant granted during the year is calculated using the Black-Scholes pricing model. This pricing model requires the input of subjective assumptions such as:

- The expected stock price volatility, which is based upon the historical volatility of Genmab’s stock price;
- The risk-free interest rate, which is determined as the interest rate on Danish government bonds (bullet issues) with a maturity of five years;
- The expected life of warrants, which is based on vesting terms, expected rate of exercise and life terms in the current warrant program.

These assumptions can vary over time and can change the fair value of future warrants granted.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Valuation Assumptions for Warrants Granted in 2019, 2018 and 2017

The fair value of each warrant granted during the year is calculated using the Black-Scholes pricing model with the following assumptions:

<table>
<thead>
<tr>
<th>Weighted Average</th>
<th>2019</th>
<th>2018</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fair value per warrant on grant date</td>
<td>425.80</td>
<td>386.61</td>
<td>366.78</td>
</tr>
<tr>
<td>Share price</td>
<td>1,483.58</td>
<td>1,034.66</td>
<td>1,123.91</td>
</tr>
<tr>
<td>Exercise price</td>
<td>1,483.58</td>
<td>1,034.66</td>
<td>1,123.91</td>
</tr>
<tr>
<td>Expected dividend yield</td>
<td>0 %</td>
<td>0 %</td>
<td>0 %</td>
</tr>
<tr>
<td>Expected stock price volatility</td>
<td>34.2 %</td>
<td>41.7 %</td>
<td>38.5 %</td>
</tr>
<tr>
<td>Risk-free interest rate</td>
<td>(0.56) %</td>
<td>(0.01) %</td>
<td>(0.38) %</td>
</tr>
<tr>
<td>Expected life of warrants</td>
<td>5 years</td>
<td>5 years</td>
<td>5 years</td>
</tr>
</tbody>
</table>

Based on a weighted average fair value per warrant of DKK 425.80 in 2019, DKK 386.61 in 2018 and DKK 366.78 in 2017, the total fair value of warrants granted amounted to DKK 131 million, 102 million and 67 million on the grant date in 2019, 2018 and 2017, respectively.

The fair value of each RSU granted during the year is equal to the closing market price on the date of grant of one Genmab A/S share. Based on a weighted average fair value per RSU of DKK 1,511.70 in 2019, DKK 1,033.95 in 2018 and DKK 1,128.30 in 2017, the total fair value of RSUs granted amounted to DKK 176 million, DKK 106 million and DKK 74 million on the grant date in 2019, 2018 and 2017, respectively.

2.4—Corporate and Deferred Tax

Taxation—Income Statement & Shareholders’ Equity

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>2019</th>
<th>2018</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current tax on result</td>
<td>444</td>
<td>161</td>
<td>133</td>
</tr>
<tr>
<td>Adjustment to prior years</td>
<td>—</td>
<td>—</td>
<td>(1)</td>
</tr>
<tr>
<td>Adjustment to deferred tax</td>
<td>294</td>
<td>458</td>
<td>626</td>
</tr>
<tr>
<td>Adjustment to valuation allowance</td>
<td>(45)</td>
<td>(479)</td>
<td>(798)</td>
</tr>
<tr>
<td>Total tax for the period in the income statement</td>
<td>693</td>
<td>140</td>
<td>(40)</td>
</tr>
</tbody>
</table>
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

A reconciliation of Genmab’s effective tax rate relative to the Danish statutory tax rate is as follows:

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>2019</th>
<th>2018</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net result before tax</td>
<td>2,859</td>
<td>1,612</td>
<td>1,064</td>
</tr>
<tr>
<td><strong>Computed 22% (2018 &amp; 2017: 22%)</strong></td>
<td>629</td>
<td>355</td>
<td>234</td>
</tr>
</tbody>
</table>

**Tax effect of:**

- Recognition of previously unrecognized tax losses and deductible temporary differences: (19) (267) (286)
- Non-deductible expenses/non-taxable income and other permanent differences, net: 75 53 14
- All other: 8 (1) (2)

**Total tax effect**: 64 (215) (274)

**Total tax for the period in the income statement**: 693 140 (40)

**Total tax for the period in shareholders’ equity**: (24) (89) (72)

Corporate tax consists of current tax and the adjustment of deferred taxes during the year. The corporate tax expense was DKK 693 million in 2019 and DKK 140 million in 2018, compared to corporate tax income of DKK 40 million in 2017. The corporate tax expense in 2019 was due to current and deferred tax expense of DKK 722 million partially offset by the reversal of valuation allowances on deferred tax assets related to future taxable income, resulting in a discrete tax benefit of DKK 29 million. The corporate tax expense in 2018 was due to current and deferred tax expense of DKK 407 million partially offset by the reversal of valuation allowances on deferred tax assets related to future taxable income, resulting in a discrete tax benefit of DKK 268 million. The corporate tax income in 2017 was due to the partial reversal of valuation allowances on deferred tax assets related to future taxable income, resulting in a discrete tax benefit of DKK 286 million, which more than offset current and deferred tax expense of DKK 246 million.

In 2019, a current tax benefit of DKK 24 million was recorded directly in shareholders’ equity, which was related to excess tax benefits for share-based instruments. In 2018, a current tax benefit of DKK 24 million and a deferred tax benefit of DKK 66 million recorded directly in shareholders’ equity, which was related to excess tax benefits for share-based instruments. In 2017, a current tax benefit of DKK 72 million was recorded directly in shareholders’ equity, which was related to excess tax benefits for share-based instruments.

**Taxation—Balance Sheet**

Significant components of the deferred tax asset are as follows:

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tax deductible losses</td>
<td>359</td>
<td>653</td>
</tr>
<tr>
<td>Share-Based Instruments</td>
<td>130</td>
<td>119</td>
</tr>
<tr>
<td>Capitalized R&amp;D Costs</td>
<td>—</td>
<td>4</td>
</tr>
<tr>
<td>Other temporary differences</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td><strong>Total deferred tax assets</strong></td>
<td>(351)</td>
<td>(398)</td>
</tr>
</tbody>
</table>

Genmab records a valuation allowance to reduce deferred tax assets to reflect the net amount that is more likely than not to be realized. Realization of our deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. The valuation allowance requires an assessment of both positive and negative evidence when determining whether it is more likely than not that deferred tax assets are recoverable; such assessment is
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

required on a jurisdiction by jurisdiction basis. Based upon the weight of available evidence at December 31, 2019, Genmab determined that it was more likely than not that a portion of our deferred tax assets would be realizable and consequently released a portion of the valuation allowance against net deferred tax assets and during the fourth quarter of 2019 recorded a discrete tax benefit of DKK 29 million (2018: DKK 268 million). The decision to reverse a portion of the valuation allowance was made after management considered all available evidence, both positive and negative, including but not limited to our historical operating results, income or loss in recent periods, cumulative income in recent years, forecasted earnings, future taxable income, and significant risk and uncertainty related to forecasts. The release of the valuation allowance resulted in the recognition of certain deferred tax assets and a decrease to corporate tax expense.

As of December 31, 2019, we had gross tax loss carry-forwards of DKK 1.6 billion for income tax purposes, as compared to DKK 2.6 billion in 2018. The reduction was driven primarily by the utilization of all remaining tax loss carry-forwards available for our parent entity, Genmab A/S. The DKK 1.6 billion in gross tax loss carry-forwards as of December 31, 2019 can be carried forward through various periods through 2038.

Accounting Policies

Corporate Tax

Corporate tax, which consists of current tax and the adjustment of deferred taxes for the year, is recognized in the income statement, except to the extent that the tax is attributable to items which directly relate to shareholders' equity or other comprehensive income. Current tax assets and liabilities for current and prior periods are measured at the amounts expected to be recovered from or paid to the tax authorities.

Deferred Tax

Deferred tax is accounted for under the liability method which requires recognition of deferred tax on all temporary differences between the carrying amount of assets and liabilities and the tax base of such assets and liabilities. This includes the tax value of tax losses carried forward.

Deferred tax is calculated in accordance with the tax regulations in the individual countries and the tax rates expected to be in force at the time the deferred tax is utilized. Changes in deferred tax as a result of changes in tax rates are recognized in the income statement.

Deferred tax assets resulting from temporary differences, including the tax value of losses to be carried forward, are recognized only to the extent that it is probable that future taxable profit will be available against which the differences can be utilized.

Management’s Judgments and Estimates

Deferred Tax

Genmab recognizes deferred tax assets, including the tax base of tax loss carry-forwards, if management assesses that these tax assets can be offset against positive taxable income within a foreseeable future. This judgment is made on an ongoing basis and is based on numerous factors, including actual results, budgets, and business plans for the coming years.

Realization of deferred tax assets is dependent upon a number of factors, including future taxable earnings, the timing and amount of which is highly uncertain. A significant portion of Genmab’s future taxable income will be driven by future events that are highly susceptible to factors outside the control of the group including commercial growth of DARZALEX, specific clinical outcomes, regulatory approval, advancement of our product pipeline, and others. In 2018, we fully released the remaining valuation allowance on deferred tax assets for our parent entity, Genmab A/S. Genmab intends to continue maintaining a valuation allowance against a significant portion of its deferred tax assets related to its
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

subsidies until there is sufficient evidence to support the reversal of all or some additional portion of these allowances. The Company may release an additional part of its valuation allowance against its deferred tax assets related to its subsidiaries. This release would result in the recognition of certain deferred tax assets and a decrease to income tax expense for the period such release is recorded.

2.5—Result Per Share

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>2019</th>
<th>2018</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net result</td>
<td>2,166</td>
<td>1,472</td>
<td>1,104</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>(Shares)</th>
<th>2019</th>
<th>2018</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average number of shares outstanding</td>
<td>63,126,771</td>
<td>61,383,972</td>
<td>60,934,308</td>
</tr>
<tr>
<td>Average number of treasury shares</td>
<td>(163,958)</td>
<td>(116,466)</td>
<td>(100,000)</td>
</tr>
<tr>
<td>Average number of shares excl. treasury shares</td>
<td>62,962,813</td>
<td>61,267,506</td>
<td>60,834,308</td>
</tr>
<tr>
<td>Average number of share-based instruments, dilution</td>
<td>674,030</td>
<td>777,491</td>
<td>1,259,874</td>
</tr>
<tr>
<td>Average number of shares, diluted</td>
<td>63,636,843</td>
<td>62,044,997</td>
<td>62,094,182</td>
</tr>
<tr>
<td>Basic net result per share</td>
<td>34.40</td>
<td>24.03</td>
<td>18.14</td>
</tr>
<tr>
<td>Diluted net result per share</td>
<td>34.03</td>
<td>23.73</td>
<td>17.77</td>
</tr>
</tbody>
</table>

In the calculation of the diluted net result per share for 2019, 299,573 warrants (of which 774 were vested) have been excluded as these share-based instruments are out of the money, compared to 177,369 warrants (of which 64,703 were vested) for 2018. In 2017, 43,019 warrants (of which none were vested) have been excluded as these share-based instruments are out of the money.

Accounting Policies

Basic Net Result Per Share

Basic net result per share is calculated as the net result for the year divided by the weighted average number of outstanding ordinary shares, excluding treasury shares.

Diluted Net Result Per Share

Diluted net result per share is calculated as the net result for the year divided by the weighted average number of outstanding ordinary shares, excluding treasury shares adjusted for the dilutive effect of share equivalents.

F-21
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

SECTION 3—OPERATING ASSETS AND LIABILITIES

3.1—Intangible Assets

<table>
<thead>
<tr>
<th>Licenses, Rights, and Patents</th>
<th>Total Intangible Assets</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019 (DKK million)</td>
<td></td>
</tr>
<tr>
<td>Cost per January 1</td>
<td>798</td>
</tr>
<tr>
<td>Additions for the year</td>
<td>99</td>
</tr>
<tr>
<td>Disposals for the year</td>
<td>—</td>
</tr>
<tr>
<td>Exchange rate adjustment</td>
<td>—</td>
</tr>
<tr>
<td>Cost at December 31</td>
<td>897</td>
</tr>
<tr>
<td>Accumulated amortization and impairment per January 1</td>
<td>(328)</td>
</tr>
<tr>
<td>Amortization for the year</td>
<td>(99)</td>
</tr>
<tr>
<td>Disposals for the year</td>
<td>—</td>
</tr>
<tr>
<td>Exchange rate adjustment</td>
<td>—</td>
</tr>
<tr>
<td>Accumulated amortization and impairment per December 31</td>
<td>(427)</td>
</tr>
<tr>
<td>Carrying amount at December 31</td>
<td>470</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Licenses, Rights, and Patents</th>
<th>Total Intangible Assets</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018 (DKK million)</td>
<td></td>
</tr>
<tr>
<td>Cost per January 1</td>
<td>392</td>
</tr>
<tr>
<td>Additions for the year</td>
<td>406</td>
</tr>
<tr>
<td>Disposals for the year</td>
<td>—</td>
</tr>
<tr>
<td>Exchange rate adjustment</td>
<td>—</td>
</tr>
<tr>
<td>Cost at December 31</td>
<td>798</td>
</tr>
<tr>
<td>Accumulated amortization and impairment per January 1</td>
<td>(268)</td>
</tr>
<tr>
<td>Amortization for the year</td>
<td>(60)</td>
</tr>
<tr>
<td>Disposals for the year</td>
<td>—</td>
</tr>
<tr>
<td>Exchange rate adjustment</td>
<td>—</td>
</tr>
<tr>
<td>Accumulated amortization and impairment per December 31</td>
<td>(328)</td>
</tr>
<tr>
<td>Carrying amount at December 31</td>
<td>470</td>
</tr>
</tbody>
</table>

Depreciation, amortization, and impairments are included in the income statement as follows:

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and development expenses</td>
<td>99</td>
<td>60</td>
<td>58</td>
</tr>
<tr>
<td>General and administrative expenses</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Total</td>
<td>99</td>
<td>60</td>
<td>58</td>
</tr>
</tbody>
</table>

There were no impairment losses recognized in 2019 or 2018. Impairment losses of DKK 22 million related to licensed assets were recognized as part of research and development costs in 2017 as certain programs were discontinued.

In December 2019, Genmab entered into a research collaboration and license agreement with CureVac AG. The strategic partnership will focus on the research and development of differentiated mRNA-based antibody products by combining CureVac’s mRNA technology and know-how with Genmab’s proprietary antibody technologies and expertise. Genmab will provide CureVac with a $10 million upfront payment and a €20 million equity investment (Refer}
to Note 3.4 for details on the equity investment). The companies will collaborate on research to identify an initial product candidate and CureVac will contribute a portion of the overall costs for the development of this product candidate, up to the time of an Investigational New Drug Application. Genmab would thereafter be fully responsible for the development and commercialization of the potential product, in exchange for $280 million in development, regulatory and commercial milestones and tiered royalties in the range from mid-single digits up to low-double digits to CureVac. The agreement also includes three additional options for Genmab to obtain commercial licenses to CureVac’s mRNA technology at pre-defined terms, exercisable within a five-year period. If Genmab exercises any of these options, it would fund all research and would develop and commercialize any resulting product candidates with CureVac eligible to receive between $275 million and $368 million in development, regulatory and commercial milestone payments for each product, dependent on the specific product concept. In addition, CureVac is eligible to receive tiered royalties in the range from mid-single digits up to low double digits per product. The carrying amount of the intangible asset related to the CureVac agreement was DKK 67 million as of December 31, 2019. The intangible asset is being amortized on a straight line basis through December 2026.

In July 2018, Genmab entered into a research collaboration and exclusive license agreement with Immatics Biotechnologies GmbH (Immatics) to discover and develop next-generation bispecific immunotherapies to target multiple cancer indications. Genmab received an exclusive license to three proprietary targets from Immatics, with an option to license up to two additional targets at predetermined economics. Under the terms of the agreement, Genmab paid Immatics an upfront fee of $54 million and Immatics is eligible to receive up to $550 million in development, regulatory and commercial milestone payments for each product, as well as tiered royalties on net sales. The carrying amount of the intangible asset related to the Immatics agreements was DKK 274 million as of December 31, 2019 and DKK 323 million as of December 31, 2018. The intangible asset is being amortized on a straight line basis through July 2025.

The group has previously acquired licenses and rights to technology at a total cost of DKK 152 million, which have been fully amortized during the period from 2000 to 2005. The licenses and rights are still in use by the group and contribute to our research and development activities.

**Accounting Policies**

**Research and Development**

The group currently has no internally generated intangible assets from development, as the criteria for recognition of an asset are not met as described below.

**Licenses and Rights**

Licenses, rights, and patents are initially measured at cost and include the net present value of any future payments. The net present value of any future payments is recognized as a liability. Milestone payments are accounted for as an increase in the cost to acquire licenses, rights, and patents. Genmab acquires licenses and rights primarily to get access to targets and technologies identified by third parties.

**Depreciation**

Licenses, rights, and patents are amortized using the straight-line method over the estimated useful life of five to seven years. Amortization, impairment losses, and gains or losses on the disposal of intangible assets are recognized in the income statement as research and development costs, general and administrative expenses or discontinued operations, as appropriate.

**Impairment**

If circumstances or changes in Genmab’s operations indicate that the carrying amount of non-current assets in a cash-generating unit may not be recoverable, management reviews the asset for impairment.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Management’s Judgments and Estimates

Research and Development

Internally Generated Intangible Assets

According to the IAS 38, “Intangible Assets,” intangible assets arising from development projects should be recognized in the balance sheet. The criteria that must be met for capitalization are that:

- the development project is clearly defined and identifiable and the attributable costs can be measured reliably during the development period;
- the technological feasibility, adequate resources to complete and a market for the product or an internal use of the product can be documented; and
- management has the intent to produce and market the product or to use it internally.

Such an intangible asset should be recognized if sufficient certainty can be documented that the future income from the development project will exceed the aggregate cost of production, development, and sale and administration of the product.

A development project involves a single product candidate undergoing a high number of tests to illustrate its safety profile and its effect on human beings prior to obtaining the necessary final approval of the product from the appropriate authorities. The future economic benefits associated with the individual development projects are dependent on obtaining such approval. Considering the significant risk and duration of the development period related to the development of biological products, management has concluded that the future economic benefits associated with the individual projects cannot be estimated with sufficient certainty until the project has been finalized and the necessary final regulatory approval of the product has been obtained. Accordingly, the group has not recognized such assets at this time and therefore all research and development costs are recognized in the income statement when incurred. Total research and development costs amounted to DKK 2,386 million in 2019, compared to DKK 1,431 million in 2018 and DKK 874 million in 2017.

Antibody Clinical Trial Material Purchased for Use in Clinical Trials

According to our accounting policies, antibody clinical trial material (antibodies) for use in clinical trials that are purchased from third parties will only be recognized in the balance sheet at cost and expensed in the income statement when consumed, if all criteria for recognition as an asset are fulfilled.

During both 2019 and 2018, no antibodies purchased from third parties for use in clinical trials have been capitalized, as these antibodies do not qualify for being capitalized as inventory under either the “Framework” to IAS/IFRS or IAS 2, “Inventories.” Management has concluded that the purchase of antibodies from third parties cannot be capitalized as the technical feasibility is not proven and no alternative use exists. Expenses in connection with purchase of antibodies are expensed as incurred.

Estimation of Useful Life

Genmab has licenses, rights, and patents that are amortized over an estimated useful life of the intangible asset. As of December 31, 2019, the carrying amount of the intangible assets was DKK 470 million (2018 – DKK 470 million). Genmab estimates the useful life of the intangible assets to be at least seven years based on the expected obsolescence of such assets. However, the actual useful life may be shorter or longer than seven years, depending on the development risk, the probability of success related to the development of a clinical drug as well as potential launch of competing products.
3.2—Property, Plant and Equipment

<table>
<thead>
<tr>
<th></th>
<th>2019 (DKK million)</th>
<th>Leasehold improvements</th>
<th>Equipment, furniture and fixtures</th>
<th>Assets under construction</th>
<th>Total property, plant and equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost per January 1</td>
<td>95</td>
<td>217</td>
<td>1</td>
<td>313</td>
<td></td>
</tr>
<tr>
<td>Additions for the year</td>
<td>3</td>
<td>64</td>
<td>48</td>
<td>115</td>
<td></td>
</tr>
<tr>
<td>Transfers between the classes</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Disposals for the year</td>
<td>—</td>
<td>(2)</td>
<td>—</td>
<td>(2)</td>
<td></td>
</tr>
<tr>
<td>Exchange rate adjustment</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td><strong>Cost at December 31</strong></td>
<td><strong>98</strong></td>
<td><strong>279</strong></td>
<td><strong>49</strong></td>
<td><strong>426</strong></td>
<td></td>
</tr>
<tr>
<td>Accumulated depreciation and impairment at January 1</td>
<td>—</td>
<td>(8)</td>
<td>(143)</td>
<td>—</td>
<td>(151)</td>
</tr>
<tr>
<td>Depreciation for the year</td>
<td>(6)</td>
<td>(34)</td>
<td>—</td>
<td>(40)</td>
<td></td>
</tr>
<tr>
<td>Disposals for the year</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Exchange rate adjustment</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Accumulated depreciation on disposals</td>
<td>—</td>
<td>2</td>
<td>—</td>
<td>—</td>
<td>2</td>
</tr>
<tr>
<td><strong>Accumulated depreciation and impairment at December 31</strong></td>
<td><strong>(14)</strong></td>
<td><strong>(175)</strong></td>
<td>—</td>
<td><strong>(189)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Carrying amount at December 31</strong></td>
<td><strong>84</strong></td>
<td><strong>104</strong></td>
<td><strong>49</strong></td>
<td><strong>237</strong></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>2018 (DKK million)</th>
<th>Leasehold improvements</th>
<th>Equipment, furniture and fixtures</th>
<th>Assets under construction</th>
<th>Total property, plant and equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost per January 1</td>
<td>11</td>
<td>170</td>
<td>68</td>
<td>249</td>
<td></td>
</tr>
<tr>
<td>Additions for the year</td>
<td>7</td>
<td>41</td>
<td>28</td>
<td>76</td>
<td></td>
</tr>
<tr>
<td>Transfers between the classes</td>
<td>83</td>
<td>12</td>
<td>(95)</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Disposals for the year</td>
<td>(6)</td>
<td>(7)</td>
<td>—</td>
<td>(13)</td>
<td></td>
</tr>
<tr>
<td>Exchange rate adjustment</td>
<td>—</td>
<td>1</td>
<td>—</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Cost at December 31</strong></td>
<td><strong>95</strong></td>
<td><strong>217</strong></td>
<td><strong>1</strong></td>
<td><strong>313</strong></td>
<td></td>
</tr>
<tr>
<td>Accumulated depreciation and impairment at January 1</td>
<td>(6)</td>
<td>(129)</td>
<td>—</td>
<td>(135)</td>
<td></td>
</tr>
<tr>
<td>Depreciation for the year</td>
<td>(8)</td>
<td>(20)</td>
<td>—</td>
<td>(28)</td>
<td></td>
</tr>
<tr>
<td>Disposals for the year</td>
<td>6</td>
<td>6</td>
<td>—</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Exchange rate adjustment</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td><strong>Accumulated depreciation and impairment at December 31</strong></td>
<td><strong>(8)</strong></td>
<td><strong>(143)</strong></td>
<td>—</td>
<td><strong>(151)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Carrying amount at December 31</strong></td>
<td><strong>87</strong></td>
<td><strong>74</strong></td>
<td><strong>1</strong></td>
<td><strong>162</strong></td>
<td></td>
</tr>
</tbody>
</table>

Depreciation, amortization, and impairments are included in the income statement as follows:

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and development expenses</td>
<td>37</td>
<td>26</td>
<td>12</td>
</tr>
<tr>
<td>General and administrative expenses</td>
<td>3</td>
<td>2</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>40</strong></td>
<td><strong>28</strong></td>
<td><strong>12</strong></td>
</tr>
</tbody>
</table>

Capital expenditures in 2019 and 2018 were primarily related to the expansion of our facilities in the Netherlands and the United States to support the growth in our product pipeline.

