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: September 7, 2022

Commission File Number: 001-38974

BIOPHYTIS S.A.

(Translation of registrant's name into English)

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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 September 7, 2022, Biophytis S.A. issued a press release announcing very promising top line results of its phase 2-3 COVA clinical study in COVID-19 related to respiratory failure. 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 September 7, 2022.

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: September 7, 2022

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

Exhibit 99.1

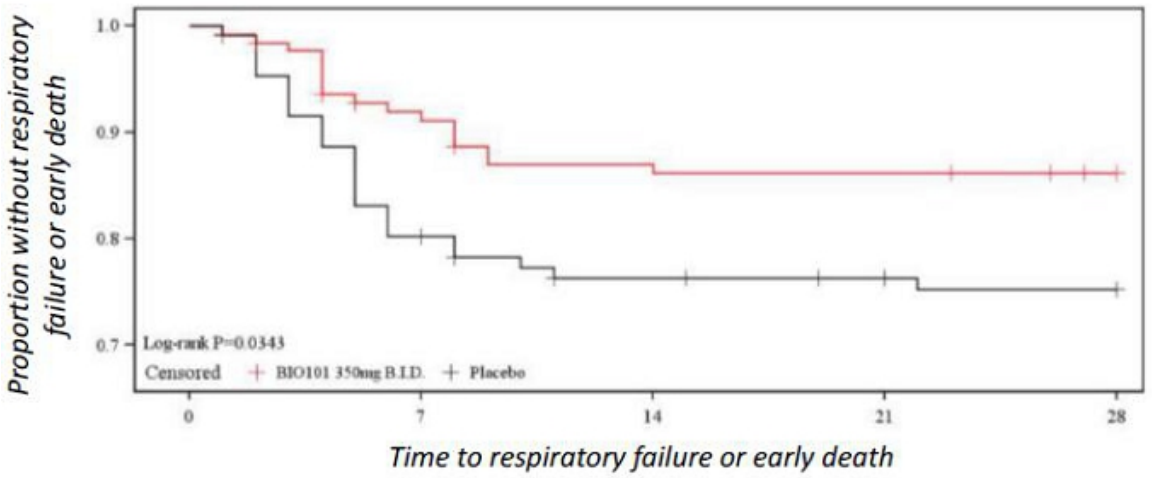
Press release

Biophytis announces very promising top line results
of its phase 2-3 COVA clinical study
in COVID-19-related respiratory failure

Paris (France), Cambridge (Massachusetts, U.S.), September 7th, 2022, 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 top-line results from its phase 2-3 COVA clinical study evaluating Sarconeos (BIO101) in the treatment of COVID-19-related respiratory failure.

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 and time to onset of these negative events were studied for 28 days in the primary analysis, with follow-up of mortality and safety until 90 days after start of treatment. The 233 treated patients were 63 years old on average, 64% of the patients were male, recruited in centers in Europe, the US and Brazil between Q3 2020 and Q1 2022, infected with the main SARS-Cov-2 variants.

In the primary analysis, Sarconeos (BIO101) reduced by 39% the risk of respiratory failure or early death at 28 days (primary endpoint) compared to placebo (15.8% vs 26.0%, adjusted difference 11.8% in favor of treatment, p=0.07). Sarconeos (BIO101) reduced both the proportion of patients with respiratory failure (12.7% vs 21.5%) and early death (0.8% vs 2.8%). Sarconeos (BIO101) also significantly (p=0.03) delayed the progression of respiratory failure or early death over 28 days maximum treatment period:



In addition, in this primary analysis, Sarconeos (BIO101) reduced the risk of death at 28 days compared to placebo, in similar proportion to the observed reduction in the risk of respiratory failure or early death and delayed its occurrence within 90 days. These effects are nonetheless not statistically significant.

Sarconeos (BIO101) presents a good safety profile, with a similar proportion of adverse events compared to placebo, particularly severe adverse events (25% vs 31%). In addition, more patients in the placebo group experienced respiratory adverse events than patients in the Sarconeos (BIO101) group (32.7% vs 22.7%, respectively), supporting the main efficacy results.

Further data analysis is still ongoing. Results of which will be communicated to the market and presented in details during a major international scientific conference in the next months.

Stanislas Veillet, CEO of Biophytis, said: "*The results obtained with Sarconeos (BIO101) in the fight against COVID-19 are very encouraging. It is the only innovative drug candidate in Europe or the United States directly targeting respiratory failure that has demonstrated clinical efficacy in hospitalized patients with hypoxemia caused by COVID-19. It could be used in combination with certain anti-viral and/or anti-inflammatory drugs, which are now part of the medical practice. We will be sharing these results in the coming months with regulatory agencies, health authorities and our partners in Europe, the United States and Brazil to determine under what conditions we could pursue the development of Sarconeos (BIO101) in COVID-19. I would like to sincerely thank all the patients, caregivers, advisors, and finally the shareholders and employees of Biophytis for their hard work, trust and dedication throughout this study, the results of which come at a time when the fear of an epidemic rebound this winter is growing*".

Dr Girish Balachandran Nair, Associate Professor of Medicine in Respiratory and Critical Care, Beaumont Hospital, Royal Oak, MI, USA and Principal Investigator of the COVA study in the USA, adds: "*These results are extremely exciting and of public interest. This is great news for the medical community and the general population at risk, especially elderly patients. Indeed, COVID-19 is becoming endemic and will persist for a long time. Sarconeos (BIO101) could provide a real therapeutic alternative for elderly patients, hospitalized with hypoxemia and at risk of respiratory failure*."

Based on these very promising results, the Company intends to make this new therapeutic solution available to COVID-19 hospitalized patients at risk of respiratory failure and early death. Actually, according to the *Johns Hopkins Coronavirus Resource Center*, during the last month in the US, Brazil and France, 2.6 million, 0.5 million and 0.6 million people respectively were infected by COVID-19 and 13.9 thousand, 4.5 thousand and 1.7 thousand died from it. Beyond COVID-19 infection, other infections such as flu can also generate Acute Respiratory Distress Syndrome (ARDS).

Biophytis is currently evaluating the possibility of amending and continuing the Early Access Program (EAP) to make Sarconeos (BIO101) available as soon as this winter to COVID-19 hospitalized patients and at risk of respiratory failure and death. An EAP has already been authorized in Brazil to treat patients in intensive care and further EAP might be filed in other territories including the USA and Europe. This is a first step towards market authorization, the conditions of which will be discussed in the coming months with the relevant regulatory authorities (FDA, EMA and ANVISA).

Press release

About the COVA study

As a reminder, the COVA clinical programme (identifier clinicaltrials.gov: 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 pandemia, the company decided in April 2022 to stop enrolment at 237 patients.

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 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

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 2021 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.

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