
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 9, 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)

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 9, 2023, Biophytis S.A. issued a press release announcing it has requested a pre-submission meeting with the EMA for the Marketing Authorisation of Sarconeos (BIO101) for the treatment of COVID-19. A copy of the press release is attached as Exhibit 99.1 to this Form 6-K.

EXHIBIT LIST

Exhibit	Description
99.1	Press Release dated May 9, 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 9, 2023

By: /s/ Stanislas Veillet

Name: Stanislas Veillet

Title: Chairman and Chief Executive Officer



Press release

Biophytis has requested a pre-submission meeting with the EMA for the Marketing Authorisation of Sarconeos (BIO101) for the treatment of COVID-19

Paris (France), Cambridge (Massachusetts, U.S.), May 9th, 2023, 08:00 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 for a pre-submission meeting request with the European Medicine Agency (EMA) to discuss filing for conditional Marketing Authorisation (cMA) in Europe for Sarconeos (BIO101) in the treatment of severe form of COVID-19.

This is the first step in the regulatory process that the company is undertaking to define the eligibility and conditions for conditional Marketing Authorisation application in Europe for Sarconeos (BIO101) in the treatment of severe forms of COVID-19. A request for a pre-submission meeting with the Food and Drug Administration (FDA) for an Emergency Use Authorisation (EUA) application in the US is expected to be filed later this quarter.

Stanislas Veillet, Chief Executive Officer of Biophytis, commented: "A few weeks ago, Biophytis held a meeting with the French Health Authority in order to discuss filing an application for early access to Sarconeos (BIO101) for patients hospitalized in France, developing severe forms of COVID-19. We have prepared the application, mainly based on the positive results of the phase 2-3 COVA study, good safety profile of Sarconeos (BIO101) and medical need associated with COVID-19 pandemic, and expect to file this Early Access application this quarter, with the objective to treat the first patients in the second half of 2023 if the authorisation is granted. The meeting with the EMA will allow definition of the eligibility and conditions for filing a conditional marketing authorisation application, this time at European level. Depending on EMA's recommendations, we could envision filing a conditional MA in the second half of 2023 or the first half of 2024. We do not forget that our main objective is to be able to treat as quickly as possible with Sarconeos (BIO101), patients developing severe form of COVID-19, at risk of respiratory failure or death in France, in Europe, but also in the United States and Brazil."

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 lead molecule drug candidate, administered orally, has completed a Phase 2 clinical trial as a treatment for sarcopenia in the United States and Europe (SARA-INT) with positive results. Biophytis is currently in discussions with regulatory authorities to initiate a Phase 3 study. Sarconeos has also obtained positive results from a Phase 2-3 clinical trial (COVA) for the treatment of severe respiratory manifestations of COVID-19 in Europe, Latin America and the United States, and has initiated the regulatory process to obtain early access in France and conditional marketing authorization in Europe 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



Press release

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 Annual Report on Form 20-F 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

Philippe Rousseau 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