**Accounting Policies**

Property, plant and equipment is mainly comprised of leasehold improvements, assets under construction, and equipment, furniture and fixtures, which are measured at cost less accumulated depreciation, and any impairment losses.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The cost is comprised of the acquisition price and direct costs related to the acquisition until the asset is ready for use. The present value of estimated liabilities related to the restoration of our offices in connection with the termination of the lease is added to the cost if the liabilities are provided for. Costs include direct costs, salary related expenses, and costs to subcontractors.

**Depreciation**

Depreciation, which is stated at cost net of any residual value, is calculated on a straight-line basis over the expected useful lives of the assets, which are as follows:

<table>
<thead>
<tr>
<th>Equipment, furniture and fixtures</th>
<th>3 - 5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Computer equipment</td>
<td>3 years</td>
</tr>
<tr>
<td>Leasehold improvements</td>
<td>5 years or the lease term, if shorter</td>
</tr>
</tbody>
</table>

The useful lives and residual values are reviewed and adjusted if appropriate on a yearly basis. Assets under construction are not depreciated.

**Impairment**

If circumstances or changes in Genmab’s operations indicate that the carrying amount of non-current assets in a cash-generating unit may not be recoverable, management reviews the asset for impairment. The basis for the review is the recoverable amount of the assets, determined as the greater of the fair value less cost to sell or its value in use. Value in use is calculated as the net present value of future cash inflow generated from the asset. If the carrying amount of an asset is greater than the recoverable amount, the asset is written down to the recoverable amount. An impairment loss is recognized in the income statement when the impairment is identified.

### 3.3—Leases

The group has entered into lease agreements with respect to office space and office equipment. The leases are non-cancelable for various periods up to 2032.

**Amounts recognized in the balance sheet**

The balance sheet shows the following amounts relating to leases:

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2019 (DKK million)</th>
<th>December 31, 2018 (DKK million)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Right-of-use assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Properties</td>
<td>173</td>
<td>—</td>
</tr>
<tr>
<td>Equipment</td>
<td>4</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total right-of-use assets</strong></td>
<td></td>
<td>177</td>
</tr>
<tr>
<td><strong>Lease liabilities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current</td>
<td>26</td>
<td>—</td>
</tr>
<tr>
<td>Non-current</td>
<td>155</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total lease liabilities</strong></td>
<td></td>
<td>181</td>
</tr>
</tbody>
</table>

There were no additions to the right-of-use assets in 2019.

F-26
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Amounts recognized in the statement of comprehensive income

The statement of comprehensive income shows the following amounts relating to leases:

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>December 31, 2019</th>
<th>December 31, 2018</th>
<th>December 31, 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Depreciation charge of right-of-use assets</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Properties</td>
<td>27</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Equipment</td>
<td>1</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total depreciation charge of right-of-use assets</strong></td>
<td>28</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Interest expense</strong></td>
<td>7</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Expense relating to short-term leases</strong></td>
<td>6</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

Interest expense is included in net financial items and expenses relating to short-term leases are included in operating expenses in the statement of comprehensive income.

The total cash outflow for leases in 2019 was DKK 38 million. See the table below for activities for lease liabilities in 2019:

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>December 31, 2018</th>
<th>Cash flows, net</th>
<th>Other changes*</th>
<th>December 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lease liabilities, due after 1 year</td>
<td>181</td>
<td>(38)</td>
<td>12</td>
<td>155</td>
</tr>
<tr>
<td>Lease liabilities, due within 1 year</td>
<td>24</td>
<td>—</td>
<td>2</td>
<td>26</td>
</tr>
<tr>
<td><strong>Total lease liabilities</strong></td>
<td>205</td>
<td>(38)</td>
<td>14</td>
<td>181</td>
</tr>
</tbody>
</table>

* Other changes include non-cash movements, including accrued interest expense which are presented as operating cash flows in the statement of cash flows when paid.

Future minimum payments under our leases as of December 31, 2019 and December 31, 2018, are as follows:

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Payment due</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than 1 year</td>
<td>32</td>
<td>31</td>
</tr>
<tr>
<td>1 to 3 years</td>
<td>64</td>
<td>65</td>
</tr>
<tr>
<td>More than 3 years but less than 5 years</td>
<td>27</td>
<td>45</td>
</tr>
<tr>
<td>More than 5 years</td>
<td>93</td>
<td>106</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>216</td>
<td>247</td>
</tr>
</tbody>
</table>

During the second quarter of 2019, Genmab A/S’s subsidiary Genmab US, Inc., entered into a lease agreement with respect to office and laboratory space with a commencement date in March 2020 and is non-cancellable until August 2031. The total future minimum payments over the term of the lease are approximately DKK 215 million and estimated capital expenditures to fit out the space are approximately DKK 176 million of which DKK 48 million have been incurred and capitalized as of December 31, 2019.

During the third quarter of 2019, Genmab A/S’s subsidiary Genmab B.V., entered into a lease agreement with respect to office and laboratory space with a commencement date in February 2022 and is non-cancellable until January 2032. The total future minimum payments over the term of the lease are approximately DKK 90 million and estimated capital expenditures to fit out the space are approximately DKK 70 million.

Please refer to note 1.2 for disclosure of the impact of adoption of IFRS 16 on our consolidated financial statements. The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods.

F-27
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Accounting Policies

All leases are recognized in the balance sheet as a right-of-use ("ROU") asset with a corresponding lease liability, except for short term assets in which the lease term is 12 months or less, or low value assets.

ROU assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. The ROU asset is depreciated over the shorter of the asset’s useful life and the lease term on a straight-line basis over the lease term. In the income statement, lease costs are replaced by depreciation of the ROU asset recognized over the lease term in operating expenses, and interest expenses related to the lease liability are classified in financial items.

Genmab determines if an arrangement is a lease at inception. Genmab leases various properties and IT equipment. Rental contracts are typically made for fixed periods. Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of fixed payments, less any lease incentives. As our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. In determining the lease term, management considers all facts and circumstances that create an economic incentive to exercise an extension option, or not exercise a termination option. Extension options (or periods after termination options) are only included in the lease term if the lease is reasonably certain to be extended (or not terminated).

ROU assets are measured at cost and include the amount of the initial measurement of lease liability, any lease payments made at or before the commencement date less any lease incentives received, any initial direct costs, and restoration costs.

Payments associated with short-term leases and leases of low-value assets are recognized on a straight-line basis as an expense in the income statement. Short-term leases are leases with a lease term of 12 months or less and low-value assets comprise IT equipment and small items of office furniture.

3.4—Other Investments

The Group’s other investments consist of a DKK 149 million (€20 million) investment in CureVac AG, the developer of mRNA technology, which was entered into on December 19, 2019. This investment is also a strategic partnership that will focus on the research and development of differentiated mRNA-based antibody products by combining CureVac’s mRNA technology and know-how with Genmab’s proprietary antibody technologies and expertise. The investment in CureVac AG is recorded at fair value through profit and loss. This investment represents 2.2% ownership of CureVac AG and is recorded at a fair value of DKK 149 million as of December 31, 2019.

The payment related to this investment was made in March 2020. As of December 31, 2019, the investment was unpaid and was recorded within other payables. Please refer to note 3.7 for additional information regarding other payables.

Accounting Policies

Other investments are measured on initial recognition at fair value, and subsequently at fair value. Changes in fair value are recognized in the income statement under financial items.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3.5—Receivables

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receivables related to collaboration agreements</td>
<td>2,849</td>
<td>1,266</td>
</tr>
<tr>
<td>Interest receivables</td>
<td>34</td>
<td>18</td>
</tr>
<tr>
<td>Other receivables</td>
<td>56</td>
<td>34</td>
</tr>
<tr>
<td>Prepayments</td>
<td>62</td>
<td>19</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>3,001</strong></td>
<td><strong>1,337</strong></td>
</tr>
<tr>
<td>Non-current receivables</td>
<td>11</td>
<td>10</td>
</tr>
<tr>
<td>Current receivables</td>
<td>2,990</td>
<td>1,327</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>3,001</strong></td>
<td><strong>1,337</strong></td>
</tr>
</tbody>
</table>

During 2019 and 2018, there were no losses related to receivables and the credit risk on receivables is considered to be limited. The provision for expected credit losses was not significant given that there have been no credit losses over the last three years and the high-quality nature (top tier life science companies) of Genmab’s customers are not likely to result in future default risk.

The receivables are mainly comprised of royalties and milestones from our collaboration agreements and non-interest bearing receivables which are due less than one year from the balance sheet date. Please refer to note 4.2 for additional information about interest receivables and related credit risk.

**Accounting Policies**

Receivables are designated as financial assets measured at amortized cost and are initially measured at fair value or transaction price and subsequently measured in the balance sheet at amortized cost, which generally corresponds to nominal value less expected credit loss provision.

Genmab utilizes a simplified approach to measuring expected credit losses and uses a lifetime expected loss allowance for all receivables. To measure the expected credit losses, receivables have been grouped based on credit risk characteristics and the days past due.

Prepayments include expenditures related to a future financial year. Prepayments are measured at nominal value.

3.6—Provisions

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provisions per January 1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Additions during the year</td>
<td>1</td>
<td>—</td>
</tr>
<tr>
<td>Used during the year</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Released during the year</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total at December 31</strong></td>
<td><strong>2</strong></td>
<td><strong>1</strong></td>
</tr>
<tr>
<td>Non-current provisions</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total at December 31</strong></td>
<td><strong>2</strong></td>
<td><strong>1</strong></td>
</tr>
</tbody>
</table>

Provisions include contractual restoration obligations related to our lease of offices. In determining the fair value of the restoration obligation, assumptions and estimates are made in relation to discounting, the expected cost to restore the offices and the expected timing of those costs.

The majority of non-current provisions are expected to be settled in 2022.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Accounting Policies

Provisions are recognized when the group has an existing legal or constructive obligation as a result of events occurring prior to or on the balance sheet date, and it is probable that the utilization of economic resources will be required to settle the obligation. Provisions are measured at management’s best estimate of the expenses required to settle the obligation.

A provision for onerous contracts is recognized when the expected benefits to be derived by the group from a contract are lower than the unavoidable cost of meeting its obligations under the contract. The provision is measured at the present value of the lower of the expected cost of terminating the contract and the expected net cost of continuing with the contract. When the group has a legal obligation to restore our office lease in connection with the termination, a provision is recognized corresponding to the present value of expected future costs. The present value of a provision is calculated using a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the obligation. The increase in the provision due to passage of time is recognized as an interest expense.

3.7—Other Payables

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liabilities related to collaboration agreements</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>Staff cost liabilities</td>
<td>48</td>
<td>30</td>
</tr>
<tr>
<td>Other liabilities</td>
<td>715</td>
<td>213</td>
</tr>
<tr>
<td>Accounts payable</td>
<td>69</td>
<td>69</td>
</tr>
<tr>
<td><strong>Total at December 31</strong></td>
<td>840</td>
<td>318</td>
</tr>
<tr>
<td>Non-current other payables</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Current other payables</td>
<td>839</td>
<td>316</td>
</tr>
<tr>
<td><strong>Total at December 31</strong></td>
<td>840</td>
<td>318</td>
</tr>
</tbody>
</table>

Accounting Policies

Other payables are initially measured at fair value and subsequently measured in the balance sheet at amortized cost. The current other payables are comprised of liabilities that are due less than one year from the balance sheet date and are in general not interest bearing and settled on an ongoing basis during the financial year. Non-current payables are measured at the present value of the expenditures expected to be required to settle the obligation using a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the obligation. The increase in the liability due to passage of time is recognized as interest expense.

Staff Costs Liabilities

Wages and salaries, social security contributions, paid leave and bonuses, and other employee benefits are recognized in the financial year in which the employee performs the associated work. Termination benefits are recognized as an expense, when the Genmab group is committed demonstrably, without realistic possibility of withdrawal, to a formal detailed plan to terminate employment. The group’s pension plans are classified as defined contribution plans, and, accordingly, no pension obligations are recognized in the balance sheet. Costs relating to defined contribution plans are included in the income statement in the period in which they are accrued and outstanding contributions are included in other payables.

Accounts Payable

Accounts payable are measured in the balance sheet at amortized cost.
Other Liabilities

Other liabilities primarily includes accrued expenses related to our research and development project costs.

SECTION 4—CAPITAL STRUCTURE, FINANCIAL RISK AND RELATED ITEMS

4.1—Capital Management

Genmab’s goal is to maintain a strong capital base so as to maintain investor, creditor and market confidence, and a continuous advancement of Genmab’s product pipeline and business in general.

Genmab is primarily financed through partnership collaboration income and had, as of December 31, 2019, a cash position of DKK 10,971 million compared to DKK 6,106 million as of December 31, 2018. The cash position supports the advancement of our product pipeline and operations.

The adequacy of our available funds will depend on many factors, including continued growth of DARZALEX sales, progress in our research and development programs, the magnitude of those programs, our commitments to existing and new clinical collaborators, our ability to establish commercial and licensing arrangements, our capital expenditures, market developments, and any future acquisitions. Accordingly, we may require additional funds and may attempt to raise additional funds through equity or debt financings, collaborative agreements with partners, or from other sources.

The Board of Directors monitors the share and capital structure to ensure that Genmab’s capital resources support the strategic goals. There was no change in the group’s approach to capital management procedures in 2019.

Neither Genmab A/S nor any of its subsidiaries are subject to externally imposed capital requirements.

4.2—Financial Risk

The financial risks of the Genmab group are managed centrally.

The overall risk management guidelines have been approved by the Board of Directors and includes the group’s investment policy related to our marketable securities. The group’s risk management guidelines are established to identify and analyze the risks faced by the Genmab group, to set the appropriate risk limits and controls and to monitor the risks and adherence to limits. It is Genmab’s policy not to actively speculate in financial risks. The group’s financial risk management is directed solely against monitoring and reducing financial risks which are directly related to the group’s operations.

The primary objective of Genmab’s investment activities is to preserve capital and ensure liquidity with a secondary objective of maximizing the income derived from security investments without significantly increasing risk. Therefore, our investment policy includes among other items, guidelines and ranges for which investments (all of which are shorter-term in nature) are considered to be eligible investments for Genmab and which investment parameters are to be applied, including maturity limitations and credit ratings. In addition, the policy includes specific diversification criteria and investment limits to minimize the risk of loss resulting from over concentration of assets in a specific class, issuer, currency, country, or economic sector.

Currently, our marketable securities are administrated by two external investment managers. The guidelines and investment managers are reviewed regularly to reflect changes in market conditions, the group’s activities and financial position. In 2016, the investment policy was amended to increase the investment limits for individual securities and reduce the percent of the total portfolio required to have a maturity of less than one year. The changes were made as a result of the higher value of our marketable securities portfolio and reduced need for short duration securities.
In addition to the capital management and financing risk mentioned in note 4.1, the group has identified the following key financial risk areas, which are mainly related to our marketable securities portfolio:

- credit risk;
- foreign currency risk; and
- interest rate risk

All our marketable securities are traded in established markets. Given the current market conditions, all future cash inflows including re-investments of proceeds from the disposal of marketable securities are invested in highly liquid and conservative investments. Please refer to note 4.4 for additional information regarding marketable securities.

**Credit Risk**

Genmab is exposed to credit risk and losses on our marketable securities, and bank deposits. The maximum credit exposure related to Genmab's cash position was DKK 10,971 million as of December 31, 2019 compared to DKK 6,106 million as of December 31, 2018. The maximum credit exposure to Genmab’s receivables was DKK 3,001 million as of December 31, 2019 compared to DKK 1,337 million as of December 31, 2018.

**Marketable Securities**

To manage and reduce credit risks on our securities, Genmab’s policy is to ensure only securities from investment grade issuers are eligible for our portfolios. No issuer of marketable securities can be accepted if it is not assumed that the credit quality of the issuer would be at least equal to the rating shown below:

<table>
<thead>
<tr>
<th>Category</th>
<th>S&amp;P</th>
<th>Moody's</th>
<th>Fitch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short-term</td>
<td>A-1</td>
<td>P-1</td>
<td>F-1</td>
</tr>
<tr>
<td>Long-term</td>
<td>A-1</td>
<td>A3</td>
<td>A-</td>
</tr>
</tbody>
</table>

Our current portfolio is spread over a number of different securities and is conservative with a focus on liquidity and security. As of December 31, 2019, 91% of our marketable securities had a triple A-rating from Moody’s, S&P, or Fitch compared to 90% at December 31, 2018. The total value of marketable securities including interest receivables amounted to DKK 7,453 million at the end of 2019 compared to DKK 5,591 million at the end of 2018.

**Bank Deposits**

To reduce the credit risk on our bank deposits, Genmab policy is only to invests its cash deposits with highly rated financial institutions. Currently, these financial institutions have a short-term Fitch and S&P rating of at least F-1 and A-1, respectively. In addition, Genmab maintains bank deposits at a level necessary to support the short-term funding requirements of the Genmab group. The total value of bank deposits including short-term marketable securities amounted to DKK 3,552 million as of December 31, 2019 compared to DKK 533 million at the end of 2018. The increase was due to higher short-term marketable securities classified as cash and cash equivalents driven by timing and working capital needs as of December 31, 2019.

**Receivables**

The credit risk related to our receivables is not significant based on the high quality nature of Genmab’s customers. As disclosed in note 2.1, Janssen is Genmab’s primary customer in which receivables are established for royalties and milestones achieved.
**Foreign Currency Risk**

Genmab’s presentation currency is the DKK; however, Genmab’s revenues and expenses are in a number of different currencies. Consequently, there is a substantial risk of exchange rate fluctuations having an impact on Genmab’s cash flows, profit (loss) and/or financial position in DKK.

The majority of Genmab’s revenue is in USD. Exchange rate changes to the USD will result in changes to the translated value of future net result before tax and cash flows. Genmab’s revenue in USD was 97% of total revenue in 2019 as compared to 96% in 2018 and 96% in 2017. The foreign subsidiaries are not significantly affected by currency risks as both revenues and expenses are primarily settled in the foreign subsidiaries’ functional currencies.

**Assets and Liabilities in Foreign Currency**

The most significant cash flows of the group are DKK, EUR, USD and GBP and Genmab hedges its currency exposure by maintaining cash positions in these currencies. Our total marketable securities were invested in EUR (12%), DKK (23%), USD (64%) and GBP (1%) denominated securities as of December 31, 2019, compared to 16%, 30%, 53%, and 1%, as of December 31, 2018.

Based on the amount of assets and liabilities denominated in EUR, USD and GBP as of December 31, 2019 and 2018, a 1% increase/decrease in the EUR to DKK exchange rate and a 10% increase/decrease in both USD to DKK exchange rate and GBP to DKK exchange rate will impact our net result before tax by approximately:

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>Percentage change in exchange rate**</th>
<th>Impact of change in exchange rate*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2019</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EUR</td>
<td>1%</td>
<td>10</td>
</tr>
<tr>
<td>USD</td>
<td>10%</td>
<td>1,053</td>
</tr>
<tr>
<td>GBP</td>
<td>10%</td>
<td>0</td>
</tr>
<tr>
<td><strong>2018</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EUR</td>
<td>1%</td>
<td>9</td>
</tr>
<tr>
<td>USD</td>
<td>10%</td>
<td>362</td>
</tr>
<tr>
<td>GBP</td>
<td>10%</td>
<td>5</td>
</tr>
</tbody>
</table>

* The analysis assumes that all other variables, in particular interest rates, remain constant.
** The movements in the income statement and equity arise from monetary items (cash, marketable securities, receivables and liabilities) where the functional currency of the entity differs from the currency that the monetary items are denominated in.

Accordingly, significant changes in exchange rates could cause our net result to fluctuate significantly as gains and losses are recognized in the income statement. Our EUR exposure is mainly related to our marketable securities, contracts and other costs denominated in EUR. Since the introduction of EUR in 1999, Denmark has committed to maintaining a central rate of 7.46 DKK to the EUR. This rate may fluctuate within a +/- 2.25% band. Should Denmark’s policy towards the EUR change, the DKK values of our EUR denominated assets and costs could be materially different compared to what is calculated and reported under the existing Danish policy towards the DKK/EUR.

