

## 1 RISK FACTORS

*An investment in Genmab's shares, including any new shares, involves a high degree of risk. In addition to the other information in this document, an investor should carefully consider the following risk factors, which we consider to be material, prior to making any investment decision with respect to the shares. If any of the following risks are realized, Genmab's business, financial position, results of operations and future growth prospects could suffer materially, its actual results of operations could differ materially from those anticipated in the forward-looking statements in this document, the trading price of the shares could decline, and investors could lose all or part of their investment. Additional risks and uncertainties not presently known, or that Genmab currently deems immaterial, may also be or become material.*

*In this section, all references to Genmab's products and product candidates are to those that are being developed by Genmab itself, those that are being developed by Genmab in collaboration with third parties, and those that have been out-licensed to and are being developed by third parties alone.*

*The risk factors below are not listed in any order of priority with regard to significance or probability. It is not possible to quantify the significance to Genmab of each individual risk factor, as each risk described below may materialize to a greater or lesser degree or have unforeseen consequences.*

### 1.1 Risks Related To Our Business

**We are heavily dependent on the success of a limited number of products and product candidates, only a few of which have entered clinical trials and only one of which has been approved for sale, and we need to continue to identify further product candidates.**

Our ultimate success is dependent upon generating revenues from our products and product candidates. To date, only one of our products, Arzerra® (ofatumumab), has been approved for sale, in the United States by the Food and Drug Administration (FDA), in the European Union by the European Commission (EC) and in certain other territories, and only for patients with chronic lymphocytic leukemia (CLL) that is refractory to both fludarabine and alemtuzumab. Effective as of 4 September 2012 Campath® (alemtuzumab) has no longer been available commercially, but it is still available for appropriate patients through the Campath Distribution Program. In order to receive Campath, the healthcare provider is required to document and comply with certain requirements. The addressable patient population for Arzerra under its current label is limited. In October 2013 applications were submitted to the US FDA and the European Medicines Agency (EMA) regulatory authorities to broaden the label for Arzerra to include use of Arzerra in combination with an alkylator-based therapy for the treatment of CLL patients who have not received prior treatment and are inappropriate for fludarabine-based therapy. Our partner GlaxoSmithKline ("GSK") is currently conducting a number of additional clinical trials for ofatumumab for other indications, which will need to be successfully completed before regulatory approvals can be applied for and obtained for any further indications, and we are subject to the risks of dependence upon GSK's continued development. See "Risks Relating to Our Strategic Collaborations - We depend on our partners' willingness and/or ability to devote resources to the development of our product candidates and/or otherwise support our business as contemplated in our partnership agreements, which may be terminated." Arzerra faces competition from existing therapies and potential competition from possible new therapies under development for CLL and other indications. See "-We face intense competition and very rapid technological change." Our future revenues from sales of ofatumumab will depend on the success of clinical trials, label expansion and approval for new indications, remaining competitive and continued development by GSK.

Under our license agreement with Janssen Biotech Inc. ("Janssen"), our lead clinical stage product candidate, daratumumab (HuMax®-CD38) is currently the subject of a Phase I/II monotherapy study for the treatment of relapsed or refractory multiple myeloma and a Phase I/II study in combination with Revlimid® (lenalidomide) and dexamethasone in relapsed or refractory multiple myeloma. In September 2013 a decision was made to start a new Phase II study of daratumumab as a monotherapy in multiple myeloma patients who have received at least three different lines of therapy including both a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD) or who are double refractory to a proteasome inhibitor and an IMiD. This Phase II study is now recruiting patients. Furthermore, a new Phase Ib study of daratumumab in combination with backbone regimens [VD (bortezomib and dexamethasone), VMP (bortezomib, melphalan and prednisone), VTD (bortezomib, thalidomide and dexamethasone) and Pom-dex (pomalidomide and dexamethasone)] to treat multiple myeloma in newly diagnosed patients (VD, VTD, VMP) or patients who have received at least two prior lines of treatment (Pom-dex) is expected to start soon. Further clinical trials will be required under our license agreement with Janssen to achieve full commercial potential of daratumumab.

Teprotumumab (RG1507) is a fully human antibody that targets the Insulin-like Growth Factor-1 Receptor (IGF-1R). Teprotumumab was created by Genmab under its collaboration with Roche. Clinical development of teprotumumab in a Phase II study of patients with active thyroid eye disease was initiated by River Vision Development Corporation, which licensed the product from Roche.

In July 2013 Genmab submitted an IND for HuMax®-TF-ADC to the US FDA and clinical trial applications to regulatory authorities in Europe, and Genmab subsequently started a Phase I study in solid tumors.

Our other product candidates currently under development are all at a pre-clinical stage of development. Genmab has over 10 active pre-clinical programs, including internal programs and those carried out with our collaboration partners.

If ofatumumab is not approved for additional indications or if one or more of our other product candidates fail to receive approval, our ability to generate increased revenues and profits will be materially delayed or impaired.

We will need to keep generating additional antibodies to identify future potential target candidates. We cannot be certain that our human antibody technology will generate antibodies against all antigens to which it is exposed in an efficient and timely manner. If our human antibody technology fails to generate further antibody product candidates that are effective, and if we or our partners do not succeed in the development of further products employing our antibody technology, our business will suffer.

**We use fully human antibody and other new technologies which have limited track records in resulting in new pharmaceutical or biologic products to generate our product candidates, and we may not be successful at developing our products or product candidates.**

Development of our current and future products and product candidates is subject to the risks of failure inherent in the development of new pharmaceutical and biologic products, and of products based on new technologies. These risks include, among others:

- delays or unplanned expenditures in product development, clinical testing or manufacturing;
- failure in clinical trials or failure to receive regulatory approvals;
- emergence of superior or equivalent products;
- inability to manufacture product candidates on a commercial scale;
- inability to market products due to third-party proprietary rights;
- election by our collaborative partners not to pursue product development;
- failure by our collaborative partners to develop products successfully; and
- failure to achieve market acceptance.

We have obtained from Medarex, now a wholly owned subsidiary of Bristol-Myers Squibb Company (“BMS”), and BMS the right to use the UltiMab® transgenic mouse technology to make fully human antibodies to target antigens. We use our fully human antibody technology to generate product candidates. We cannot be certain that any particular product candidate that we choose to develop using our fully human antibody technology will demonstrate safety, potency and clinical efficacy. Only a limited number of our fully human antibody product candidates have entered clinical trials. To date, only one product employing our fully human antibody technology, Arzerra, has been approved for sale, for patients with CLL that is refractory to fludarabine and alemtuzumab. In addition, we are aware of only four other fully human monoclonal antibody products that have been developed using Medarex’s transgenic mouse technology by other companies: Stelara® (ustekinumab), Simponi® (golimumab), both developed by Centocor Ortho Biotech, Ilaris® (canakinumab), developed by Novartis Pharma, and Yervoy® (ipilimumab), developed by Medarex/BMS. We are also aware of only three fully human monoclonal antibody products developed by Amgen, Inc. using a fully human antibody technology that is similar to our fully human antibody technology: Vectibix® (panitumumab), Xgeva® (denosumab) and Prolia® (denosumab). There can be no assurances that our fully human antibody technology will result in the development of further approved products.

Because of these risks, our research and development efforts or those of our collaborative partners may not result in any commercially viable products. If a significant portion of our development activities is not successfully completed, required regulatory approvals are not obtained or any approved products are not commercially successful, our business, financial condition and results of operations may be materially harmed.

We have developed our own proprietary antibody technology platforms, including the DuoBody® platform and the HexaBody™ platform. The DuoBody platform is a technology for creating bispecific antibodies, and the HexaBody platform is a technology for enhancing effector functions of antibodies. Neither of these platforms has been validated in the clinic.

**We may fail to identify, select or capitalize on the best product candidate for our fully human antibody technology and the indications we seek to address.**

Part of our strategy is to identify the best disease targets and develop unique best-in-class or first-in-class antibodies to address them. We may not be successful in identifying, developing, commercializing or otherwise capitalizing on product candidates, and we may use our limited resources on efforts that may be significantly delayed or discontinued.

We have previously clinically tested zanolimumab (HuMax-CD4®) for the treatment of rheumatoid arthritis (RA), psoriasis, as well as cutaneous T-cell lymphoma (CTCL) and peripheral T-cell lymphoma (PTCL). In September 2002, we announced the winding down of the development of the product for RA after review of initial results of a Phase II study showing no significant difference between the American College of Rheumatology (ACR) scores from patients receiving placebo compared to patients treated with zanolimumab in combination with methotrexate. In December 2003, we announced the winding down of our development of the product for psoriasis after results from our Phase IIb study indicated that zanolimumab did not achieve statistically significant results in this indication. And in October 2008, Genmab announced the winding down of its development of the product for CTCL and the discontinuation of the zanolimumab program after a portfolio review. The zanolimumab program was subsequently out-licensed, first to TenX Biopharma, Inc. and, following TenX Biopharma's bankruptcy, to Emergent BioSolutions, Inc. Emergent BioSolutions, Inc. has subsequently provided notice of termination of the license agreement covering zanolimumab, and the program will revert to Genmab.

Genmab has also previously clinically tested zalutumumab (HuMax®-EGFr) for the treatment of refractory head and neck cancer. In March 2010, Genmab announced that data of a Phase III study showed no statistically significant median overall survival benefit for patients receiving zalutumumab in combination with best supportive care compared to patients only receiving best supportive care. In October 2010, Genmab announced that based on the feedback from preliminary, non-binding discussions with a number of selected European regulatory authorities and the FDA, Genmab believed that a Marketing Authorization Application (MAA) could be pursued based on the Phase III study data but that additional clinical study data would be required to submit a regulatory application in the United States. In June 2011, Genmab announced the winding down of the zalutumumab clinical program as no satisfactory partner to take zalutumumab forward had been found.

In our collaboration with GSK, we have also tested ofatumumab (HuMax®-CD20) as monotherapy in rituximab refractory follicular non-Hodgkin's lymphoma (NHL). The data from that study was announced in August 2009 and showed that the overall response rate was not of a magnitude that would support further development of ofatumumab as monotherapy in this patient population. Instead a combination therapy of ofatumumab in combination with bendamustine (Treanda®) was initiated in this patient population, and a Phase III study is ongoing.

If we decide to discontinue any of our development activities, we will not be able to make a return on our investment and our business, financial condition and results of operations may be materially harmed.

**We must conduct expensive, time-consuming clinical trials for our product candidates which are subject to the risks of delays.**

Product candidates employing our human antibody technology must demonstrate that they are safe and effective for use in humans through pre-clinical testing and "adequate and well controlled" clinical trials in order to be approved for commercial sale. Conducting clinical trials is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity, novelty and intended use of the product candidate, and can often be several years or longer. The commencement and rate of completion of clinical trials may be delayed by many factors, including:

- inability to manufacture sufficient quantities of qualified current Good Manufacturing Procedure (cGMP) materials for clinical trials;
- slower than expected rates of patient recruitment;
- the need or desire to modify our manufacturing processes;
- modification of clinical protocols;

- delays, suspension or termination of clinical trials due to the institutional review board (IRB) or Ethics Committee responsible for overseeing the clinical study at a particular study site or country;
- inability to observe patients adequately after treatment;
- change in regulatory requirements for clinical trials;
- unforeseen safety issues; and
- government or regulatory delays or “clinical holds,” including delays resulting from efforts by competitors to influence the regulatory process by actions such as petitions to alter approval requirements for the types of products we are seeking to develop.

Delays associated with products for which we are directly conducting pre-clinical or clinical trials will cause us to incur additional operating expenses. Moreover, we will be affected by delays associated with the pre-clinical testing and clinical trials of certain product candidates being conducted by our partners over whom we have little or no control.

**Our success in early clinical trials may not be indicative of results obtained in later clinical trials, the outcome of which is always uncertain, and our product candidates may not successfully complete clinical trials.**

Even if we obtain positive results from pre-clinical or early clinical trials, we may not achieve the same success in future trials. The results of our 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. Our own clinical development efforts for zanolimubab for the treatment of RA and psoriasis are an example of that. 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 for product candidates employing our human antibody technology. The failure of clinical trials to demonstrate safety and efficacy for our desired indications could harm the development of that product candidate as well as other product candidates employing the same technology, and our business will suffer.

