

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

February 28, 2019

David Eatwell Chief Financial Officer Genmab A/S Kalvebod Brygge 43 1560 Copenhagen V, Denmark

Re: Genmab A/S

**Draft Registration Statement on Form F-1** 

Submitted on February 5, 2019

CIK No. 0001434265

Dear Mr. Eatwell:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

## <u>Draft Registration Statement on Form F-1</u>

#### Prospectus Summary, page 1

- 1. We note your references to "low double digit royalties," "royalties [in] low double-digits," and "royalties with rates in the double-digits" on pages 5, 97, 139, 150, and 152. Please revise your disclosure throughout the prospectus to narrow the royalty range to no more than ten percentage points (for example between twenty and thirty percent).
- 2. Please define "stringent complete response" and explain how it differs from complete response. In addition, please explain what you mean by "blockbuster status."

## <u>Implications of Being an Emerging Growth Company and a Foreign Private Issuer, page 10</u>

3. Please provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

## Risk Factors, page 16

4. Please add risk factor disclosure addressing the risks to investors posed by the arbitration, exclusive forum and jury trial waiver provisions contained in your deposit agreement.

#### Use of Proceeds, page 70

5. Please disclose the principal reasons for the offering, as you do not disclose any specific plans for the proceeds. Please refer to Item 4.A of Form F-1 and Item 3.C of Form 20-F.

## Key Components of Our Results and Related Trends, page 78

6. Regarding your expectations for Arzerra net sales in the near future, as set forth in the third full paragraph on page 79, please disclose whether you expect them to decrease. In this regard, we note your disclosure about Novartis' ongoing transition of Arzerra to limited availability in most jurisdictions. Please also update your disclosure in the prospectus summary as necessary.

## <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> <u>Research and Development Expenses, page 83</u>

7. We note that your table on page 84 shows third-party costs incurred for research, contract manufacturing of your product candidates and clinical and regulatory services, which also presents other costs and overhead consisting of third-party costs for your pre-clinical stage programs, personnel, facilities and other indirect costs not directly charged to development programs. Please disclose your research and development expenses incurred to date similar to the presentation in this table.

#### **Business**

#### Griffin (MMY2004), page 118

8. Please disclose what were the adverse and serious adverse events referenced in the "safety data" subsection on page 119. In addition, please disclose all adverse events in the MIRROR study on page 131.

#### MIRROR, page 131

9. We note your reference here that "[i]maging showed that all subQ of atumum ab doses demonstrated efficacy." As currently drafted, this statement could imply that the FDA has

approved, or will more easily approve, your product candidates. Please revise throughout the prospectus to remove any implication that your product candidates are more likely than others to receive FDA approval or explain to us why such statements are appropriate given the stage of your product candidates.

### Collaboration with Novartis, page 132

10. We note your references to "decreasing global demand for Arzerra" on page 133 and Novartis' decision to transition the commercial availability of the drug to limited availability through manged access programs. Please disclose the reasons for decreased global demand of the drug, if known.

#### Collaborations and Other Agreements for our Partnered Product Candidates, page 151

11. Regarding the descriptions of the Immatics Research Collaboration and Novo Nordisk DuoBody Collaboration on page 153, please disclose what the "tiered royalties on net sales," or their ranges, are under the Immantics Research Collaboration. Also, please disclose the maximum aggregate milestone payments under the Nordisk DuoBody Collaboration.

## Other Enabling Technologies

## Medarex UltiMAb System License, page 154

12. Please file the license agreement with Medarex as an exhibit to your registration statement or tell us why you believe it is not required to be filed. In addition, please disclose the aggregate milestone and royalty payments under this agreement.

## **Management**

## Compensation, page 185

13. Please update the aggregate compensation for your officers and directors for the fiscal year ended December 31, 2018.

## Certain Senior Management Agreements, page 187

14. Please either tell us why you believe you are not required to file the senior management agreements as exhibits to the registration statement or file them as exhibits. Please refer to Item 8.A of Form F-1 and Item 601(b)(10) of regulation S-K.

#### Jury Trial Waiver, page 219

15. Please disclose here that the waiver of the right to a jury trial contained in the deposit agreement is not intended to be deemed a waiver by any holder or beneficial owner of ADSs of the company's or the depositary's compliance with the U.S. federal securities laws and the rules and regulations promulgated thereunder. In addition, please ensure that the filed deposit agreement provides that no disclaimer of liability under the Securities Act

or the Exchange Act is intended by any provision of the deposit agreement. Finally, please ensure that the arbitration provision in the deposit agreement provides that the provision does not preclude holders and beneficial owners from pursuing claims under the Securities Act or the Exchange Act in federal courts.

#### Notes to the Consolidated Financial Statements

## 1.2 New Accounting Policies and Disclosures, page F-12

16. With respect to your adoption of IFRS 15, you disclose that you will recognize sales-based royalties and commercial sales-based milestones in the period to which the sales relate based on estimates provided by collaborations partners, which is consistent with your current accounting policies. However, on page F-14, you disclose that your current accounting policy is to recognize revenue when third-party results are available and are deemed to be reliable. Please tell us why you believe it is appropriate to delay recognition until the sales information is received under paragraph B63 of IFRS 15.

#### Part II

## Exhibit Index, page II-3

- 17. Please either file the following agreements as exhibits to your registration statement or tell us why you believe they are not required to be filed:
  - agreement with BioNTech, which is discussed on page 78;
  - collaboration agreement with Roche, which is discussed on page 152;
  - agreement with Lundbeck, which is discussed on page 152; and
  - direct license from Immunex Corporation, which is discussed on page 152.
- 18. Please file a list of your subsidiaries as an exhibit to your registration statement. Please refer to Item 601(b)(21) of Regulation S-K.

#### Signatures, page II-4

19. Please revise the introductory language to the registrant's signature block to add the certification required by Form F-1 that the registrant has reasonable grounds to believe it meets all of the requirements for filing Form F-1.

You may contact Isaac Esquivel at (202) 551-3395 or Kate Tillan at (202) 551-3604 if you have questions regarding comments on the financial statements and related matters. Please contact Tonya K. Aldave at (202) 551-3601 or Dietrich King at (202) 551-8071 with any other questions.

Sincerely,

Division of Corporation Finance Office of Healthcare & Insurance

cc: Harald Halbhuber