The USD currency exposure was mainly related to cash deposits, marketable securities, and receivables related to our collaborations with Janssen and Novartis. Significant changes in the exchange rate of USD to DKK could cause the net result to change materially as shown in the table above. In prior years, Genmab has entered into derivative contracts to hedge a portion of the associated currency exposure of royalty payments from net sales of DARZALEX by Janssen. As of December 31, 2019, there were no derivatives outstanding.

The GBP currency exposure is mainly related to contracts and marketable securities denominated in GBP.

F-33
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Interest Rate Risk

Genmab’s exposure to interest rate risk is primarily related to the marketable securities, as we currently do not have significant interest bearing debts.

 Marketable Securities

The securities in which the group has invested bear interest rate risk, as a change in market derived interest rates may cause fluctuations in the fair value of the investments. In accordance with the objective of the investment activities, the portfolio of securities is monitored on a total return basis.

To control and minimize the interest rate risk, the group maintains an investment portfolio in a variety of securities with a relatively short effective duration with both fixed and variable interest rates.

As of December 31, 2019, the portfolio has an average effective duration of approximately 1.1 years (2018: 1.4 years) and no securities have an effective duration of more than 9 years (2018: 8 years), which means that a change in the interest rates of one percentage point will cause the fair value of the securities to change by approximately 1.1% (2018: 1.4%). Due to the short-term nature of the current investments and to the extent that we are able to hold the investments to maturity, we consider our current exposure to changes in fair value due to interest rate changes to be insignificant compared to the fair value of the portfolio.

As of December 31, 2019, and December 31, 2018, the maturity profile of our marketable securities is as follows:

<table>
<thead>
<tr>
<th>Year of Maturity</th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td></td>
<td>2,880</td>
</tr>
<tr>
<td>2020</td>
<td>3,891</td>
<td>1,574</td>
</tr>
<tr>
<td>2021</td>
<td>2,190</td>
<td>505</td>
</tr>
<tr>
<td>2022</td>
<td>493</td>
<td>138</td>
</tr>
<tr>
<td>2023</td>
<td>102</td>
<td>75</td>
</tr>
<tr>
<td>2024+</td>
<td>743</td>
<td>401</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>7,419</td>
<td>5,573</td>
</tr>
</tbody>
</table>

4.3—Financial Assets and Liabilities

<table>
<thead>
<tr>
<th>Categories of Financial Assets and Liabilities</th>
<th>Note</th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Financial assets measured at fair value through profit or loss</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marketable securities</td>
<td>4.4</td>
<td>7,419</td>
<td>5,573</td>
</tr>
<tr>
<td>Other Investments</td>
<td>3.4</td>
<td>149</td>
<td>—</td>
</tr>
<tr>
<td>Financial assets measured at amortized cost</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Receivables ex. prepayments</td>
<td>3.5</td>
<td>2,939</td>
<td>1,318</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>3.552</td>
<td>533</td>
<td></td>
</tr>
<tr>
<td>Financial liabilities measured at amortized cost:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other payables</td>
<td>3.7</td>
<td>(840)</td>
<td>(318)</td>
</tr>
<tr>
<td>Lease Liabilities</td>
<td>3.3</td>
<td>(181)</td>
<td>—</td>
</tr>
</tbody>
</table>

Fair Value Measurement

Marketable Securities

All fair market values are determined by reference to external sources using unadjusted quoted prices in established markets for our marketable securities (Level 1).
Other Investments

The Group’s other investments consist of a DKK 149 million investment in CureVac AG, the developer of mRNA technology, which was entered into on December 19, 2019 (Level 3).

Accounting Policies

Classification of Categories of Financial Assets and Liabilities

Genmab classifies its financial assets held into the following measurement categories:

- those to be measured subsequently at fair value (either through other comprehensive income, or through profit or loss), and
- those to be measured at amortized cost.

The classification depends on the business model for managing the financial assets and the contractual terms of the cash flows. For assets measured at fair value, gains and losses will either be recorded in profit or loss or other comprehensive income. Genmab reclassifies debt investments when and only when its business model for managing those assets changes. Further details about the accounting policy for each of the categories are outlined in the respective notes.

Fair Value Measurement

The Genmab group measures financial instruments, such as marketable securities, at fair value at each balance sheet date. Management assessed that financial assets and liabilities measured at amortized costs such as bank deposits, receivables and other payables approximate their carrying amounts largely due to the short-term maturities of these instruments.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either:

- In the principal market for the asset or liability, or
- In the absence of a principal market, in the most advantageous market for the asset or liability.

The principal or the most advantageous market must be accessible by the Genmab group. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

The Genmab group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

For financial instruments that are measured in the balance sheet at fair value, IFRS 13 for financial instruments requires disclosure of fair value measurements by level of the following fair value measurement hierarchy for:

- Level 1 – Quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2 – Inputs other than quoted prices included within level 1 that are observable for the asset and liability, either directly (that is, as prices) or indirectly (that is, derived from prices)
- Level 3 – Inputs for the asset or liability that are not based on observable market data (that is, unobservable inputs).
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

For assets and liabilities that are recognized in the financial statements on a recurring basis, the group determines whether transfers have occurred between levels in the hierarchy by re-assessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period. Any transfers between the different levels are carried out at the end of the reporting period. There have not been any transfers between the different levels during 2019 and 2018.

4.4—Marketable Securities

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost at January 1</td>
<td>5,494</td>
<td>4,195</td>
</tr>
<tr>
<td>Additions for the year</td>
<td>5,812</td>
<td>3,521</td>
</tr>
<tr>
<td>Disposals for the year</td>
<td>(3,926)</td>
<td>(2,222)</td>
</tr>
<tr>
<td>Cost at December 31</td>
<td>7,380</td>
<td>5,494</td>
</tr>
</tbody>
</table>

Fair value adjustment at January 1 | 79       | (120)    |
Fair value adjustment for the year | (40)     | 199      |
Fair value adjustment at December 31 | 39       | 79       |

Net book value at December 31 | 7,419    | 5,573    |

Net book value in percentage of cost | 101 %   | 101 %    |

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>Market value 2019</th>
<th>Average effective duration</th>
<th>Share %</th>
<th>Market value 2018</th>
<th>Average effective duration</th>
<th>Share %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kingdom of Denmark bonds and treasury bills</td>
<td>462</td>
<td>1.84</td>
<td>6 %</td>
<td>508</td>
<td>1.94</td>
<td>6 %</td>
</tr>
<tr>
<td>Danish mortgage-backed securities</td>
<td>1,227</td>
<td>2.33</td>
<td>17 %</td>
<td>1,177</td>
<td>2.58</td>
<td>21 %</td>
</tr>
<tr>
<td><strong>DKK portfolio</strong></td>
<td><strong>1,689</strong></td>
<td><strong>2.20</strong></td>
<td><strong>23 %</strong></td>
<td><strong>1,685</strong></td>
<td><strong>2.39</strong></td>
<td><strong>30 %</strong></td>
</tr>
<tr>
<td>EUR portfolio</td>
<td>European government bonds and treasury bills</td>
<td>873</td>
<td>1.33</td>
<td>12 %</td>
<td>875</td>
<td>1.38</td>
</tr>
<tr>
<td>USD portfolio</td>
<td>US government bonds and treasury bills</td>
<td>4,778</td>
<td>0.63</td>
<td>64 %</td>
<td>2,938</td>
<td>0.84</td>
</tr>
<tr>
<td>GBP portfolio</td>
<td>UK government bonds and treasury bills</td>
<td>79</td>
<td>0.55</td>
<td>1 %</td>
<td>75</td>
<td>0.55</td>
</tr>
<tr>
<td><strong>Total portfolio</strong></td>
<td><strong>7,419</strong></td>
<td><strong>1.07</strong></td>
<td><strong>100 %</strong></td>
<td><strong>5,573</strong></td>
<td><strong>1.39</strong></td>
<td><strong>100 %</strong></td>
</tr>
<tr>
<td>Marketable securities</td>
<td>7,419</td>
<td></td>
<td></td>
<td>5,573</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Interest Income**

Total interest income amounted to DKK 120 million in 2019 compared to DKK 63 million in 2018. The increase was due to the combination of higher yield and level of investment in marketable securities in 2019 as compared to 2018.

**Fair Value Adjustment**

The total fair value adjustment was an expense of DKK 40 million in 2019 compared to income of DKK 199 million in 2018. Fair value adjustments were primarily driven by foreign exchange movements and the timing of maturities and purchases of marketable securities.

Please refer to note 4.2 for additional information regarding the risks related to our marketable securities.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Accounting Policies

Marketable securities consist of investments in securities with a maturity greater than three months at the time of acquisition. Measurement of marketable securities depends on the business model for managing the asset and the cash flow characteristics of the asset. There are two measurement categories into which the group classifies its debt instruments:

- Amortized cost: Assets that are held for collection of contractual cash flows, where those cash flows represent solely payments of principal and interest, are measured at amortized cost. Interest income from these financial assets is included in finance income using the effective interest rate method. Any gain or loss arising on derecognition is recognized directly in profit or loss and presented in other gains/(losses), together with foreign exchange gains and losses. Impairment losses are presented as a separate line item in the statement of profit or loss.

- Fair value through profit and loss (FVPL): Assets that do not meet the criteria for amortized cost or FVOCI are measured at FVPL. A gain or loss on a debt investment that is subsequently measured at FVPL is recognized in profit or loss and presented net within other gains/(losses) in the period in which it arises.

Genmab’s portfolio is managed and evaluated on a fair value basis in accordance with its investment guidelines and the information provided internally to management. This business model does not meet the criteria for amortized cost or FVOCI and as a result marketable securities are measured at fair value through profit and loss. This classification is consistent with the prior year’s classification. Genmab invests its cash in deposits with major financial institutions, in Danish mortgage bonds, and notes issued by the Danish, European and American governments. The securities can be purchased and sold using established markets.

Transactions are recognized at trade date.

4.5—Financial Income and Expenses

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>2019</th>
<th>2018</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Financial income:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest and other financial income</td>
<td>120</td>
<td>63</td>
<td>41</td>
</tr>
<tr>
<td>Realized and unrealized gains on marketable securities (fair value through the income statement), net</td>
<td>9</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Realized and unrealized gains on fair value hedges, net</td>
<td>—</td>
<td>2</td>
<td>30</td>
</tr>
<tr>
<td>Realized and unrealized exchange rate gains, net</td>
<td>99</td>
<td>179</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total financial income</strong></td>
<td><strong>228</strong></td>
<td><strong>243</strong></td>
<td><strong>72</strong></td>
</tr>
<tr>
<td>Financial expenses:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest and other financial expenses</td>
<td>7</td>
<td>—</td>
<td>2</td>
</tr>
<tr>
<td>Realized and unrealized losses on marketable securities (fair value through the income statement), net</td>
<td>—</td>
<td>11</td>
<td>20</td>
</tr>
<tr>
<td>Realized and unrealized exchange rate losses, net</td>
<td>—</td>
<td>—</td>
<td>330</td>
</tr>
<tr>
<td><strong>Total financial expenses</strong></td>
<td><strong>7</strong></td>
<td><strong>11</strong></td>
<td><strong>352</strong></td>
</tr>
<tr>
<td><strong>Net financial items</strong></td>
<td><strong>221</strong></td>
<td><strong>232</strong></td>
<td><strong>280</strong></td>
</tr>
<tr>
<td>Interest and other financial income on financial assets measured at amortized cost</td>
<td>22</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>Interest and other financial expenses on financial liabilities measured at amortized cost</td>
<td>—</td>
<td>—</td>
<td>3</td>
</tr>
</tbody>
</table>

Realized and unrealized exchange rate gains, net of DKK 99 million in 2019 and DKK 178 million in 2018 were driven by foreign exchange movements, which positively impacted our USD denominated portfolio and cash holdings. The USD strengthened against the DKK during 2019 and 2018, resulting in realized and unrealized exchange rates gains.
More specifically, the USD/DKK foreign exchange rate increased from 6.5213 at December 31, 2018 to 6.6759 at December 31, 2019, and from 6.2067 at December 31, 2017 to 6.5213 at December 31, 2018.

Realized and unrealized exchange rate losses, net of DKK 330 million in 2017 were driven by foreign exchange movements, which negatively impacted our USD denominated portfolio and cash holdings. The USD weakened significantly against the DKK during 2017, resulting in realized and unrealized exchange rates losses. More specifically, the USD/DKK foreign exchange rate decreased from 7.0528 at December 31, 2016 to 6.2067 at December 31, 2017. Please refer to note 4.2 for additional information on foreign currency risk.

Accounting Policies

Financial income and expenses include interest as well as realized and unrealized exchange rate adjustments and realized and unrealized gains and losses on marketable securities (designated as fair value through the income statement) and realized gains and losses and write-downs of other securities and equity interests (designated as available-for-sale financial assets). Interest and dividend income are shown separately from gains and losses on marketable securities and other securities and equity interests. Gains or losses relating to the ineffective portion of a cash flow hedge and changes in time value are recognized immediately in the income statement as part of the financial income or expenses.

4.6—Share-Based Instruments

Restricted Stock Unit Program

Genmab A/S has established an RSU program (equity-settled share-based payment transactions) as an incentive for all the Genmab group’s employees, members of the Executive Management, and members of the Board of Directors. RSUs are granted by the Board of Directors in accordance with authorizations given to it by Genmab A/S’ shareholders and are subject to the incentive guidelines (Remuneration Principles) adopted by the general meeting.

Under the terms of the RSU program, RSUs are subject to a cliff vesting period and become fully vested on the first banking day of the month following a period of three years from the date of grant. If an employee, member of Executive Management, or member of the Board of Directors ceases their employment or board membership prior to the vesting date, all RSUs that are granted, but not yet vested, shall lapse automatically.

However, if an employee, a member of the Executive Management or a member of the Board of Directors ceases employment or board membership due to retirement or age limitation in Genmab A/S’ articles of association, death, serious sickness or serious injury then all RSUs that are granted but not yet vested shall remain outstanding and will be settled in accordance with their terms.

In addition, for an employee or a member of the Executive Management, RSUs that are granted, but not yet vested shall remain outstanding and will be settled in accordance with their terms in instances where the employment relationship is terminated by Genmab without cause.

Within 30 days of the vesting date, the holder of an RSU receives one share in Genmab A/S for each RSU. In jurisdictions in which Genmab as an employer is required to withhold tax and settle with the tax authority on behalf of the employee, Genmab withholds the number of RSUs that are equal to the monetary value of the employee’s tax obligation from the total number of RSUs that otherwise would have been issued to the employee upon vesting (“net settlement”). Genmab A/S may at its sole discretion in extraordinary circumstances choose to make cash settlement instead of delivering shares.

The RSU program contains anti-dilution provisions if changes occur in Genmab’s share capital prior to the vesting date and provisions to accelerate vesting of RSUs in the event of change of control as defined in the RSU program.
RSU Activity in 2019, 2018 and 2017

<table>
<thead>
<tr>
<th></th>
<th>Number of RSUs held by the Board of Directors</th>
<th>Number of RSUs held by the Executive Management</th>
<th>Number of RSUs held by employees</th>
<th>Number of RSUs held by former members of the Board of Directors and employees</th>
<th>Total RSUs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding at January 1, 2017</td>
<td>18,688</td>
<td>64,258</td>
<td>18,291</td>
<td>1,150</td>
<td>102,387</td>
</tr>
<tr>
<td>Granted*</td>
<td>7,661</td>
<td>19,599</td>
<td>38,691</td>
<td>–</td>
<td>65,951</td>
</tr>
<tr>
<td>Settled</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Transferred</td>
<td>(2,021)</td>
<td>–</td>
<td>(1,484)</td>
<td>3,505</td>
<td>–</td>
</tr>
<tr>
<td>Cancelled</td>
<td>–</td>
<td>–</td>
<td>(23)</td>
<td>(271)</td>
<td>(294)</td>
</tr>
<tr>
<td><strong>Outstanding at December 31, 2017</strong></td>
<td><strong>24,328</strong></td>
<td><strong>83,857</strong></td>
<td><strong>55,475</strong></td>
<td><strong>4,384</strong></td>
<td><strong>168,044</strong></td>
</tr>
<tr>
<td>Outstanding at January 1, 2018</td>
<td>24,328</td>
<td>83,857</td>
<td>55,475</td>
<td>4,384</td>
<td>168,044</td>
</tr>
<tr>
<td>Granted*</td>
<td>5,224</td>
<td>18,020</td>
<td>79,395</td>
<td>–</td>
<td>102,639</td>
</tr>
<tr>
<td>Settled</td>
<td>(9,425)</td>
<td>(35,725)</td>
<td>(2,300)</td>
<td>(47,450)</td>
<td>–</td>
</tr>
<tr>
<td>Transferred</td>
<td>–</td>
<td>–</td>
<td>(3,358)</td>
<td>3,358</td>
<td>–</td>
</tr>
<tr>
<td>Cancelled</td>
<td>–</td>
<td>–</td>
<td>(1,466)</td>
<td>(2,865)</td>
<td>(4,331)</td>
</tr>
<tr>
<td><strong>Outstanding at December 31, 2018</strong></td>
<td><strong>20,127</strong></td>
<td><strong>66,152</strong></td>
<td><strong>130,046</strong></td>
<td><strong>2,577</strong></td>
<td><strong>218,902</strong></td>
</tr>
<tr>
<td>Outstanding at January 1, 2019</td>
<td>20,127</td>
<td>66,152</td>
<td>130,046</td>
<td>2,577</td>
<td>218,902</td>
</tr>
<tr>
<td>Granted*</td>
<td>3,708</td>
<td>25,793</td>
<td>87,168</td>
<td>73</td>
<td>116,742</td>
</tr>
<tr>
<td>Settled</td>
<td>(2,631)</td>
<td>(19,080)</td>
<td>(478)</td>
<td>(22,189)</td>
<td>–</td>
</tr>
<tr>
<td>Transferred</td>
<td>(1,251)</td>
<td>–</td>
<td>(8,355)</td>
<td>9,606</td>
<td>–</td>
</tr>
<tr>
<td>Cancelled</td>
<td>–</td>
<td>–</td>
<td>(5,548)</td>
<td>(5,548)</td>
<td>–</td>
</tr>
<tr>
<td><strong>Outstanding at December 31, 2019</strong></td>
<td><strong>19,953</strong></td>
<td><strong>72,865</strong></td>
<td><strong>208,859</strong></td>
<td><strong>6,230</strong></td>
<td><strong>307,907</strong></td>
</tr>
</tbody>
</table>

*RSUs held by the Board of Directors includes RSUs granted to employee-elected Board Members as employees of Genmab A/S or its subsidiaries.

Please refer to note 5.1 for additional information regarding the number of RSUs held by the Executive Management and the Board of Directors. The weighted average fair value of RSUs granted was DKK 1,511.70, DKK1,033.95 and DKK 1,128.30 in 2019, 2018 and 2017, respectively.

Warrant Program

Genmab A/S has established warrant programs (equity-settled share-based payment transactions) as an incentive for all the Genmab group’s employees, and members of the Executive Management. Warrants are granted by the Board of Directors in accordance with authorizations given to it by Genmab A/S’ shareholders. Warrant grants to Executive Management are subject to the incentive guidelines (Remuneration Principles) adopted by the general meeting.

Under the terms of the warrant programs, warrants are granted at an exercise price equal to the share price on the grant date. According to the warrant programs, the exercise price cannot be fixed at a lower price than the market price at the grant date. In connection with exercise, the warrants shall be settled with the delivery of shares in Genmab A/S. The warrant programs contain anti-dilution provisions if changes occur in Genmab’s share capital prior to the warrants being exercised.

Warrants Granted From August 2004 Until April 2012

Under the August 2004 warrant program, warrants can be exercised starting from one year after the grant date. As a general rule, the warrant holder may only exercise 25% of the warrants granted per full year of employment or affiliation with Genmab after the grant date.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

However, the warrant holder will be entitled to continue to be able to exercise all warrants on a regular schedule in instances where the employment relationship is terminated by Genmab without cause.

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

Warrants Granted From April 2012 Until March 2017

Following the Annual General Meeting in April 2012, a new warrant program was adopted by the Board of Directors. Whereas warrants granted under the August 2004 warrant program will lapse on the tenth anniversary of the grant date, warrants granted under the new April 2012 warrant program will lapse at the seventh anniversary of the grant date. All other terms in the warrant programs are identical.

Warrants Granted From March 2017

In March 2017, a new warrant program was adopted by the Board of Directors. Whereas warrants granted under the April 2012 warrant program vested annually over a four year period, warrants granted under the new March 2017 warrant program are subject to a cliff vesting period and become fully vested three years from the date of grant. All other terms in the warrant programs are identical.