**We may conduct clinical tests of our product candidates in combination with other therapeutic products or combined with drug-linker materials in the form of antibody-drug conjugates (ADCs), which exposes us to risks related to those products or to drug-linker materials.**

A part of our clinical development strategy for certain of our product candidates, including ofatumumab and daratumumab, is that we seek to identify patients or patient subsets within a disease category in the hope that our product candidates may result in an increased benefit when taken together with other therapeutic products. For example, we have tested or are currently testing: ofatumumab in combination with fludarabine and cyclophosphamide to treat CLL in relapsed patients; ofatumumab in combination with bendamustine for the treatment of front line and relapsed CLL; ofatumumab in combination with chlorambucil in previously untreated patients with CLL; and daratumumab in combination with Revlimid® (lenalidomide) and dexamethasone in relapsed or refractory multiple myeloma. We may obtain regulatory approval for treatment of a disease indication based on the prescription of our product candidate in combination with these other therapeutic products. This exposes us to certain risks related to those other therapeutic products, including the risks that such products will be found to have safety concerns, which could potentially result in removal from the market, or will become obsolete. For example, in May 2012, the FDA issued a safety announcement relating to the risk of second primary malignancies in patients with newly diagnosed multiple myeloma that have received Revlimid. In addition, on 18 July 2013 Celgene, in consultation with the FDA, discontinued treatment with Revlimid in the open-label, Phase III ORIGIN® trial for 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.

Also, we may decide to use our antibodies in an antibody drug conjugate (ADC) setting using third party drug-linker technology. Currently, we are performing clinical trials with one such product, HuMax-TF-ADC, making use of Seattle Genetics’ drug-linker technology. This exposes us to certain risks related to the use of often very potent drug-linker materials, including the risks that such materials will be found to have safety concerns, which could potentially result in removal from the market, or that such materials will become obsolete.

## **We may never obtain the additional regulatory approvals we need to market our product candidates.**

Following completion of clinical trials, the results are evaluated and, depending on the outcome, submitted to the FDA in the form of a Biologics License Application (BLA) or a New Drug Application (NDA), in order to obtain FDA approval of the product and authorization to commence commercial marketing. In responding to a BLA or NDA, the FDA may require additional testing or information, may require that the product labeling be modified, may impose post-approval study or reporting requirements or other restrictions on product distribution, or may deny the application. The timing of final FDA review and action varies greatly, but can take years in some cases and often involves the input of an FDA advisory committee of outside experts. Product sales in the U.S. may commence only when a BLA or NDA is approved. Similar pre-marketing approvals and other regulatory requirements apply in Europe and elsewhere.

To date, we have received approval from the FDA in the United States, a conditional approval from the European Commission in the European Union and as well as other territories for the commercial sale of Arzerra for patients with CLL that is refractory to fludarabine and alemtuzumab. No other product candidate developed by Genmab or in collaboration with our partners has been determined by the FDA or any other governmental body to be safe, effective and potent.

Product candidates that appear promising in the early phases of development, such as in early human clinical trials, may fail to achieve regulatory approval for a number of reasons, such as the product candidate did not demonstrate acceptable clinical trial results even though it demonstrated positive pre-clinical trial results; the product candidate was not effective in treating the specified disease or condition; the product candidate had harmful side effects on humans or presented unacceptable safety risks; the governing regulatory authorities (such as the FDA and EMA) denied approval to the product candidate altogether or denied a commercially important indicated use. We may spend several years completing our testing for any particular product candidate, and failure can occur at any stage. Negative or inconclusive results or adverse medical events during a clinical trial could also cause the regulator or us to terminate a clinical trial or require that we repeat it or conduct additional clinical trials. Additionally, data obtained from pre-clinical studies and clinical trials can be interpreted in different ways and the FDA or other regulatory authorities may interpret the results of our studies and trials less favorably than we do. Even if we and our collaboration partners believe the pre-clinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering any of our product candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials of our product candidates and result in the FDA or other regulatory authorities denying approval of our product candidates for any or all targeted indications. We cannot guarantee that we will obtain the required regulatory approvals to market our products. Even if we obtain such approvals, we may never be able to produce commercially successful products for reasons including the product candidate not being economical for us to manufacture and/or not being cost-effective in light of alternative therapies.

## **Our product candidates may receive warnings from the regulatory authorities regarding use in certain patient populations.**

In September 2013, the FDA placed its strongest warning, a Black Box warning, on safety labels of our CD20 antibody product, Arzerra, and Genentech's CD20 antibody products, Rituxan and Gazyva<sup>TM</sup> – and their generics. The warning applies to patients taking Rituxan, Gazyva or Arzerra who have been previously infected with hepatitis B. Taking any of these cancer drugs can “reactivate” the infection and potentially lead to death.

## **Our product candidates may not gain market acceptance.**

Even if clinical trials demonstrate sufficient levels of safety and efficacy of products developed by us or our partners using our technology and all regulatory approvals have been obtained, products employing our human antibody technology may not gain market acceptance among physicians, patients, third-party payers and the medical community. The current delivery systems for human antibody products, including Arzerra and our product candidates, are intravenous and subcutaneous injection, which are generally less well received by patients than oral, self-administered therapy. The degree of market acceptance of any product candidates employing our technology will depend on a number of factors, including:

- establishment and demonstration of clinical efficacy, potency and safety, especially as compared to conventional treatments;
- cost-effectiveness;
- alternative treatment methods;

- reimbursement policies of government and third-party payers; and
- marketing and distribution support for our product candidates.

Any failure by our product candidates that obtain regulatory approval to achieve market acceptance or commercial success would adversely affect our financial results.

**The successful commercialization of our human antibody products may depend on obtaining coverage and reimbursement for use of these products from third-party payers.**

Sales of pharmaceutical products largely depend on the reimbursement of patients' medical expenses by government health care programs and private health insurers. Without the financial support of governments or third-party payers, the market for products employing our fully human antibody technology may be limited. We cannot be sure that governments or third-party payers will reimburse sales of products employing our fully human antibody technology, or enable us or our partners to sell them at profitable prices.

Governments and third-party payers control health care costs by limiting both coverage and the level of reimbursement for new health care products. Some governments have introduced price controls and further limits on spending and more governments may follow in the future. For example, in the future, the U.S. government may institute price controls and further limits on Medicare and Medicaid spending. Internationally, medical reimbursement systems vary with differing degrees of regulation. Pricing controls and reimbursement limitations could affect the payments we receive from sales of products employing our human antibody technology. In addition, some of our product candidates are designed to treat chronic diseases such as RA. Government health care systems and third-party payers have instituted and may institute further limits on reimbursement for treatments of such chronic diseases. These third-party payers are increasingly challenging the price and examining the cost-effectiveness of medical products and services more generally. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. For example, together with GSK, we are conducting a post-marketing study in order to demonstrate the cost-effectiveness of Arzerra. This and similar post-marketing studies may require us to use a significant amount of our resources. Our product candidates may not be considered cost-effective. These controls and limitations could harm our ability and the ability of our partners to sell products employing our fully human antibody technology in commercially acceptable quantities at profitable prices.

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

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Developments by our competitors may render our fully human antibody technology obsolete or non-competitive. We are aware of several pharmaceutical and biotechnology companies that are actively engaged in research and development in areas related to antibody therapy. These companies have commenced clinical trials of antibody products or have successfully commercialized antibody products. Many of these companies are addressing the same diseases and disease indications as the antibody products developed by us and our partners. We also compete with pharmaceutical companies engaged in research and development of small molecule compounds, including tyrosine kinase inhibitors such as ibrutinib, and imatinib, targeting the same diseases and disease indications as the antibodies developed by us and our partners.

The new tyrosine kinase inhibitor, ibrutinib (Imbruvica®), which has been approved for mantle cell lymphoma (MCL) and which is currently in development for treatment of CLL by Pharmacyclics, Inc. and Johnson & Johnson, may offer a potential new standard in leukemia treatment. Pharmacyclics, Inc. and Johnson & Johnson are conducting a Phase III clinical study with ibrutinib vs. ofatumumab in patients with relapsed or refractory CLL. The clinical study has been stopped early as an interim analysis has shown significant improvement in progression-free survival and overall survival upon administration of ibrutinib.

Also, we compete with companies that offer antibody generation services to companies that have antigens. These competitors have specific expertise or technology related to antibody development. We compete directly with entities such as Medarex/BMS, Amgen, Kirin (now Kyowa Hakko Kirin) and Regeneron with respect to the generation of fully human antibodies from transgenic mice. We also compete with Cambridge Antibody Technology, which was acquired by AstraZeneca in June 2006, and MorphoSys AG with respect to the generation of fully human antibodies derived from phage display technology, and with PDL BioPharma with respect to humanized mouse antibodies. The use of antibodies is only one of several processes for the development of disease treatments and other technologies can also be applied to the treatment of the diseases that we are pursuing. Such technologies may be more advanced than ours and may be more acceptable than our antibody products.

We also compete with other companies that develop antibody formats and technologies. Genentech, Inc., Zymeworks, Pfizer-Rinat and Merck GmbH, among others, have bispecific antibody technologies which may compete with our DuoBody technology.

Furthermore, several companies have effector enhancing technologies that may compete with our HexaBody technology.

Some of our competitors have received regulatory approval or are developing or testing product candidates that compete directly with product candidates employing our or our licensors' antibody technology. Many of these companies and institutions, either alone or together with their partners, have substantially greater financial resources and larger research and development divisions than do we or our partners. In addition, many of these competitors have significantly greater experience than us in:

- developing products;
- undertaking pre-clinical testing and clinical trials;
- obtaining FDA, European and other regulatory approvals of products; and
- manufacturing and marketing products.

Accordingly, we may not obtain patent protection, receive regulatory approval or commercialize products before our competitors. If we commence commercial product sales, we will be competing against companies with greater marketing and manufacturing capabilities, areas in which we have limited or no experience.

We also face intense competition from other pharmaceutical and biotechnology companies in establishing partnerships, as well as relationships with academic and research institutions, and in licensing proprietary technology. These competitors, either alone or with their partners, may succeed in developing technologies or products that are more effective than ours.

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. We are aware of several pharmaceutical and biotechnology companies which are actively engaged in research and development in areas related to antibody therapy that have commenced clinical trials of antibody products or have successfully commercialized antibody products. Some of these companies, such as ImClone (part of Eli Lilly), BMS, Johnson & Johnson Development Corporation (JJDC), Wyeth (now part of Pfizer), Amgen, Roche, Genentech (part of Roche), Abbott Laboratories, UCB, Biogen Idec, Takeda, Merck KGaA, MorphoSys, Tanox (acquired by Genentech), Trubion Pharmaceuticals (acquired by Emergent BioSolutions), Seattle Genetics, Immunogen, Sanofi Aventis, Regeneron, Alexion and Facet Biotech (a spin-out of PDL BioPharma, now part of Abbott), are addressing diseases and disease indications which are being targeted by us. Many of these companies and institutions, either alone or together with their partners, have substantially greater financial resources and larger research and development divisions than we have. In addition, many of these competitors, either alone or together with their partners, have substantially greater experience than us in developing products, undertaking pre-clinical testing and human clinical trials, obtaining FDA and other regulatory approvals of products and manufacturing and marketing products. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or EU approval or commercializing products more rapidly than us.

Other technologies can also be applied to the treatment of the diseases that we are pursuing. For example, immunoconjugates, monoclonal antibodies linked to toxins or radioactive isotopes and other immunotherapy products are being developed by others. In addition, the application of recombinant DNA technology to develop potential products consisting of proteins (cytokines) that occur normally in the body in small amounts has been underway for some time. Included in this group are interleukin-2, interferons alpha, beta and gamma, tumor necrosis factor (TNF), colony stimulating factors and a number of other biological response modifiers.

Continuing development of conventional chemotherapies and other drugs carries with it the potential for discovery of an agent active against various diseases.

We are aware that Genentech, Roche and Biogen Idec have commercialized an antibody directed against CD20 (rituximab, Rituxan®, Mabthera®). In 2013 their follow-on CD20 antibody product (obinutuzumab, Gazyva™) was approved by the FDA for the treatment of previously untreated patients with CLL in combination with chlorambucil. Cell Therapeutics, Bayer Schering and GlaxoSmithKline are also marketing radio labeled antibodies directed to CD20. We are also aware of the following anti-CD20 programs. Several companies are developing antibodies against CD20: Genentech/Roche (ocrelizumab), Immunomedics Inc. (veltuzumab), MentriK Biotech (ocaratzumab, AME-133), TG Therapeutics/LFB (ublitzumab), Innovent (IBI-301), Biocon/Vaccinex (BVX20-CD20), Biomedics Japan (BM-Ca), InNexus (DXL-625), Amgen/AstraZeneca (mAb 1.5.3),

MedImmune/AstraZeneca (MEDI-552), Regeneron (CD20 mAb) Agila/Strides Acrolab (IBPM-001RX), Fraville/Verenium (CD20 mAb). In addition, CD20 monoclonal antibodies (mAbs) are being developed in novel formats: (a) Bispecific CD20 antibodies: TrionPharma (fBTA05), Immunomedics (20-74-74, CD20-CD22 bmAbs), Wayne State University/Barbara Ann Karmanos Cancer Institute (CD3/CD20 bmAb), Eberhard Karls University (CD20xCD95); (b) Radiolabeled CD20 mAbs: Algeta (227-Th-rituximab), Stanford University (64-Cu-DOTA-rituximab), University of Basel (177-Lu-DOTA-rituximab); and (c) Immunocytokines: Immunomedics (veltuzumab-IFN alpha2b), Immunogene (IGN-002), EMD Lexigen Research Center Corp/Biovation Ltd/City of Hope (DI-Leu16-IL2). Furthermore, several companies, including Green Cross, Curaxys, Shanghai CP Guojian Pharmaceuticals, iBIO, Lentigen, TL biopharmaceutical (TEVA/Lonza), Viropro, Dr Reddy's/CFR Pharmaceuticals/Cinnagen, Probiomed, BioXpress, Celltrion, Aprogen, Natco, Coherus BioSciences/Daiichi Sankyo, Gedeon Richter/Stada, GTC, Epicyte, Center of Molecular Immunology, Sandoz, Pfizer, Actavis (in collaboration with Amgen) and Merck & Co, Inc., are developing rituximab biosimilars or biobetters. Finally, BioXpress noted the development of an ofatumumab biosimilar.

