United States securities and exchange commission logo

November 10, 2020

Sijmen de Vries, M.D. MBA
Chief Executive Officer
Pharming Group N.V.
Darwinweg 24
2333 CR Leiden
The Netherlands

Re: Pharming Group N.V.
Draft Registration Statement on Form F-1
Submitted October 14, 2020
CIK No. 0001828316

Dear Dr. de Vries:

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 submitted October 14, 2020

Prospectus Summary
Message from the CEO, page 1

1. We note your claim that you have been at the forefront of developing ground-breaking new therapies for the safe, effective treatment of rare diseases since 1988. However, based on the subsequent disclosure in your document, it appears that only one of your product candidates has been approved and determined to be safe and effective by health regulatory authorities. Please revise your statement accordingly to clarify that only one of your products has been found to be safe and effective to date. Please also provide us with the basis for your claim that you are at the forefront of developing new therapies for rare diseases.

Our Marketed Product: RUCONEST for the treatment of acute HAE attacks, page 2

2. We note your statement that you are currently developing a new generation low-volume formulation of RUCONEST for intramuscular administration or other routes of administration. Please update your disclosure to briefly describe how

RUCONEST is
currently administered.
rhC1INH for the treatment of COVID-19, page 3

3. We note your discussion of the compassionate use program involving the administration
of rhC1INH for the treatment of COVID-19. Please revise your disclosure here and
elsewhere in the document where the results of the compassionate use program are
described to clarify that the results from this program do not provide a guarantee that
rhC1INH will be deemed to be safe or effective for the treatment of COVID-19, and that
extensive clinical testing and regulatory approval will be required before rhC1INH can be
commonly prescribed for the treatment of COVID-19. Please also revise to avoid
characterizing the results of the program as "encouraging" as this may create an inference
that your product is more likely to be found safe and effective, which is a determination
solely in the authority of regulatory agencies such as the FDA. Please make similar
revisions throughout your document, such as where you describe certain results as
"particularly promising" or positive.
4. We note your discussion of your current clinical trial of rhC1INH for the treatment of
COVID-19 and your planned clinical trial in the U.S. Please update your disclosure to
clarify (i) the phase (1, 2 or 3) of the clinical trial you are conducting, the trial's endpoints
and when you expect to report topline results and (ii) whether an IND has been submitted
for your planned clinical trial in the U.S.
Implications of Being an Emerging Growth Company and a Foreign Private Issuer, page 6

5. Please supplementally 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
Risks Related to Our Business, page 11

6. We note your disclosure on page F-40 that you have granted the China Shanghai Institute
of Pharmaceutical Industry an exclusive license to commercialize RUCONEST in China.
Please update your disclosure in the Risk Factors section to clarify, if true, that you will
not be able to launch RUCONEST in China.

Industry and Market Data, page 48

7. Your statement that no independent source has verified your internal company research
may imply an inappropriate disclaimer of responsibility with respect to such research.
Please either delete this statement or specifically state that you are liable for such
information.
Selected Consolidated Financial Data
Interim Financial Statements, page 51

8. Please clarify whether the interim financial statements for the nine months ended
September 30 are unaudited in this section and other relevant sections of the filing.

Key Business Measures, page 53

9. "Adjusted EBITDA" includes an adjustment for impairment and reversal of impairment for the periods presented. It appears that a 2.6 million impairment charge in 2018 was reversed in 2019 due to the down prioritized development track of a small variant of RUCONEST. Based on your disclosures on page F-32, it appears that there was an additional impairment of 1.9 million which was recorded and offset against the 2.6 million reversal. Please tell us why the 1.9 million impairment was not recognized as an adjustment in 2019 on page 53. In that regard, please tell us how you considered Question 100.02 of the Staff's Non-GAAP Compliance and Disclosure Interpretations and Rule 100(b) of Regulation G.

Management 's Discussion and Analysis of Financial Condition and Results of Operations
Results of Operations
Cost of Research and Development, page 59

10. Please disclose the costs incurred during each period presented for each of your key research and development projects/product candidates discussed on pages 2 and 66. If you do not track your research and development costs by project/product candidates, please disclose that fact. Provide other quantitative or qualitative disclosure that provides more transparency as to the type of research and development expenses incurred (i.e. by nature or type of expense) for your research and development expenses.

Liquidity and Capital Resources, page 61

11. Please include a discussion of your 125 million in convertible bonds due in 2025 in this section. Refer to Item 5.B. of Form 20-F (incorporated into Item 4 of Form F-1).

Business
Acute Kidney Injury (AKI), page 73

12. Please update your description of the Phase 2 investigator-initiated study rhC1INH in patients at risk of nephropathy resulting for contrast-enhanced examinations to include the

following:

- The primary and secondary endpoints of the trial and whether they were achieved.
- A brief explanation of statistical significance.
- Whether any adverse events and/or serious adverse events occurred that were linked to treatment. If any such events occurred, please include the nature of each such event and the number of patients that experienced it.