F-40
## Warrant Activity in 2019, 2018 and 2017

<table>
<thead>
<tr>
<th></th>
<th>Number of warrants held by the Board of Directors</th>
<th>Number of warrants held by the Executive Management</th>
<th>Number of warrants held by former members of the Executive Management, Board of Directors and employees</th>
<th>Total warrants</th>
<th>Weighted average exercise price</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outstanding at January 1, 2017</strong></td>
<td>129,742</td>
<td>877,418</td>
<td>644,097</td>
<td>3,190,311</td>
<td>311.52</td>
</tr>
<tr>
<td>Granted*</td>
<td>4,125</td>
<td>59,819</td>
<td>118,745</td>
<td>—</td>
<td>182,689</td>
</tr>
<tr>
<td>Exercised</td>
<td>(31,625)</td>
<td>(377,500)</td>
<td>(131,709)</td>
<td>(835,618)</td>
<td>257.19</td>
</tr>
<tr>
<td>Expired</td>
<td>—</td>
<td>—</td>
<td>(8,200)</td>
<td>(8,200)</td>
<td>348.20</td>
</tr>
<tr>
<td>Cancelled</td>
<td>—</td>
<td>—</td>
<td>(73)</td>
<td>(10,996)</td>
<td>722.48</td>
</tr>
<tr>
<td>Transfers</td>
<td>(10,000)</td>
<td>—</td>
<td>(56,765)</td>
<td>66,765</td>
<td>—</td>
</tr>
<tr>
<td><strong>Outstanding at December 31, 2017</strong></td>
<td>92,242</td>
<td>559,737</td>
<td>574,295</td>
<td>1,518,186</td>
<td>436.01</td>
</tr>
<tr>
<td>Exercisable at year end</td>
<td>79,380</td>
<td>472,119</td>
<td>262,414</td>
<td>1,084,371</td>
<td>233.81</td>
</tr>
<tr>
<td>Exercisable warrants in the money at year end</td>
<td>78,400</td>
<td>464,832</td>
<td>241,241</td>
<td>1,053,786</td>
<td>201.27</td>
</tr>
<tr>
<td><strong>Outstanding at January 1, 2018</strong></td>
<td>92,242</td>
<td>559,737</td>
<td>574,295</td>
<td>1,518,186</td>
<td>436.01</td>
</tr>
<tr>
<td>Granted*</td>
<td>3,161</td>
<td>50,464</td>
<td>222,882</td>
<td>—</td>
<td>276,507</td>
</tr>
<tr>
<td>Exercised</td>
<td>(20,925)</td>
<td>(130,000)</td>
<td>(46,883)</td>
<td>(311,897)</td>
<td>241.34</td>
</tr>
<tr>
<td>Expired</td>
<td>—</td>
<td>—</td>
<td>(37,875)</td>
<td>(37,875)</td>
<td>253.76</td>
</tr>
<tr>
<td>Cancelled</td>
<td>—</td>
<td>—</td>
<td>(4,582)</td>
<td>(17,129)</td>
<td>940.01</td>
</tr>
<tr>
<td>Transfers</td>
<td>—</td>
<td>—</td>
<td>(39,624)</td>
<td>39,624</td>
<td>—</td>
</tr>
<tr>
<td><strong>Outstanding at December 31, 2018</strong></td>
<td>74,478</td>
<td>480,201</td>
<td>706,088</td>
<td>1,423,210</td>
<td>592.14</td>
</tr>
<tr>
<td>Exercisable at year end</td>
<td>62,647</td>
<td>355,347</td>
<td>297,128</td>
<td>867,865</td>
<td>295.02</td>
</tr>
<tr>
<td>Exercisable warrants in the money at year end</td>
<td>60,688</td>
<td>340,775</td>
<td>257,115</td>
<td>807,279</td>
<td>230.43</td>
</tr>
<tr>
<td><strong>Outstanding at January 1, 2019</strong></td>
<td>74,478</td>
<td>480,201</td>
<td>706,088</td>
<td>1,423,210</td>
<td>592.14</td>
</tr>
<tr>
<td>Granted*</td>
<td>3,925</td>
<td>—</td>
<td>303,066</td>
<td>228</td>
<td>307,219</td>
</tr>
<tr>
<td>Exercised</td>
<td>(15,750)</td>
<td>(132,400)</td>
<td>(56,237)</td>
<td>(299,431)</td>
<td>212.23</td>
</tr>
<tr>
<td>Expired</td>
<td>—</td>
<td>—</td>
<td>(2,000)</td>
<td>(2,000)</td>
<td>129.75</td>
</tr>
<tr>
<td>Cancelled</td>
<td>—</td>
<td>—</td>
<td>(15,374)</td>
<td>(15,374)</td>
<td>1,049.34</td>
</tr>
<tr>
<td>Transfers</td>
<td>(319)</td>
<td>—</td>
<td>(93,944)</td>
<td>94,263</td>
<td>—</td>
</tr>
<tr>
<td><strong>Outstanding at December 31, 2019</strong></td>
<td>62,334</td>
<td>347,801</td>
<td>858,973</td>
<td>1,413,624</td>
<td>862.03</td>
</tr>
<tr>
<td>Exercisable at year end</td>
<td>50,227</td>
<td>230,233</td>
<td>225,855</td>
<td>638,248</td>
<td>407.89</td>
</tr>
<tr>
<td>Exercisable warrants in the money at year end</td>
<td>50,227</td>
<td>227,733</td>
<td>219,403</td>
<td>627,061</td>
<td>385.84</td>
</tr>
</tbody>
</table>

*Warrants held by the Board of Directors includes warrants granted to employee-elected Board Members as employees of Genmab A/S or its subsidiaries.

Please refer to note 5.1 for additional information regarding the number of warrants held by the Executive Management and the Board of Directors.

As of December 31, 2019, the 1,413,624 outstanding warrants amounted to 2% of the share capital, compared to 2% for 2018 and 2017.
For exercised warrants in 2019 the weighted average share price at the exercise date amounted to DKK 1,267.92, compared to DKK 1,206.11 in 2018 and DKK 1,368.32 in 2017.

### Weighted Average Outstanding Warrants at December 31, 2019

<table>
<thead>
<tr>
<th>Exercise price DKK</th>
<th>Grant Date</th>
<th>Number of warrants outstanding</th>
<th>Weighted average remaining contractual life (in years)</th>
<th>Number of warrants exercisable</th>
</tr>
</thead>
<tbody>
<tr>
<td>31.75</td>
<td>October 14, 2011</td>
<td>5,950</td>
<td>1.79</td>
<td>5,950</td>
</tr>
<tr>
<td>40.41</td>
<td>June 22, 2011</td>
<td>80,205</td>
<td>1.48</td>
<td>80,205</td>
</tr>
<tr>
<td>46.74</td>
<td>June 2, 2010</td>
<td>85,000</td>
<td>0.42</td>
<td>85,000</td>
</tr>
<tr>
<td>55.85</td>
<td>April 6, 2011</td>
<td>5,500</td>
<td>1.27</td>
<td>5,500</td>
</tr>
<tr>
<td>66.60</td>
<td>December 9, 2010</td>
<td>35,500</td>
<td>0.94</td>
<td>35,500</td>
</tr>
<tr>
<td>67.50</td>
<td>October 14, 2010</td>
<td>3,250</td>
<td>0.79</td>
<td>3,250</td>
</tr>
<tr>
<td>68.65</td>
<td>April 21, 2010</td>
<td>3,325</td>
<td>0.31</td>
<td>3,325</td>
</tr>
<tr>
<td>147.50</td>
<td>April 17, 2013</td>
<td>1,500</td>
<td>0.30</td>
<td>1,500</td>
</tr>
<tr>
<td>199.00</td>
<td>June 12, 2013</td>
<td>1,000</td>
<td>0.45</td>
<td>1,000</td>
</tr>
<tr>
<td>210.00</td>
<td>February 10, 2014</td>
<td>2,750</td>
<td>1.11</td>
<td>2,750</td>
</tr>
<tr>
<td>220.40</td>
<td>October 15, 2014</td>
<td>17,750</td>
<td>1.79</td>
<td>17,750</td>
</tr>
<tr>
<td>225.30</td>
<td>June 12, 2014</td>
<td>4,625</td>
<td>1.45</td>
<td>4,625</td>
</tr>
<tr>
<td>225.90</td>
<td>December 6, 2013</td>
<td>137,059</td>
<td>0.93</td>
<td>137,059</td>
</tr>
<tr>
<td>231.50</td>
<td>October 10, 2013</td>
<td>3,665</td>
<td>0.78</td>
<td>3,665</td>
</tr>
<tr>
<td>337.40</td>
<td>December 15, 2014</td>
<td>50,986</td>
<td>1.96</td>
<td>50,986</td>
</tr>
<tr>
<td>466.20</td>
<td>March 26, 2015</td>
<td>8,100</td>
<td>2.24</td>
<td>8,100</td>
</tr>
<tr>
<td>623.50</td>
<td>June 11, 2015</td>
<td>2,575</td>
<td>2.45</td>
<td>2,575</td>
</tr>
<tr>
<td>636.50</td>
<td>October 7, 2015</td>
<td>21,000</td>
<td>2.77</td>
<td>21,000</td>
</tr>
<tr>
<td>815.50</td>
<td>March 17, 2016</td>
<td>12,449</td>
<td>3.21</td>
<td>8,390</td>
</tr>
<tr>
<td>939.50</td>
<td>December 10, 2015</td>
<td>73,162</td>
<td>2.94</td>
<td>73,162</td>
</tr>
<tr>
<td>962.00</td>
<td>June 7, 2018</td>
<td>14,564</td>
<td>5.44</td>
<td>—</td>
</tr>
<tr>
<td>1,025.00</td>
<td>December 10, 2018</td>
<td>206,097</td>
<td>5.94</td>
<td>—</td>
</tr>
<tr>
<td>1,032.00</td>
<td>December 15, 2017</td>
<td>131,444</td>
<td>4.96</td>
<td>—</td>
</tr>
<tr>
<td>1,050.00</td>
<td>September 21, 2018</td>
<td>27,082</td>
<td>5.73</td>
<td>—</td>
</tr>
<tr>
<td>1,136.00</td>
<td>October 6, 2016</td>
<td>18,450</td>
<td>3.77</td>
<td>14,089</td>
</tr>
<tr>
<td>1,145.00</td>
<td>December 15, 2016</td>
<td>83,287</td>
<td>3.96</td>
<td>62,190</td>
</tr>
<tr>
<td>1,147.50</td>
<td>June 6, 2019</td>
<td>21,343</td>
<td>6.43</td>
<td>—</td>
</tr>
<tr>
<td>1,155.00</td>
<td>March 29, 2019</td>
<td>7,959</td>
<td>6.25</td>
<td>—</td>
</tr>
<tr>
<td>1,161.00</td>
<td>March 1, 2019</td>
<td>19,830</td>
<td>6.17</td>
<td>—</td>
</tr>
<tr>
<td>1,210.00</td>
<td>April 10, 2018</td>
<td>14,881</td>
<td>5.28</td>
<td>—</td>
</tr>
<tr>
<td>1,233.00</td>
<td>June 9, 2016</td>
<td>13,763</td>
<td>3.44</td>
<td>9,903</td>
</tr>
<tr>
<td>1,334.50</td>
<td>October 11, 2019</td>
<td>62,848</td>
<td>6.78</td>
<td>—</td>
</tr>
<tr>
<td>1,402.00</td>
<td>March 28, 2017</td>
<td>8,736</td>
<td>4.24</td>
<td>—</td>
</tr>
<tr>
<td>1,408.00</td>
<td>June 8, 2017</td>
<td>5,151</td>
<td>4.44</td>
<td>—</td>
</tr>
<tr>
<td>1,424.00</td>
<td>February 10, 2017</td>
<td>1,526</td>
<td>4.11</td>
<td>774</td>
</tr>
<tr>
<td>1,427.00</td>
<td>March 29, 2017</td>
<td>8,400</td>
<td>4.25</td>
<td>—</td>
</tr>
<tr>
<td>1,432.00</td>
<td>October 5, 2017</td>
<td>17,901</td>
<td>4.76</td>
<td>—</td>
</tr>
<tr>
<td>1,615.00</td>
<td>December 5, 2019</td>
<td>195,011</td>
<td>6.93</td>
<td>—</td>
</tr>
</tbody>
</table>

| Total            |                      | 1,413,624                  | 4.05                                                  | 638,248                       |
# Weighted Average Outstanding Warrants at December 31, 2018

<table>
<thead>
<tr>
<th>Exercise price DKK</th>
<th>Grant Date</th>
<th>Number of warrants outstanding</th>
<th>Weighted average remaining contractual life (in years)</th>
<th>Number of warrants exercisable</th>
</tr>
</thead>
<tbody>
<tr>
<td>31.75</td>
<td>October 14, 2011</td>
<td>7,525</td>
<td>2.79</td>
<td>7,525</td>
</tr>
<tr>
<td>40.41</td>
<td>June 22, 2011</td>
<td>85,975</td>
<td>2.48</td>
<td>85,975</td>
</tr>
<tr>
<td>45.24</td>
<td>April 25, 2012</td>
<td>1,000</td>
<td>0.32</td>
<td>1,000</td>
</tr>
<tr>
<td>46.74</td>
<td>June 2, 2010</td>
<td>85,000</td>
<td>1.42</td>
<td>85,000</td>
</tr>
<tr>
<td>55.85</td>
<td>April 6, 2011</td>
<td>8,500</td>
<td>2.27</td>
<td>8,500</td>
</tr>
<tr>
<td>66.60</td>
<td>December 9, 2010</td>
<td>37,750</td>
<td>1.94</td>
<td>37,750</td>
</tr>
<tr>
<td>67.50</td>
<td>October 14, 2010</td>
<td>3,250</td>
<td>1.79</td>
<td>3,250</td>
</tr>
<tr>
<td>68.65</td>
<td>April 21, 2010</td>
<td>5,450</td>
<td>1.31</td>
<td>5,450</td>
</tr>
<tr>
<td>79.25</td>
<td>October 9, 2012</td>
<td>5,000</td>
<td>0.78</td>
<td>5,000</td>
</tr>
<tr>
<td>80.55</td>
<td>December 5, 2012</td>
<td>111,750</td>
<td>0.93</td>
<td>111,750</td>
</tr>
<tr>
<td>90.00</td>
<td>January 31, 2013</td>
<td>1,375</td>
<td>1.08</td>
<td>1,375</td>
</tr>
<tr>
<td>129.75</td>
<td>October 8, 2009</td>
<td>5,075</td>
<td>0.77</td>
<td>5,075</td>
</tr>
<tr>
<td>147.50</td>
<td>April 17, 2013</td>
<td>7,750</td>
<td>1.30</td>
<td>7,750</td>
</tr>
<tr>
<td>174.00</td>
<td>June 17, 2009</td>
<td>25,000</td>
<td>0.46</td>
<td>25,000</td>
</tr>
<tr>
<td>199.00</td>
<td>June 12, 2013</td>
<td>1,000</td>
<td>1.45</td>
<td>1,000</td>
</tr>
<tr>
<td>210.00</td>
<td>February 10, 2014</td>
<td>3,088</td>
<td>2.11</td>
<td>3,088</td>
</tr>
<tr>
<td>220.40</td>
<td>October 15, 2014</td>
<td>33,800</td>
<td>2.79</td>
<td>33,800</td>
</tr>
<tr>
<td>225.30</td>
<td>June 12, 2014</td>
<td>7,975</td>
<td>2.45</td>
<td>7,975</td>
</tr>
<tr>
<td>225.90</td>
<td>December 6, 2013</td>
<td>175,047</td>
<td>1.93</td>
<td>175,047</td>
</tr>
<tr>
<td>231.50</td>
<td>October 10, 2013</td>
<td>7,850</td>
<td>1.78</td>
<td>7,850</td>
</tr>
<tr>
<td>234.00</td>
<td>April 15, 2009</td>
<td>6,100</td>
<td>0.29</td>
<td>6,100</td>
</tr>
<tr>
<td>337.40</td>
<td>December 15, 2014</td>
<td>90,945</td>
<td>2.96</td>
<td>90,945</td>
</tr>
<tr>
<td>466.20</td>
<td>March 26, 2015</td>
<td>11,061</td>
<td>3.24</td>
<td>6,664</td>
</tr>
<tr>
<td>623.50</td>
<td>June 11, 2015</td>
<td>6,350</td>
<td>3.45</td>
<td>3,913</td>
</tr>
<tr>
<td>636.50</td>
<td>October 7, 2015</td>
<td>24,500</td>
<td>3.77</td>
<td>16,250</td>
</tr>
<tr>
<td>815.50</td>
<td>March 17, 2016</td>
<td>14,837</td>
<td>4.21</td>
<td>6,362</td>
</tr>
<tr>
<td>939.50</td>
<td>December 10, 2015</td>
<td>80,874</td>
<td>3.94</td>
<td>57,880</td>
</tr>
<tr>
<td>962.00</td>
<td>June 7, 2018</td>
<td>14,714</td>
<td>6.44</td>
<td>—</td>
</tr>
<tr>
<td>1,025.00</td>
<td>December 10, 2018</td>
<td>210,437</td>
<td>6.94</td>
<td>—</td>
</tr>
<tr>
<td>1,032.00</td>
<td>December 15, 2017</td>
<td>133,637</td>
<td>5.96</td>
<td>—</td>
</tr>
<tr>
<td>1,050.00</td>
<td>September 21, 2018</td>
<td>33,226</td>
<td>6.73</td>
<td>—</td>
</tr>
<tr>
<td>1,136.00</td>
<td>October 6, 2016</td>
<td>19,450</td>
<td>4.77</td>
<td>9,725</td>
</tr>
<tr>
<td>1,145.00</td>
<td>December 15, 2016</td>
<td>86,660</td>
<td>4.96</td>
<td>43,675</td>
</tr>
<tr>
<td>1,210.00</td>
<td>April 10, 2018</td>
<td>14,954</td>
<td>6.28</td>
<td>—</td>
</tr>
<tr>
<td>1,233.00</td>
<td>June 9, 2016</td>
<td>14,438</td>
<td>4.44</td>
<td>6,713</td>
</tr>
<tr>
<td>1,402.00</td>
<td>March 28, 2017</td>
<td>8,736</td>
<td>5.24</td>
<td>—</td>
</tr>
<tr>
<td>1,408.00</td>
<td>June 8, 2017</td>
<td>5,224</td>
<td>5.44</td>
<td>—</td>
</tr>
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<td>1,424.00</td>
<td>February 10, 2017</td>
<td>1,606</td>
<td>5.11</td>
<td>478</td>
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<tr>
<td>1,427.00</td>
<td>March 29, 2017</td>
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<td>5.25</td>
<td>—</td>
</tr>
<tr>
<td>1,432.00</td>
<td>October 5, 2017</td>
<td>17,901</td>
<td>5.76</td>
<td>—</td>
</tr>
<tr>
<td>592.14</td>
<td></td>
<td>1,423,210</td>
<td>3.76</td>
<td>867,865</td>
</tr>
</tbody>
</table>

## 4.7—Share Capital

**Share Capital**

The share capital comprises the nominal amount of the parent company’s ordinary shares, each at a nominal value of DKK 1. All shares are fully paid.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

On December 31, 2019, the share capital of Genmab A/S comprised 65,074,502 shares of DKK 1 each with one vote. There are no restrictions related to the transferability of the shares. All shares are regarded as negotiable instruments and do not confer any special rights upon the holder, and no shareholder shall be under an obligation to allow his/her shares to be redeemed.

Until April 10, 2023, the Board of Directors is authorized to increase the nominal registered share capital on one or more occasions by up to nominally DKK 7,500,000 by subscription of new shares that shall have the same rights as the existing shares of Genmab. The capital increase can be made by cash or by non-cash payment and with or without pre-emption rights for the existing shareholders. Within the authorizations to increase the share capital by nominally DKK 7,500,000 shares, the Board of Directors may on one or more occasions and without pre-emption rights for the existing shareholders of Genmab issue up to nominally DKK 2,000,000 shares to employees of Genmab, and Genmab’s subsidiaries, by cash payment at market price or at a discount price as well as by the issue of bonus shares. No transferability restrictions or redemption obligations shall apply to the new shares, which shall be negotiable instruments in the name of the holder and registered in the name of the holder in Genmab’s Register of Shareholders. The new shares shall give the right to dividends and other rights as determined by the Board in its resolution to increase capital.

On July 17, 2019, the Board of Directors partly exercised the authority in accordance with the authorization described above, to increase the share capital without pre-emption rights for the existing shareholders by nominally DKK 2,850,000. Additionally, on July 17, 2019, the Board of Directors partly exercised the authority to increase the share capital without pre-emption rights for the existing shareholders by nominally DKK 427,500. The remaining amount of the authorization is thus DKK 4,222,500.

Until March 17, 2021, the Board of Directors is authorized by one or more issues to raise loans against bonds or other financial instruments up to a maximum amount of DKK 3 billion with a right for the lender to convert his/her claim to a maximum of nominally DKK 4,000,000 equivalent to 4,000,000 new shares (convertible loans). Convertible loans may be raised in DKK or the equivalent in foreign currency (including US dollar (USD) or euro (EUR)). The Board of Directors is also authorized to effect the consequential increase of the capital. Convertible loans may be raised against payment in cash or in other ways. The subscription of shares shall be with or without pre-emption rights for the shareholders and the convertible loans shall be offered at a subscription price and conversion price that in the aggregate at least corresponds to the market price of the shares at the time of the decision of the Board of Directors. The time limit for conversion may be fixed for a longer period than five (5) years after the raising of the convertible loan.

By decision of the general meeting on April 9, 2014, the Board of Directors was authorized to issue on one or more occasions warrants to subscribe Genmab A/S’ shares up to a nominal value of DKK 500,000. This authorization shall remain in force for a period ending on April 9, 2019. Further, by decision of the general meeting on March 28, 2017, the Board of Directors was authorized to issue on one or more occasions warrants to subscribe Genmab A/S’ shares up to a nominal value of DKK 500,000. This authorization shall remain in force for a period ending on March 28, 2022. Moreover, by decision of the General Meeting on March 29, 2019 the Board of Directors is authorized to issue on one or more occasions additional warrants to subscribe Genmab A/S’ shares up to a nominal value of DKK 500,000 to Genmab A/S’ employees as well as employees of Genmab A/S’ directly and indirectly owned subsidiaries, excluding executive management, and to make the related capital increases in cash up to a nominal value of DKK 500,000. This authorization shall remain in force for a period ending on March 28, 2024.

Subject to the rules in force at any time, the Board of Directors may reuse or reissue lapsed non-exercised warrants, if any, provided that the reuse or reissue occurs under the same terms and within the time limitations set out in the authorization to issue warrants.

As of December 31, 2019, a total of 346,337 warrants have been issued and a total of 9,988 warrants have been reissued under the March 28, 2017 authorization, and a total of 283,282 warrants have been issued and a total of 76 warrants have been reissued under the March 29, 2019 authorization. A total of 370,381 warrants remain available for issue and a total of 7,883 warrants remain available for reissue as of December 31, 2019.