Pharmacyclics, Inc. and Johnson & Johnson are developing ibrutinib (Imbruvica®), approved for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. An application for approval to treat CLL with ibrutinib has also been filed.

Cephalon, Inc. (part of Teva) is developing bendamustine (Treanda®), approved for treatment of CLL and NHL.

Sanofi, under license from ImmunoGen, is developing the CD38 humanized monoclonal antibody, SAR-650984, for the treatment of hematological cancers.

MorphoSys, in collaboration with Celgene, is developing MOR-202 (MOR-03087), a fully human monoclonal antibody generated by phage-display technology and directed against CD38, for the treatment of multiple myeloma.

Takeda Pharmaceutical Company Limited has a pre-clinical program for CD38 monoclonal antibodies.

BMS and Facet Biotech (now a wholly owned subsidiary of Abbott Laboratories, formerly PDL BioPharma) are developing elotuzumab, a humanized monoclonal antibody targeting the CD2 cell surface glycoprotein CS-1 for the potential intravenous treatment of multiple myeloma.

Celgene Corporation is commercializing lenalidomide (Revlimid®) and pomalidomide (Pomalyst®) for the treatment of multiple myeloma.

Amgen is commercializing carfilzomib (Kyprolis®) for the treatment of patients with multiple myeloma who have received at least two prior therapies, including treatment with bortezomib (Velcade®) and an immunomodulatory therapy.

Janssen Pharmaceuticals, Inc., Takeda and Millennium are commercializing bortezomib (Velcade®) for the treatment of multiple myeloma.

Biotest is developing BT-062 (indatuximab ravtansine), an immunoconjugate consisting of a chimerized monoclonal anti-CD138 IgG4 antibody plus the tubulin polymerization inhibitor DM4, developed using ImmunoGen's TAP technology, for the treatment of multiple myeloma.

Immune System Therapeutics and Medarex (BMS) are collaborating on development of MDX-1097, a chimerized anti-kappa light chain monoclonal antibody for potential treatment of blood cancers including multiple myeloma.

Altor Biosciences is developing a tissue factor antibody in cancers and other diseases that over express tissue factor.

Effective as of 4 September 2012 Genzyme Corporation (now part of Sanofi) has withdrawn alemtuzumab (Campath®), a lymphocyte-depleting humanized monoclonal antibody, from commercial use for CLL. It will still be available to appropriate patients via the Campath Distribution Program. Under the trade name Lemtrada™, alemtuzumab is being developed for use in relapsing multiple sclerosis. In September 2013 Lemtrada was approved by EMA for first line use in multiple sclerosis, while in December 2013 it failed to obtain approval by the FDA for this indication.

## **We could be exposed to competition from biosimilars or “follow-on” versions of our products.**

Under current United States law and FDA policy, generic versions of conventional chemical drug compounds, sometimes referred to as small molecule compounds, may be approved through an abbreviated approval process. In general terms, the generic applicant references an approved innovator product for which full clinical data demonstrating safety and effectiveness exist for the approved conditions of use. The generic applicant in turn needs only demonstrate that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use (labeling) as the referenced innovator drug, and that the generic product is absorbed in the body at the same rate and to the same extent as the referenced innovator drug (this is known as bioequivalence). In addition, the generic drug application must contain information regarding the manufacturing processes and facilities that will be used to ensure product quality, and must contain certifications to patents listed with the FDA for the referenced innovator drug.

There is no such abbreviated approval process under current law for biologic products approved through a BLA, such as monoclonal antibodies, cytokines, growth factors, enzymes, interferons and certain other proteins. However, in February 2012, the FDA issued three draft documents covering scientific and quality considerations for demonstrating biosimilarity to a reference product in order to gain approval using the “biosimilar” pathway. The agency intends to use a risk-based, “totality-of-the-evidence” approach to assess biosimilarity, which is in keeping with how it reviews small molecule or innovator biologic products. In order to gain FDA approval, biosimilarity must be demonstrated against a single reference product that has been approved in the US. However, under certain circumstances, animal or clinical study data from comparison to a non-US licensed product can be used to support the application, if sufficient justification is given. A biosimilar is typically expected to have the same primary amino acid sequence as its reference product. However, this is not mandatory. Minor modifications that are unlikely to have an effect on safety, purity, or potency may be acceptable where sufficiently justified by the applicant. Biosimilar applications in the US should generally include comparative analytical studies, animal studies, and human clinical studies (including immunogenicity and pharmacokinetic and/or pharmacodynamic studies). A high level of similarity between a biosimilar and its reference product demonstrated in analytical work can be used as justification for more selective or targeted approaches in subsequent animal or clinical studies. The initial guidance focuses on general therapeutic protein products, rather than addressing specific aspects such as for biosimilar monoclonal antibodies, which are considered more complex and pose further issues. Guidance states that the agency should be consulted on whether an application is appropriate if a product cannot be adequately characterized with state-of-the-art technology. If biosimilar monoclonal antibodies are approved, such products would be significantly less costly than ours to bring to market, and could lead to the existence of multiple lower priced competitive products. This would substantially limit our ability to obtain a return on the investments we have made in those products.

In June 2012, the EMA released its guideline on similar biological medicinal products containing monoclonal antibodies, non-clinical and clinical aspects. This guideline complements its “Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues” (EMA/CHMP/BMWP/42832/2005/), which sets forth the general requirements for demonstration of the similar nature of two biological products in terms of safety and efficacy. In September 2013 the European Commission approved the antibody product Remsima (infliximab), a biosimilar of Remicade®, for the treatment of rheumatoid arthritis, Crohn’s disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis.

## **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 both 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 where there are government price controls or other market dynamics that, in each case, make the products lower priced. 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 partly due 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 potential impact could become even greater if there is a further change in relevant protective legislation or if state or local governments taking further steps to import products from abroad.

**We currently rely on one contract manufacturer to provide production of our product candidates for clinical trials and do not have any arrangements in place 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. In 2009, we decided our manufacturing facility was no longer core to our strategy. The manufacturing facility was subsequently sold to Baxter Healthcare Corporation on 28 February 2013.

GSK is responsible for the manufacture of Arzerra, and Janssen for the manufacture of daratumumab. For the products where we are responsible for manufacturing, we currently rely upon one single source third-party contract manufacturing organization, Lonza, to manufacture and supply large quantities of our product candidates. While we believe that we have access to adequate facilities for the limited production of product candidates for clinical trials, these facilities may not be adequate for the production of sufficient quantities of any products for commercial sale in the future.

The manufacture of pharmaceutical and biologic products in compliance with cGMP regulations requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. 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 FDA and European regulations;
- production costs; and
- development of advanced manufacturing techniques and process controls.

If our manufacturer were to encounter any of these difficulties or otherwise fails 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.

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, a requirement for all pharmaceutical products. It would take a substantial period of time for a contract facility which 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.

Our current agreement with Lonza does not provide for the entire supply of the bulk drug necessary for additional clinical trials or for full-scale commercialization. In the event that we and Lonza cannot agree to the terms and conditions for them to provide some or all of our bulk drug clinical and commercial supply needs, or if Lonza terminates the agreement in response to a breach by us, we would not be able to manufacture the bulk drug on a commercial scale until a qualified alternative supplier is identified, which could also delay the development of, and impair our ability to commercialize, our product candidates. If we are unable to maintain access to sufficient manufacturing capacity within our planned time and cost parameters, the development and sales of our products and our financial performance may be materially harmed.

**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 rely on GSK for conducting all clinical studies with ofatumumab, and Janssen will be responsible for all new clinical studies with daratumumab. We do not currently have the ability to independently conduct any clinical trials. We rely on collaborative partners and other third parties, such as CROs, to conduct clinical trials on our product candidates. The third parties with whom we 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, and 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 have no sales or marketing capabilities and, if we are unable to partner or develop adequate sales and marketing capabilities, we may be unable to directly commercialize our antibody products.**

We have no sales, marketing or distribution capabilities. We rely on GSK for the sales, marketing and distribution of Arzerra under the terms of our collaboration agreement. We rely on Janssen for the potential future sales, marketing and distribution of daratumumab under the terms of our license agreement. In respect of our other product candidates, we may enter into arrangements with third parties, including our strategic partners, to sell, market and distribute certain of our products. There is no guarantee that any of our strategic partners will elect to sell, market and distribute the products that may result from our collaboration. Further, if any of these partners do elect to sell, market and distribute such products, we are likely to have limited control over such activities. If these partners do not elect to sell, market and distribute such products, we may need to enter into distribution or co-marketing arrangements with other third parties. We may not be able to enter into marketing and sales arrangements with others on acceptable terms, if at all. To the extent that we enter into marketing and sales arrangements with other companies, our revenues, if any, will depend on the terms of any such arrangements and the efforts of others. These efforts may not be successful. We may choose to market some of our antibody products directly through our own sales and marketing force. In order to do this, we will have to develop a sales and marketing organization and establish distribution capability. Developing a sales and marketing force would be expensive and time-consuming and could delay product launch. If we choose to market any of our antibody products directly but are unable to successfully implement a marketing and sales force, our business will suffer.

**We may face product liability claims related to the use or misuse of products employing our human antibody technology.**

Our business exposes us to potential product liability risks which are inherent in research and development, pre-clinical and clinical testing, manufacturing, marketing and use of human 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.

Generally, our 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. Any of these events could result in a product liability claim. Any such claims against us, regardless of their merit, could result in significant awards against us, which could materially harm our business, financial condition and results of operations.

**Our operations involve hazardous materials and are subject to environmental controls and regulations.**

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. We cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or environmental discharge, we may be held liable for any resulting damages, which may exceed our financial resources and may materially adversely affect our business, financial condition and results of operations.

**Our business can be harmed by events that damage our reputation or the reputation of our fields of research.**

As a biotechnology company, our reputation as a trusted and socially responsible partner is crucial to our business partners, which operate in a highly regulated industry and under media and public, as well as regulatory, scrutiny, and is thus essential to our ability to conduct business.

While we are dedicated to being a trusted and socially responsible company and to complying with all relevant laws, standards and guidelines as well as our contractual obligations, we may inadvertently breach such laws, standards, guidelines and contractual obligations, which may impact our reputation as a trusted partner. Even if we adhere to all of these laws, standards, guidelines and obligations, our reputation could still be harmed by events that are outside our control, including the failure of any of our product candidates to successfully complete clinical trials, any serious adverse events that may occur during those clinical trials, claims or allegations of breach of intellectual property rights by us or shortcomings of our contract manufacturers and/or contract research organizations. Furthermore, as there are other companies developing human monoclonal antibody products, actions by such companies that damage the market perception of human monoclonal antibody products, whether the safety, efficacy or otherwise, could also have a negative impact on us.

**Our business could be harmed by controversy relating to genetically engineered animals and animal testing.**

Many of our activities involve the use of genetically engineered animals and animal testing. These types of activities have been the subject of controversy and adverse publicity. Animal rights groups and numerous other organizations and individuals have attempted to stop genetic engineering activities and animal testing by, amongst other things, lobbying for legislation and regulation in these areas. If the use of genetically engineered animals and animal testing is restricted by legislation or regulation it may adversely affect our business.

**We may be adversely affected by the current global economic environment.**

Our business could be adversely affected by general conditions in the global economy and in the global financial markets. The recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. The continued uncertainty over the outcome of various international financial support programs and the possibility that other countries may experience similar financial pressures could further disrupt global markets.

We cannot anticipate all the ways in which the current global economic climate and global financial market conditions could adversely impact our business.

We are exposed to risks associated with reduced profitability and the potential financial instability of our collaboration partners, many of which may be adversely affected by volatile conditions in the financial markets. For example, unemployment and underemployment, and the resultant loss of insurance, may decrease the demand for healthcare services and pharmaceuticals. Concerns about sovereign debt have led to austerity programs in the affected countries. High levels of government debt throughout the developed world have led to calls for more widespread austerity. In the United States, there has been a large focus on the future trajectory of healthcare costs and controlling these costs has been a subject of focus in other major markets as well where governmental austerity programs are, in many cases, forcing spending reductions or restraint on government provided healthcare which may result in reduced demand or pricing pressure which lowers margins. As a result, our collaboration partners may experience reductions in revenues, profitability and/or cash flow that could lead them to reduce their support of our programs. We have exposure to European government obligations through our investment portfolio. Although the government bonds in our investment portfolio had a triple A-rating at the end of September 2013, there can be no assurances that the credit rating of any of the sovereign issuers in which we invest will not be impaired.

