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 15, 2021

Commission File Number: 001-38974

BIOPHYTIS S.A.

(Translation of registrant's name into English)

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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 15, 2021, Biophytis S.A. issued a press release announcing DMC second interim analysis efficacy results in the promising zone allowing continuation of phase 2-3 COVA study with Sarconeos (BIO101) in 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 September 15, 2021.

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 15, 2021

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

Exhibit 99.1

Press Release

Biophytis announces DMC second interim analysis efficacy results in the promising zone allowing continuation of phase 2/3 COVA study with Sarconeos (BIO101) in COVID-19

- **The independent DMC (Data Monitoring Committee) recommends continuation of Part 2 of the Phase 2-3 Study ("the COVA Study") without any protocol amendment**
- **The second Interim Analysis ("IA2") based on 155 hospitalized patients shows no futility, with efficacy results in the promising zone, indicating that BIO101 remains a candidate treatment for acute respiratory failure associated with COVID-19**
- **To date, 200 patients have been enrolled in COVA study and 15 additional sites in USA, Brazil, France, UK and Belgium will be opened to accelerate patient recruitment and report top line results depending on the evolution of the pandemic in Q1 2022**

Paris (France), Cambridge (Massachusetts, U.S.), September 15th, 2021 - 8:00 a.m. CET - Biophytis SA (NasdaqCM: BPTS, Euronext Growth Paris: ALBPS), a clinical-stage biotechnology company focused on the development of therapeutics that slow the degenerative processes associated with aging and improve functional outcomes for patients suffering from age-related diseases, including severe respiratory failure in patients suffering from COVID-19, today announces the recommendation by the Data Monitoring Committee (DMC) to continue the Phase 2-3 COVA study without any modification of the protocol, after the interim efficacy data were found in the promising zone in the Interim Analysis 2 based on 155 COVID-19 patients hospitalized with respiratory failure. This recommendation completes previous safety evaluation performed by DMC last August (Press Release August, 16th) that confirmed the good safety profile of Sarconeos (BIO101).

Dr Muriel Lins, COVA trial coordinator in Belgium declared: "with the emergence of the delta variant in Europe, we are happy that this second interim analysis leads to continuation of the COVA study. Patient recruitment will be continued intensively in Belgium and in France to reach full completion of the study".

Dr Girish Nair COVA trial coordinator in USA declared "USA Investigators are welcoming the continuation of the COVA trial as a very good opportunity to restart recruitment when the DMC meeting outcome will be shared with the FDA".

Stanislas Veillet, CEO of Biophytis declared: "We are thrilled with the DMC recommendation following the second Interim Analysis to continue the COVA study unmodified. The DMC recommendation suggests that the trial is well on track to lead to conclusive efficacy results at final analysis. We hope that Sarconeos (BIO101) will become one of the first drug candidates able to restore breathing capabilities of hospitalized patients in severe conditions, and therefore avoiding their admission to ICUs. The whole Company is now focused on the next milestones, ie complete the trial as soon as possible, as well as its industrial scaling up and regulatory approval in Europe, USA and Brazil. We want to be ready for commercialization of our Sarconeos (BIO101) in COVID-19 first half of 2022".

The COVA DMC has met on September 10th 2021 for the Interim Analysis 2 to review the safety and efficacy data of the first 155 randomized patients. The DMCs recommendation is based on the promising zone analysis published by Mehta and Pocock in 2011, and especially on the conditional power for the primary endpoint evaluated with interim analysis. The COVA study primary endpoint is the proportion of participants with "negative events" of either the following: all cause mortality; respiratory failure defined as requiring mechanical ventilation or Extracorporeal Membrane Oxygenation (ECMO).

Interim analysis 2 results shows that the study is currently in the promising zone, therefore the sample size remains unmodified per the current protocol ie between 310 and 465 patients, indicating that Sarconeos (BIO101) remains a candidate treatment for acute respiratory failure associated with COVID-19. The study is not in the unfavourable zone, that would have led to stopping for futility, and has not demonstrated statistically significant efficacy yet, which would have led to early stopping for efficacy.

The DMC recommendation will be shared with all regulatory agencies to continue patients recruitment. 35 clinical centers are now opened to recruit COVID-19 patiens in the USA, Brazil, France and Belgium. Today, 200 patients are randomised in COVA trial. To accelerate recruitment, 15 additional sites will be opened in USA, Brazil, France, UK and Belgium, where the COVA study is already approved. With this new network of 50 sites, top line results of the study are expected in Q1 2022, depending on the evolution of the pandemic.

The COVA clinical program (clinicaltrials.gov identifier: NCT04472728) is a global, multicentre, double-blind, placebo-controlled, group-sequential and adaptive design two-part Phase 2-3 study assessing 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, and tolerability and efficacy 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 pivotal randomized study investigating the safety and efficacy of Sarconeos (BIO101) on the respiratory function of 310 to 465 COVID-19 patients (including the 50 patients from Part 1 of the study).

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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 ordinary shares are listed on Euronext Growth (Ticker: ALBPS -ISIN: FR0012816825) and the ADS (American Depositary Shares) are listed on Nasdaq (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 "Risks and uncertainties the Company is to face" section from the Company's 2020 Annual Report available on BIOPHYTIS website (www.biophytis.com) and as exposed in the “Risks 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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