



DIVISION OF  
CORPORATION FINANCE

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

July 16, 2019

Prof. Ugur Sahin, M.D.  
Chief Executive Officer  
BioNTech SE  
An der Goldgrube 12  
D-55131 Mainz  
Germany

**Re: BioNTech SE**  
**Draft Registration Statement on Form F-1**  
**Submitted June 19, 2019**  
**CIK No. 0001776985**

Dear Dr. Sahin:

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.

Draft Registration Statement on Form F-1

Prospectus Summary

Overview, page 1

1. Please provide us with support for your characterization of your immunotherapeutic platforms and product candidates as first-in-class. Please also balance your summary disclosure by disclosing that no mRNA immunotherapy has been approved in your new category of therapeutics as well as the risks and costs associated with some of your product candidates being classified as gene therapies.

Our Pipeline, page 3

2. Please revise your pipeline table here and in other sections of the prospectus to mark clearly what phase each product candidate is currently in. We note that there is no clear separation in the pipeline table between Phase 1, Phase 2 and Phase 3 and it is not clear to which clinical phase the arrows point. Please also ensure that the graphical depiction of status in the table corresponds with the disclosure in the prospectus regarding how far along each candidate is in the development process.
3. Please tell us why you believe it is material to investors to include the product candidates identified merely as "to be selected" or left blank in several places in your pipeline table. We also note that you do not provide specific targets/indications for these product candidates. In this regard, we note that it appears that all of these product candidates are in preliminary stages of development.

Implications of Being an Emerging Growth Company and a Foreign Private Issuer, page 7

4. 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.

Use of Proceeds, page 95

5. We note your disclosure that you intend to use the proceeds of this offering to advance your clinical programs, advance additional product candidates into clinical trials, advance additional preclinical product candidates, develop additional product candidates and expand your manufacturing and laboratory capacity. Please specify how far in the development of each of your pipeline projects you expect to reach with the proceeds of the offering. If any material amounts of other funds are necessary to accomplish the specified purposes, state the amounts and sources of other funds needed for each specified purpose and the sources. Refer to Instruction 3 to Item 504 of Regulation S-K.

Critical Accounting Policies and Use of Estimates

Stock-Based Compensation, page 116

6. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features.

Business

Our MVT-5873 (BNT321) Trials, page 182

7. To the extent material to understanding the status of the product candidate discussed in this section, please disclose why the trial is currently paused.

XIV. Third-Party Collaborations, page 186

8. We note that for some of your collaboration agreements you have not disclosed all of the material terms of the agreements, such as aggregate milestone payments and royalty ranges or royalties rates. Please disclose the following:

- the aggregate future potential milestone payments and the royalty rates or a royalty range under the Genentech agreement described on page 187;
- the sales milestone payments and royalties under the Genmab next-generation immunomodulator collaboration agreement on page 189;
- the running royalties under the LSU license agreement on page 225; and
- the aggregate future potential milestone payments and royalties under the Cellscript and mRNA Ribotherapeutics license agreement on page 225.

In addition, if any other collaboration or license agreements contain milestone and royalty provisions that have not been disclosed in this section, please disclose such information about these provisions.

Sanofi -- Intratumoral Therapy Collaboration, page 188

9. We note your references to "low double digits" royalties on pages 189 and 192. Please revise your disclosure on each of the referenced pages to narrow the royalty range to no more than ten percentage points (for example, between twenty and thirty percent).

Related Party Transactions, page 241

10. We note your disclosure on page F-56 that "purchases of various goods and services controlled by key management personnel" accounted for approximately €11.16 million in 2018 and €6.55 in 2017. Please disclose these transactions in your related party transactions section or otherwise clarify which disclosure includes these transactions.

4 Revenue from contracts with customers, page F-31

11. Please expand your disclosures to include the amounts of the upfront payments received from Genentech and Sanofi, how you determined the amount to recognize in the periods presented and the amounts that have been included in deferred revenue.

Part II

Item 7. Recent Sales of Unregistered Securities, page II-1

12. For each of the transactions listed in this section please disclose the consideration

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received. As to any securities sold otherwise than for cash, state the nature of the transaction and the nature and aggregate amount of consideration received by the registrant. Refer to Item 701 of Regulation S-K.

Exhibits

13. We note your reference to the two secured credit facilities with Deutsche Bank AG on page 111. Please file these facilities as exhibits to your registration statement and describe all of their material terms or tell us why you believe they are not required to be filed.

General

14. Please revise throughout to remove any references regarding regulatory approval or safety and efficacy of your product candidates. We note, by way of example, the statement that you "have tested [your] lead mRNA product candidates in over 250 patients and have already demonstrated signs of single-agent clinical efficacy in [your] two lead programs" on page 5, that four of your therapeutic platforms "generated promising early evidence of clinical efficacy in several cancer types" on page 126, and that you "observed efficacy for 22 patients who received BNT111 as a monotherapy" on page 167.

You may contact Vanessa Robertson at (202) 551-3649 or Lisa Vanjoske at (202) 551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Tonya K. Aldave at (202) 551-3601 or Justin Dobbie, Legal Branch Chief, at (202) 551-3469 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Healthcare & Insurance

cc: Eric Blanchard, Esq.