## **1.2 Risks relating to Our Strategic Collaborations**

**We depend on a variety of strategic partnerships and 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 the in- and out-licensing of our technology. Our ability to continue our current partnerships and to enter into additional partnerships

is dependent in large part on our ability to successfully demonstrate that our fully human antibody technology and other platform technologies are attractive methods of 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 a company that is one of our competitors, that company could be less willing to continue its collaboration with us. In addition, a company that has a strategy of purchasing companies rather than entering into partnership arrangements might have less incentive to enter into a collaboration agreement with us. Moreover, disputes may arise with respect to the ownership of rights to any technology or products developed with any current or future partner. 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 product candidates. 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 will be able to develop and commercialize;
- significantly increase our need for capital; and/or
- place additional strain on management's time.

Any of the above may materially harm our business, financial condition and results of operations.

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

We depend on our partners to support our business, including for the development or co-development of a number of the products and product candidates generated through the use of our fully human antibody technology. In particular, we have granted: GSK worldwide exclusive rights to co-develop and commercialize ofatumumab (Arzerra) in cancer indications and to develop and commercialize ofatumumab in autoimmune indications; Janssen worldwide exclusive rights to develop and commercialize daratumumab; and Janssen, Novartis Pharma AG, Kyowa Hakko Kirin Co. and Eli Lilly and Company each a worldwide, non-exclusive license to our DuoBody technology platform. In addition, we have created antibodies under a collaboration with Roche, and we have created antibodies to three central nervous system (CNS) targets under an agreement with H. Lundbeck A/S. Furthermore, we have granted Seattle Genetics, Inc. an exclusive option to co-develop and co-commercialize HuMax®-TF-ADC (Tissue Factor) with us, and we have entered into a collaboration with ADC Therapeutics regarding HuMax-TAC-ADC. Reference is made to the Section "2 OUR CURRENT COLLABORATIONS" herein.

The successful development and commercialization of ofatumumab, daratumumab and teprotumumab (RG1507) are dependent, in large part, on the actions of our partners, which are partly outside of our control. Positive Phase II clinical data have been announced for ofatumumab in a subcutaneous formulation for treatment of relapsing-remitting multiple sclerosis (RRMS). It is within the absolute discretion of GSK whether to initiate a Phase III clinical study based on these data.

Our dependence on our partners subjects us to a number of risks, including:

- our partners have significant discretion whether to pursue planned activities;
- we cannot control the quantity and nature of the resources our partners may devote to product candidates;
- our partners may not develop products generated using our antibody technology as expected; and
- business combinations or significant changes in a partner's business strategy may adversely affect that partner's willingness or ability to continue to pursue these product candidates.

Our licensing partners generally have the right to terminate our partnerships at any time. For example, GSK has the right to terminate the Co-development and Collaboration Agreement concerning ofatumumab at any time by providing nine months' prior written notice to us. Also, Janssen has the right to terminate our License Agreement concerning daratumumab with 150 days' written notice to us. Any termination of these or our other partnerships could significantly delay the development and commercialization of our product candidates and materially harm our business, financial condition and results of operations.

We may, now or in the future, rely on our partners to:

- access proprietary antigens and/or technologies for the development of product candidates;

- access skills and information that we do not possess
- fund our research and development activities;
- fund and conduct pre-clinical testing and clinical trials;
- seek and obtain regulatory approvals for product candidates;
- manufacture products; and/or
- commercialize and market future products.

If we do not realize the contemplated benefits from our partners, our business, financial condition and results of operations may be materially harmed.

**We do not have exclusive use of Medarex's transgenic mouse technology and may compete with Medarex or its potential licensees for targets.**

Under the terms of our technology agreement with Medarex, we have obtained a limited number of exclusive commercial licenses of which three (3) are still left. Furthermore, Medarex is obliged to grant to us non-exclusive commercial licenses for any target we specify, so long as Medarex has not previously granted exclusive rights to such target to an unrelated third party or does not have its own pre-existing development program in place with respect to the selected target. We may compete directly with Medarex and its other potential licensees for licenses to targets and for collaborative arrangements with other companies. Medarex may continue to license its transgenic mouse technology to others, and other companies may take licenses to use this transgenic mouse technology to create antibodies to particular targets before we are able to do so. Other than the product licenses that we have already obtained from Medarex and those that we may obtain from Medarex in the future, nothing restricts Medarex from competing with us or granting licenses to targets to our competitors. Competition to licenses in respect of targets either from Medarex directly or from third party competitors could impair our ability to identify and develop new product candidates.

**Our collaboration agreements expose us to exchange rate risk.**

Our functional currency, the currency in which we present our financial statements, is the Danish Krone. However, a number of our collaboration agreements may require us to make payments, and receive revenues, in currencies other than Danish Kroner, particularly U.S. dollars, British Pounds and Euros. Our principal future funding commitments and revenues are under our collaboration agreement with GSK for the development of ofatumumab, our DuoBody technology agreements with Janssen and Novartis, respectively, our agreement with Lundbeck as well as our agreement with Janssen for the development of daratumumab.

Our funding commitment under our collaboration agreement with GSK for ofatumumab in cancer indications is capped at a total of GBP 145 million, including a yearly cash funding cap of GBP 17 million for six years starting in 2010. To reduce Genmab's long term GBP/DKK currency exposure associated with the annual funding obligation of GBP 17 million, Genmab has entered into derivative contracts to hedge the associated currency exposure for the period from 2013 to 2015. We are exposed to credit loss in the event of non-performance by our counterparty, which is a financial institution with a long term rating of A- from S&P. Changes in the GBP to DKK forward exchange rate also impact the valuation of the derivative contracts.

Revenues associated with our DuoBody technology agreements with Janssen and Novartis, respectively and our license agreement with Janssen for the development of daratumumab will be in U.S. dollars. Revenues associated with our agreement with Lundbeck will be in Euros.

**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, may 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.

### 1.3 Risks Related to Regulation

**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 human antibody technology are subject to extensive and rigorous government regulation, including regulation by the FDA, the U.S. Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice, state and local governments and their European and foreign counterparts. The FDA and European regulatory agencies regulate the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of biopharmaceutical products. The FDA regulates human antibodies as biologics (while reviewed by the Center for Drug Evaluation and Research) under the Public Health Services Act, while European regulatory agencies regulate human antibodies in the same manner as drugs. If products employing our human antibody technology are marketed in countries outside of Europe and the United States, they will also be subject to extensive regulation by other governments. The regulatory review and approval or licensing process, which includes pre-clinical testing and clinical trials of each product candidate, is lengthy, expensive and uncertain. Securing FDA licensure and European regulatory agency approval requires the submission of extensive pre-clinical and clinical data and supporting information to the FDA and European regulatory agencies for each indication to establish the product candidate's safety and efficacy. The approval and licensure processes take many years, require substantial resources, involve post-marketing surveillance, and may involve ongoing post-marketing studies. Delays in obtaining regulatory approvals may:

- adversely affect the successful commercialization of any product that we or our collaborative partners develop;
- impose costly procedures on us or our partners;
- diminish any competitive advantages in the market place that we or our partners may attain; and
- adversely affect our receipt of revenues or royalties.

Material changes to an approved product, such as manufacturing changes or additional labeling claims, require further FDA and European regulatory agency review and approval before marketing. Once obtained, any approvals may be withdrawn or revoked because of unforeseen safety, effectiveness or potency concerns or failure to comply with governmental regulations. Further, if we, our partners or our contract manufacturers fail to comply with applicable FDA, European regulatory agency and other regulatory requirements at any stage during the regulatory process, the FDA, European regulatory agencies and other regulatory agencies may impose sanctions, including:

- delays or clinical holds;
- warning letters;
- fines;
- importation restrictions;
- product recalls or seizures;
- injunctions;
- refusal of the FDA and/or European or other regulatory agency to review pending market approval applications or supplements to approval applications;
- total or partial suspension of production;
- suspension or debarment from selling FDA-regulated products to the U.S. government for periods of time that vary depending on the cause of such suspension or debarment;
- civil penalties;
- withdrawal or revocation of previously approved marketing applications or licenses; and
- criminal prosecutions.

In some instances, we also rely on our partners to conduct pre-clinical and clinical development studies to demonstrate the safety, effectiveness and potency of each product and to direct the regulatory approval and licensure processes for products employing our human antibody technology. Our partners may not be able to conduct clinical testing or obtain necessary approvals from the FDA, EMA or other regulatory authorities for any product candidates employing our human antibody technology. If they fail to obtain required governmental approvals, our partners will be delayed or precluded from marketing these products. As a result, the commercial use of products employing our technology will be limited and our business may suffer.

**Even if approved, our products will be subject to extensive post-approval regulation.**

Once a product is approved, numerous post-approval requirements apply. Among other things, the holder of an approved BLA or an NDA 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 or NDA. 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. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act. 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. 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.

Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we comply with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw a product approval.

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).

Both, the FDA and EMA approvals obtained for Arzerra are conditional upon completing additional clinical trials which must verify the clinical benefit of Arzerra. In the US, a clinical study comparing Arzerra plus chlorambucil v. chlorambucil alone in previously untreated CLL patients was agreed as the confirmatory study. Positive primary endpoint data for this study was announced in May 2013 which data form the basis of the sBLA that was submitted to the FDA in October 2013. A positive opinion by the FDA will convert the conditional approval to a full approval. In the EU, a clinical study comparing Arzerra against physician's best choice in relapsed or refractory CLL patients with bulky disease was agreed as the confirmatory study. Should these studies fail to verify that the clinical benefit is conferred by Arzerra, the FDA and EMA may withdraw or modify the approval.

**Recent publicity concerning the safety risk of certain drug products may result in an even more stringent regulatory approval process and post-approval regulation.**

In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress and the Governmental Accounting Office in the U.S., medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials and the drug approval process. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought. In, addition, because of the serious public health risks of high profile adverse safety events with certain products, the FDA may require, as a condition of approval, costly risk management programs which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising.

**We and our manufacturing partners must obtain and maintain current good manufacturing practices (cGMP).**

We depend on Lonza Biologics Plc. to manufacture our products and product candidates generated by employing our fully human antibody technology. Before commercializing a new drug, manufacturers must comply with the applicable FDA, European, or other regulatory agency cGMP regulations which include quality control and quality assurance requirements as well as the maintenance of records and documentation. Manufacturing facilities are subject to pre-approval and ongoing periodic inspection by the FDA, European regulatory agencies and other corresponding governmental agencies, including unannounced inspections, and must be licensed before they can be used in commercial manufacturing of products employing our technology. Manufacturers of our component materials may be unable to comply with these cGMP requirements and with other FDA, European and other regulatory requirements. The FDA or similar European or other 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. We have little control over our manufacturers' compliance with these regulations and standards. After regulatory approvals or licensure are obtained, the subsequent discovery of previously unknown manufacturing, quality control or regulatory documentation problems or failure to maintain compliance with the regulatory requirements 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 our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products, and we 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 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 and our contract research organizations must adhere to current good clinical practices (cGCP).**

We depend on our contract research organizations such as INC Research and PRA International, as well as other third parties to carry out our development activities for us. In order to develop a new drug, pharmaceutical companies must conduct clinical studies and in order to do so the pharmaceutical company, and its contract research organizations must comply with the applicable FDA, European, or other regulatory agency cGCP regulations. While we maintain a high degree of sponsor oversight, we cannot assure that such contract research organizations will be able to comply adequately with the applicable regulations.

**We may experience additional pricing pressures due to changes to legislation in the United States and other territories.**

In the United States, traditionally the largest market for pharmaceutical and biologic products and the current largest market for Arzerra, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future revenues and profitability. Federal and state lawmakers regularly propose and, at times, enact legislation that results in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, in March 2010, President Obama signed one of the most significant healthcare reform measures in decades, the Affordable Care Act. It contains a number of provisions, including those governing enrollment in U.S. federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs.

In addition, although on 28 June 2012 the United States Supreme Court has upheld the constitutionality of most of the Affordable Care Act, some states have indicated that they intend not to implement certain sections of the Affordable Care Act, and some members of the U.S. Congress are still working to repeal it. At this time, it remains unclear whether there will be any changes made to the Affordable Care Act, whether to certain provisions or its entirety. We cannot assure you that the Affordable Care Act, as currently enacted, or as amended in the future, will not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to the healthcare reform, if any, will affect our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For instance, on 2 August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created measures for spending reductions by the Congress. The Joint Select Committee, which was tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, failed to achieve its targeted deficit reduction and thus triggered automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. More recently, on 19 September 2011, President Obama presented his Plan for Economic

Growth and Deficit Reduction, which includes \$248 billion in Medicare savings over ten years and \$73 billion in savings in Medicaid and other health programs.

