
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: July 10, 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 July 10, 2023, Biophytis S.A. issued a press release announcing it has filed with the FDA 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 July 10, 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: July 10, 2023

By: /s/ Stanislas Veillet

Name: Stanislas Veillet

Title: Chairman and Chief Executive Officer



Press release

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

Paris (France) and Cambridge (Massachusetts, U.S.), July 10, 2023 – 07:00am CET - Biophytis SA (Nasdaq CM: BPTS, Euronext Growth Paris: ALBPS) (the “Company” or “Biophytis”), a clinical-stage biotechnology company specializing in the development of therapies aimed at slowing the degenerative processes associated with aging and improving functional outcomes in patients suffering from age-related diseases, including respiratory failure in patients affected by COVID-19, today announced that it has filed for approval on the Food and Drug Administration (FDA) portal to launch its SARA-31 program in the U.S., the first ever Phase 3 study in sarcopenia.

The launch of the Phase 3 program follows promising results from the SARA-INT Phase 2b study and discussions with health authorities in 2022. Based on the results of the previous study and feedback from the U.S. government agency, Biophytis is starting its Phase 3 program by filing the first ever Phase 3 application (SARA-31) in sarcopenia with the FDA. This follows the recent submission to the European Medicines Agency.

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 ($3 \leq \text{SPPB} \leq 7$) with low walking speed (4-m Gait speed ≤ 0.8 m/s) and low grip strength (HGS $< 20\text{kg}$ 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 during the third quarter of 2023, which would enable Biophytis to initiate the study in the United States. The principal investigator will be Roger A. Fielding, PhD, who heads the Nutrition, Physiology, Exercise and Sarcopenia (NEPS) Laboratory at Tufts University in Boston.

Stanislas Veillet, Chairman and CEO of Biophytis stated: *« Following the success of SARA-INT's phase 2b clinical trial, the filing of an application with the EMA in mid-May and with the FDA today for the launch of a phase 3 clinical trial in sarcopenia is a major milestone in the development of our drug candidate. We are pioneers in the field of sarcopenia and intend to be the first company to launch, in partnership with global or regional pharmaceutical companies, a phase 3 clinical development program in this indication. »*

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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), enabling the preparation of conditional marketing authorization (CMA) applications in Europe and Emergency Use Authorization (EUA) applications in the United States. 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 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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