
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: March 22, 2021

Commission File Number: 001-38974

BIOPHYTIS S.A.
(Translation of registrant's name into English)

Stanislas Veillet
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(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 March 22, 2021, Biophytis S.A. issued a press release giving an update on its Phase 2-3 COVA study on COVID-19. 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>	<u>Press Release dated March 22, 2021.</u>

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: March 22, 2021

By: /s/ Stanislas Veillet

Name: Stanislas Veillet

Title: Chairman and Chief Executive Officer



Biophytis gives updates on its Phase 2-3 COVA study on COVID-19

- The Company receives a favorable opinion from the DMC on the safety of Sarconeos (BIO101) in the COVA study following first interim analysis
- Patient enrollment has now reached 97 of the 155 planned for the second interim analysis
- A total of 28 clinical centers are now opened and recruiting in the United States, Brazil, France & Belgium.

Paris (France), Cambridge (Massachusetts, US) – March 22, 2021, 08:00 a.m. CET – Biophytis SA (Nasdaq CM: BPTS, Euronext Growth Paris: ALBPS), (“Biophytis” or the “company”), a clinical-stage biotechnology company focused on 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, announces that the independent Data Monitoring Committee (DMC) for the COVA study has delivered a favorable opinion on the safety of Sarconeos (BIO101) in patients infected with COVID-19, following the scheduled interim analysis of the 50 participants from Part 1 of the study, as well as the progression of patients enrollment, which has now reached 97 of the 155 planned for the second interim analysis.

A total of 28 clinical centers of the 30 targeted are now opened and recruiting in the United States, Brazil, France and Belgium. Upon the second interim analysis, based on the safety and efficacy data from 155 patients, the DMC will re assess the total size of the cohort, estimated today at 310 patients, and the continuation of the trial.

Stanislas Veillet, Chief Executive Officer of Biophytis, said: “In the persistent pressured healthcare context of COVID-19, we are extremely pleased with the opinion delivered by the DMC on the safety of Sarconeos (BIO101) in the framework of our COVA trial. This opinion allows us to push our mission forward with continued recruitment into Part 2 of the COVA study. We have now enrolled 97 out of the targeted 155 participants planned for the second interim analysis. Our 28 sites are recruiting in the United States, Brazil, France and Belgium. Our next milestone is now the second interim analysis, where we will get from DMC the green light for continuing our trial, as well as the final number of patients needed for the study”.



The COVA clinical program (clinicaltrials.gov identifier NCT04472728) is a global, multicenter, double-blind, placebo-controlled, group-sequential and adaptive design two-part study. It is a Phase 2-3 study that assesses Sarconeos (BIO101) in patients aged 45 and older, hospitalized with severe respiratory manifestations of COVID-19

Part 1 of the COVA Study is a Phase 2 exploratory proof of concept study providing preliminary data on the safety, tolerability and activity of Sarconeos (BIO101) in 50 hospitalized patients with severe respiratory manifestations related to COVID-19.

Part 2 of the COVA Study is a Phase 3 randomized study investigating the safety and efficacy of Sarconeos (BIO101) on the respiratory function of 310 COVID-19 patients (including the 50 patients from Part 1 of the study).

The study results (Part 1 and Part 2) are expected in Q2 2021, subject to any COVID-19-related delays and the impact of the current pandemic.

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, being developed as a treatment for sarcopenia in a Phase 2 clinical trial in the United States and Europe (SARA-INT). It is also being 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 common shares are listed on Euronext Growth (Ticker: ALBPS - ISIN: FR0012816825) and ADSs 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, as these statements are subject to various risks and uncertainties, including, without limitation the risks described in our annual report on Form 2-F for the fiscal year ended December 31, 2020 and other filings with the U.S. Securities and Exchange Commission. 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. In France, please also refer to the "Risk Factors" section of the Company's 2020 Full Year Report available on the Biophytis website (www.biophytis.com). 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.

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