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: February 2, 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 February 2, 2023, Biophytis S.A. issued a press release announcing positive final results of the phase 2-3 COVA study with Sarconeos (BIO101) in severe 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 February 2, 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: February 2, 2023

By: /s/ Stanislas Veillet
Name: Stanislas Veillet
Title: Chairman and Chief Executive Officer

Exhibit 99.1

Press release

Biophytis announces positive final results
of the phase 2-3 COVA study with Sarconeos (BIO101)
in severe COVID-19

- **COVA study met primary end point with 44% significant reduction in the risk of respiratory failure or early death**
- **Filing for Early Access Programs to Sarconeos (BIO101) is being initated while preparing for Marketing Authorisation in Europe and the USA**

Paris (France), Cambridge (Massachusetts, U.S.), February 2, 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 released the final results from its phase 2-3 COVA clinical study evaluating Sarconeos (BIO101) in the treatment of COVID-19-related respiratory failure. Biophytis announces today final results following the reintegration of data from 54 patients, among 233 patients treated, that were missing in the Top Line analysis released on September 7, 2022. The final analysis demonstrates that COVA study met the primary endpoint, with a 44% statistically significant reduction (p = 0.043) in the risk of respiratory failure or early death in hospitalized patients with severe COVID-19, in line with positive Post-Hoc analysis released on November 3, 2022.

Stanislas Veillet, CEO of Biophytis, said: *" The COVA study is positive, with a statistically significant reduction of 44% in the risk of respiratory failure or early death, demonstrating the therapeutic potential of Sarconeos (BIO101) in the treatment of severe COVID-19. This huge success is the result of Biophytis scientific excellence and hard work of the clinical and medical teams involved in the COVA clinical study in France, Belgium, the USA and in Brazil. This is tremendous news for patients worldwide, especially for the elderly with co-morbidities, who are at high risk of developing severe COVID-19, despite the great progress made in vaccination and anti-viral treatments now available. While there is a resurgence of COVID-19 patients in China and still unacceptable levels of patients dying from COVID-19 in Europe, the USA and Brazil, Sarconeos (BIO101) may offer an effective therapeutic option to reduce further the threat of COVID-19 pandemic. We are now accelerating the start of our Early Access Program, with the target to give access to Sarconeos (BIO101) in Brazil and France in the second half of 2023, while preparing for filing conditional Marketing Authorisation (CMA) in Europe and Emergency Use Authorization (EUA) in the USA. "*

Press release

Biophytis is now initiating key regulatory activities to give access to Sarconeos (BIO101) to hospitalized patients with severe COVID-19 at risk of respiratory failure and death in 2023. The strategy to give access to Sarconeos (BIO101) as quickly as possible is to file for Early Access Programs (EAP) in France and Brazil, while filing for conditional Marketing Authorisation (CMA) in Europe and Emergency Use Authorization (EUA) in the USA. An EAP has already been approved in 2022 in Brazil to treat COVID-19 patients at critical stage in Intensice Care Units (ICU) and the request to lift the hold given completion of the study and positive results is pending. The filing of the request for starting the EAP program in France is being prepared and will be made in Q1 2023 with the objective to be granted approval in Q2 2023. Requests for pre-submission meetings regarding conditional Marketing Authorisation in Europe and Emergency Use Authorization in the USA are under preparation and will be sent in Q1 2023, targeting an approval later in 2023, depending on feedback from authorities.

Biophytis will present the results in detail at the American Thoracic Society conference in Washington, DC, USA in May 2023 and at the European Respiratory Society Lung Science meeting in Estoril, Portugal, in March 2023.

Final COVA study results

The objective of the study was to investigate the efficacy and safety of Sarconeos (BIO101), 350 mg BID in hospitalized COVID-19 patients with hypoxemia, at risk of respiratory failure requiring high flow oxygen or mechanical ventilation, and death. The proportion of patients and time to respiratory failure or early death were studied at 28 days in the primary analysis, corresponding to the maximum treatment period, with follow-up of mortality and safety for at least 90 days.

The 233 treated patients (Intent To Treat, ITT population) were 63 years old on average, 64% of the patients were male, recruited in 37 centers in Europe, the US and Brazil between Q3 2020 and Q1 2022, infected with the main SARS-Cov-2 variants. The trial ended early before reaching the 310 patients originally planned, due to stalled recruitment. The sub-population of patients without major protocol deviations (Per Protocol, PP sub-population) included 180 patients with similar baseline demographics and disease characteristics as the ITT population.

The study met its pre-defined primary endpoint demonstrating a statistically significant difference between Sarconeos (BIO101) and placebo in the proportion of patients with respiratory failure or early death at day 28, representing a relative reduction of risk of 44% (p=0.043, Cochran-Mantel-Haenszel test). Moreover, the analysis of time to respiratory failure or early death had shown significant differences over 28 days in the Kaplan Meier curves for Sarconeos (BIO101) versus placebo (p=0.022). The pre-specified analysis of time to death over the complete follow-up period over 90 days showed that mortality rate with Sarconeos (BIO101) was reduced compared to placebo in the ITT population (p=0.083) and in the PP population (p=0.038). Post hoc Kaplan-Meier analysis released on November 3, 2022 confirmed the effect of Sarconeos (BIO101) on the primary endpoint and on mortality at day 90.

Sarconeos (BIO101) has a very good safety profile, with a lower proportion of patients with adverse events compared to placebo (57% vs. 64%), in particular a lower frequency of serious, mostly respiratory, adverse events (25% vs. 31%).

About the COVA study

As a reminder, the COVA clinical study (clinicaltrials.gov identifier: NCT04472728) is an international, multi-centre, double-blind, placebo-controlled, group-sequential and adaptive two-part study. It is a phase 2-3 study evaluating Sarconeos (BIO101) in patients aged 45 years and older, hospitalised with severe respiratory manifestations of COVID-19. Part 1 of the COVA study is an exploratory Phase 2 proof-of-concept study designed to provide preliminary data on the safety, tolerability and efficacy of Sarconeos (BIO101) in 50 hospitalised patients with severe respiratory failure in patients suffering from COVID-19. Part 2 of the COVA study is a randomised phase 3 study investigating the safety and efficacy of Sarconeos (BIO101) on respiratory function in patients. Due to the evolution of the pandemic, the company decided in April 2022 to stop enrolment at 238 enrolled patients, below the originally planned number of 310.

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.

Press release

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