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 15, 2023

Commission File Number: 001-38974

BIOPHYTIS S.A.

(Translation of registrant's name into English)

Stanislas Veillet
Biophytis S.A.
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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 May 15, 2023, Biophytis S.A. issued a press release announcing that the company has filed with the EMA for authorization to initiate SARA-31 phase 3 study in sarcopenia. 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 15, 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 15, 2023

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

Exhibit 99.1

Press release

Biophytis has filed with the EMA for authorization to initiate SARA-31 phase 3 study in sarcopenia

Paris (France), Cambridge (Massachusetts, U.S.), May 15, 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 submitted the application for Clinical Trial Authorization (CTA) to initiate SARA-31, the first phase 3 study in sarcopenia, on the European portal of the EMA (European Medicines Agency).

The launch of the Phase 3 program follows encouraging results from the SARA-INT Phase 2b study and interactions with health authorities in 2022. Based on the Phase 2b results and feedback from the agencies, Biophytis is starting its Phase 3 programme by filing the first Phase 3 (SARA-31) application in Europe.

The objective of the SARA-31 phase 3 study in sarcopenia is to evaluate the efficacy and safety of Sarconeos (BIO101) in the treatment of sarcopenic patients at risk of mobility disability. Approximately 900 patients over 65 years of age with severe sarcopenia ($3 \leq SPPB \leq 7$) with low walking speed (4-m Gait speed $\leq$ 0.8 m/s) and low grip strength (HGS < 20kg for women and < 35.5 kg for men) will be included. They will be treated for a minimum of 12 months and a maximum of 36 months, receiving either placebo or 350mg of Sarconeos (BIO101) twice daily. The primary endpoint will be the assessment of the risk of Major Mobility Disability (MMD), measured by the ability to walk 400m in less than 15 minutes over time. In addition to this primary endpoint, the following secondary endpoints will be assessed: walking speed (4-m walking speed from the Short Physical Performance Battery (SPPB) test), handgrip strength (HGS) and patient-reported quality of life (Patient Reported Outcome SarQol, a questionnaire developed specifically for sarcopenia).

Biophytis expects a response from the regulatory authorities in the next quarter, which would allow Biophytis to initiate the study in Belgium in the following quarter. In addition, Biophytis is currently working on the preparation of the documents to be submitted to the FDA in order to request approvals to initiate the phase 3 study also in the United States. Finally, the principal investigator of the study will be Roger A. Fielding, PhD, who heads the Nutrition, Physiology, Exercise and Sarcopenia (NEPS) laboratory at Tufts University in Boston, who will continue with his contribution to the clinical development plan of Sarconeos(BIO101).

Stanislas Veillet, CEO of Biophytis stated: "*Sarcopenia has only recently been recognised as a diagnosable disease, with no effective treatment option, despite the enormous medical need. Following the successful completion of the SARA-INT Phase 2b trial to assess the safety and efficacy of Sarconeos (BIO101) in patients over 65 years of age with sarcopenia and at risk of mobility disability, the submission of the EMA application to initiate a Phase 3 trial in sarcopenia marks the beginning of a new milestone in the development of our drug candidate. There is currently no drug approved in the world for sarcopenia. We are pioneers in this field and intend to continue to establish our leadership by being the first company to launch, in partnership with global or regional pharmaceutical companies, a Phase 3 clinical development program in this indication.*"

Press release

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 promising results. Sarconeos has also obtained positive results from a Phase 2-3 clinical trial (COVA) for the treatment of severe forms of COVID-19 in Europe, Latin America and the United States. 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 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.

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