By decision of the general meeting on March 17, 2016, the Board of Directors was authorized to repurchase Genmab A/S’ shares up to a nominal value of DKK 500,000 (500,000 shares). This authorization shall remain in force
for a period ending on March 17, 2021. In addition, by decision of the general meeting on March 29, 2019, the Board of Directors was authorized to repurchase Genmab A/S’ shares up to a nominal value of DKK 500,000 (500,000 shares). This authorization shall remain in force for a period ending on March 28, 2024.

As of December 31, 2019, a total of 225,000 shares, with a nominal value of DKK 225,000, have been repurchased under the March 17, 2016 authorization. A total of 775,000 shares, with a nominal value of DKK 775,000, remain available to repurchase as of December 31, 2019.

**Share Premium**

The share premium reserve is comprised of the amount received, attributable to shareholders’ equity, in excess of the nominal amount of the shares issued at the parent company’s offerings, reduced by any external expenses directly attributable to the offerings. The share premium reserve can be distributed.

**Changes in Share Capital During 2013 to 2019**

The share capital of DKK 65 million at December 31, 2019 is divided into 65,074,502 shares at a nominal value of DKK 1 each.

<table>
<thead>
<tr>
<th></th>
<th>Number of shares</th>
<th>Share capital (DKK million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 31, 2013</td>
<td>51,755,722</td>
<td>51.8</td>
</tr>
<tr>
<td>Shares issued for cash</td>
<td>4,600,000</td>
<td>4.6</td>
</tr>
<tr>
<td>Exercise of warrants</td>
<td>611,697</td>
<td>0.6</td>
</tr>
<tr>
<td>December 31, 2014</td>
<td>56,967,419</td>
<td>57.0</td>
</tr>
<tr>
<td>Exercise of warrants</td>
<td>2,563,844</td>
<td>2.6</td>
</tr>
<tr>
<td>December 31, 2015</td>
<td>59,531,263</td>
<td>59.6</td>
</tr>
<tr>
<td>Exercise of warrants</td>
<td>818,793</td>
<td>0.8</td>
</tr>
<tr>
<td>December 31, 2016</td>
<td>60,350,056</td>
<td>60.4</td>
</tr>
<tr>
<td>Exercise of warrants</td>
<td>835,618</td>
<td>0.8</td>
</tr>
<tr>
<td>December 31, 2017</td>
<td>61,185,674</td>
<td>61.2</td>
</tr>
<tr>
<td>Exercise of warrants</td>
<td>311,897</td>
<td>0.3</td>
</tr>
<tr>
<td>December 31, 2018</td>
<td>61,497,571</td>
<td>61.5</td>
</tr>
<tr>
<td>Shares issued for cash</td>
<td>3,277,500</td>
<td>3.3</td>
</tr>
<tr>
<td>Exercise of warrants</td>
<td>299,431</td>
<td>0.3</td>
</tr>
<tr>
<td>December 31, 2019</td>
<td>65,074,502</td>
<td>65.1</td>
</tr>
</tbody>
</table>

On July 22, 2019, gross proceeds from the issuance of new shares amounted to $506 million (DKK 3,368 million) with a corresponding increase in share capital of 2,850,000 ordinary shares or 28,500,000 ADSs. The underwriters exercised in full their option to purchase an additional 427,500 ordinary shares or 4,275,000 ADSs bringing the total shares issued to 3,277,500 and total gross proceeds of the offering to $582 million (DKK 3,873 million), which was completed on July 23, 2019.

During 2019, 299,431 new shares were subscribed at a price of DKK 31.75 to DKK 1,424.00 in connection with the exercise of warrants under Genmab’s warrant program.
During 2018, 311,897 new shares were subscribed at a price of DKK 40.41 to DKK 1,233.00 in connection with the exercise of warrants under Genmab’s warrant program.

During 2017, 835,618 new shares were subscribed at a price of DKK 31.75 to DKK 1,233.00 in connection with the exercise of warrants under Genmab’s warrant program.

During 2016, 818,793 new shares were subscribed at a price of DKK 31.75 to DKK 636.50 in connection with the exercise of warrants under Genmab’s warrant program.

During 2015, 2,563,844 new shares were subscribed at a price of DKK 26.75 to DKK 364.00 in connection with the exercise of warrants under Genmab’s warrant program.

During 2014, 611,697 new shares were subscribed at a price of DKK 26.75 to DKK 234.00 in connection with the exercise of warrants under Genmab’s warrant program.

On January 24, 2014 Genmab completed a private placement with the issuance of 4,600,000 new shares.

### Treasury Shares

<table>
<thead>
<tr>
<th>Shareholding at December 31, 2016</th>
<th>Number of shares</th>
<th>Share capital (DKK million)</th>
<th>Proportion of share capital %</th>
<th>Cost (DKK million)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>100,000</td>
<td>0.10</td>
<td>0.2</td>
<td>118</td>
</tr>
<tr>
<td>Purchase of treasury shares</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shareholding at December 31, 2017</td>
<td>100,000</td>
<td>0.1</td>
<td>0.2</td>
<td>118</td>
</tr>
<tr>
<td>Purchase of treasury shares</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shares used for funding RSU program</td>
<td>125,000</td>
<td>0.1</td>
<td>0.2</td>
<td>146</td>
</tr>
<tr>
<td></td>
<td>(47,450)</td>
<td></td>
<td>(0.1)</td>
<td>(56)</td>
</tr>
<tr>
<td>Shareholding at December 31, 2018</td>
<td>177,550</td>
<td>0.2</td>
<td>0.3</td>
<td>208</td>
</tr>
<tr>
<td>Shares used for funding RSU program</td>
<td>(13,629)</td>
<td></td>
<td></td>
<td>(16)</td>
</tr>
<tr>
<td>Shareholding at December 31, 2019</td>
<td>163,921</td>
<td>0.2</td>
<td>0.3</td>
<td>192</td>
</tr>
</tbody>
</table>

Genmab has two authorizations to repurchase shares as of December 31, 2019. The first authorization, granted on March 17, 2016, authorizes the Board of Directors to repurchase up to a total of 500,000 shares (with a nominal value of DKK 500,000) and shall lapse on March 17, 2021. The second authorization, granted on March 29, 2019, authorizes the Board of Directors to repurchase up to an additional 500,000 shares (with a nominal value of DKK 500,000) and shall lapse on March 28, 2024. The authorizations are intended to cover obligations in relation to the RSU program and reduce the dilution effect of share capital increases resulting from future exercises of warrants.

During 2018, Genmab acquired 125,000 of its own shares, approximately 0.2% of share capital, to cover its obligations under the RSU program. The total amount paid to acquire the shares, including directly attributable costs, was DKK 146 million and has been recognized as a deduction to shareholders’ equity. These shares are classified as treasury shares and are presented within retained earnings as of December 31, 2019 and 2018. The shares were acquired in accordance with the authorization granted by the Annual General Meeting in March 2016. There were no acquisitions of treasury shares in 2019 or 2017.
SECTION 5—OTHER DISCLOSURES

5.1—Remuneration of the Board of Directors and Executive Management

The total remuneration of the Board of Directors and Executive Management is as follows:

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>2019</th>
<th>2018</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wages and salaries</td>
<td>42</td>
<td>34</td>
<td>39</td>
</tr>
<tr>
<td>Share-based compensation expenses</td>
<td>38</td>
<td>32</td>
<td>28</td>
</tr>
<tr>
<td>Defined contribution plans</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>81</strong></td>
<td><strong>67</strong></td>
<td><strong>68</strong></td>
</tr>
</tbody>
</table>

The remuneration packages for the Board of Directors and Executive Management are described below in further detail. The remuneration packages are denominated in DKK, EUR, or USD. The Compensation Committee performs an annual review of the remuneration packages. All incentive and variable remuneration shall be considered and adopted at the company’s annual general meeting.

In accordance with Genmab’s accounting policies, described in note 2.3, share-based compensation is included in the income statement and reported in the remuneration tables in this note. Such share-based compensation expense represents a calculated fair value of instruments granted and does not represent actual cash compensation received by the board members or executives. Please refer to note 4.6 for additional information regarding Genmab’s share-based compensation programs.

*Remuneration to the Board of Directors*

**Annual board base fee and fees for committee work**

*Purpose and link to strategy:* Ensure Genmab can attract qualified individuals to the Board of Directors.

*Opportunity:* Basic board fee of DKK 400,000—Deputy Chairman receives double and Chairman receives triple; Audit and Finance Committee membership basic fee of DKK 100,000 with Chairman receiving fee of DKK 150,000 plus a fee per meeting of DKK 10,000; Compensation Committee membership basic fee of DKK 80,000 with Chairman receiving fee of DKK 120,000 plus a fee per meeting of DKK 10,000; Nominating and Corporate Governance Committee membership basic fee of DKK 70,000 with Chairman receiving fee of DKK 100,000 plus a fee per meeting of DKK 10,000; and Scientific Committee membership basic fee of DKK 100,000 with Chairman receiving fee of DKK 130,000 plus a fee per meeting of DKK 10,000.

*Changes compared to 2018 and 2017:* None.

*Share-Based Compensation*

*Purpose and link to strategy:* Share-based instruments constitute a common part of the remuneration paid to members of the Board of Directors in competing international biotech and biopharmaceutical companies. The use of share-based instruments enables Genmab to remain competitive in the international market and to be able to attract and retain qualified members of the Board of Directors on a continuous basis.

*Performance metrics:* To ensure the Board of Directors’ independence and supervisory function, vesting of restricted stock units (RSUs) granted to members of the Board of Directors shall not be subject to fulfilment of forward-looking performance criteria.

*Opportunity:* A new member of the Board of Directors may be granted RSUs upon election corresponding to a value (at the time of grant) of up to four (4) times the fixed annual base fee.
In addition the members of the Board of Directors may be granted RSUs corresponding to a value (at the time of grant) of up to one (1) times the fixed annual base fee, for the Chairman the value shall be of up to two (2) times the fixed annual base fee and for the Deputy Chairman the value shall be of up to one point five (1.5) times the fixed annual base fee on an annual basis.

The share-based compensation expense for 2019 of DKK 5 million shown below includes the amortization of the non-cash share-based compensation expense relating to warrants granted before 2014 and RSUs granted over several periods. Following an amendment of the guidelines for incentive-based remuneration of the Board of Directors and Executive Management by the general meeting in 2014, share-based compensation granted to board members may only be in the form of RSUs. Please refer to note 4.6 for additional information regarding the “Number of RSUs held” and “Number of warrants held” overviews.

Changes compared to 2018 and 2017: None.

Remuneration to the Executive Management

Base Salary

Purpose and link to strategy: Reflect the individual’s skills and experience, role and responsibilities.

Performance metrics: Any increase based both on individual and company performance as well as benchmark analysis.

Opportunity: Fixed.

Changes compared to 2018 and 2017: Effective, January 1, 2019, base salary increased by 3% for the CEO, CFO, and 10% for the CDO in local currency, compared to 3% for the CEO and 3% for CFO, effective January 1, 2018 and 2017 and 3% for the CDO effective July 1, 2018 and 2017.

Pension and other benefits

Purpose and link to strategy: Provide a framework to save for retirement; provide customary benefits including car and telephone allowance; provide sign-on bonus for new Executive Management; and provide tax equalization payment for executive management.

Performance metrics: None

Opportunity: With respect to providing a framework to save for retirement, executive management is given a fixed amount or percentage of base salary. With respect to providing a sign-on bonus for new Executive Management, a new
member of the Executive Management may receive a sign-on payment upon engagement subject to certain claw-back provisions. With respect to providing tax equalization payment for Executive Management, the CEO received €0.5 million and CFO received $0.1 million payments for tax equalization for the higher tax rate in Denmark versus their resident countries of the Netherlands and the United States.

Changes compared to 2018 and 2017: CEO received a tax equalization payment in 2019

**Annual Cash Bonus**

**Purpose and link to strategy:** Incentivize executives to achieve key objectives on an annual basis

**Performance metrics:** Achievement of predetermined and well-defined annual milestones

**Opportunity:** Maximum 60% to 100% of annual gross salaries dependent on their position.

Extraordinary bonuses are awarded up to a maximum up to 15% of their annual gross salaries, based on the occurrence of certain special events or achievements. In 2019, the current Executive Management team received a total cash bonus of DKK 15 million (2018: DKK 11 million).

Changes compared to 2018 and 2017: None.

**Share-Based Compensation**

**Purpose and link to strategy:** Incentivize executives over the longer term aligned to strategy and creation of shareholder value.

**Performance metrics:** Linked to Genmab’s financial and strategic priorities as an incentive to increase the future value of the company but also in recognition of past contributions and accomplishments.

**Opportunity:** As a main rule, the members of the executive management may on an annual basis be granted share-based instruments corresponding to a value (at the time of grant) of up to two (2) times the member’s annual base salary, calculated before any pension contribution and bonus payment, in the year of grant. However, in exceptional cases, international, and in particular US based, members of the executive management, may on an annual basis be granted share-based instruments corresponding to a value (at the time of grant) of up to four (4) times the member’s annual base salary, calculated before any pension contribution and bonus payment, in the year of grant.

Notwithstanding the above, in no event may the value (at the time of grant) of share-based instruments granted to a member of the executive management on an annual basis exceed DKK 25 million. Annual grant of share-based instruments to members of the executive management is used primarily as an incentive to increase the future value of the company but also in recognition of past contributions and accomplishments.

Furthermore, a new member of the executive management may be granted share-based instruments upon engagement or promotion. The share-based instruments granted to the members of the executive management may be in the form of restricted stock units or a combination of restricted stock units and warrants (options to subscribe for shares in the company). If members of the executive management are granted a combination of restricted stock units and warrants, the proportional value of the warrants may not exceed 25% of the total value (at the time of grant). Vesting of restricted stock units and warrants granted to members of the executive management may be subject to fulfillment of forward-looking performance criteria as determined by the board of directors.

The share-based compensation expense for 2019 of DKK 33 million shown below includes the amortization of the non-cash share-based compensation expense relating to warrants & RSUs granted over several periods. In 2019, 25,793 RSUs were granted to the Executive Management, with a total fair value of DKK 42 million (2018: 50,464 warrants and
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

18,020 RSUs, with a fair value of DKK 37 million). Please refer to note 4.6 for additional information regarding the “Number of RSUs held” and “Number of warrants held” overviews.

Changes compared to 2018 and 2017: Two changes related to Executive Management’s shared-based compensation in 2019 compared to 2018: (1) the members of the executive management may on an annual basis be granted share-based instruments corresponding to a value (at the time of grant) of up to four times the member’s annual base salary (2018: two times the member’s annual salary), and (2) the proportional value of the warrants may not exceed 25% of the total value at the time of grant (2018: 50%). None in 2017.

Shareholding requirement for members of Executive Management

Purpose and link to strategy: Incentivize executives over the longer term aligned to strategy and creation of shareholder value

Performance metrics: None.

Opportunity: Each member of the Executive Management shall be required to hold a number of Genmab A/S shares corresponding to the value of such member’s annual base salary:

· The number of shares shall be fixed at commencement of the employment as, or promotion to, member of the Executive Management

· May be built up over a five (5) year period from the date of employment or promotion

· For current members of the Executive Management, the number of shares is finally fixed at the date of adoption of these Remuneration Principles (April 10, 2018)

· The Board of Directors may diverge from this shareholding requirement

The Company shall be entitled to reclaim in full or in part variable components of remuneration paid to the member of the Executive Management on the basis of data, which proved to be misstated.

Warrants granted to the members of the Executive Management will be subject to an additional two (2) year lock-in period upon vesting.

F-50

<table>
<thead>
<tr>
<th></th>
<th>Defined Contribution Plans</th>
<th>Other Benefits</th>
<th>Annual Cash Bonus</th>
<th>Share-Based compensation expenses</th>
<th>Total</th>
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<td><strong>Total</strong></td>
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<td>10.6</td>
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<td>55.9</td>
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<th>Total</th>
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<td>56.1</td>
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</table>

Please refer to the section “Senior Management” in the Management section for additional information regarding the Executive Management.

**Severance Payments:**

In the event Genmab terminates the service agreements with each member of the Executive Management team without cause, Genmab is obliged to pay the Executive Officer his existing salary for one or two years after the end of the one year notice period. However, in the event of termination by Genmab (unless for cause) or by a member of Executive Management as a result of a change of control of Genmab, Genmab is obliged to pay a member of the Executive Management a compensation equal to his/her existing total salary (including benefits) for up to two years in addition to the notice period. It furthermore follows from Genmab’s warrant and RSU programs, that in certain “good leaver” situations outstanding warrants and RSUs awarded under these programs will continue to vest which could potentially make the termination payments exceed two years of remuneration. In case of the termination of the service agreements of the Executive Management without cause, the total impact on our financial position is estimated to approximately DKK 46 million as of December 31, 2019, compared to DKK 42 million in 2018 and DKK 40 million in 2017. Please refer to note 5.5 for additional information regarding the potential impact in the event of change of control of Genmab.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Number of Ordinary Shares Owned and Share-Based Instruments Held

<table>
<thead>
<tr>
<th>Number of ordinary shares owned</th>
<th>December 31, 2018</th>
<th>Acquired</th>
<th>Sold</th>
<th>Transfers</th>
<th>December 31, 2019</th>
<th>Market value (DKK million)*</th>
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<td><strong>Board of Directors</strong></td>
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<td>478 (478)</td>
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<td>Rolf Hoffmann</td>
<td>1,050</td>
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<td>—</td>
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<td></td>
<td><strong>42,087</strong></td>
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<td><strong>50,690</strong></td>
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<tr>
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<td><strong>799,435</strong></td>
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*Market value is based on the closing price of the parent company's shares on the NASDAQ Copenhagen A/S at the balance sheet date or the last trading day prior to the balance sheet date.

** Stepped down from the Board of Directors at the Annual General Meeting in March 2019.

<table>
<thead>
<tr>
<th>Number of ordinary shares owned</th>
<th>December 31, 2017</th>
<th>Acquired</th>
<th>Sold</th>
<th>Transfers</th>
<th>December 31, 2018</th>
<th>Market value (DKK million)*</th>
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<tr>
<td><strong>Board of Directors</strong></td>
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<tr>
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<tr>
<td>Rick Hibbert</td>
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</tr>
<tr>
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*Market value is based on the closing price of the parent company's shares on the NASDAQ Copenhagen A/S at the balance sheet date or the last trading day prior to the balance sheet date.
### Board of Directors

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<th>Name</th>
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<th>Sold 2016</th>
<th>Transfers 2016</th>
<th>Acquired 2017</th>
<th>Sold 2017</th>
<th>Transfers 2017</th>
<th>Market value (DKK million)*</th>
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<tr>
<td>Mats Pettersson</td>
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<tr>
<td>Rick Hibbert</td>
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<td><strong>Total</strong></td>
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### Executive Management

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<td>658.6</td>
<td>676.6</td>
</tr>
<tr>
<td>David A. Eatwell</td>
<td>2,500</td>
<td>15,000</td>
<td>—</td>
<td>17,500</td>
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<td>—</td>
<td>18.0</td>
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<tr>
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<td>676.6</td>
<td>695.8</td>
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*Market value is based on the closing price of the parent company's shares on the NASDAQ Copenhagen A/S at the balance sheet date or the last trading day prior to the balance sheet date.

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### Notes

- Each employee-elected Board Member was granted warrants as an employee of Genmab A/S or its subsidiaries.
- Stepped down from the Board of Directors at the Annual General Meeting in March 2019.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

<table>
<thead>
<tr>
<th>Number of warrants held</th>
<th>December 31, 2017</th>
<th>Granted</th>
<th>Exercised</th>
<th>Expired</th>
<th>Transfers</th>
<th>December 31, 2018</th>
<th>Black – Scholes value warrants granted in 2018 (DKK million)</th>
<th>Weighted average exercise price outstanding warrants</th>
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<td>Anders Gersel Pedersen</td>
<td>32,750</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>29,000</td>
<td>116.83</td>
<td></td>
</tr>
<tr>
<td>Pernille Erenbjerg</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Paolo Paolletti</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Rolf Hoffmann</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Deirdre F. Connelly</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Peter Storm Kristensen</td>
<td>2,515</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>2,515</td>
<td>663.38</td>
<td></td>
</tr>
<tr>
<td>Rick Hibbert*</td>
<td>1,451</td>
<td>350</td>
<td>(925)</td>
<td>—</td>
<td>—</td>
<td>876</td>
<td>0.1</td>
<td>998.81</td>
</tr>
<tr>
<td>Daniel J. Bruno*</td>
<td>16,776</td>
<td>2,811</td>
<td>(3,750)</td>
<td>—</td>
<td>—</td>
<td>15,437</td>
<td>1.0</td>
<td>922.01</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>92,242</td>
<td>3,161</td>
<td>(20,925)</td>
<td>—</td>
<td>—</td>
<td>74,478</td>
<td>1.1</td>
<td>348.74</td>
</tr>
</tbody>
</table>

| **Executive Management**|                   |         |           |         |           |                   |                                                 |                                  |
| Jan van de Winkel       | 164,892           | 23,266  | (80,000)  | —       | —         | 88,086            | 8.5                                            | 748.36                           |
| David A. Eatwell        | 373,056           | 12,145  | (50,000)  | —       | —         | 335,201           | 4.4                                            | 215.41                           |
| Judith Klimovsky       | 21,879            | 15,053  | (10,000)  | —       | —         | 16,932            | 5.5                                            | 1,118.99                         |
| **Total**               | 559,737           | 50,464  | (130,000) | —       | —         | 480,201           | 18.5                                           | 404.84                           |

| **Total**               | 651,979           | 53,625  | (150,925) | —       | —         | 554,679           | 19.6                                           | 397.31                           |

* Each employee-elected Board Member was granted warrants as an employee of Genmab A/S or its subsidiaries.