There have been, and we expect there will continue to be, a number of legislative and regulatory proposals at the U.S. federal and state levels as well as in other territories directed at containing or lowering the cost of health care, thus resulting in continuing pressure on healthcare providers to cut costs. We cannot predict the initiatives that may be adopted in the future or their full impact. As a result, the availability of capital and our ability (or that of our collaboration partners) to set prices, that we believe are fair for our products and our ability to generate revenues and achieve or maintain profitability may be adversely affected.

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

**We are dependent on our own proprietary rights and on in-licensed patents and proprietary rights which we and our licensors must adequately protect.**

Our success depends in part on our ability to:

- protect trade secrets;
- apply for, obtain, protect and enforce patents;
- operate without infringing upon the proprietary rights of others;
- in-license certain technologies;
- develop and gain access to new technologies, including but not limited to antibody drug conjugate (ADC) technology; and
- rely on licensors enforcing their patent rights.

We have obtained the rights to the transgenic mouse technology from Medarex which owns or has licensed the rights to this technology. Furthermore, we have obtained a license from Seattle Genetics to use its ADC technology under our collaboration regarding HuMax-TF-ADC. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that such proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. Medarex and Seattle Genetics protect their proprietary positions, and we protect our proprietary position by filing and prosecuting patent applications in the United States, Europe, Japan and a number of other countries related to our proprietary technology, inventions and improvements that are important to the development of our business. We are dependent on our licensors, including Medarex and Seattle Genetics, to enforce their patent rights. While a number of patents have been issued in the United States, Europe, Japan and other countries relating to our human antibody technology, Medarex and Seattle Genetics may not be able to obtain patent protection in other countries. Medarex's and Seattle Genetics' pending patent rights that we already have license to, patent applications that we have filed and may file in the future, or those we may license from third parties, including Medarex and Seattle Genetics, may not result in patents being issued. The patent position of biotechnology companies involves complex legal and factual questions and the issues are particularly complex for transgenic animal technology in Europe. As a result, enforceability cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from third parties may not provide sufficient protection against competitors. Also, patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, others may independently develop similar technologies or duplicate any technology that we and/or licensors have developed that falls outside the scope of our or their patents. The laws of other countries may not protect our intellectual property rights to the same extent as do the laws of the United States or European countries.

In addition to patents, we rely on trade secrets and proprietary know-how. We seek protection, in part, through confidentiality and proprietary information clauses in agreements with relevant third parties. These clauses may not provide protection for our human antibody technology or adequate remedies in the event of unauthorized use or disclosure of confidential and proprietary information. Our counterparties may breach these agreements. Furthermore, our trade secrets may otherwise become known to, or be independently developed by, our competitors.

We have obtained national trademark registration of our corporate name, Genmab<sup>®</sup> and the Y-shaped Genmab logo<sup>®</sup> in the US and in Denmark. These trademarks are also registered as community trademarks in the European Union. We have also obtained trademark registration of HuMax<sup>®</sup>, UniBody<sup>®</sup> and DuoBody<sup>®</sup> in Denmark, the US and the European Union. Additionally we have obtained or applied for registration of the trademarks above in a number of other countries just as we have obtained or applied for registration of other trademarks, including HexaBody<sup>™</sup>, in Denmark, the US and the European Union and other countries. We may, however, not be able to obtain protection in all countries that we consider to be of importance to us. Furthermore, some of our trademarks

have been challenged by third parties in the past. Currently, an opposition has been filed by Sandoz A/S at OHIM (Office for Harmonization in the Internal Market (Trade Marks and Designs)) (the European Union agency responsible for managing the Community trademarks) against the HexaBody trademark application. Genmab may be subject to further challenges against its trademarks in the future.

**We risk challenges to the validity of our own or our in-licensed proprietary rights.**

The biotechnology and pharmaceutical industries have been characterized by extensive litigation regarding patents and other intellectual property rights. The agreements we have with Medarex in respect of in-licensed proprietary technology are governed by New Jersey law and many of our other agreements are governed by laws of various other jurisdictions. The defence and prosecution of contractual or intellectual property lawsuits, United States Patent and Trademark Office (USPTO) interference proceedings, European Patent Office oppositions and related legal and administrative proceedings in the United States, Europe and internationally, involve complex legal and factual questions. As a result, such proceedings are costly and time-consuming to pursue and their outcome is uncertain. Litigation may be necessary to:

- protect and enforce our in-licensed patents and any existing and future patents of our own;
- enforce or clarify the terms of the licenses we have been granted or may be granted in the future;
- enforce or clarify the terms of licenses that we have granted to others or may grant in the future;
- protect and enforce trade secrets, know-how and other proprietary rights that we own or in-license; or
- determine the enforceability, scope and validity of the proprietary rights of third parties and defend against claims of infringement.

If we become involved in any litigation, interference or other administrative proceedings, we will incur substantial expense and the efforts of our technical and management personnel will be diverted. An adverse determination may subject us to significant liabilities or require us to seek licenses. Such licenses may not be available from third parties on commercially reasonable terms. Therefore, we and our collaborative partners may be restricted or prevented from manufacturing and selling products employing our human antibody technology. This could have a material adverse effect on our business, financial condition and results of operations.

**Competitors may have rights that could prevent us from making, developing, using or selling antibodies to particular targets.**

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Even though we have received a license to the patents pertaining to the transgenic mouse technology, this does not mean that we and our permitted licensees of this technology will have exclusive rights to antibodies against all targets that could be made using this technology, or that we or our licensees will have the right to make, develop, use or sell such antibodies.

The patents covering the transgenic mouse technology include patents that cover particular human monoclonal antibodies. These patents do not cover all human antibodies.

The patents may not protect against the importation of products, such as antibodies, made using transgenic mouse technology.

Moreover, other parties could have blocking patent rights to products made using the transgenic mouse technology, such as antibodies, and their production and uses, either because of a proprietary position covering the antibody or the antibody's target. For example, we are aware of certain United States and European patents held by third parties relating to particular antibody targets, to human monoclonal antibodies against such targets and to the manufacture and use of such antibodies.

With respect to third party patent rights, we are aware of a United States patent issued to Cabilly on 18 December 2001 and assigned to Genentech, Inc. and City of Hope relating to the production of recombinant antibodies in host cells (the "Cabilly II patent"). Re-examination of the Cabilly II patent was separately requested by unidentified third parties in May and December 2005 on the ground, among others, that the Cabilly II patent was unpatentable for obviousness-type double patenting over a related patent previously issued in 1989 to Cabilly and assigned to Genentech, Inc. and City of Hope. This earlier Cabilly patent expired in 2006. The two re-examination requests were subsequently merged.

On 25 February 2008 the USPTO issued a final Office Action rejecting all claims of the Cabilly II patent. Genentech filed a Notice of Appeal on 22 October 2008. An Appeal Brief providing arguments in support of the

appeal was filed on 9 December 2008. On 23 February 2009 the USPTO issued a Notice of Intent to Issue an Ex Parte Reexamination Certificate based on amended claims filed on 13 February 2009. On 12 April 2011 a further patent in the series was issued to Genentech, Inc. and City of Hope relating to the production of recombinant antibodies in host cells (the “Cabilly III patent”).

In April 2003 MedImmune filed a lawsuit in the District Court seeking a Declaratory Judgment that the Cabilly II patent is invalid and that MedImmune has no obligation to make royalty payments under a license agreement with Genentech. The District Court dismissed the lawsuit for lack of subject matter jurisdiction on the ground that there was no actual “case or controversy” between MedImmune and Genentech because MedImmune was continuing to fulfill its obligations under the license agreement. MedImmune appealed to the Court of Appeals for the Federal Circuit, which affirmed the decision of the District Court, and appealed then to the United States Supreme Court. On 9 January 2007 the United States Supreme Court handed down a decision holding that a sufficient “case or controversy” exists between MedImmune and Genentech to satisfy jurisdiction such that MedImmune should be allowed to go forward with its suit without first having to terminate or break its license agreement with Genentech. The United States Supreme Court did not express any opinion on the merits of the underlying dispute regarding the Cabilly II patent. The case was remanded to the District Court to go forward on the merits. In May 2008 MedImmune and Genentech announced that they reached a settlement in the case.

Furthermore, on 30 May 2008 Centocor (now Janssen Biotech, Inc.) filed a Declaratory Judgment Action at the Central District Court in California seeking a ruling that the Cabilly II patent is invalid. Subsequently the parties reached a settlement of the case.

On 8 October 2009 GSK filed a declaratory judgment action at the United States District Court for the Southern District of Florida seeking a declaration that the Cabilly II patent is invalid, unenforceable and not infringed by Arzerra. The case was transferred to the Central District Court in California. On 26 March 2012 GSK entered into a settlement with Genentech and City of Hope regarding Arzerra with respect to the Cabilly II and III patents.

On 25 January 2011 Human Genome Sciences (HGS) filed a declaratory judgment action in the United States District Court for the District of Delaware seeking a declaration that the Cabilly II patent is invalid, unenforceable and not infringed by Benlysta® (belimumab). On 12 April 2011, HGS filed a second declaratory judgment action in the U.S. District Court in Delaware, seeking a similar declaration with respect to the Cabilly III patent. Both cases were subsequently transferred to the U.S. District Court for the Central District of California, where they were joined with a third action filed by Genentech and City of Hope against HGS and GlaxoSmithKline (GSK) for infringement of the Cabilly III patent. Genentech and City of Hope assert that the Cabilly II and Cabilly III patents are valid and enforceable and that HGS and GSK are infringing both the Cabilly II and Cabilly III patents by the commercialization of Benlysta. The parties entered into a settlement agreement in 2012.

In March 2013 Eli Lilly and Company and ImClone Systems LLC (jointly, “Lilly”) filed a declaratory judgment action seeking a declaration that the Cabilly II and III patents are invalid, unenforceable and not infringed by the antibody product Erbitux® (cetuximab). In May 2013 Bristol-Myers Squibb (BMS) filed a declaratory judgment action seeking a declaration that the Cabilly II and III patents are invalid, unenforceable and not infringed by the antibody drugs, Erbitux® (cetuximab) and Yervoy® (ipilimumab). Both cases were filed in the United States District Court, Northern District of California. At City of Hope's and Genentech's request, both cases have been transferred to the United States District Court, Central District of California. Both cases are at the early stages of discovery. We are not a party in these litigations and have no influence over their settlement or other dispositions.

We generally produce our antibody products as recombinant antibodies from host cells, and may choose to produce other products in this way. Accordingly, if any of our antibody products are produced in the manner covered by these patents in the United States or in other countries and imported into the United States prior to the expiry of the Cabilly II and III patents. Unless the Cabilly II and III patents are invalidated in the Lilly or BMS lawsuits, we may need to obtain a license from Genentech and City of Hope should one be available. If the patents are upheld in the Lilly and BMS litigations or the litigations are settled and we are unable to obtain a license on commercially reasonable terms, we may be restricted from producing our recombinant antibody products using the methods and/or compositions covered by Genentech’s patents in the United States prior to the expiry of the Cabilly II and III patents in 2018.

On 23 March 2010 Genentech, Inc. and Biogen Idec, Inc. filed a declaratory relief complaint at the United States District Court, Southern District of California against GSK for patent infringement under a United States patent on a method of treating chronic lymphocytic leukemia with anti-CD20 antibodies (the “CLL patent”), wherein the method does not comprise treatment with radio-labeled anti-CD20 antibodies, based on GSK’s manufacture, marketing and sale of Arzerra in the United States for patients with CLL that is refractory to

fludarabine and alemtuzumab. The United States District Court, Southern District of California entered final judgement in favor of GSK on 17 November 2011 based on construction of certain terms of the patent claims; a judgment that was appealed to the U.S. Court of Appeals for the Federal Circuit together with the court order on the patent claim construction by Genentech and Biogen Idec on 6 December 2011. On 16 April 2013 the U.S. Court of Appeals for the Federal Circuit upheld the original decision by the United States District Court in favor of GSK. On 17 May 2013 Genentech and Biogen Idec filed for a re-hearing en banc (i.e. before all judges of the court). On 15 July 2013 the U.S. Court of Appeals for the Federal Circuit upheld its judgment in favor of GSK. This decision has become final since Genentech and Biogen Idec did not request further review by the US Supreme Court.

In addition to the Cabilly patents and the CLL patent, we are also aware of certain United States patents owned by third parties relating to antibody expression in particular types of host cells, including CHO cells and mammalian lymphocytic cells. These patents may be relevant to our current or future manufacturing techniques.