Please also revise your disclosure to briefly explain the miTT, PP and PCI measures in your chart on page 74 and how they relate to the overall NGAL level measured.

Leniolisib for the treatment of Activated Phosphoinositide 3-kinase Delta Syndrome, page 75

13. We note your statement that leniolisib has proven to be safe to date. Safety is a determination that is solely within the authority of the FDA and foreign regulators. You may state that your product candidate has been well-tolerated, if true. We further note that leniolisib has been evaluated in a Phase 1 clinical trial. Please

update your description of
this clinical trial to include the number of subjects in the trial; the primary and secondary
endpoints and whether they were achieved; and whether any AEs or SAEs occurred that
were linked to treatment and the nature and number of these AEs/SAEs. Finally, please
update your description of the ongoing Phase 2/3 clinical trial of leniolisib to disclose the
endpoints of this trial.

Manufacturing, page 77

14. We note your disclosure on pages 19-20 which indicates that you rely on a sole supplier
for certain of your components and materials and that in some cases, there are no
alternative sources of supply for certain of the components used to produce your product
candidates. Please update your discussion in "Manufacturing" to include a discussion of
how you obtain the supplies for your product candidates, including your reliance on a
single supplier, and whether there are alternative sources of supply the raw materials and
components used in your product candidates.

To the extent you are substantially dependent on any agreements with your suppliers,
please identify them, describe the material terms and file the agreements as exhibits. If
you believe you are not substantially dependent on the agreements, please provide us with
an analysis supporting your belief.

Material Agreements, page 80

15. Please update your description of your agreement with Novartis to include the following:

- the date of the agreement;
- each parties' rights and obligations under the agreement;
- disclose separately the aggregate amount of all potential development, regulatory and commercial milestone payments;

- disclose the amount of option fees for additional targets, if any;
- quantify the royalty rate, or a range no greater than 10 percentage points per tier;
- disclose when royalty provisions expire, and if the expiration is based on a number of years following commercialization, disclose the number of years;
- disclose the expiration date; and
- describe any termination provisions.

16. We note your disclosure on pages 57 and F-60 regarding your agreement with Bausch
Health Companies Inc. (formerly Valeant Pharmaceuticals International) pursuant to
which you acquired North American commercialization rights to RUCONEST and under
which you may be required to make additional milestone payments. Please expand your
disclosure to describe the material terms of this agreement, such as term and termination
provisions and the parties' rights and obligations, including payment terms. Also, please
file the agreement as an exhibit or tell us why you do not believe it is required to be filed.

Related Party Transactions, page 104

17. Please file the agreement for your investment in BioConnection B.V. as an exhibit to your
registration statement or provide us with your analysis explaining why this agreement is

not required to be filed.
Stock Exchange Listing, page 123

18. We note your disclosure that you intend to apply to list your ADSs on the Nasdaq Global Market. Please tell us which listing standard you will rely on in your application. We may have further comment.

Description of American Depositary Shares
Governing Law, page 136

19. We note your disclosure that the deposit agreement provides that the depositary may, in its sole discretion, require that any dispute or difference arising from the agreement be referred to and finally settled by arbitration. Please clarify whether this provision precludes an ADS holder from pursuing claims under federal securities laws in federal courts and add risk factor disclosure, as appropriate. Also provide risk factor disclosure of the risks related to the provision that ADS holders irrevocably agree that any legal suit, action or proceeding against or involving the depositary brought by ADR holders or beneficial owners, arising out of or based upon the deposit agreement, the ADSs, the ADRs or the transactions contemplated thereby, may only be instituted in a state or federal court in New York, New York.

Jury Trial Waiver, page 137

20. We note your disclosure regarding the waiver of jury trial provision. Please include a risk factor to highlight the material risks related to this provision, including the possibility of less favorable outcomes, uncertainty regarding its enforceability, the potential for

increased costs to bring a claim, whether it may discourage or limit suits against you or the depositary and whether the provision applies to purchasers in secondary transactions. Also disclose whether this provision would apply if the ADS holder were to withdraw the ordinary shares.

2.3 Accounting principles and policies
Research and Development Costs, page F-17

21. We note your disclosure that any expenditure capitalised is amortized over the period of expected useful life of the related patents. Please further expand your policy to disclose when you typically begin amortization of development costs including when you typically obtain the related patents that would allow for amortization to commence. Please clarify whether the patents are obtained in conjunction with receiving approval for commercialization of the underlying product candidate. In that regard, your disclosures should highlight when you typically view such assets to meet the conditions of paragraph 97 of IAS 38.

You may contact Ameen Hamady at 202-551-3891 or Brian Cascio at 202-551-3676 if you have questions regarding comments on the financial statements and related matters. Please contact Alan Campbell at 202-551-4224 or Mary Beth Breslin at 202-551-3625 with any other questions.

Sincerely,