<table>
<thead>
<tr>
<th>Number of warrants held</th>
<th>December 31, 2016</th>
<th>Granted</th>
<th>Exercised</th>
<th>Expired</th>
<th>Transfers</th>
<th>December 31, 2017</th>
<th>Black – Scholes value warrants granted in 2017 (DKK million)</th>
<th>Weighted average exercise price outstanding warrants</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Board of Directors</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mats Pettersson</td>
<td>38,750</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>38,750</td>
<td>187.96</td>
<td></td>
</tr>
<tr>
<td>Anders Gersel Pedersen</td>
<td>54,000</td>
<td>—</td>
<td>(21,250)</td>
<td>—</td>
<td>—</td>
<td>32,750</td>
<td>108.80</td>
<td></td>
</tr>
<tr>
<td>Burton G. Malkiel</td>
<td>14,500</td>
<td>—</td>
<td>(4,500)</td>
<td>(10,000)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Pernille Erenbjerg</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Paolo Paolletti</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Rolf Hoffmann</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Deirdre F. Connelly</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Peter Storm Kristensen</td>
<td>1,917</td>
<td>598</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>2,515</td>
<td>0.2</td>
<td>663.38</td>
</tr>
<tr>
<td>Rick Hibbert*</td>
<td>1,962</td>
<td>239</td>
<td>(750)</td>
<td>—</td>
<td>—</td>
<td>1,451</td>
<td>0.1</td>
<td>531.65</td>
</tr>
<tr>
<td>Daniel J. Bruno*</td>
<td>18,613</td>
<td>3,286</td>
<td>(5,125)</td>
<td>—</td>
<td>—</td>
<td>16,776</td>
<td>1.1</td>
<td>799.19</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>129,742</td>
<td>4,125</td>
<td>(31,625)</td>
<td>(10,000)</td>
<td>—</td>
<td>92,242</td>
<td>1.4</td>
<td>289.39</td>
</tr>
</tbody>
</table>

| **Executive Management**|                   |         |           |         |           |                   |                                                 |                                  |
| Jan van de Winkel       | 392,841           | 24,461  | (252,500) | —       | —         | 164,802           | 8.2                                            | 455.68                           |
| David A. Eatwell        | 484,577           | 13,479  | (125,000) | —       | —         | 337,056           | 4.6                                            | 183.50                           |
| Judith Klimovsky       | —                 | 21,879  | —         | —       | —         | 21,879            | 8.5                                            | 1,183.65                         |
| **Total**               | 877,418           | 59,819  | (377,500) | —       | —         | 559,737           | 21.3                                           | 302.73                           |

| **Total**               | 1,067,160         | 63,944  | (409,125) | (10,000)| —         | 651,979           | 22.7                                           | 300.84                           |
### Board of Directors

<table>
<thead>
<tr>
<th>Name</th>
<th>December 31, 2017</th>
<th>Granted</th>
<th>Settled</th>
<th>Transfers</th>
<th>December 31, 2018</th>
<th>Granted</th>
<th>Settled</th>
<th>Transfers</th>
<th>December 31, 2019</th>
<th>Fair value RSUs granted in 2018 (DKK million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mats Pettersson</td>
<td>4,818</td>
<td>780</td>
<td>(2,300)</td>
<td>—</td>
<td>3,298</td>
<td>495</td>
<td>(957)</td>
<td>—</td>
<td>2,836</td>
<td>0.8</td>
</tr>
<tr>
<td>Anders Gersel Pedersen</td>
<td>3,613</td>
<td>390</td>
<td>(1,725)</td>
<td>—</td>
<td>2,278</td>
<td>247</td>
<td>(718)</td>
<td>—</td>
<td>1,807</td>
<td>0.4</td>
</tr>
<tr>
<td>Pernille Erenbjerg</td>
<td>3,959</td>
<td>390</td>
<td>(2,700)</td>
<td>—</td>
<td>1,649</td>
<td>247</td>
<td>(478)</td>
<td>—</td>
<td>1,418</td>
<td>0.4</td>
</tr>
<tr>
<td>Paolo Paolletti</td>
<td>3,959</td>
<td>390</td>
<td>(2,700)</td>
<td>—</td>
<td>1,649</td>
<td>247</td>
<td>(478)</td>
<td>—</td>
<td>1,418</td>
<td>0.4</td>
</tr>
<tr>
<td>Rolf Hoffmann</td>
<td>1,509</td>
<td>390</td>
<td>—</td>
<td>—</td>
<td>1,899</td>
<td>247</td>
<td>(478)</td>
<td>—</td>
<td>2,146</td>
<td>0.4</td>
</tr>
<tr>
<td>Deirdre P. Connelly</td>
<td>1,509</td>
<td>585</td>
<td>—</td>
<td>—</td>
<td>2,094</td>
<td>371</td>
<td>—</td>
<td>—</td>
<td>2,465</td>
<td>0.6</td>
</tr>
<tr>
<td>Peter Storm Kristensen*</td>
<td>1,091</td>
<td>390</td>
<td>(1,439)</td>
<td>—</td>
<td>1,481</td>
<td>351</td>
<td>—</td>
<td>—</td>
<td>1,832</td>
<td>0.6</td>
</tr>
<tr>
<td>Rick Hibbert*</td>
<td>2,946</td>
<td>1,394</td>
<td>—</td>
<td>—</td>
<td>4,340</td>
<td>1,157</td>
<td>—</td>
<td>—</td>
<td>5,497</td>
<td>1.8</td>
</tr>
<tr>
<td>Mijke Zachariasse*</td>
<td>1,439</td>
<td>346</td>
<td>188</td>
<td>—</td>
<td>4,340</td>
<td>1,157</td>
<td>—</td>
<td>—</td>
<td>5,497</td>
<td>1.8</td>
</tr>
<tr>
<td>Daniel J. Bruno*</td>
<td>66,152</td>
<td>29,501</td>
<td>(21,711)</td>
<td>(1,251)</td>
<td>86,279</td>
<td>25,793</td>
<td>(19,080)</td>
<td>(1,251)</td>
<td>72,818</td>
<td>47.6</td>
</tr>
</tbody>
</table>

* Each employee-elected Board Member was granted 390 RSUs as a member of the Board of Directors. The remaining RSUs were granted as an employee of Genmab A/S or its subsidiaries.

### Executive Management

<table>
<thead>
<tr>
<th>Name</th>
<th>December 31, 2017</th>
<th>Granted</th>
<th>Settled</th>
<th>Transfers</th>
<th>December 31, 2018</th>
<th>Granted</th>
<th>Settled</th>
<th>Transfers</th>
<th>December 31, 2019</th>
<th>Fair value RSUs granted in 2018 (DKK million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan van de Winkel</td>
<td>47,597</td>
<td>8,308</td>
<td>(22,400)</td>
<td>—</td>
<td>33,505</td>
<td>15,479</td>
<td>(11,387)</td>
<td>—</td>
<td>22,893</td>
<td>16.7</td>
</tr>
<tr>
<td>David A. Eatwell</td>
<td>7,204</td>
<td>5,375</td>
<td>(13,325)</td>
<td>—</td>
<td>12,579</td>
<td>10,314</td>
<td>(7,693)</td>
<td>—</td>
<td>22,893</td>
<td>16.7</td>
</tr>
<tr>
<td>Judith Klimovsky</td>
<td>2,094</td>
<td>371</td>
<td>—</td>
<td>—</td>
<td>2,094</td>
<td>371</td>
<td>—</td>
<td>—</td>
<td>2,465</td>
<td>0.6</td>
</tr>
</tbody>
</table>

* Each employee-elected Board Member was granted 247 RSUs as a member of the Board of Directors. The remaining RSUs were granted as an employee of Genmab A/S or its subsidiaries.

F-55
### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### Fair value

<table>
<thead>
<tr>
<th>Number of RSUs held</th>
<th>December 31, 2016</th>
<th>Granted</th>
<th>Settled</th>
<th>Transfers</th>
<th>December 31, 2017</th>
<th>Fair value RSUs granted in 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(DKK million)</td>
</tr>
<tr>
<td><strong>Board of Directors</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mats Pettersson</td>
<td>4,043</td>
<td>775</td>
<td>—</td>
<td>—</td>
<td>4,818</td>
<td>0.8</td>
</tr>
<tr>
<td>Anders Gersel Pedersen</td>
<td>3,032</td>
<td>581</td>
<td>—</td>
<td>—</td>
<td>3,613</td>
<td>0.6</td>
</tr>
<tr>
<td>Burton G. Malkiel</td>
<td>2,021</td>
<td>—</td>
<td>—</td>
<td>(2,021)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Pernille Erenbjerg</td>
<td>3,571</td>
<td>388</td>
<td>—</td>
<td>—</td>
<td>3,959</td>
<td>0.4</td>
</tr>
<tr>
<td>Paolo Paoletti</td>
<td>3,571</td>
<td>388</td>
<td>—</td>
<td>—</td>
<td>3,959</td>
<td>0.4</td>
</tr>
<tr>
<td>Rolf Hoffmann</td>
<td>—</td>
<td>1,509</td>
<td>—</td>
<td>—</td>
<td>1,509</td>
<td>2.0</td>
</tr>
<tr>
<td>Deirdre P. Connelly</td>
<td>—</td>
<td>1,509</td>
<td>—</td>
<td>—</td>
<td>1,509</td>
<td>2.0</td>
</tr>
<tr>
<td>Peter Storm Kristensen*</td>
<td>508</td>
<td>503</td>
<td>—</td>
<td>—</td>
<td>1,091</td>
<td>0.6</td>
</tr>
<tr>
<td>Rick Hibbert*</td>
<td>458</td>
<td>466</td>
<td>—</td>
<td>—</td>
<td>924</td>
<td>0.5</td>
</tr>
<tr>
<td>Daniel J. Bruno*</td>
<td>1,484</td>
<td>1,462</td>
<td>—</td>
<td>—</td>
<td>2,946</td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td><strong>18,688</strong></td>
<td><strong>7,661</strong></td>
<td>—</td>
<td>(2,021)</td>
<td><strong>24,328</strong></td>
<td><strong>8.8</strong></td>
</tr>
<tr>
<td><strong>Executive Management</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jan van de Winkel</td>
<td>39,606</td>
<td>7,991</td>
<td>—</td>
<td>—</td>
<td>47,597</td>
<td>8.2</td>
</tr>
<tr>
<td>David A. Eatwell</td>
<td>24,652</td>
<td>4,404</td>
<td>—</td>
<td>—</td>
<td>29,056</td>
<td>4.5</td>
</tr>
<tr>
<td>Judith Klimovsky</td>
<td>—</td>
<td>7,204</td>
<td>—</td>
<td>—</td>
<td>7,204</td>
<td>8.5</td>
</tr>
<tr>
<td></td>
<td><strong>64,258</strong></td>
<td><strong>19,599</strong></td>
<td>—</td>
<td>—</td>
<td><strong>83,857</strong></td>
<td><strong>21.3</strong></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>82,946</strong></td>
<td><strong>27,260</strong></td>
<td>—</td>
<td>(2,021)</td>
<td><strong>108,185</strong></td>
<td><strong>30.1</strong></td>
</tr>
</tbody>
</table>

* Each employee-elected Board Member was granted 388 RSUs as a member of the Board of Directors. The remaining RSUs were granted as an employee of Genmab A/S or its subsidiaries.

Following Genmab A/S’ Annual General Meeting on March 29, 2019, the Board of Directors is comprised of five independent directors, one non-independent director, and three employee-elected directors. Mats Pettersson, Dr. Anders Gersel Pedersen, Deirdre P. Connelly, Pernille Erenbjerg, Rolf Hoffmann and Dr. Paolo Paoletti were re-elected to the Board of Directors for a one year period. Peter Storm Kristensen, Mijke Zachariasse and Dan Bruno were elected to the Board of Directors by the employees for a three year period. Dr. Rick Hibbert stepped down from the Board of Directors. The reclassification of the employee elected board members’ shares and share-based instruments is shown in the transferred column of the tables above. The Board of Directors convened and constituted itself with Mats Pettersson as Chairman and Deirdre P. Connelly as Deputy Chairman.

Other than the remuneration to the Board of Directors and the Executive Management and the transactions detailed in the tables above, no other significant transactions with the Board of Directors or the Executive Management took place during 2019.

5.2—Related Party Disclosures

Genmab’s related parties are the parent company’s Board of Directors, Executive Management, and close members of the family of these persons.

**Transactions with the Board of Directors and Executive Management**

Genmab has not granted any loans, guarantees, or other commitments to or on behalf of any of the members of the Board of Directors or Executive Management. Other than the remuneration and other transactions relating to the Board of Directors and Executive Management described in note 5.1, no other significant transactions have taken place with the Board of Directors or the Executive Management during 2019, 2018 or 2017.
5.3—Company Overview

Genmab A/S (parent company) holds investments either directly or indirectly in the following subsidiaries:

<table>
<thead>
<tr>
<th>Name</th>
<th>Domicile</th>
<th>Ownership and votes 2019</th>
<th>Ownership and votes 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genmab B.V.</td>
<td>Utrecht, the Netherlands</td>
<td>100 %</td>
<td>100 %</td>
</tr>
<tr>
<td>Genmab Holding B.V.</td>
<td>Utrecht, the Netherlands</td>
<td>100 %</td>
<td>100 %</td>
</tr>
<tr>
<td>Genmab US, Inc.</td>
<td>New Jersey, USA</td>
<td>100 %</td>
<td>100 %</td>
</tr>
<tr>
<td>Genmab K.K.</td>
<td>Tokyo, Japan</td>
<td>100 %</td>
<td>—</td>
</tr>
</tbody>
</table>

5.4—Commitments

Guarantees and Collaterals

There were no bank guarantees as of December 31, 2019 or 2018.

Other Purchase Obligations

The group has entered into a number of agreements primarily related to research and development activities. These short term contractual obligations amounted to DKK 564 million as of December 31, 2019, all of which is due in less than two years (2018: DKK 787 million).

We also have certain contingent commitments under our license and collaboration agreements that may become due for future payments. As of December 31, 2019, these contingent commitments amounted to approximately DKK 9,520 million in potential future development, regulatory and commercial milestone payments to third parties under license and collaboration agreements for our pre-clinical and clinical-stage development programs as compared to DKK 5,595 million as of December 31, 2018. These milestone payments generally become due and payable only upon the achievement of certain development, clinical, regulatory or commercial milestones. The events triggering such payments or obligations have not yet occurred.

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.

5.5—Contingent Assets, Contingent Liabilities and Subsequent Events

Contingent Assets and Liabilities

License and Collaboration Agreements

We are entitled to potential milestone payments and royalties on successful commercialization of products developed under license and collaboration agreements with our partners. Since the size and timing of such payments are uncertain until the milestones are reached, the agreements may qualify as contingent assets. However, it is impossible to measure the value of such contingent assets, and, accordingly, no such assets have been recognized.

As part of the license and collaboration agreements that Genmab has entered into, once a product is developed and commercialized, Genmab may be required to make milestone and royalty payments. It is impossible to measure the value of such future payments, but Genmab expects to generate future income from such products which will exceed any milestone and royalty payments due, and accordingly no such liabilities have been recognized.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Derivative Financial Instruments

Genmab has entered into an International Swaps and Derivatives Association master agreement.

The master agreement with Genmab’s financial institution counterparty also includes a credit support annex which contains provisions that require Genmab to post collateral should the value of the derivative liabilities exceed DKK 50 million (2018: DKK 50 million). As of December 31, 2019 and 2018, Genmab has not been required to post any collateral. There were no outstanding receivables related to derivative financial instruments as of December 31, 2019 or 2018.

In addition, the agreement requires Genmab to maintain a cash position of DKK 258.5 million at all times or the counterparty has the right to terminate the agreement. Upon termination, the DKK 50 million (2018: DKK 50 million) threshold amount is no longer applicable and the value of the derivative liability, if any, could be due to the counterparty upon request.

Legal Matter – MorphoSys Patent Infringement Complaint

In April 2016, MorphoSys filed a complaint at the U.S. District Court of Delaware against Genmab and Janssen Biotech, Inc. for patent infringement based on activities relating to the manufacture, use and sale of DARZALEX in the United States, which was subsequently amended to include two additional MorphoSys patents. In addition, a further claim by Janssen and us that the three MorphoSys patents were unenforceable due to inequitable conduct by MorphoSys was included in the case. On January 25, 2019, the District Court ruled on summary judgment that the three MorphoSys patents were invalid for lack of enablement. MorphoSys had the opportunity to appeal the District Court’s decision. On January 31, 2019, MorphoSys dismissed its infringement claims against us and Janssen, and we and Janssen, in turn, dismissed our inequitable conduct claims against MorphoSys. As such, there will be no further proceedings in the case.

Change of Control

In the event of a change of control, change of control clauses are included in some of our collaboration, development and license agreements as well as in service agreements for certain employees.

Collaboration, Development and License Agreements

We have entered into collaboration, development and license agreements with external parties, which may be subject to renegotiation in case of a change of control event in Genmab A/S. However, any changes in the agreements are not expected to have significant influence on our financial position.

Service Agreements with Executive Management and Employees

The service agreements with each member of the Executive Management may be terminated by Genmab with no less than 12 months’ notice and by the member of the Executive Management with no less than six months’ notice. In the event of a change of control of Genmab, the termination notice due to the member of the Executive Management is extended to 24 months. In the event of termination by Genmab (unless for cause) or by a member of Executive Management as a result of a change of control of Genmab, Genmab is obliged to pay a member of Executive Management a compensation equal to his/her existing total salary (including benefits) for up to two years in addition to the notice period. In case of a change of control event and the termination of service agreements of the Executive Management, the total impact on our financial position is estimated to approximately DKK 106 million as of December 31, 2019 (2018: DKK 98 million).

In addition, Genmab has entered into service agreements with 22 (2018: 26) current employees according to which Genmab may become obliged to compensate the employees in connection with a change of control of Genmab. If Genmab as a result of a change of control terminates the service agreement without cause, or changes the working conditions to the detriment of the employee, the employee shall be entitled to terminate the employment relationship.
without further cause with one month’s notice in which case Genmab shall pay the employee a compensation equal to one-half, one or two times the employee’s existing annual salary (including benefits). In case of the change of control event and the termination of all 22 service agreements the total impact on our financial position is estimated to approximately DKK 75 million as of December 31, 2019 (2018: DKK 81 million). Please refer to note 4.6 for additional information regarding change of control clauses related to share-based instruments granted to the Executive Management and employees.

**Subsequent Events**

No events have occurred subsequent to the balance sheet date that could significantly affect the financial statements as of December 31, 2019.

**Accounting Policies**

**Contingent Assets and Liabilities**

Contingent assets and liabilities are assets and liabilities that arose from past events but whose existence will only be confirmed by the occurrence or non-occurrence of future events that are beyond Genmab’s control.

Contingent assets and liabilities are not to be recognized in the financial statements, but are disclosed in the notes.

**5.6—Fees to Auditors Appointed at the Annual General Meeting**

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>2019</th>
<th>2018</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>PricewaterhouseCoopers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Audit services</td>
<td>1.9</td>
<td>1.1</td>
<td>1.1</td>
</tr>
<tr>
<td>Audit-related services</td>
<td>2.3</td>
<td>0.1</td>
<td>0.4</td>
</tr>
<tr>
<td>Tax and VAT services</td>
<td>0.5</td>
<td>0.4</td>
<td>0.7</td>
</tr>
<tr>
<td>Other services</td>
<td>2.4</td>
<td>0.1</td>
<td>—</td>
</tr>
<tr>
<td>Total</td>
<td>7.1</td>
<td>1.7</td>
<td>2.2</td>
</tr>
</tbody>
</table>

Fees for other services than statutory audit of the financial statements provided by PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab amounted to DKK 5.2 million (DKK 0.6 million in 2018 and DKK 1.1 million in 2017). Other services than statutory audit of the financial statements comprise services relating to Genmab’s IPO on the Nasdaq in the U.S., tax and VAT compliance, agreed-upon procedures, opinions relating to grants, educational training and accounting advice.

**5.7—Adjustments to Cash Flow Statement**

<table>
<thead>
<tr>
<th>(DKK million)</th>
<th>Note</th>
<th>2019</th>
<th>2018</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjustments for non-cash transactions:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation, amortization and impairment</td>
<td>3.1, 3.2</td>
<td>139</td>
<td>88</td>
<td>70</td>
</tr>
<tr>
<td>Share-based compensation expenses</td>
<td>2.3, 4.6</td>
<td>147</td>
<td>91</td>
<td>76</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Total adjustments for non-cash transactions</td>
<td></td>
<td>291</td>
<td>179</td>
<td>146</td>
</tr>
<tr>
<td>Changes in working capital:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Receivables</td>
<td>(1,658)</td>
<td>(768)</td>
<td>270</td>
<td></td>
</tr>
<tr>
<td>Deferred income</td>
<td>—</td>
<td>—</td>
<td>(77)</td>
<td></td>
</tr>
<tr>
<td>Other payables</td>
<td>440</td>
<td>134</td>
<td>47</td>
<td></td>
</tr>
<tr>
<td>Total changes in working capital</td>
<td>(1,218)</td>
<td>(634)</td>
<td>240</td>
<td></td>
</tr>
</tbody>
</table>
5.8—Collaborations and Technology Licenses

Our Collaborations

We enter into collaborations with biotechnology and pharmaceutical companies to advance the development and commercialization of our product candidates and to supplement our internal pipeline. We seek collaborations that will allow us to retain significant future participation in product sales through either profit-sharing or royalties paid on net sales. Below is an overview of some of our collaborations that have had a significant impact or that we expect may in the near term have a significant impact on our financial results.