We are also aware of (i) a European patent which was granted on 30 November 2005, owned by a third party relating to the use of a CD20 antibody in the manufacture of a medicament for the treatment of RA and; (ii) a European patent owned by a third party relating to the production of antibodies in Chinese Hamster Ovary cells using serum-free media. We, as well as seven other parties, have filed oppositions to the patent mentioned in clause (i) above. The patent was revoked at the oral proceedings held on 11 September 2008. The decision has been appealed by the patent proprietor. At an oral hearing on 1 June 2010 the Board of Appeal revoked a broad claim to the use of an anti-CD20 antibody and remitted the case to the Opposition Division to assess novelty and inventive step of a claim limited to the use of rituximab. The patent was revoked at oral proceedings on 13 March 2012. The decision has been appealed by the patent proprietor on 23 May 2012, and appeal proceedings are ongoing. With respect to the patent mentioned in clause (ii) above, we and twelve other parties have filed oppositions to this patent. The patent was revoked at oral proceedings held on 25 November 2008. The decision has been appealed by the patent proprietor. Oral proceedings were scheduled for 10 November 2011, but subsequently the patent proprietor withdrew his request for oral proceedings. On 5 October 2011 the appeal was dismissed and the decision to revoke the patent was upheld.

We are aware of a US patent that has been issued by the USPTO which contains claims to anti-CD38 antibodies defined by functional characteristics, which might potentially be relevant to our current or planned activities under the license agreement with Janssen regarding daratumumab.

Further, we are aware of a European patent that may be relevant to our planned activities against which we are preparing to file an opposition, as well as a number of third party patent applications which, if granted with claims as drafted as of the date of this document, may cover our current or planned activities.

If our antibody products or their commercial use or production meet all of the requirements of any valid claims of the aforementioned patents, then we may need a license to one or more of these patents.

**We do not own all of the intellectual property upon which our business depends.**

We have entered into several license agreements with a number of biotechnology and pharmaceutical companies in order to acquire rights to various technologies, patents and manufacturing processes for the development and commercialization of our product candidates. These include the transgenic technology licensed from Medarex and the ADC technology licensed from Seattle Genetics. Our inability to maintain existing license agreements or enter into new license agreements on favorable terms may have a material adverse effect on our ability to identify, develop and commercialize product candidates.

**We may need to obtain licenses to patents and patent applications.**

We seek to obtain licenses to patents and patent applications when, in our judgment, such licenses are necessary to conduct our business. If any licenses are required, there can be no assurance that we will be able to obtain any such license on commercially favorable terms, if at all, and if these licenses are not obtained, we might be prevented from using certain of our technologies for the generation of our recombinant fully human antibody products. Our failure to obtain a license to any technology that we require may have a material adverse effect on our business, financial condition and results of operations. We cannot assure that our products and/or actions in developing or selling our recombinant human antibody products will not infringe such patents. Moreover, our owned or licensed proprietary rights may not prevent others from developing competitive products using our technology or other technologies. Similarly, others may obtain patents that could limit our ability and the ability of our licensees to use, import, manufacture, market, or sell products or impair our competitive position and the competitive position of our licensees.

## 1.5 Risks Related to Our Finances

### **We have only generated limited operating revenues and our future commercial potential is hard to predict.**

As the majority of our products are still under development, commercial revenues have only been generated from the commercial sale of Arzerra and not from the commercial sale of any other products, although we have received up-front and milestone payments under collaboration agreements in respect of Arzerra and some of our other product candidates. If Arzerra is not approved for additional indications or if one or more of our other product candidates fails to receive approval, our ability to generate increased revenues and profits will be materially delayed or impaired.

Because our collaborative partner, GSK, has only commercially sold Arzerra since November 2009 and none of our other product candidates have completed development and obtained regulatory approval, our commercial revenue and profit potential are unproven and our limited operating history makes it difficult for an investor to evaluate our business and prospects. Our technology may not result in any meaningful benefits to our current or potential collaborative partners. Further, due to our limited operating history, we may have difficulty accurately forecasting our revenue. Investors should consider our business and prospects in light of the heightened risks and unexpected expenses and problems we may face as a development stage company in a new and rapidly evolving industry.

### **We have incurred operating losses and these losses may continue.**

We have incurred operating losses and as of 30 September 2013, we had accumulated deficits since the inception of the Company of DKK 5,421,022 thousand. Our losses have resulted principally from:

- limited operating revenue being generated since incorporation;
- research, development, clinical trials and manufacturing costs relating to the development of our product candidates;
- non-cash impairments related to our manufacturing facility; and
- general and administrative costs relating to our operations.

We intend to continue to make significant investments in:

- pre-clinical testing and clinical trials;
- research and development;
- establishing new collaborations; and
- new technologies.

We do not know when or if we or our present and future partners will complete any pending or future product development efforts, receive any regulatory approvals or successfully commercialize further approved products. We may continue to incur substantial operating losses even if our revenues increase. As a result, we cannot predict the extent of future losses.

We expect to report operating income for 2013, mainly driven by our collaboration agreements with GSK and Janssen. Assuming the further development of daratumumab progresses successfully and in accordance with our plans, we currently anticipate that revenue growth driven by daratumumab milestones will continue in 2014. We also currently anticipate a modest increase in operating expenses in 2014. However, due to the non-recurring nature of milestones, the future development of daratumumab and dependence on the expansion of the Arzerra label, among other items, it is not possible to reliably project our operating result for 2014 or for future periods, and we may report operating losses in the future.

### **We may need substantial additional funding. We may not be able to obtain sufficient funds to grow our business or continue our operations.**

We will continue to expend substantial resources for development, including costs associated with developing our fully human antibody technology, bispecific antibody technology, our effector enhancing technology and potentially other novel antibody technologies, and conducting pre-clinical testing and clinical trials. Our future liquidity and capital requirements will depend on:

- the size and complexity of research and development programs;
- the scope and results of pre-clinical testing and clinical trials;

- the retention of existing and establishment of further partnerships (including our ability to receive up-front, milestone, license and other payments);
- continued scientific progress in our research and development programs;
- the time and expense involved in seeking regulatory approvals;
- competing technological and market developments;
- the time and expense involved in filing and prosecuting patent applications and enforcing patents; and
- the cost of conducting commercialization activities and arrangements and in-licensing products.

If we require additional funding, we may be unable to raise sufficient funds through equity or debt financing, collaborative agreements with partners or from other sources to complete development of any of our product candidates or to continue operations. As a result, we may need to delay, reduce or eliminate research and development programs or pre-clinical or clinical trials, and our business will suffer.

To the extent that we raise additional capital through the issuance of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that could adversely affect your rights as a shareholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, or grant licenses on terms that are not favorable to us.

**We have 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.**

Our financial statements are presented in Danish Kroner. However, much of our revenues, expenses and investments are in currencies other than Danish Kroner, particularly U.S. dollars, British Pounds and Euros. Therefore, our revenues, expenses and any future investment or other income may be vulnerable to fluctuations in exchange rates. Although Genmab maintains cash positions in all these major currencies to form a natural hedge of such transactions in foreign currency and we have as of the date of this document entered into to a derivative contract to cover our exposure to exchange rate fluctuations between British Pounds and Danish Kroner in relation to our funding commitment under our GSK collaboration, these measures may not adequately protect us from the adverse impact of exchange rate fluctuations.

As of the date of this document we maintain an investment portfolio in cash, cash equivalents and short-term investments and we are therefore also subject to interest risks and credit risks, among others. To the extent that we are able to hold our marketable securities to maturity and there are no defaults, they will mature at par, which will reverse any unrealized losses. If the uncertainties in the credit and capital markets continue or the ratings on our securities are downgraded, we may incur further unrealized losses or conclude that the decline in value is other than temporary and then incur realized losses.

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

## **1.6 Risks Relating to Our Management and Growth**

**We may have difficulty attracting and retaining key personnel.**

We are highly dependent on the members of our Senior Leadership Team and scientific staff, the loss of whose services could adversely affect the achievement of planned development objectives. In particular, we are dependent on the services of Dr. Jan G. J. van de Winkel, our President and Chief Executive Officer, and David Eatwell, our Chief Financial Officer.

For us to further expand product development, marketing and commercialization plans, we will need to hire additional qualified scientific personnel to perform research and development. We will also need to hire personnel with expertise in clinical testing, government regulation, manufacturing and finance. We may not be able to attract and retain personnel on acceptable terms, given the competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. There can be no assurance that we will be able to attract and retain such personnel on acceptable terms given the competition for experienced scientists from numerous pharmaceutical and chemical companies, specialized biotechnology firms, universities and other research institutions.

**We may have difficulties in managing our growth and expanding our operations successfully as we approach commercialization of additional product candidates.**

As we advance our product candidates through the development and commercialization process, we will need to expand our development, regulatory, manufacturing capabilities or contract with other organizations to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various collaborators, suppliers and other organizations. Our ability to manage our operations and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. Such growth could place a strain on our administrative and operational infrastructure. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Any inability to manage our growth could adversely affect our business, results of operations and prospects and the value of our shares.

### **1.7 Risks Related to our Shares and the Private Placement**

**Genmab's main shareholders hold a significant portion of our shares and their interests may conflict with the interests of Genmab's other shareholders.**

Genmab's main shareholders hold a significant portion of the shares and their interests may conflict with the interests of Genmab's other shareholders. Genmab's main shareholders are: Johnson & Johnson Development Corporation, Glaxo Group Ltd., ATP, AES. and Hendrikus Hubertus Franciscus Stienstra (partly through Mercurius Beleggingsmaatschappij B.V., Stimex Participatie Maatschappij B.V., De Thermen Beheer B.V. and Mosam Onroerend Goed B.V.) and FMR LLC (Fidelity Management and Research). Genmab's Directors and Executive Management and Senior Vice Presidents together with Genmab's main shareholders own approximately 42.2 percent of the shares as of the date of this document. As a result, these persons may have the ability to determine and/or significantly influence the outcome of matters submitted to Genmab's shareholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of Genmab's assets. In addition, such shareholders may have the ability to control Genmab's management and affairs. Such concentration of ownership may affect the market price of the shares and may discourage certain types of transactions, including those involving actual or potential change of control of Genmab (whether through merger, consolidation, take-over or other business combination), which might otherwise have a positive effect on the market price of the shares.

**The market price of the shares has been and may continue to be highly volatile.**

Following the Private Placement, the market price of the shares may be highly volatile and could be subject to significant fluctuations in response to various factors, some or many of which may be beyond Genmab's control and which may be unrelated to our business, operations or prospects. Matters which could affect the price of the shares include actual or anticipated variations in operating results, announcements relating to clinical trial results, announcements of technological innovations by us or our competitors, new products or services introduced by us or announced by us or our competitors, conditions, or trends or changes in the biotechnology and pharmaceutical industries, changes in the market valuations of other similar companies, additions or departures of key personnel and further sales of shares by Genmab.

In addition, the market for technology companies in particular has experienced significant price and volume fluctuations that may be unrelated or disproportionate to the operating performance of those companies. There has been particular volatility in the market prices of securities of biotechnology and life sciences companies. These general market and industry factors may adversely affect the market price of the Shares, regardless of our operating performance.

The trading price of the shares has been, and could continue to be, subject to wide fluctuations in response to these factors, including the sale or attempted sale of a large number of shares into the market. During 1 July 2010 to 31 December 2013, the sale prices of the shares have ranged between DKK 23.23 and DKK 254.9.

**If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding the shares adversely, the price and trading volume of the shares could decline.**

The trading market for the shares will be influenced by the research and reports that industry or securities analysts publish about us or our business. We are followed by analysts. If one or more of the analysts who cover us or our industry downgrade the shares, the market price of the shares could decline. If one or more of these analysts

ceases coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which could cause the market price of the shares or trading volume to decline.

**Purchasers of the new shares and shares may suffer immediate and substantial dilution of their investment.**

The price paid by the investors for the new shares may be significantly greater than the book value per share of Genmab's issued and outstanding share capital after the Private Placement. Accordingly, the investors may suffer immediate and substantial dilution of its investment. In addition, as of 30 September 2013, there were outstanding warrants in respect of 5,746,874 shares at a weighted average exercise price of approximately DKK 210.86, representing approximately 11.10 percent of Genmab's issued and outstanding share capital as at the date of this document and up to approximately 10.09 percent of Genmab's issued shares following the Private Placement. If any of such warrants are exercised, the investors will suffer further dilution.

Genmab may issue additional shares in the future without pre-emptive rights to Genmab's existing shareholders and at a price that may cause further dilution of the investment made by the investors or Genmab's shareholders in the shares.

In addition, Genmab has adopted a warrant plan which allows warrants to be granted at prices that, depending on the market price of the shares on the date such warrants are granted, may be higher than the book value per share of the shares already outstanding. Similarly, warrants may be granted in the future at prices that are lower than the price paid by the investors. Reference is made to Section 20.3 Employees – Warrant Programs of the Prospectus of 16 October 2012 available on the website of NASDAQ OMX Copenhagen.

