



DIVISION OF
CORPORATION FINANCE

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

November 29, 2020

Kevin Ali
Chief Executive Officer
Organon & Co.
30 Hudson Street
Jersey City, NJ 07302

**Re: Organon & Co.
Draft Registration Statement on Form 10
Submitted November 2, 2020
CIK No. 0001821825**

Dear Mr. Ali:

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 10 submitted November 2, 2020

Exhibit 99.1 Information Statement
Industry, Ranking and Market Data, page ii

1. Your statement that you have not independently verified third-party market and industry data may imply an inappropriate disclaimer of responsibility with respect third-party information included in your registration statement. Please either delete this statement or specifically state that you are liable for such information.

Company Overview, page 7

2. We note your disclosure that the sizeable impacts of loss of exclusivity for many of your products have passed and that you expect your portfolio will continue to deliver strong,

reliable operating profit. Please revise to disclose which of your material products no longer have patent protection and when related market exclusivity ended. To the extent practicable, please quantify the impacts of loss of exclusivity and disclose when the material impacts to your sales occurred.

3. We note your market statistics for the global market for biosimilars and the estimate of the aggregate market value of biologics that will lose patent protection in the next decade. Please balance this disclosure with disclosure of the current size of the markets for your existing biosimilars and make it clear that you do not currently have product candidates that address the broad market of biologic products that will lose patent protection in the next decade. Additionally, we note your disclosure on page 10 that you believe your biosimilars exhibit substantial early stage growth potential. Please revise this statement and similar statements throughout your registration statement to remove any implication that you will be successful in securing any particular market share. As examples only, we note your disclosure on page 83 that you believe you are poised to capture significant market share within a large but untapped biosimilars market, and on page 84 that you believe you are poised to continue the initial success "[you] have realized to date." Where you discuss your established brands market and strategy beginning on page 86, revise to briefly explain what you mean by direct product promotion to capture an improved operating leverage position and potential growth and further investment in selling models that strengthen your portfolio and in digital omni-channel selling capabilities.

Summary of Risks Related to Organon's Business and the Separation, page 14

4. Please add a bullet point that highlights the risks related to your indebtedness that you expect to incur to finance the cash distribution to Merck, as discussed on page 35. Please also highlight under an appropriate heading your dependence on your collaboration with Samsung Bioepis for the development of biosimilars, as discussed on page 31.

Risk Factors

We expect to have limited in-house research and development capabilities and will rely on future acquisitions, partnerships..., page 23

5. Please clarify the limitations on the intellectual property licenses for Nexplanon / Implanon NXT.

Potential indemnification liabilities to Merck pursuant to the separation agreement could adversely affect us....., page 33

6. Please expand your disclosure to discuss any pending material litigation for which you have agreed to indemnify Merck.

There could be significant income tax liability if the Spin-off or certain related transactions are determined to be taxable..., page 33

7. Please expand this risk factor to disclose the liabilities that Organon would incur if the spin-off is determined to be taxable.

Management's Discussion and Analysis of Financial Condition and Results of Operations

Critical Accounting Estimates

Impairments of Long-Lived Assets, page 68

8. Please tell us and expand the disclosure to indicate the nature and origin of the goodwill and intangible asset balances reported. Disclose the methodology used to determine the goodwill and intangible assets balances attributable to the carve-out business. Tell us if any of your reporting units can be considered to be at risk as defined in ASC 350 (i.e., fair value is not substantially in excess of the carrying value), and tell us the magnitude of the excess of the fair value over carrying value at your last testing date. Refer to the effects of the COVID-19 pandemic as necessary in your response. To the extent your reporting units are not at risk of failing the quantitative goodwill impairment test, please disclose this fact.

Our Biosimilars Products, page 84

9. We note the table on page 84 that includes the global sales for the biologics comparable to your biosimilars. Please revise your presentation to make clear, if true, that the expected sales figures for your biosimilar products will be less than the global sales listed in the table for the commercialized biologics.
10. We note that your collaboration partner reached settlement agreements with AbbVie and Roche in order for you to launch Hadlima and Ontruzant, respectively. Please explain the need for the settlement agreements and any limitations on your ability to commercialize these products.

Intellectual Property, page 92

11. With respect to your material patents, please disclose the specific products, product groups and technologies to which such patents relate, whether they are owned or licensed, the type of patent protection you have, the expiration dates, the applicable jurisdictions and whether there are any contested proceedings or third-party claims.

Samsung Bioepis Development and Commercialization Agreement, page 109

12. Please disclose the aggregate future milestone payments to be paid pursuant to the Samsung Bioepis agreement and any royalty rates or royalty range not to exceed ten percent, term and termination provisions. Please also file the agreement as an exhibit or tell us why you believe such filing is not required.

Kevin Ali
Organon & Co.
November 29, 2020
Page 4

Combined Financial Statement of Organon & Co
Combined Statement of Equity, page F-5

13. Please reconcile the Net transfers to Parent amounts presented on the Combined Statement of Equity on page F-5 to the amounts presented on the Combined Statement of Cash Flows on page F-6 for all periods presented.

Note 2. Basis of Presentation, page F-7

14. We acknowledge your disclosure that explains that your financial statements have been prepared on a standalone basis, and were derived from Merck's consolidated financial statements and accounting records. In addition, please include a statement, if true, that the assets, liabilities, revenue and expenses directly attributable to your operations have been reflected in your financial statements on a historical cost basis, as included in the consolidated financial statements of Merck. Please refer to ASC 805-50-30-5 and 30-6 as applicable in your response.
15. Please include a statement, if true, that the accounting policies of the carve-out business reflect the historical accounting policies applied by the parent entity, Merck, or include disclosure that clarifies any departure. If the preparation of carve-out financial statements resulted in adoption of an accounting principle or a change in accounting principle, please disclose that fact, and explain why the adoption was considered appropriate. Please refer to ASC 250-10-45-1 and 45-2 in your response.

Exhibits

16. Please file the transition services agreement, manufacturing and supply agreement, trademark assignment and license agreement and intellectual property license agreement as exhibits to your registration statement on Form 10, or tell us why you believe these agreements are not required to be filed as exhibits.

You may contact Ibolya Ignat at 202-551-3636 or Angela Connell at 202-551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Christopher Edwards at 202-551-6761 or Christine Westbrook at 202-551-5019 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Eric Scarazzo, Esq.