Collaboration with Janssen (Daratumumab/DARZALEX)

In August 2012, we entered into a global license, development, and commercialization agreement with Janssen for daratumumab (marketed as DARZALEX for the treatment of MM). Under this agreement, Janssen is fully responsible for developing and commercializing daratumumab and all costs associated therewith. We receive tiered royalty payments between 12% and 20% based on Janssen’s annual net product sales. The royalties payable by Janssen are limited in time and subject to reduction on a country-by-country basis for customary reduction events, including upon patent expiration or invalidation in the relevant country and upon the first commercial sale of a biosimilar product in the relevant country (for as long as the biosimilar product remains for sale in that country). Pursuant to the terms of the agreement, Janssen’s obligation to pay royalties under this agreement will expire on a country-by-country basis on the later of the date that is 13 years after the first sale of daratumumab in such country or upon the expiration of the last-to-expire relevant product patent (as defined in the agreement) covering daratumumab in such country. We are also eligible to receive certain additional payments in connection with development, regulatory and sales milestones.

Sales of DARZALEX have grown since it received its first marketing approval in the United States in 2015. In the fourth quarter of 2019, we moved from the 18% royalty tier (applicable to net sales exceeding $2.0 billion in a calendar year) to the royalty tier of 20% on the portion of net 2019 sales exceeding $3.0 billion. The total amount of potential milestone payments under the contract is approximately $1,015 million, and to date, we have recorded approximately $835 million in milestone payments from Janssen and could be entitled to receive up to $180 million in further payments if certain additional milestones are met.

Collaboration with Novartis (Ofatumumab)

Ofatumumab is commercialized by Novartis under a co-development and collaboration agreement with us, which it acquired from GSK in 2015. Under the agreement with Novartis, we are entitled to royalties of 20% of worldwide net sales of ofatumumab for the treatment of cancer and 10% of worldwide net sales for non-cancer treatments, as well as certain potential regulatory and sales milestones, of which only certain sales milestones remain. Novartis is fully responsible for all costs associated with developing and commercializing ofatumumab.

Collaboration with Seattle Genetics (Tisotumab vedotin)

In October 2011, we entered into a license and collaboration agreement with Seattle Genetics. In August 2017, Seattle Genetics exercised an option it was granted pursuant to this agreement to co-develop and co-commercialize tisotumab vedotin with us. All costs and profits for tisotumab vedotin will be shared on a 50:50 basis.

Our cost-sharing arrangement with Seattle Genetics in respect of the co-development and co-commercialization of tisotumab vedotin is such that, from time to time, one partner may be required to bear certain costs in furtherance of the collaboration for which it would be entitled to seek reimbursement of 50% of the costs from the other partner. Such reimbursements may not be immediate or may be offset by other costs incurred or profits received by one or both partners. As a result, we may incur costs for which we are not ultimately responsible, and this may affect our working capital, liquidity and availability of resources for other projects. On the other hand, we may also be responsible for reimbursing Seattle Genetics in respect of the portion of its spending in furtherance of the collaboration for which we are responsible. In addition, we record all development expenses incurred by us in connection with this collaboration as
research and development expenses, while reimbursements received from Seattle Genetics related to such development expenses are recorded in revenue as reimbursement income.

**Collaboration with BioNTech (DuoBody-PD-L1x4-1BB and DuoBody-CD40x4-1BB)**

In May 2015, we entered an agreement with BioNTech to jointly research, develop and commercialize bispecific antibody products using our DuoBody technology platform and antibodies. If BioNTech and us jointly select any product candidates for clinical development, development costs and product ownership will be shared equally going forward. If one of the companies does not wish to move a product candidate forward, the other company is entitled to continue developing the product on predetermined licensing terms. The agreement also includes provisions which will allow the parties to opt out of joint development at key points. Two product candidates are currently in development in connection with this agreement, DuoBody-PD-L1x4-1BB and DuoBody-CD40x4-1BB. We submitted CTAs for these products in 2019 and dosed the first patient in a Phase I/II study for DuoBody-PD-L1x4-1BB in May 2019 and dosed the first patient in a Phase I/II for DuoBody-CD40x4-1BB in September 2019.

Our cost sharing arrangement with BioNTech is similar to the one with Seattle Genetics described above with respect to tisotumab vedotin.

**In-Licensed Technology**

While not material in 2018 or in 2019, in the future, our results and financial condition could be affected by milestone payments and royalties related to technology we have licensed or acquired. This includes payments under our asset purchase agreement with IDD Biotech in connection with our development of HexaBody-DR5/DR5, our ADC license agreement with Seattle Genetics in connection with our enapotamab vedotin antibody and our research, collaboration and exclusive license agreement with Immatics to discover and develop next-generation bispecific immunotherapies to target multiple cancer indications.

**Collaboration with CureVac**

During December 2019, Genmab entered into a research collaboration and license agreement with CureVac AG. The strategic partnership will focus on the research and development of differentiated mRNA-based antibody products by combining CureVac’s mRNA technology and know-how with Genmab’s proprietary antibody technologies and expertise.

Under the terms of the agreement Genmab will provide CureVac with a $10 million upfront payment. The companies will collaborate on research to identify an initial product candidate and CureVac will contribute a portion of the overall costs for the development of this product candidate, up to the time of an Investigational New Drug Application. Genmab would thereafter be fully responsible for the development and commercialization of the potential product, in exchange for $280 million in development, regulatory and commercial milestones and tiered royalties in the range from mid-single to low-double digits to CureVac. The agreement also includes three additional options for Genmab to obtain commercial licenses to CureVac’s mRNA technology at pre-defined terms, exercisable within a five-year period. If Genmab exercises any of these options, it would fund all research and would develop and commercialize any resulting product candidates with CureVac eligible to receive between $275 million and $368 million in development, regulatory and commercial milestone payments for each product, dependent on the specific product concept. In addition, CureVac is eligible to receive tiered royalties in the range from mid-single digits up to low double digits per product. CureVac would retain an option to participate in development and/or commercialization of one of the potential additional programs under pre-defined terms and conditions. Further, Genmab made a €20 million equity investment in CureVac. Refer to note 3.4 for additional information regarding Genmab’s equity investment in CureVac.

**Collaboration with Immatics**

In July 2018, Genmab entered into a research collaboration and exclusive license agreement with Immatics Biotechnologies GmbH (Immatics) to discover and develop next-generation bispecific immunotherapies to target
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

multiple cancer indications. Genmab received an exclusive license to three proprietary targets from Immatics, with an option to license up to two additional targets at predetermined economics. Under the terms of the agreement, Genmab paid Immatics an upfront fee of $54 million and Immatics is eligible to receive up to $550 million in development, regulatory and commercial milestone payments for each product, as well as tiered royalties on net sales.
Genmab A/S ("Genmab" or the "Company") had the following securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934 (the "Exchange Act"): 

<table>
<thead>
<tr>
<th>Title of each class</th>
<th>Trading symbol</th>
<th>Name of each exchange on which registered</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Depositary Shares, each representing one-tenth ordinary share</td>
<td>GMAB</td>
<td>The NASDAQ Global Select Market</td>
</tr>
<tr>
<td>Ordinary shares, nominal value DKK 1 per share</td>
<td>GMAB</td>
<td>The NASDAQ Global Select Market*</td>
</tr>
</tbody>
</table>

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

This exhibit contains a description of the rights of (i) the holders of ordinary shares and (ii) the holders of ADSs. The following summary is subject to and qualified in its entirety by Genmab’s articles of association (the “Articles of Association”) and by applicable Danish law, particularly the Danish Companies Act (Selskabsloven) (the “DCA”). This is not a summary of all the significant provisions of the Articles of Association or of Danish law and does not purport to be complete. Capitalized terms used but not defined herein have the meanings given to them in the Company’s annual report on Form 20-F to which this description of securities registered under section 12 of the Exchange Act (the “Description of Securities”) is an exhibit and in the form of Amended and Restated Deposit Agreement (the “Deposit Agreement”), filed as Exhibit (a)(3) to Genmab’s registration statement on Form F-1 filed with the SEC on July 16, 2019.

**ORDINARY SHARES**

**Item 9. General**

**Item 9.A.3 Pre-emptive rights**

*Denmark.* As a general rule, shareholders of the Company are entitled to subscribe for new shares in proportion to their existing shareholdings in the event of a cash increase of the share capital. Such a cash increase of the share capital can be resolved by the general meeting by at least two-thirds of the votes cast as well as at least two-thirds of the share capital represented at the general meeting.

However, in the below-mentioned scenarios, the general meeting may resolve to depart from the shareholders’ right to proportionate subscription if the following voting requirements are met:

- two-thirds majority requirement: if the new shares issued in connection with the capital increase are subscribed for at market price for the benefit of some of the existing shareholders, the above-mentioned two-thirds majority requirement applies;

- consent requirement: if the new shares issued in connection with the capital increase are subscribed for at a discount for the benefit of some of the existing shareholders, consent from the shareholders who do not get an opportunity to participate in the capital increase must be obtained;

- two-thirds majority requirement: if the new shares issued in connection with the capital increase are subscribed for at market price for the benefit of parties other than the existing shareholders (i.e., a third party or employees of the company), the above-mentioned two-thirds majority requirement applies; and

- nine-tenths majority requirement: if the new shares issued in connection with the capital increase are subscribed for at discount for the benefit of parties other than the existing shareholders or the employees of the company, the voting requirement is at least nine-tenths of the votes cast as well as at least nine-tenths of the share capital represented at the general meeting.

The board of directors may resolve to increase Genmab’s share capital without pre-emptive subscription rights for existing shareholders pursuant to the authorizations currently in force.
Unless future issuances of new shares are registered under the Securities Act or with any authority outside Denmark, U.S. shareholders and shareholders in jurisdictions outside Denmark may be unable to exercise their pre-emptive subscription rights under U.S. securities law.

**Delaware.** Under the Delaware General Corporation Law, stockholders have no pre-emptive rights to subscribe for additional issues of stock or to any security convertible into such stock unless, and to the extent that, such rights are expressly provided for in the certificate of incorporation.

**Item 9.A.5 Type and class of securities**

The Company’s ordinary shares are listed on the Nasdaq Copenhagen and are registered under Section 12(b) of the Exchange Act in connection with the listing of the Company’s ADSs (but not for trading) and have a nominal value of DKK 1 per share. All ordinary shares are issued in registered form.

**Item 9.A.6 Limitations or qualifications**

Not applicable.

**Item 9.A.7 Other rights**

Not applicable.

**Item 10.B Memorandum and articles of association**

**Item 10.B.3 Shareholder rights**

**Dividends**

**Denmark.** Under Danish law, the distribution of ordinary and interim dividends requires the approval of a company’s shareholders at a company’s general meeting. In addition the shareholders may authorize the board of directors to distribute interim dividends. The shareholders may not resolve to the distribution of dividends in excess of the recommendation from the board of directors and Genmab may only pay out dividends from Genmab’s distributable reserves, which are defined as results from operations carried forward and reserves that are not bound by law after deduction of loss carried forward. It is possible under Danish law to pay out interim dividends. The decision to pay out interim dividends shall be accompanied by a balance sheet, and the board of directors determines whether it will be sufficient to use the statement of financial position from the annual report or if an interim statement of financial position for the period from the annual report period until the interim dividend payment shall be prepared. If interim dividends are paid out later than six months following the end of the financial year for the latest annual report, an audited interim balance sheet showing that there are sufficient funds shall always be prepared.

**Delaware.** Under the Delaware General Corporation Law, a Delaware corporation may pay dividends out of its surplus (the excess of net assets over capital), or in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year (provided that the amount of the capital of the corporation is not less than the aggregate amount of the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets). In determining the amount of surplus of a Delaware corporation, the assets of the corporation, including stock of subsidiaries owned by the corporation, must be valued at their fair market value as determined by the board of directors, without regard to their historical book value. Dividends may be paid in the form of shares, property or cash.

**Voting Rights**

Pursuant to the Articles of Association, each share with a nominal value of DKK 1 carries one vote at general meetings.

**Denmark.** Each share confers the right to cast one vote at the general meeting of shareholders, unless the Articles of Association provide otherwise. Each holder of shares may cast as many votes as it holds shares. Shares that are held by Genmab or its direct or indirect subsidiaries do not confer the right to vote.

**Delaware.** Under the Delaware General Corporation Law, each stockholder is entitled to one vote per share of stock, unless the certificate of incorporation provides otherwise. In addition, the certificate of incorporation may provide for cumulative voting at all elections of directors of the corporation, or at elections held under specified circumstances. Either the certificate of incorporation or
the bylaws may specify the number of shares and/or the amount of other securities that must be represented at a meeting in order to constitute a quorum, but in no event can a quorum consist of less than one-third of the shares entitled to vote at a meeting.

Stockholders as of the record date for the meeting are entitled to vote at the meeting, and the board of directors may fix a record date that is no more than 60 nor less than 10 days before the date of the meeting, and if no record date is set then the record date is the close of business on the day next preceding the day on which notice is given, or if notice is waived then the record date is the close of business on the day next preceding the day on which the meeting is held. The determination of the stockholders of record entitled to notice or to vote at a meeting of stockholders shall apply to any adjournment of the meeting, but the board of directors may fix a new record date for the adjourned meeting.

**Adoption of Shareholder Resolutions**

All resolutions put to the vote of shareholders at general meetings are subject to adoption by a simple majority of votes, unless the DCA or the Articles of Association prescribes other requirements.

**Notice of Meeting**

**Denmark.** According to the DCA and as implemented in the Articles of Association, general meetings in listed limited liability companies shall be convened by the board of directors with a minimum of three weeks’ notice and a maximum of five weeks’ notice. A convening notice shall also be forwarded to shareholders recorded in Genmab’s shareholders’ register who have requested such notification. There are specific requirements as to the information and documentation required to be disclosed in connection with the convening notice.

**Delaware.** Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than 10 nor more than 60 days before the date of the meeting and shall specify the place, date, hour and purpose or purposes of the meeting.

**Shareholder Proposals**

**Denmark.** According to the DCA, extraordinary general meetings of shareholders will be held whenever Genmab’s board of directors or its appointed auditor requires. In addition, one or more shareholders each representing at least 5% of the registered share capital of the company may, in writing, require that a general meeting be convened. If such a demand is made, the board of directors shall convene the general meeting within two weeks thereafter (after providing three to five weeks notice).

All shareholders have the right to present proposals for adoption at the annual general meeting, provided that the proposals are submitted at least six weeks prior to the meeting. In the event that the request is made at a later date, the board of directors will determine whether the proposals were made in due time to be included on the agenda.

**Delaware.** Delaware law does not specifically grant stockholders the right to bring business before an annual or special meeting of stockholders. However, if a Delaware corporation is subject to the SEC’s proxy rules, a stockholder who owns at least $2,000 in market value, or 1% of the corporation’s securities entitled to vote, may propose a matter for a vote at an annual or special meeting in accordance with those rules.

**Action by Written Consent**

**Denmark.** Under Danish law, shareholders may take action and pass resolutions by written consent if such consent is unanimous. However, for a listed company, this method of adopting resolutions is generally not feasible.

**Delaware.** Although permitted by Delaware law, publicly listed companies do not typically permit stockholders of a corporation to take action by written consent.

**Appraisal Rights**

**Denmark.** The concept of appraisal rights does not exist under Danish law, except in connection with statutory redemption rights according to the DCA.

According to Section 73 of the DCA, a minority shareholder may require a majority shareholder that holds more than 90% of the company’s registered share capital and votes to redeem his or her shares. Similarly, a majority shareholder holding more than 90% of the company’s share capital and votes may, according to Section 70 of the DCA, squeeze out the minority shareholders. In the
event that the parties cannot agree to the redemption squeeze out price, this shall be determined by an independent evaluator appointed by the court. Additionally, there are specific regulations in Sections 249, 267, 285 and 305 of the DCA that require compensation in the event of national or cross-border mergers and demergers. Moreover, shareholders who vote against a cross-border merger or demerger are, according to Sections 286 and 306 of the DCA, entitled to have their shares redeemed.

**Delaware.** The Delaware General Corporation Law provides for stockholder appraisal rights, or the right to demand payment in cash of the judicially determined fair value of the stockholder’s shares, in connection with certain mergers and consolidations.

**Shareholder Suits**

**Denmark.** Under Danish law, only a company itself can bring a civil action against a third party; an individual shareholder does not have the right to bring an action on behalf of a company. However, if shareholders representing at least 10% of the share capital have opposed at a general meeting a decision to grant discharge to a member of Genmab’s board of directors or its registered managers or refrain from bringing law suits against, among other persons, a member of its board of directors or a registered manager, a shareholder may bring a derivative action on behalf of our company against, among other persons, a member of its board of directors or a registered manager. An individual shareholder may, in its own name, have an individual right to take action against such third party in the event that the cause for the liability of that third party also constitutes a negligent act directly against such individual shareholder.

**Delaware.** Under the Delaware General Corporation Law, a stockholder may bring a derivative action on behalf of the corporation to enforce the rights of the corporation. An individual also may commence a class action suit on behalf of himself and other similarly situated stockholders where the requirements for maintaining a class action under Delaware law have been met. A person may institute and maintain such a suit only if that person was a stockholder at the time of the transaction which is the subject of the suit. In addition, under Delaware case law, the plaintiff normally must be a stockholder at the time of the transaction that is the subject of the suit and throughout the duration of the derivative suit. Delaware law also requires that the derivative plaintiff make a demand on the directors of the corporation to assert the corporate claim before the suit may be prosecuted by the derivative plaintiff in court, unless such a demand would be futile.

**Inspection of Books and Records**

**Denmark.** According to Section 150 of the DCA, a shareholder may, at the annual general meeting or at a general meeting whose agenda includes such item, request an inspection of the Company’s books regarding specific issues concerning the management of the Company or specific annual reports. If approved by shareholders with a simple majority, one or more investigators are elected. If the proposal is not approved by a simple majority but 25% of the share capital votes in favor of the proposal, then the shareholder can request the court to appoint an investigator, however, the request will only be allowed if the court finds it to be based on reasonable grounds.

**Delaware.** Under the Delaware General Corporation Law, any stockholder may inspect certain of the corporation’s books and records, for any proper purpose, during the corporation’s usual hours of business.

**Notice Convening Annual and Extraordinary General Meetings**

General meetings shall be held in the municipality of Copenhagen or in the greater Copenhagen area (Storkøbenhavn). General meetings shall be convened by the board of directors giving not less than three weeks’ and not more than five weeks’ notice. General meetings shall be announced by notification to Nasdaq Copenhagen and through publication on our website. Furthermore, all shareholders registered in Genmab’s shareholders’ register who have so requested shall be notified by letter or email. The notice shall set out the time and place for the general meeting and the issues to be considered at the general meeting. If the general meeting is to consider a proposal to amend the Articles of Association, then the notice shall specify the material content of the proposal. The notice calling the general meeting as well as other documents prepared for and in connection with the general meeting shall be prepared in English and, if decided by Genmab’s board of directors, also in Danish.

A shareholder’s right to attend general meetings and to vote is determined on the basis of the shares that the shareholder owns on the registration date which date is one week before the general meeting is held.

Any shareholder shall be entitled to attend general meetings, provided he or she has requested an admission card from our offices not later than three days prior to the relevant meeting. The admission card will be issued to the shareholders registered in our shareholders’ register. The shareholder may attend in person or be represented by proxy, and a shareholder shall be entitled to attend together with an advisor. A shareholder may vote by proxy or by mail, and a form for this use shall be made available on Genmab’s website no later than three weeks prior to the general meeting. A vote by mail must be received by Genmab not later than three days prior to the general meeting in order to be counted at the general meeting.
Extraordinary general meetings shall be held as directed by the shareholders at the general meeting, the board of directors or an auditor, or upon a written request to the board of directors by shareholders holding not less than 5% of the share capital for consideration of a specific issue. The general meeting shall be convened (after providing three to five weeks notice) within 14 days after the proper request has been received by Genmab’s board of directors.

Shareholder Identification

The EU has adopted an amendment to the shareholder rights directive, or Directive 2017/828. The amendment has been implemented in Denmark and entered into force on June 10, 2019. The main purpose of the rules is to strengthen shareholder participation in listed companies. Pursuant to these rules, Genmab may request from central security depositaries, or CSDs, depositaries and other intermediaries information about the identity of its shareholders and the number of shares, share class and date of acquisition of the shares held by its shareholders. The intermediaries will be required to transmit such requests on shareholder identification between them in order to provide Genmab with the requested information.

Redemption provisions

No shareholder shall be obliged to let his shares be redeemed in full or in part by Genmab or by any other party, except as provided in the DCA.

Rights to share in any surplus in the event of liquidation

If Genmab is liquidated, any assets remaining after payment of its debts, liquidation expenses and all of its remaining obligations will be distributed among shareholders proportionally to their shareholding in the Company.

Item 10.B.4 Changes to shareholder rights

Shareholder Vote on Certain Reorganizations

Denmark. Under Danish law, all amendments to the Articles of Association shall be approved by the general meeting of shareholders with a minimum of two-thirds of the votes cast and two-thirds of the share capital represented at the general meeting. The same applies to solvent liquidations, mergers with the company as the discontinuing entity, mergers with the company as the continuing entity if shares are issued in connection therewith and demergers. Under Danish law, it is debatable whether the shareholders must approve a decision to sell all or virtually all of the company’s business/assets.

Delaware. Under the Delaware General Corporation Law, the vote of a majority of the outstanding shares of capital stock entitled to vote thereon generally is necessary to approve a merger or consolidation or the sale of all or substantially all of the assets of a corporation. The Delaware General Corporation Law permits a corporation to include in its certificate of incorporation a provision requiring for any corporate action the vote of a larger portion of the stock or of any class or series of stock than would otherwise be required. However, under the Delaware General Corporation Law, no vote of the stockholders of a surviving corporation to a merger is needed, unless required by the certificate of incorporation, if (1) the agreement of merger does not amend in any respect the certificate of incorporation of the surviving corporation, (2) the shares of stock of the surviving corporation are not changed in the merger and (3) the number of shares of common stock of the surviving corporation into which any other shares, securities or obligations to be issued in the merger may be converted does not exceed 20% of the surviving corporation’s common stock outstanding immediately prior to the effective date of the merger. In addition, stockholders may not be entitled to vote in certain mergers with other corporations that own 90% or more of the outstanding shares of each class of stock of such corporation, but the stockholders will be entitled to appraisal rights.