**Future sales of Shares may cause the market price of the shares to decline.**

Sales or issues of substantial numbers of shares after the Private Placement, or the perception that such issues or sales could occur, could adversely affect the market price of the shares and/or Genmab's ability to raise capital through an issue of shares or other securities in the future at a time and at a price that we may consider acceptable.

**Genmab has never paid any dividends and do not foresee doing so in the foreseeable future.**

Genmab has never made any dividend payment or distribution. We do not, as of the date of this document, contemplate the payment of cash dividends or distributions for the foreseeable future.

**The rights of holders of shares are governed by Danish Law.**

Genmab is a public limited liability company organized under the laws of Denmark. The rights of holders of shares are governed by Danish law and by Genmab's Articles of Association. These rights may differ from the typical rights of shareholders in the United States, as well as other jurisdictions.

**Genmab's Executive Management and Board of Directors will have broad discretion as to the use of proceeds of this Private Placement.**

Genmab's Executive Management and Board of Directors will have broad discretion regarding how to use the net proceeds of the Private Placement. The investors will be relying on the judgment of the Executive Management and the Board of Directors regarding the application of the proceeds of the Private Placement. The results and effectiveness of Genmab's use of the proceeds from this Private Placement are uncertain.

**Shareholders outside Denmark may be subject to exchange rate risk.**

The shares are denominated in Danish Kroner. Accordingly, an investment in the shares by an investor whose principal currency is not the Danish Kroner may expose an investor to foreign currency exchange rate risk. Any depreciation of the Danish Kroner against a foreign currency would reduce the value of an investment in the shares in terms of such foreign currency.

**Genmab may be classified as a passive foreign investment company ("PFIC") which could result in materially adverse tax consequences to U.S. shareholders.**

Generally, a PFIC is a non-U.S. corporation that, in any tax year, receives passive income in an amount equal to 75 percent or more of its gross income or holds assets for the production of passive income representing 50 percent or more of the average quarterly value of its assets determined, broadly speaking, on a consolidated basis

with its subsidiaries. For these purposes, passive income generally includes dividends, interest, gains from the sale of investment property, rents and royalties other than certain rents and royalties that are received in connection with the active conduct of a trade or business. A company's status as a PFIC must be determined after the close of every year based on the income, assets and operations of the company for that year.

Based on its current and anticipated operations and finances, Genmab does not believe that it was a PFIC for the year ended 31 December 2013 and, based on the nature of its current assets and operations, Genmab does not anticipate becoming a PFIC in the current year or future years. However, because this is a factual determination that must be determined annually, no assurance can be provided that Genmab will not be a PFIC in the current or any future year or that the U.S. Internal Revenue Service will not assert that Genmab was a PFIC in any particular year.

If Genmab were a PFIC at any time during a U.S. shareholder's holding period in the shares, special, likely materially adverse, U.S. federal income tax consequences would result for such shareholder. These consequences generally include, among other things, (i) treatment of the U.S. shareholder's gain on the sale of shares as ordinary income rather than capital gain and an additional interest charge on the deferral of passive income received by the PFIC but not distributed to the U.S. shareholder, (ii) ineligibility of dividends received by the non-corporate U.S. shareholder for reduced rates of taxation that might otherwise be available for qualified dividends and (iii) additional information reporting requirements for U.S. shareholders. U.S. shareholders should consult with their tax advisors as to the effect, if any, of these rules on their investment in the shares, including the desirability of making any elections that may be available to them under the PFIC rules.

**There is a limited public market in Denmark for the shares, which may impair the ability of investors purchasing in the placement to sell their shares.**

There is a limited public market in Denmark for the shares, which may impair the ability of investors participating in the private placement to sell their shares at the time or times they wish or at an acceptable price, and may increase the volatility of the price of the shares. In particular the volatility of the price of the shares may be affected by exercises of warrants and the issue of warrant shares.

## 2 OUR CURRENT COLLABORATIONS

In support of our strategy to build a broad portfolio of product candidates and facilitate their potential commercialization, Genmab has established and continues to pursue collaborations with major pharmaceutical and biotechnology companies. These collaborations give our partners access to our antibody creation and development capabilities and technologies, help us bring our product candidates closer to the market and give us access to promising technologies to create new therapeutics. We have key collaborations with GSK, Janssen, Roche, Lundbeck, Novartis and Seattle Genetics, world leading research-based pharmaceutical and healthcare companies. Our partners generally have the right to terminate our collaborations at any time without cause, subject to notice periods.

Partner	Date signed	Brief description
<b>Product Collaborations</b>		
GlaxoSmithKline	December 2006	Granted exclusive worldwide rights to co-develop and commercialize ofatumumab to GSK
Janssen	August 2012	Granted exclusive worldwide rights to develop and commercialize daratumumab to Janssen
Amgen	October 2001	Granted exclusive worldwide rights to develop and commercialize antibodies to IL15 to Amgen
Emergent BioSolutions	May 2011	Granted exclusive worldwide rights to develop and commercialize zanolimumab to Emergent BioSolutions. (The license agreement has subsequently been terminated by Emergent BioSolutions and the program will revert to Genmab.)
Cormorant Pharmaceuticals	May 2012	Granted worldwide license to HuMax-IL8
Roche (River Vision Development Corporation)	May 2001	Granted exclusive worldwide rights to develop and commercialize teprotumumab (RG1507) to Roche, which has granted a sublicense to River Vision Development Corporation.
ADC Therapeutics	June 2013	Collaboration agreement regarding HuMax-TAC-ADC
<b>Technology Collaborations</b>		
Medarex/BMS	February 1999	Access to the UltiMAb® platform for creating human antibodies
Seattle Genetics	September 2010 and April 2011	Antibody-drug conjugate (ADC) research collaboration agreements. (One of these collaborations has been discontinued.)
Novartis	June 2012	Collaboration and license agreement to create and develop bispecific antibodies using our DuoBody technology platform
Janssen	July 2012	Collaboration to create and develop bispecific antibodies using our DuoBody technology platform. Collaboration expanded in December 2013.
Concortis Biosystems	March 2012	Research and collaboration agreement regarding multiple options to take commercial licenses to their ADC technology
Kyowa Hakko Kirin Co., Ltd.	December 2012	Research collaboration with Kyowa Hakko Kirin Co., Ltd. to create bispecific antibodies using Genmab's DuoBody technology
Eli Lilly and Company	January 2014	Research collaboration with Eli Lilly to use and evaluate Genmab's DuoBody technology for the creation of bispecific antibodies

Partner	Date signed	Brief description
<b>Discovery Collaborations</b>		
Lundbeck	October 2010	Antibody development collaboration for disorders of the central nervous system

## 2.1 Product Collaborations

### *GlaxoSmithKline*

In December 2006, we granted exclusive worldwide rights to co-develop and commercialize ofatumumab to GSK. Under the terms of the agreement, Genmab received a license fee of DKK 582 million and GSK invested DKK 2,033 million to subscribe in Genmab shares. We are also entitled to receive potential milestone payments. As of 30 September 2013, total milestone payments received under the GSK agreement amounted to DKK 1,086 million since inception.

In addition, Genmab is entitled to receive tiered double-digit royalties on global sales of ofatumumab. From 2008, the parties shared certain development costs, and GSK is responsible for commercial manufacturing and commercialization expenses.

Under the terms of a December 2008 amendment to the agreement, Genmab received a one-time payment of USD 4.5 million from GSK upon the FDA's acceptance for review of the filing of the first BLA for ofatumumab in an oncology indication in the USA in exchange for terminating its option to co-promote ofatumumab.

In July 2010, GSK and Genmab announced a further amendment to the ofatumumab agreement. Under the terms of the amendment, GSK has taken responsibility for developing ofatumumab in autoimmune indications whilst continuing to jointly develop ofatumumab with Genmab in cancer indications. Genmab received an upfront payment of GBP 90 million (DKK 815 million at the date of the agreement) from GSK in connection with the amendment. Future milestones due to Genmab under the oncology development program were reduced by 50%. There was no change in royalty tiers to Genmab in the oncology program. GSK is solely responsible for funding the development in autoimmune indications and Genmab has forgone development milestones for autoimmune indications and the first two sales milestones while retaining a double digit royalty on sales. Additionally, as part of this further amendment, Genmab's future funding commitment for the development of ofatumumab in cancer indications will be capped at a total of GBP 145 million (DKK 1,314 million at the date of the agreement), including a yearly cash funding cap of GBP 17 million (DKK 154 million at the date of the agreement) for six years starting in 2010.

### *Janssen (Daratumumab)*

On 30 August 2012, Genmab entered into a license agreement with Janssen pursuant to which Genmab granted Janssen worldwide exclusive rights to develop and commercialize our CD38 antibody (daratumumab), a first-in-class, fully human antibody. Under the terms of the license agreement Genmab received an upfront payment of USD 55 million (DKK 327 million at the date of the agreement) and pursuant to a share subscription agreement JJDC (Janssen's ultimate parent company) made an equity investment in the Company through the subscription of 5,400,000 new shares at a subscription price of DKK 88 per new share of a nominal value of DKK 1 for an aggregate subscription price of DKK 475 million. Janssen is solely responsible for the development and commercialization of daratumumab, but Genmab continues to handle certain of the ongoing and planned clinical trials against full reimbursement of all costs by Janssen. For a limited period of time, Genmab will continue to be responsible for the manufacturing of daratumumab against full reimbursement by Janssen at the expiry of which Janssen will take over full responsibility for the manufacturing as well. In addition, Genmab will be entitled to receive tiered double digit royalties on global sales of daratumumab as well as development, regulatory and sales milestones. The total value of both the license agreement entered with Janssen and the share subscription agreement entered with JJDC to Genmab, including the upfront payment development and sales milestones and the equity investment is above USD 1.1 billion (DKK 6.8 billion at the date of the agreement). In December 2013 the first milestone was triggered by progress in the clinical development of daratumumab. Genmab received a USD 8 million milestone payment from Janssen in connection with this event.

### *Amgen*

Genmab has obtained a direct license for exclusive worldwide rights to Amgen's patent estate relating to antibodies to IL15 and the IL15 receptor. In July 2003, Amgen exercised its commercialization options for the

HuMax-IL15 antibody program (now AMG 714) and the IL15 receptor program and expanded the agreement to include a new antibody program. Under the terms of the expanded and amended agreement, Genmab will be entitled to receive milestone payments and royalties on commercial sales. In connection with the option exercise, Genmab received the first milestone payment of USD 10 million. Amgen is responsible for all future development costs for products and product candidates targeting the IL15 pathway and Genmab participated in the pre-clinical development of the new program.

Amgen has discontinued development of AMG 714 in psoriasis and rheumatoid arthritis based on disappointing results from clinical studies. Amgen is exploring options to maximize the value of this asset, but at this time, no further internal development of a lead indication is planned.

### ***Emergent BioSolutions***

In May 2011, Emergent BioSolutions Inc. acquired the rights to zanolimumab, a fully human antibody targeting CD4, from TenX Biopharma, Inc. Genmab's license agreement with Emergent BioSolutions was slightly modified compared to the previous agreement with TenX Biopharma. Zanolimumab will be developed for the treatment of cutaneous T-cell lymphoma (CTCL) and peripheral T-cell lymphoma (PTCL). Emergent BioSolutions has provided notice of termination, and the program will now revert to Genmab.

### ***Cormorant Pharmaceuticals***

In May 2012, we entered into a license agreement with Cormorant Pharmaceuticals AB pursuant to which Cormorant was granted an exclusive, worldwide license to our HuMax-IL8 antibody (formerly HuMax-Inflam). Under the terms of the agreement, Genmab received an upfront payment and will be entitled to milestone payments and royalties on net sales. Cormorant intends to evaluate HuMax-IL8 for treatment of select cancers and will be responsible for all future costs of developing, manufacturing and commercializing HuMax-IL8.

### ***Roche***

Under Genmab's agreement with Roche, we have utilized our broad antibody expertise and development capabilities to create human antibodies to a wide range of disease targets identified by Roche. If the products are successful, Genmab will receive milestone and royalty payments. Roche is fully responsible for the development of these products. Under certain circumstances, Genmab may obtain rights to develop products based on disease targets identified by Roche.

Roche has sublicensed teprotumumab (RG1507), generated under the collaboration between Roche and Genmab, to River Vision Development Corporation who is conducting a Phase II clinical trial in patients with active thyroid eye disease. If successful, Genmab is entitled to receive milestone and royalty payments.

Roche has discontinued its development of inclacumab (RG1512 or RO4905417), a fully human monoclonal antibody created by Genmab under the collaboration with Roche that is designed to selectively inhibit P-selectin, an adhesion molecule that is believed to play a pivotal role in inflammation, thrombosis and the development of atherosclerosis. Inclacumab was being investigated for cardiovascular disease. Roche's decision to discontinue the program was a strategic decision not due to safety or data concerns. Roche will make inclacumab available for partnering.

