UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the Month of August 2022

Commission File Number: 001-39822

Pharming Group N.V.

(Exact Name of Registrant as Specified in Its Charter)

Darwinweg 24
2333 CR Leiden
The Netherlands
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

Filed as Exhibit 99.1 to this Report on Form 6-K is a press release of Pharming Group N.V., or the Company, dated August 1, 2022.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Pharming Group Receives Accelerated Assessment in Europe for leniolisib for the Treatment of Rare Immunodeficiency, APDS

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Pharming Group N.V.

By: /s/ Sijmen de Vries

Name: Sijmen de Vries
Title: CEO

Date: August 1, 2022

Pharming Group Receives Accelerated Assessment in Europe for leniolisib for the Treatment of Rare Immunodeficiency, APDS

EMA accelerated assessment allows a shorter review period for leniolisib from a standard 210 days to 150 days

Pharming is on track to submit its Marketing Authorisation Application for leniolisib in H2 2022

Leiden, The Netherlands, August 1, 2022: Pharming Group N.V. ("Pharming" or "the Company") (EURONEXT Amsterdam: PHARM/Nasdaq: PHAR) announces that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has granted an accelerated assessment for the Marketing Authorisation Application (MAA) for leniolisib. Leniolisib has been studied for the treatment of activated PI3K delta syndrome (APDS), a rare primary immunodeficiency, in adults and adolescents age 12 or older in the European Economic Area (EEA). Pharming is on track and plans to submit its MAA for leniolisib to the EMA in October 2022.

Accelerated assessment reduces the timeframe for the CHMP to review an MAA from 210 days to 150 days. The EMA will grant, upon request, accelerated assessment of an MAA if they decide the product is of major interest for public health and therapeutic innovation.

The clinical development for leniolisib includes positive data from a Phase II/III study of the product, which met both its co-primary endpoints in the target patient population of evaluated reduction in lymph node size and correction of immunodeficiency. The primary efficacy results demonstrated clinical efficacy of leniolisib over placebo with a statistically significant reduction from baseline in the log10 transformed sum of product of diameters (SPD) in the index lymphadenopathy lesions ($p=0.0012$) and normalization of immune dysfunction, as evidenced by increased proportion of naïve B cells from baseline ($p<0.0001$). The shrinking of lymphadenopathy lesions and increased proportion of naïve B cells are important in patients as they indicate a reduction in APDS disease markers.

In the study, leniolisib was generally well-tolerated, with the majority of reported adverse events in both treatment groups classified as mild. There were no adverse events that led to discontinuation of study treatment, there were no deaths, and the incidence of serious adverse events (SAEs) was lower in the leniolisib group than the placebo group. None of the SAEs were suspected to be related to study treatment.

Anurag Relan, Chief Medical Officer of Pharming, commented:
"The acceptance of an accelerated regulatory review for leniolisib underlines the high unmet need for patients with APDS, with the product potentially being the first approved treatment for this rare disease. This is an important milestone for the APDS community and for Pharming

and is built on the successful Phase II/III data, which we first reported in February 2022. We remain focused on progressing leniolisib through the regulatory review process, with our MAA on track for submission in October of this year, as we seek to make this important new product available to immunologists, hematologists, and their patients in Europe."

About Activated Phosphoinositide 3-Kinase δ Syndrome (APDS)

APDS is a rare primary immunodeficiency that affects approximately one to two people per million. Also known as PASLI, it is caused by variants in either of two genes, *PIK3CD* or *PIK3R1*, that regulate maturation of white blood cells. Variants of these genes lead to hyperactivity of the PI3Kδ (phosphoinositide 3-kinase delta) pathway.[1,2] Balanced signaling in the PI3Kδ pathway is essential for physiological immune function. When this pathway is hyperactive, immune cells fail to mature and function properly, leading to immunodeficiency and dysregulation.[1,3] APDS is characterized by severe, recurrent sinopulmonary infections, lymphoproliferation, autoimmunity, and enteropathy.[4,5] Because these symptoms can be associated with a variety of conditions, including other primary immunodeficiencies, people with APDS are frequently misdiagnosed and suffer a median 7-year diagnostic delay.[6] As APDS is a progressive disease, this delay may lead to an accumulation of damage over time, including permanent lung damage and lymphoma.[4-7] The only way to definitively diagnose this condition is through genetic testing.

About Leniolisib

Leniolisib is a small-molecule inhibitor of the delta isoform of the 110 kDa catalytic subunit of class IA PI3K with immunomodulating and potentially anti-neoplastic activities. Leniolisib inhibits the production of phosphatidylinositol-3-4-5-trisphosphate (PIP3). PIP3 serves as an important cellular messenger specifically activating AKT (via PDK1) and regulates a multitude of cell functions such as proliferation, differentiation, cytokine production, cell survival, angiogenesis, and metabolism. Unlike PI3Kα and PI3Kβ, which are ubiquitously expressed, PI3Kδ and PI3Kγ are expressed primarily in cells of hematopoietic origin. The central role of PI3Kδ in regulating numerous cellular functions of the adaptive immune system (B-cells and, to a lesser extent, T cells) as well as the innate immune system (neutrophils, mast cells, and macrophages) strongly indicates that PI3Kδ is a valid and potentially effective therapeutic target for several immune diseases. To date, leniolisib has been well tolerated during both the Phase 1 first-in-human trial in healthy subjects and the Phase II/III registration-enabling study.

About Pharming Group N.V.

Pharming Group N.V. (EURONEXT Amsterdam: PHARM/Nasdaq: PHAR) is a global biopharmaceutical company dedicated to transforming the lives of patients with rare, debilitating, and life-threatening diseases. Pharming is commercializing and developing an innovative portfolio of protein replacement therapies and precision medicines, including small molecules, biologics, and gene therapies that are in early to late-stage development. Pharming is headquartered in Leiden, Netherlands, and has employees around the globe who serve

patients in over 30 markets in North America, Europe, the Middle East, Africa, and Asia-Pacific. For more information, visit www.pharming.com.

Forward-looking Statements

This press release contains forward-looking statements, including with respect to timing and progress of Pharming's preclinical studies and clinical trials of its product candidates, Pharming's clinical and commercial prospects, Pharming's ability to overcome the challenges posed by the COVID-19 pandemic to the conduct of its business, and Pharming's expectations regarding its projected working capital requirements and cash resources, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to the scope, progress and expansion of Pharming's clinical trials and ramifications for the cost thereof; and clinical, scientific, regulatory and technical developments. In light of these risks and uncertainties, and other risks and uncertainties that are described in Pharming's 2021 Annual Report and the Annual Report on Form 20-F for the year ended December 31, 2021 filed with the U.S. Securities and Exchange Commission, the events and circumstances discussed in such forward-looking statements may not occur, and Pharming's actual results could differ materially and adversely from those anticipated or implied thereby. Any forward-looking statements speak only as of the date of this press release and are based on information available to Pharming as of the date of this release.

Inside Information

This press release relates to the disclosure of information that qualifies, or may have qualified, as inside information within the meaning of Article 7(1) of the EU Market Abuse Regulation.

References

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5. Maccari ME, et al. Front Immunol. 2018;9:543.
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