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 11, 2023

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 September 11, 2023, Biophytis S.A. issued a press release announcing that it has obtained FDA Authorization to initiate the 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 September 11, 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: September 11, 2023

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

Exhibit 99.1

Press release

Biophytis obtains FDA Authorization to initiate the SARA-31 phase 3 study in sarcopenia

Paris (France) and Cambridge (Massachusetts, USA), September 11, 2023 – 07:00 am CET – Biophytis SA (Nasdaq CM : BPTS, Euronext Growth Paris : ALBPS), («Biophytis»), 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, today announced that it has received FDA *(Food and Drug Administration)* authorization to launch its SARA-31 study in the US, the first ever phase 3 study in sarcopenia.

This authorization complements the positive opinion obtained this summer from the Belgian authorities to conduct the SARA-31 phase 3 study. The company still needs to obtain authorizations from ethics committees in the countries before launching this study.

The effective start of the study is scheduled for 2024, and will depend on the conclusion of partnership agreements and the Company's financial resources.

Stanislas Veillet, Chief Executive Officer of Biophytis, commented: *"FDA approval suggests authorities may be increasingly aware of the growing need for effective therapeutics against a major disease in an aging society. We can count on the growing interest of the medical community in Europe and the United States to conduct our clinical study and provide a therapeutic response with Sarconeos (BIO101) in the coming years in the treatment of sarcopenia that currently lacks effective pharmaceutical treatment and which is on the rise due to the aging of the population".*

About SARA-31

The aim of phase 3 is to evaluate the efficacy and safety of Sarconeos (BIO101) in the treatment of sarcopenic patients at risk of motor disability. Around 900 patients aged over 65 will be included with sarcopenia (Short Physical Performance Battery (SPPB) score between 3 and 7), with low walking speed (4-meter walking speed ≤ 0.8 m/s) and low hand grip strength (HGS < 20kg for women and < 35.5 kg for men). They will be treated for a minimum of 12 months and a maximum of 36 months, receiving either placebo or 350 mg of Sarconeos (BIO101) twice daily. The primary efficacy parameter will be the time to onset of Major Mobility Disability (MMD), measured by the inability to walk 400m in less than 15 minutes without sitting, help from another person or use of a walker. This main measure will be supplemented by the following secondary effectiveness measures: walking speed (4-m walking speed from the SPPB test), hand grip strength and patient-reported quality of life (*Patient Reported Outcome SarQol*, a questionnaire specifically developed for sarcopenia).

Roger A. Fielding, PhD, sarcopenia expert and laboratory director at Tufts University, Boston, will be the principal investigator of the SARA-31 study. He is continuing his contribution to the Sarconeos (BIO101) clinical development program in this indication.

About BIOPHYTIS

Biophytis SA is a clinical-stage biotechnology company specializing in the development of drug candidates for age-related diseases. Sarconeos (BIO101), our lead drug candidate, is a small molecule in development for age-related neuromuscular (sarcopenia and Duchenne muscular dystrophy) and cardiorespiratory (Covid-19) diseases. Promising clinical results were obtained in the treatment of sarcopenia in an international phase 2 study, enabling the launch of a phase 3 study in this indication (SARA project). The safety and efficacy of Sarconeos (BIO101) in the treatment of severe COVID-19 were studied in a positive international phase 2-3 clinical trial (COVA project). A pediatric formulation of Sarconeos (BIO101) is currently being developed for the treatment of Duchenne Muscular Dystrophy (DMD, MYODA project). 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 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 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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