### ***ADC Therapeutics Sarl***

On 17 June 2013 Genmab and ADC Therapeutics Sarl entered into an agreement to develop a new antibody-drug conjugate (ADC) product combining Genmab's HuMax-TAC antibody and ADC Therapeutics' PBD-based warhead and linker technology. The Companies have been conducting *in vitro* and *in vivo* studies since 2012 to investigate different warhead and linker combinations with HuMax-TAC, and now have the product ready for pre-IND pre-clinical development. The product will be developed for multiple cancer indications.

Genmab and ADC Therapeutics will each initially have an equal share in the product. In the first instance, ADC Therapeutics will lead and fund pre-clinical development. Prior to the submission of an application to conduct clinical studies in patients (IND filing), Genmab may elect to retain equal ownership of the product. Genmab will not incur any development costs prior to the IND filing decision and Genmab will maintain a minimum 25% ownership stake in the product as it moves into clinical development.

## 2.2 Technology Collaborations

### *Medarex*

#### *General*

Genmab commenced commercial operations as an independent company in February 1999, established by contribution of a technology license from Medarex, Inc., a wholly owned subsidiary of Bristol-Myers Squibb, through one of its wholly owned subsidiaries GenPharm International, Inc., and a financial contribution from a group of unrelated third party investors. Initially, Medarex contributed a license to its transgenic mouse technology for producing antibodies to particular targets in exchange for approximately 44 percent of our share capital. During Genmab's initial 12 months of operation, Medarex agreed to expand our license to provide Genmab with broader rights to this technology in exchange for further equity, thereby maintaining its level of ownership in Genmab's share capital. In addition, in connection with a private placement in May 2000, Medarex subscribed for shares in Genmab, thus maintaining its approximately 44 percent ownership level. In August 2000, Medarex received an additional 279,760 shares in connection with the Genomics Agreement (as described below and now terminated) to increase its ownership to approximately 45 percent of Genmab's share capital. After Genmab's initial public offering completed in October 2000, Medarex held approximately 33 percent of the Company's share capital. In July 2003, Medarex received another 246,914 shares as payment under the Genomics Agreement. Subsequently, Medarex has sold all its shares in Genmab. Our collaboration with Medarex was negotiated on an arm's length basis and includes broad rights to use Medarex's transgenic mouse technology to develop fully human monoclonal and bispecific antibody products.

#### *Transgenic Mouse Technology Agreement*

Our transgenic mouse technology agreement with Medarex (the "Technology Agreement"), provides us with broad rights to Medarex's UltiMAB platform. Under the terms of the Technology Agreement, we have the right to develop an unlimited number of antibody products for worldwide commercialization.

In order for us to commercialize antibody products under the Technology Agreement, we must first obtain a "commercial license" from Medarex. A commercial license provides us with worldwide exclusivity to use the transgenic mouse technologies for a particular antibody product. In order to minimize the up-front expenses, at our option we can enter into non-exclusive "research licenses" with Medarex which allow us to conduct pre-clinical research on antibodies to a specified target or targets for specified terms and which may be renewed a limited number of times.

Under the terms of the Technology Agreement, Medarex is obliged to grant to us commercial and/or research licenses for any target we specify, so long as Medarex has not previously granted exclusive rights to such target to an unrelated third party or does not have its own pre-existing development program in place with respect to the selected target. After having acquired worldwide rights to zanolimumab, all our commercial licenses are worldwide and we expect all new commercial licenses to be worldwide as well.

The Technology Agreement is for an unlimited duration and cannot be terminated by Medarex unless we materially breach the terms of the agreement or become insolvent. Our principal obligation under the Technology Agreement is to make milestone and royalty payments in connection with specific product licenses. An individual commercial or research license may not be terminated unless we fail to meet our payment obligations thereunder or we fail to enter into clinical trials with a licensed product within a commercially reasonable period of time. The right to a specified target will only revert to Medarex if a commercial license is discontinued.

The technology we receive under the Technology Agreement also includes rights to certain patents owned by Xenotech, L.P., a group consisting of Xenotech, Amgen, Cell Genesys, Inc. and Japan Tobacco, Inc. (the "Xenotech Group"). Medarex's right to these patents originate from a cross license agreement of March 1997 between GenPharm and the Xenotech Group.

In June 2005, we licensed from Medarex the European and Asian rights to utilize Medarex's UltiMAB technology to develop and commercialize antibodies raised against the CD4 antigen, including zanolimumab. With the addition of these new territories, we now hold worldwide rights to zanolimumab. Under the terms of the agreement, we paid Medarex an upfront payment of USD 1 million for these rights. Medarex is also entitled to potential total milestone and license fee payments of USD 13.5 million, as well as royalties that could reach double digits for a successfully commercialized CD4 product in the new territories. The European and Asian rights had previously been licensed to Eisai Co., Ltd. but after reacquiring them, Medarex licensed the rights to us. We have no payment obligations to Eisai.

### ***Paid-up Commercial Licenses***

Under the Technology Agreement, we received sixteen (16) fully paid-up commercial licenses. Consequently, with the exception of certain milestone and royalty payments owed to Medarex related to the expansion of the CD4 territory to become worldwide, we do not owe any license fees or royalty payments to Medarex for zanolimumab, AMG 714 (HuMax-IL15), zalutumumab (HuMax-EGFr), ofatumumab (HuMax-CD20), HuMax-TAC, daratumumab (HuMax-CD38), HuMax-TF and HuMax-IL8 and five other product candidates we have in pre-clinical or clinical development as of the date of this document. For these product candidates we have the worldwide commercial rights. To date, we have used thirteen (13) of these fully paid-up commercial licenses.

### ***Unlimited Royalty Bearing Commercial Licenses***

For any product we develop that does not use a fully paid-up commercial license, we will owe Medarex, on a product-by-product basis, up-front license fees, milestone payments and low single-digit percentage royalties. The terms for such payment obligations have been determined on an arm's length basis.

### ***Summary of License Status***

The following summarizes our current commercial and research license status under the Technology Agreement:

- 16 fully paid-up commercial licenses, of which we are as of the date of this document using 13. We have no further payment obligations to Medarex with respect to these commercial licenses.
- An unlimited number of royalty-bearing commercial licenses, of which we are as of the date of this document using 12. Upon exercising our rights to these licenses, we will owe Medarex, on a product-by-product basis, additional up-front license fees, milestone payments and royalties. Such commercial licenses and the resulting payment obligations were determined on an arm's length basis.
- An unlimited number of fee-bearing research licenses, of which we are as of the date of this document using three. We will owe Medarex a small research license fee upon taking this type of research license as well as a modest renewal fee if we decide to renew the research license. Such research licenses and the resulting payment obligations were determined on an arm's length basis.

### ***Ability to Use Kyowa Hakko Kirin Technology***

We also have the option to create, develop and commercialize antibodies using the Kyowa Hakko Kirin mouse technology ("KM" or "HAC"). We may develop these antibodies using the same commercial licenses that we use to develop HuMAB antibodies. If we use a royalty-bearing commercial license, we will pay a modest premium on any milestone or royalty payments due. If we use a fully paid-up commercial license, we will owe to Medarex modest milestone and royalty payments. Our ofatumumab antibody is an antibody developed using the KM mouse technology.

### ***Seattle Genetics***

In October 2011, following a research collaboration agreement of September 2010, Genmab and Seattle Genetics, Inc. entered into an antibody-drug conjugate (ADC) license and collaboration agreement. Under the agreement, Genmab has rights to utilize Seattle Genetics' ADC technology with its HuMax-TF antibody. Seattle Genetics received an undisclosed upfront payment and has the right to exercise a co-development and co-commercialization option for any resulting ADC products at the end of Phase I clinical development.

Genmab is responsible for research, manufacturing, pre-clinical development and Phase I clinical evaluation of HuMax-TF ADC. Seattle Genetics will receive research support payments for any assistance provided to Genmab. If Seattle Genetics opts into the HuMax-TF-ADC product at the end of Phase I, the companies would co-develop and share all future costs and profits for the product on a 50:50 basis. If Seattle Genetics does not opt in to the HuMax-TF-ADC product, Genmab would pay Seattle Genetics fees, milestones and mid-single digit royalties on worldwide net sales of the product.

No milestone payments have been triggered yet under this collaboration.

In April 2011, Genmab entered into a second ADC research collaboration agreement with Seattle Genetics. Under the new agreement, Genmab has rights to utilize Seattle Genetics' ADC technology with HuMax-CD74, an antibody in pre-clinical development to target CD74, which is expressed on a wide range of hematological

malignancies and solid tumors. After evaluation of the viability of the HuMax-CD74-ADC program, the parties agreed to discontinue the project.

***Novartis (DuoBody Technology)***

On 4 June 2012 we executed a collaboration and license agreement with Novartis pursuant to which we will use our DuoBody technology platform to create and develop bispecific antibodies. Genmab is creating panels of bispecific antibodies to two disease target combinations identified by Novartis. All research work on the programs is fully funded by Novartis. Under the terms of the agreement, Genmab received an upfront payment of approximately USD 2 million (DKK 12 million at the date of the agreement). If all milestones in the agreement are achieved, the total potential value of the agreement to Genmab would be approximately USD 175 million (DKK 1,055 million at the date of the agreement), plus research funding and royalties. In June 2013, the first development milestone was reached as part of our DuoBody collaboration with Novartis, triggering a payment to Genmab of USD 500,000.

***Janssen (DuoBody Technology)***

On 12 July 2012, we entered into a research and collaboration agreement with Janssen and its affiliates to create and develop bispecific antibodies using our DuoBody technology platform. Genmab will create panels of bispecific antibodies to multiple disease target combinations identified by Janssen, who will in turn fully fund research at Genmab.

Under the terms of the agreement, Genmab and Janssen will collaborate on the research of up to 10 DuoBody programs and Genmab received an upfront payment of USD 3.5 million (DKK 21 million at the date of the agreement) from Janssen and all research by Genmab will be fully funded by Janssen. In addition, Genmab will potentially be entitled to milestone and license payments of up to approximately USD 175 million (DKK 1,062 million at the date of the agreement) for each product as well as royalties on any commercialized products.

To date we have earned USD 7.5 million of milestones under the collaboration.

On 4 December 2013 the collaboration with Janssen was expanded to allow Janssen to work on up to 10 additional DuoBody programs. Genmab will receive an initial payment of \$2 million (approximately DKK 11 million) from Janssen. For each of the 10 additional programs that Janssen successfully initiates, develops and commercializes, Genmab will potentially be entitled to milestone and license payments of up to approximately \$174 million (DKK 956 million) to \$219 million (DKK 1.2 billion), depending on the date each program is initiated. In the most favorable scenario in which all 10 additional programs are successfully initiated, developed and commercialized, Genmab would receive average milestone and license payments of approximately \$191 million (DKK 1.0 billion) for each of the 10 programs. In addition, Genmab will be entitled to royalties on sales of any commercialized products.

***Concortis Biosystems (ADC Technology)***

On 2 March 2012 we entered into a master research and collaboration agreement with Concortis Biosystems Corp (a wholly-owned subsidiary of Sorrento Therapeutics, Inc.) regarding multiple options to take commercial licenses to their ADC technology.

***Kyowa Hakko Kirin Co., Ltd. (DuoBody Technology)***

On 5 December 2012 Genmab and Kyowa Hakko Kirin Co., Ltd. entered into a research collaboration to create bispecific antibodies using Genmab's DuoBody technology. If successful, the parties may decide to enter into a commercial license agreement to develop a new DuoBody product.

***Eli Lilly and Company (DuoBody Technology)***

On 14 January 2014 Genmab and Eli Lilly entered into a research collaboration to use and evaluate Genmab's DuoBody technology for the creation of bispecific antibodies. If successful, the parties may decide to enter into a commercial license agreement to develop a new DuoBody product.

## 2.3 Discovery Collaborations

### *Lundbeck*

In October 2010, Genmab and Lundbeck entered into an agreement to create and develop human antibody therapeutics for disorders of the central nervous system (CNS). Genmab is creating novel human antibodies to three targets identified by Lundbeck. Lundbeck has access to Genmab's antibody creation and development capabilities, including its UniBody platform. Lundbeck has an option to take selected antibodies into clinical development at its own cost and subject to the payment of milestones and single-digit royalties to Genmab upon successful development and commercialization. Genmab has a similar option to take selected antibodies into clinical development for cancer indications at its own cost and subject to the payment of milestones and single-digit royalties to Lundbeck.

Under the terms of the agreement, Genmab received an upfront payment of €7.5 million (DKK 56 million at the date of the agreement). Lundbeck will fully fund the development of the antibodies. If all milestones in the agreement are achieved, the total value of the agreement to Genmab would be approximately €8 million (DKK 283 million at the date of the agreement), plus single-digit royalties. To date Genmab has received four pre-clinical milestones triggering milestone payments to Genmab of €4.5 million (approximately DKK 33.5 million) in total.