Amendments to Governing Documents

Denmark. All resolutions made by the general meeting may be adopted by a simple majority of the votes, subject only to the mandatory provisions of the DCA and the Articles of Association. Resolutions concerning all amendments to the Articles of Association must be passed by two-thirds of the votes cast as well as two-thirds of the share capital represented at the general meeting. Certain resolutions, which limit a shareholder’s ownership or voting rights, are subject to approval by a nine-tenth majority of the votes cast and the share capital represented at the general meeting. Decisions to impose any or increase any obligations of the shareholders towards the company require unanimity.

Delaware. Under the Delaware General Corporation Law, a corporation’s certificate of incorporation may be amended only if adopted and declared advisable by the board of directors and approved by a majority of the outstanding shares entitled to vote, and the bylaws may be amended with the approval of a majority of the outstanding shares entitled to vote and may, if so provided in the certificate of incorporation, also be amended by the board of directors.
Item 10.B.6 Limitations

There are no restrictions on the rights of non-resident or foreign shareholders to hold or exercise voting rights with respect to Genmab’s shares.

Item 10.B.7 Change in control

The Articles of Association do not contain any provisions that would have the effect of delaying, deferring or preventing a change in control of the Company and that would operate only with respect to a merger, acquisition or corporate restructuring involving the Company (or any of its subsidiaries).

Item 10.B.8 Disclosure of shareholdings

Genmab’s constitutional documents do not contain any provisions governing the ownership threshold above which shareholder ownership must be disclosed. However, pursuant to the DCA, public and private limited liability companies are required to register with the Danish Business Authority information regarding shareholders who own at least 5% of the share capital or the voting rights. Pursuant to this provision, Genmab files registrations with the Danish Public Shareholders’ Register of the Danish Business Authority. Shareholders that exceed or fall below the ownership threshold must notify Genmab, and Genmab will subsequently file the information with the Danish Business Authority. Reporting is further required upon passing or falling below thresholds of 10%, 15%, 20%, 25%, 50%, 90%, and 100% as well as one third and two thirds of the votes or the share capital. This also applies to beneficial holders of Genmab’s shares, such as holders of the ADSs.

Item 10.B.9 Differences in the law

With respect to Items 10.B.2-10.B.8, Genmab has identified in the responses above where the Danish law applicable to Genmab is significantly different from the comparable Delaware law.

Item 10.B.10 Changes in capital

The requirements imposed by the Articles of Association governing changes in capital are not more stringent than is required by law.

AMERICAN DEPOSITARY SHARES

Item 12.A Debt securities

Not applicable.

Item 12.B Warrants and Rights

Not applicable.

Item 12.C Other securities

Not applicable.

Item 12.D.1 Depositary

Deutsche Bank Trust Company Americas has been appointed as the depositary pursuant to the Deposit Agreement. The depositary’s corporate office at which the ADSs are administered and the principal executive office is located at 60 Wall Street, New York, NY 10005, USA. Danske Bank A/S has been appointed as the custodian for the depositary.

Item 12.D.2 Description of the ADSs

Genmab’s ADSs are listed on the NASDAQ Global Select Market and traded under the symbol ‘GMAB’. Each ADS represents ownership of one tenth of one ordinary share. Each ADS also represents ownership of any other securities, cash or other property which may be held by the depositary in respect of such shares.
Dividends and Other Distributions

Receipt of Dividends and Other Distributions

The depositary has agreed to pay to holders of the ADSs the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after deducting its fees and expenses. Holders will receive these distributions in proportion to the number of shares their ADSs represent as of the record date (which will be as close as practicable to the record date for Genmab’s shares) set by the depositary with respect to the ADSs.

- **Cash.** The depositary will convert or cause to be converted any cash dividend or other cash distribution Genmab pays on the shares or any net proceeds from the sale of any shares, rights, securities or other entitlements under the terms of the Deposit Agreement into U.S. dollars if it can do so on a practicable basis, and can transfer the U.S. dollars to the United States and will distribute promptly the amount thus received. If the depositary shall determine in its judgment that such conversions or transfers are not practical or lawful or if any government approval or license is needed and cannot be obtained at a reasonable cost within a reasonable period or otherwise sought, the Deposit Agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold or cause the custodian to hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid and such funds will be held for the respective accounts of the ADS holders. It will not invest the foreign currency and it will not be liable for any interest for the respective accounts of the ADS holders.

Before making a distribution, any taxes or other governmental charges, together with fees and expenses of the depositary, that must be paid, will be deducted. See “Item 10—Material U.S. Federal Income Tax Considerations” and “Item 10—Material Danish Income Tax Considerations” in the annual report on Form 20-F to which this Description of Securities is an exhibit. It will distribute only whole U.S. dollars and cents and will round down fractional cents to the nearest whole cent. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, holders may lose some or all of the value of the distribution.

- **Shares.** For any shares Genmab distributes as a dividend or free distribution (such shares considered bonus shares under the DCA), either (1) the depositary will distribute additional ADSs representing such shares or (2) existing ADSs as of the applicable record date will represent rights and interests in the additional shares distributed, to the extent reasonably practicable and permissible under law, in either case, net of applicable fees, charges and expenses incurred by the depositary and taxes and/or other governmental charges. The depositary will only distribute whole ADSs. It will try to sell shares which would require it to deliver a fractional ADS and distribute the net proceeds in the same way as it does with cash. The depositary may sell a portion of the distributed shares sufficient to pay its fees and expenses and any taxes and governmental charges in connection with that distribution.

- **Elective Distributions in Cash or Shares.** If Genmab offers Genmab’s shareholders the option to receive dividends in either cash or shares (such shares considered bonus shares under the DCA), the depositary, after consultation with Genmab and having received timely notice as described in the Deposit Agreement of such elective distribution by Genmab, has discretion to determine to what extent such elective distribution will be made available to holders of the ADSs. Genmab must timely first instruct the depositary to make such elective distribution available to holders and furnish it with satisfactory evidence that it is legal to do so. However, the depositary could decide it is not legal or reasonably practicable to make such elective distribution available to holders. In such case, the depositary shall, on the basis of the same determination as is made in respect of the shares for which no election is made, distribute either cash in the same way as it does in a cash distribution, or additional ADSs representing shares in the same way as it does in a share distribution. The depositary is not obligated to make available to holders a method to receive the elective distribution in shares rather than in ADSs. There can be no assurance that holders will be given the opportunity to receive elective distributions on the same terms and conditions as Genmab’s shareholders.

- **Rights to Purchase Additional Shares.** If Genmab offers its shareholders any rights to subscribe for additional shares, the depositary shall, having received timely notice as described in the Deposit Agreement of such distribution by Genmab, consult with Genmab, and Genmab must determine whether it is lawful and reasonably practicable to make these rights available to holders. Genmab must first instruct the depositary to make such rights available to holders and furnish the depositary with satisfactory evidence that it is legal to do so. However, if the depositary decides it is not legal or reasonably practicable to make the rights available but that it is lawful and reasonably practicable to sell the rights, the depositary will endeavor to sell the rights and, in a riskless principal capacity or otherwise, at such place and upon such
If the depositary makes rights available to holders, it will establish procedures to distribute such rights and enable holders to exercise the rights upon their payment of applicable fees, charges and expenses incurred by the depositary and taxes and/or other governmental charges. The depositary shall not be obliged to make available to holders a method to exercise such rights to subscribe for shares (rather than ADSs).

U.S. securities laws may restrict transfers and cancellation of the ADSs represented by shares purchased upon exercise of rights. For example, holders may not be able to trade these ADSs freely in the United States. In this case, the depositary may deliver restricted depositary shares that have the same terms as the ADSs described in this section except for changes needed to put the necessary restrictions in place.

There can be no assurance that holders will be given the opportunity to exercise rights on the same terms and conditions as Genmab’s shareholders or be able to exercise such rights.

• **Other Distributions.** Subject to receipt of timely notice, as described in the Deposit Agreement, from Genmab with the request to make any such distribution available to holders, and provided the depositary has determined such distribution is lawful and reasonably practicable and feasible and in accordance with the terms of the Deposit Agreement, the depositary will distribute to holders anything else Genmab distributes on deposited securities by any means it may deem practicable, upon their payment of applicable fees, charges and expenses incurred by the depositary and taxes and/or other governmental charges. If any of the conditions above are not met, the depositary will endeavor to sell, or cause to be sold, the property Genmab distributed and distribute the net proceeds in the same way as it does with cash; or, if it is unable to sell such property, the depositary may dispose of such property in any way it deems reasonably practicable under the circumstances for nominal or no consideration, such that holders may have no rights to or arising from such property.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. Genmab has no obligation to register ADSs, shares, rights or other securities under the Securities Act. Genmab also has no obligation to take any other action to permit the distribution of ADSs, shares, rights or any other property to ADS holders. This means that holders may not receive the distributions Genmab makes on its shares or any value for them if Genmab and/or the depositary determines that it is illegal or not practicable for Genmab or the depositary to make them available to holders.

**Deposit, Withdrawal and Cancellation**

**Cancellation**

Holders may turn in their ADSs at the depositary’s corporate trust office or by providing appropriate instructions to their broker. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the ADSs to holders or a person the holder designates at the office of the custodian. Or, at holder’s request, risk and expense, the depositary will deliver the deposited securities at its corporate trust office, to the extent permitted by law.

**Interchange between Certificated ADSs and Uncertificated ADSs**

Holders may surrender their certificated American depositary receipts (“ADRs”) to the depositary for the purpose of exchanging their certificated ADR for uncertificated ADSs. The depositary will cancel such certificated ADRs and will send holders a statement confirming that they are the owners of uncertificated ADSs. Alternatively, upon receipt by the depositary of a proper instruction from a holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to holders a certificated ADR evidencing those ADSs.

**Voting Rights**

Holders may instruct the depositary to vote the shares or other deposited securities underlying their ADSs at any meeting at which they are entitled to vote pursuant to any applicable law, the provisions of the Articles of Association, and the provisions of or governing the deposited securities. Voting instructions may be given only in respect of a number of ADSs representing an integral number of shares or other deposited securities. *Otherwise, holders could exercise their right to vote directly if they withdraw the shares. However, they may not know about the meeting sufficiently enough in advance to withdraw the shares.*
If Genmab asks for holders’ instructions and upon timely notice from Genmab by regular, ordinary mail delivery, or by electronic transmission, as described in the Deposit Agreement, the depositary will notify holders of the upcoming meeting at which such holders are entitled to vote pursuant to any applicable law, the provisions of Genmab’s Articles of Association, and the provisions of or governing the deposited securities, and arrange to deliver Genmab’s voting materials to such holders. The materials will include or reproduce (a) such notice of meeting or solicitation of consents or proxies; (b) a statement that the ADS holders at the close of business on the ADS record date will be entitled, subject to any applicable law, the provisions of the Articles of Association, and the provisions of or governing the deposited securities, to instruct the depositary as to the exercise of the voting rights, if any, pertaining to the shares or other deposited securities represented by such holder’s ADSs; and (c) a brief statement as to the manner in which such instructions may be given to the depositary. Voting instructions may be given only in respect of a number of ADSs representing an integral number of shares or other deposited securities. For instructions to be valid, the depositary must receive them in writing or before the date specified. The depositary will try, as far as practical, subject to applicable law and the provisions of the Articles of Association, to vote or to have its agents vote the shares or other deposited securities (in person or by proxy) as holders instruct. The depositary will only vote or attempt to vote as holders instruct.

A precondition for exercising any such voting rights is that the ADS holder providing voting instructions on the ADS record date remains a holder with respect to such ADSs on the record date fixed by the Company under Danish law for such meeting. By providing voting instructions to the depositary, the ADS holder is deemed to agree that it will remain as a holder of the ADSs for which it is providing voting instructions until at least the Danish record date or such other date required under applicable Danish law, and the depositary shall only be obligated to confirm the ownership of ADS holders as of the ADS record date.

Genmab cannot assure holders that they will receive the voting materials in time to ensure that they can instruct the depositary to vote the shares underlying their ADSs. In addition, there can be no assurance that ADS holders and beneficial owners generally, or any holder or beneficial owner in particular, will be given the opportunity to vote or cause the depositary or the custodian, as applicable, to vote on the same terms and conditions as Genmab’s shareholders.

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 their right to vote and they may have no recourse if the shares underlying their ADSs are not voted as they requested.

In order to give holders a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if Genmab requests the depositary to act, it will give the depositary notice of any such meeting and details concerning the matters to be voted at least 30 days in advance of the meeting date.

**Reclassifications, Recapitalizations and Mergers**

<table>
<thead>
<tr>
<th>If Genmab:</th>
<th>Then:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changes the nominal or par value of Genmab’s shares</td>
<td>The cash, shares or other securities received by the depositary will become deposited securities. Each ADS will automatically represent its equal share of the new deposited securities.</td>
</tr>
<tr>
<td>Reclassifies, splits up or consolidates any of the deposited securities</td>
<td>The depositary may distribute some or all of the cash, shares or other securities it received. It may also deliver new ADSs or ask holders to surrender their outstanding ADRs in exchange for new ADRs identifying the new deposited securities.</td>
</tr>
<tr>
<td>Distributes securities on the shares that are not distributed to holders, or</td>
<td></td>
</tr>
<tr>
<td>Recapitalizes, reorganizes, merges, liquidates, sells all or substantially all of Genmab’s assets, or takes any similar action</td>
<td></td>
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</tbody>
</table>

**Amendment and Termination**

**Amendment**

Genmab may agree with the depositary to amend the Deposit Agreement and the form of ADR without their consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, including expenses incurred in connection with foreign exchange control regulations and other charges specifically payable by ADS holders under the Deposit Agreement, or materially prejudices a substantial existing right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. At the time an amendment becomes effective, holders are considered, by continuing to hold their ADSs, to agree to the amendment and to be bound by the ADRs and the Deposit Agreement as amended. If any new laws are adopted which would require the Deposit Agreement to be amended in order to comply therewith, Genmab and the depositary may amend the Deposit Agreement in accordance with such laws and such amendment may become effective before notice thereof is given to ADS holders.
**Termination**

The depositary will terminate the Deposit Agreement if Genmab asks it to do so, in which case the depositary will give notice to holders at least 90 days prior to termination. The depositary may also terminate the Deposit Agreement if the depositary has told Genmab that it would like to resign, or if Genmab has removed the depositary, and in either case Genmab has not appointed a new depositary within 90 days. In either such case, the depositary must notify holders at least 30 days before termination.

After termination, the depositary and its agents will do the following under the Deposit Agreement but nothing else: collect distributions on the deposited securities, sell rights and other property and deliver shares and other deposited securities upon cancellation of ADSs after payment of any fees, charges, taxes or other governmental charges. Six months or more after the date of termination, the depositary may sell any remaining deposited securities by public or private sale. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the Deposit Agreement, for the pro rata benefit of the ADS holders that have not surrendered their ADSs. It will not invest the money and has no liability for interest. After such sale, the depositary’s only obligations will be to account for the money and other cash. After termination, Genmab shall be discharged from all obligations under the Deposit Agreement except for Genmab’s obligations to the depositary thereunder.

**Books of Depositary**

The depositary will maintain ADS holder records at its depositary office. Holders may inspect such records at such office during regular business hours but solely for the purpose of communicating with other holders in the interest of business matters relating to the Company, the ADRs and the Deposit Agreement.

The depositary will maintain facilities in the Borough of Manhattan, The City of New York to record and process the issuance, cancellation, combination, split-up and transfer of ADRs.

These facilities may be closed at any time or from time to time when such action is deemed necessary or advisable by the depositary in connection with the performance of its duties under the Deposit Agreement or at Genmab’s reasonable written request.

**Limitations on Obligations and Liability**

**Limits on Genmab’s Obligations and the Obligations of the Depositary and the Custodian; Limits on Liability to Holders of ADSs**

The Deposit Agreement expressly limits Genmab’s obligations and the obligations of the depositary and the custodian. It also limits Genmab’s liability and the liability of the depositary. The depositary and the custodian:

- are only obligated to take the actions specifically set forth in the Deposit Agreement without gross negligence or willful misconduct;
- are not liable if any of Genmab or Genmab’s respective controlling persons or agents are prevented or forbidden from, or subjected to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing required by the terms of the Deposit Agreement and any ADR, by reason of any provision of any present or future law or regulation of the United States or any state thereof, the Kingdom of Denmark or any other country, or of any other governmental authority or regulatory authority or stock exchange, or on account of the possible criminal or civil penalties or restraint, or by reason of any provision, present or future, of the Articles of Association or any provision of or governing any deposited securities, or by reason of any act of God or war or other circumstances beyond its control (including, without limitation, nationalization, expropriation, currency restrictions, work stoppage, strikes, civil unrest, revolutions, rebellions, explosions and computer failure);
- are not liable by reason of any exercise of, or failure to exercise, any discretion provided for in the Deposit Agreement or in the Articles of Association or provisions of or governing deposited securities;
- are not liable for any action or inaction of the depositary, the custodian or Genmab or their or Genmab’s respective controlling persons or agents in reliance upon the advice of or information from legal counsel, any person presenting shares for deposit or any other person believed by it in good faith to be competent to give such advice or information;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the Deposit Agreement;
• are not liable for any special, consequential, indirect or punitive damages for any breach of the terms of the Deposit Agreement, or otherwise;

• may rely upon any documents Genmab believes in good faith to be genuine and to have been signed or presented by the proper party;

• disclaim any liability for any action or inaction or inaction of any of Genmab or Genmab’s respective controlling persons or agents in reliance upon the advice of or information from legal counsel, accountants, any person presenting shares for deposit, holders and beneficial owners (or authorized representatives) of ADSs, or any person believed in good faith to be competent to give such advice or information; and

• disclaim any liability for inability of any holder to benefit from any distribution, offering, right or other benefit made available to holders of deposited securities but not made available to holders of ADS.

The depositary and any of its agents also disclaim any liability (i) for any failure to carry out any instructions to vote, the manner in which any vote is cast or the effect of any vote or failure to determine that any distribution or action may be lawful or reasonably practicable or for allowing any rights to lapse in accordance with the provisions of the Deposit Agreement, (ii) the failure or timeliness of any notice from Genmab, the content of any information submitted to it by Genmab for distribution to holders or for any inaccuracy of any translation thereof, (iii) any investment risk associated with the acquisition of an interest in the deposited securities, the validity or worth of the deposited securities, the credit-worthiness of any third party, (iv) any tax consequences that may result from ownership of ADSs, shares or deposited securities, or (v) for any acts or omissions made by a successor depositary whether in connection with a previous act or omission of the depositary or in connection with any matter arising wholly after the removal or resignation of the depositary, provided that in connection with the issue out of which such potential liability arises the depositary performed its obligations without gross negligence or willful misconduct while it acted as depositary.

In the Deposit Agreement, Genmab agrees to indemnify the depositary under certain circumstances.

Requirements for Depositary Actions

Before the depositary will issue, deliver or register a transfer of an ADS, split-up, subdivide or combine ADSs, make a distribution on an ADS, or permit withdrawal of shares, the depositary may require:

• payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities and payment of the applicable fees, expenses and charges of the depositary;

• satisfactory proof of the identity and genuineness of any signature or any other matters contemplated in the Deposit Agreement; and

• compliance with (A) any laws or governmental regulations relating to the execution and delivery of ADRs or ADSs or to the withdrawal or delivery of deposited securities and (B) such reasonable regulations and procedures as the depositary may establish, from time to time, consistent with the Deposit Agreement and applicable laws, including presentation of transfer documents.

The depositary may refuse to issue and deliver ADSs or register transfers of ADSs generally when the register of the depositary or Genmab’s transfer books are closed or at any time if the depositary or Genmab determines that it is necessary or advisable to do so.

Holders’ Right to Receive the Shares Underlying Their ADSs

Holders have the right to cancel their ADSs and withdraw the underlying shares at any time except:

• when temporary delays arise because: (1) the depositary has closed its transfer books or Genmab has closed its transfer books; (2) the transfer of shares is blocked to permit voting at a shareholders’ meeting; or (3) Genmab is paying a dividend on its shares;

• when holders owe money to pay fees, taxes and similar charges;

11
• 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, or

• other circumstances specifically contemplated by Section I.A.(I) of the General Instructions to Form F-6 (as such General Instructions may be amended from time to time); or

• for any other reason if the depositary or Genmab determines, in good faith, that it is necessary or advisable to prohibit withdrawals.

The depositary shall not knowingly accept for deposit under the Deposit Agreement any shares or other deposited securities required to be registered under the provisions of the Securities Act, unless a registration statement is in effect as to such shares.

This right of withdrawal may not be limited by any other provision of the Deposit Agreement.
### Genmab A/S

#### Subsidiaries of the Registrant

<table>
<thead>
<tr>
<th>Name</th>
<th>Jurisdiction of Incorporation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genmab B.V.</td>
<td>The Netherlands</td>
</tr>
<tr>
<td>Genmab US, Inc.</td>
<td>Delaware, United States</td>
</tr>
</tbody>
</table>
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)) 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) [INTENTIONALLY OMITTED]
   (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: March 30, 2020

/s/ Jan G. van de Winkel
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)) 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) [INTENTIONALLY OMITTED]

   (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: March 30, 2020

/s/ Anthony Pagano
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, 2019 (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: March 30, 2020

/s/ Jan G. van de Winkel
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, 2019 (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: March 30, 2020

/s/ Anthony Pagano
CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (333-232693) of Genmab A/S of our report dated March 30, 2020, relating to the consolidated financial statements, which appears in this Form 20-F.

/s/ PricewaterhouseCoopers
Statsautoriseret Revisionspartnerselskab
Hellerup, Denmark
March 30, 2020

PricewaterhouseCoopers Statsautoriseret Revisionspartnerselskab, CVR-nr. 3377 1231