
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: December 17, 2021

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 December 16, 2021, Biophytis S.A. issued a press release announcing that the company is to meet with FDA to advance Sarconeos (BIO101) development in Sarcopenia from Phase 2 to Phase 3. A copy of the press release is attached as Exhibit 99.1 to this Form 6-K.

EXHIBIT LIST

Exhibit	Description
<u>99.1</u>	<u>Press Release dated December 16, 2021.</u>

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: December 17, 2021

By: /s/ Stanislas Veillet

Name: Stanislas Veillet

Title: Chairman and Chief Executive Officer



Press Release

Biophytis to meet with FDA to advance Sarconeos (BIO101) development in Sarcopenia from Phase 2 to Phase 3

- Following Phase 2b/SARA-INT clinically meaningful results, Biophytis is starting first regulatory activities to advance from Phase 2 to Phase 3 development
- A Type B/End-of-Phase 2 meeting is planned with FDA (Food and Drug Administration) on January 24th, 2022, to discuss these results and the Phase 3 protocol design
- Assuming potential agreement and approval from US authorities Biophytis intends to initiate its Phase 3 program in Sarcopenia in H2 2022

Paris, France, and Cambridge, Massachusetts, USA – December 16, 2021, 08:00 a.m. CET – Biophytis SA (NasdaqCM: BPTS, Euronext Growth Paris: ALBPS), (“Biophytis” or the “company”) is 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 announces to enter into first regulatory activities to advance Sarconeos (BIO101) development in sarcopenia from Phase 2 to Phase 3 development, with a Type B/End-of-Phase 2 meeting with FDA (Food and Drug Administration), USA, on January 24th, 2022, to discuss SARA-INT results (Phase 2b study) and the Phase 3 protocol design.

Stanislas Veillet, CEO of Biophytis said: *“With the completion of Phase 2 and the preparation of Phase 3 with US regulators, Biophytis intends to initiate its Phase 3 program in H2 2022. Sarconeos (BIO101) is the first drug candidate with the potential to enter into Phase 3 and to be approved for the treatment of Sarcopenia. We are very committed to move forward in this program to provide elderly people with a unique therapeutic solution for improving their mobility capabilities”*.

SARA-INT Phase 2b study, which has evaluated Sarconeos for the treatment of sarcopenia, has demonstrated that Sarconeos (BIO101), at the highest dose (350 mg bid), showed a clinically meaningful improvement in the 400-Meter Walk Test (400MWT), the primary endpoint of the study, including in sub-populations at higher risk of mobility disability, after 6 months of treatment. In addition, Sarconeos (BIO101) showed a very good safety profile at the doses of 175 mg bid and of 350 mg bid with no difference of treatment-related Serious Adverse Events (SAE) between treatment groups.

Biophytis is now entering into key regulatory activities to advance Sarconeos development in sarcopenia from Phase 2 to Phase 3 registrational program, with the Type-B meeting (End-of-Phase 2 meeting) with regulators to discuss Phase 2b results and Phase 3 protocol. Biophytis intends to target, in the Phase 3, similar population and endpoints which were evaluated in Phase 2. First meeting will be with FDA (Food and Drug Administration) in the USA on January 24th, 2022, with expected feedback early March 2022. Similar process is currently being organized with the EMA (European Medicine Agency); calendar will be communicated very beginning of 2022.



Assuming potential agreement and approval from health authorities Biophytis intends to initiate its Phase 3 program in Sarcopenia in H2 2022, depending on the evolution of COVID-19 pandemic.

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, 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 with a Phase 2 clinical trial which has been performed 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 2021 Half Year 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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