

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

DIVISION OF CORPORATION FINANCE

September 26, 2018

Stephane Bancel Chief Executive Officer Moderna, Inc. 200 Technology Square Cambridge, MA 02139

> Re: Moderna, Inc. Draft Registration Statement on Form S-1 Submitted August 30, 2018 CIK No. 0001682852

Dear Mr. Bancel:

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 S-1

Prospectus Summary, page 1

1. Please disclose how many of your clinical trials are in USA and how many are abroad and in what countries. In addition, clearly identify which product candidate trials are conducted abroad.

## Our pipeline and progress, page 3

2. 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 these

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statements are appropriate given the stage of your product candidates. For example, refer to the following statements:

- "[a]lthough the tested doses demonstrated sufficient safety and tolerability to warrant further study, we chose not to continue dose escalation, as we have developed a follow-on candidate, mRNA-1893, that we believe has significantly greater potency" on page 3;
- "ten out of ten have demonstrated sufficient safety and tolerability to warrant continued advancement within a trial or for further development" on page 3;
- "[w]e have demonstrated safe, repeatable dosing with negligible or undetectable loss in potency, liver damage, and immune system activation across multiple preclinical studies" on page 129;
- "[w]e have repeatedly demonstrated safety and tolerability of our mRNA and LNP systems in preclinical studies" on page 133;
- "[b]ased on data observed to date, five of five Phase 1 clinical trials have shown promising safety and tolerability profiles for state of development" on page 143; and
- "[w]e have demonstrated efficacy in a PA mouse model in a long-term repeat dose study" on page 237.
- 3. We note your reference to an "undisclosed vaccine" on page 175 and its inclusion in the summary section and the pipeline. Please either disclose what the vaccine is or remove it from the pipeline graphics throughout the prospectus.
- 4. It appears based on your disclosure that mRNA-1944 and MRNA-5671 are not in Phase 1 clinical trials yet. Please revise all pipelines graphics included in the prospectus to show the arrows for these two program in pre-clinical development column, instead of in the Phase 1 column. Please similarly revise the graphic depicting mRNA-1777, as it appears it has not yet commenced Phase 2 clinical trials.

## Implications of being an emerging growth company, page 9

5. 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 80

6. We note your disclosure that you intend to use the proceeds of this offering to fund further development of your mRNA technology platform and the creation of new modalities and to fund drug discovery and clinical development, further expansion of your manufacturing platform and capabilities, and infrastructure to support your pipeline. For each of the identified purposes, please include the amount of proceeds to be dedicated to that purpose. In addition, please specify how far in the development of each of the listed

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clinical trials 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.

Management's Discussion and Analysis of Financial Condition and Results of Operations Critical accounting policies and significant judgments and estimates Stock-based compensation, page 101

- 7. 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.
- 8. In the first paragraph on page 105 you indicate that your Series G preferred stock was issued in an arm's length transaction. It is apparent that the pricing of this issuance in January and February 2018 was at \$10.06 per share. It is also apparent that your Series H preferred stock was issued at \$25.00 per share in May 2018. Please address the following:
  - Demonstrate to us that your Series G preferred stock was indeed issued in an arm's length transaction. In your response tell us:
    - who led the pricing negotiations for the investors;
    - who participated in the issuance and the number of shares they purchased; and
    - the beneficial ownership percentage held by each investor in the Series G financing prior to the completion of this round of financing.
  - Explain to us why the Series H preferred stock was priced 149% higher than that of the Series G preferred stock less than three months after the completion of the Series G round. In your response tell us:
    - whether the Series H preferred stock has significant incremental preferences over those of the Series G preferred stock and, if so, describe the differences;
    - whether the Series H preferred stock was an arm's length transaction; and
    - whether there were any contemporaneous agreements with the investor.
  - Explain to us why the preferred stock increased 149% in value from February 12, 2018 to May 7, 2018 when your common stock increased in value only about 4% from February 28, 2018 to June 26, 2018 and only about 21% from February 28, 2018 to August 16, 2018.

# **Business**

# 34 of 36 IND-enabling GLP toxicology studies, page 156

9. Please disclose what "adverse toxicity findings" you reference here.

## RSA vaccine (mRNA-1777): Clinical data, page 163

10. Please disclose what were the "five SAEs all deemed unrelated to study product" referenced on page 166.

#### H10N8 vaccine (mRNA-1440) and H7N9 vaccine (mRNA-1851): Clinical data, page 177

11. We note your disclosure that "[a]t doses up to 100 µg administered IM, safety and reactogenicity profiles for our H10N8 vaccine were comparable to licensed adjuvanted and unadjuvanted influenza vaccines." Please tell us whether you conducted studies of the H10N8 vaccine on a head to head basis. If not, please remove this comparison from your disclosure or tell us why you believe such comparison is appropriate.

#### Adverse events for the Phase 1 a/b trial for AZD8601, page 221

12. Please disclose what were the adverse and serious adverse events referenced under the table on page 221. In addition, please define "ECG."

#### Third-Party Strategic Alliances, page 252

13. We note your references to "low-double digits" on page 254," "double digits" and "lowdouble digits" on page 255, "low-double digits" on page 256, and "low double-digits percentage" on page 259 when describing royalty payments under various contracts. Please revise your disclosure in each of the referenced cases to narrow the royalty range to no more than ten percentage points (for example between twenty and thirty percent).

Notes to Consolidated Financial Statements Note 7: Commitments and Contingencies Licenses to Patented Technology, page F-46

14. Please revise your disclosure to indicate the aggregate potential milestone payments due under your license agreements. In addition, disclose this information in footnote (4) to your contractual obligations table on page 112 and in your relevant Business disclosure on pages 269 and 270.

Note 9: Redeemable Convertible Preferred Stock and Common Stock Redeemable Convertible Preferred Stock Conversion, page F-51

15. Please revise your disclosure here and throughout your filing to explain why the number of common shares issuable upon conversion of your Series A, B and H preferred stock is variable as indicated in The Offering on page 12. Also, tell us whether the variability in the number of common shares issuable upon conversion of your Series A, B and H preferred stock triggers a contingent beneficial conversion feature.

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You may contact Mary Mast at (202) 551-3613 or Mark Brunhofer at (202) 551-3638 if you have questions regarding comments on the financial statements and related matters. Please contact Tonya K. Aldave at (202) 551-3601 or J. Nolan McWilliams at (202) 551-3217 with any other questions.

Sincerely,

Division of Corporation Finance Office of Healthcare & Insurance

cc: Gregg L. Katz, Esq.