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

Date of report: May 26, 2023

Commission File Number: 001-38974

BIOPHYTIS S.A.

(Translation of registrant's name into English)

Stanislas Veillet
Biophytis S.A.
Sorbonne University—BC 9, Bâtiment A 4ème étage
4 place Jussieu
75005 Paris, France
+33 1 44 27 23 00
(Address of principal executive office)

+33 1 44 27 23 00 (Address of principal executive office)
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): □

On May 26, 2023, Biophytis S.A. issued a press release announcing that the company has filed with the French National Authority for Health (HAS) an application for Early Access Authorisation (EAA) for Sarconeos (BIO101. A copy of the press release is attached as Exhibit 99.1 to this Form 6-K.

EXHIBIT LIST

Exhibit	Description
<u>99.1</u>	Press Release dated May 26, 2023.

SIGNATURES

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.

BIOPHYTIS S.A.

Date: May 26, 2023 By: /s/ Stanislas Veillet

Name: Stanislas Veillet

Title: Chairman and Chief Executive Officer



Press release

Biophytis has filed with the French National Authority for Health (HAS) an application for Early Access Authorisation (EAA) for Sarconeos (BIO101) in the treatment of severe forms of COVID-19

Paris (France), Cambridge (Massachusetts, U.S.), March 26, 2023, 8am CET – Biophytis SA (NasdaqCM: BPTS, Euronext Growth Paris: ALBPS) (the "Company" or "Biophytis"), a clinical-stage biotechnology company focused on the development of therapeutics that slow the degenerative processes associated with aging, including severe respiratory failure in patients suffering from COVID-19, today announced that it has filed, through its pharmaceutical partner Intsel Chimos, an application for Early Access Authorisation (EAA) in France with the French National Authority for Health (HAS) for the use of Sarconeos (BIO101)¹ in the treatment of adult patients with a severe form of COVID-19, who are at risk of developing a critical form of the disease and for whom therapeutic alternatives are not appropriate.

Following the positive results of the COVA phase 2-3 study, Biophytis met with the HAS on March 9, 2023 for a pre-submission meeting to review the eligibility requirements of the application. The Company is now pursuing this regulatory process by submitting the EAA application. If the application is approved by the HAS, the early access programme will allow certain patients with severe forms of COVID-19 to be treated in France with Sarconeos (BIO101), while awaiting conditional Marketing Authorisation (MA) in Europe. Biophytis expects a response by Q3 2023 at the latest, depending on the delays taken by the HAS, and the first patients could be treated as early as Q4 2023. The industrial scale production of Sarconeos (BIO101) has been initiated with pharmaceutical subcontracting partners (CDMOs), in order to be able to treat up to 6,000 patients if the EAA is approved. Distribution will be handled by Intsel Chimos, with whom a partnership was signed in March 2023.

Stanislas Veillet, CEO of Biophytis, said: "We have demonstrated, through the positive results of the COVA study, a statistically significant 44% reduction in the risk of respiratory failure or early death. With the submission of our application for the early access program, we therefore intend to accelerate the availability in France of Sarconeos (BIO101) to hospitalized patients with severe forms of COVID-19 via our partner Intsel Chimos."

Corinne Truffault, CEO of Intsel Chimos, said: "We are delighted and very proud to accompany Biophytis in this new regulatory step to obtain the EAA for Sarconeos (BIO101) in the treatment of severe forms of Covid-19. In parallel, we are preparing to ensure the distribution and availability of this treatment to patients in France as soon as the EAA is approved by the HAS."

1 Sarconeos (BIO101) is the code name for Biophytis' drug candidate. The active molecule is 20-hydroxyecdysone (20E)





ABOUT EARLY ACCESS

Early access in France is granted by the HAS after the opinion of the National Agency for the Safety of Medicines and Health Products (ANSM) on the presumed efficacy and safety of the drug candidate. This is a system that allows the early availability and financial coverage, on an exceptional and derogatory basis, of certain medicinal products that meet an unmet therapeutic need, that are likely to be innovative, and that are not yet authorised in a therapeutic indication.

About BIOPHYTIS

Biophytis SA is a clinical-stage biotechnology company specialized in the development of therapeutics that are aimed at slowing the degenerative processes associated with aging and improving functional outcomes for patients suffering from age-related diseases, including severe respiratory failure in patients suffering from COVID-19. Sarconeos (BIO101), our leading drug candidate, is a small molecule, administered orally, planned to be developed as a treatment for sarcopenia in upcoming Phase 3 clinical trials in the United States, Brazil and Europe (SARA-31 and SARA-32). It has also been studied in a clinical two-part Phase 2-3 study (COVA) for the treatment of severe respiratory manifestations of COVID-19 in Europe, Latin America, and the US. A pediatric formulation of Sarconeos (BIO101) is being developed for the treatment of Duchenne Muscular Dystrophy (DMD). The Company is based in Paris, France, and Cambridge, Massachusetts. The Company's ordinary shares are listed on Euronext Growth (Ticker: ALBPS -ISIN: FR0012816825) and ADSs (American Depositary Shares) are listed on Nasdaq Capital Market (Ticker BPTS – ISIN: US09076G1040). For more information visit www.biophytis.com

Disclaimer

This press release contains forward-looking statements. Forward-looking statements include all statements that are not historical facts. In some cases, you can identify these forward-looking statements by the use of words such as "outlook," "believes," "expects," "potential," "continues," "may," "will," "should," "could," "seeks," "predicts," "intends," "trends," "plans," "estimates," "anticipates" or the negative version of these words or other comparable words. Such forward-looking statements are based on assumptions that Biophytis considers to be reasonable. However, there can be no assurance that the statements contained in such forward-looking statements will be verified, which are subject to various risks and uncertainties. The forward-looking statements contained in this press release are also subject to risks not yet known to Biophytis or not currently considered material by Biophytis. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. Please also refer to the "Risk and uncertainties the Company is to face" section from the Company's 2022 Half Year Financial Report available on BIOPHYTIS website (www.biophytis.com) and as exposed in the "Risk Factors" section of form 20-F as well as other forms filed with the SEC (Securities and Exchange Commission, USA). We undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as required by law.





Biophytis Contact for Investor Relations

Nicolas Fellmann, CFO Investors@biophytis.com

Media Contacts

Antoine Denry : antoine.denry@taddeo.fr +33 6 18 07 83 27 Agathe Boggio : agathe.boggio@taddeo.fr +33 7 62 77 69 42