
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: October 4, 2021

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 October 4, 2021, Biophytis S.A. issued a press release announcing promising full results from the SARA-INT Phase 2b trial of Sarconeos (BIO101) in Sarcopenia at the 11th annual International Conference on Frailty and Sarcopenia Research (ICFSR) September 29 – October 2, 2021. 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 October 4, 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: October 4, 2021

By: /s/ Stanislas Veillet

Name: Stanislas Veillet

Title: Chairman and Chief Executive Officer



Press release

Biophytis announces promising full results from the SARA-INT Phase 2b trial of Sarconeos (BIO101) in Sarcopenia at the 11th annual International Conference on Frailty and Sarcopenia Research (ICFSR) September 29 – October 2, 2021

- 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
- Sarconeos (BIO101) showed a very good safety profile at the doses of 175 mg bid and of 350 mg bid with no Serious Adverse Events (SAE) related to the product
- Biophytis is preparing to start a phase 3 program with Sarconeos (BIO101) at the highest dose (350 mg bid) in 2022, targeting similar population and endpoints

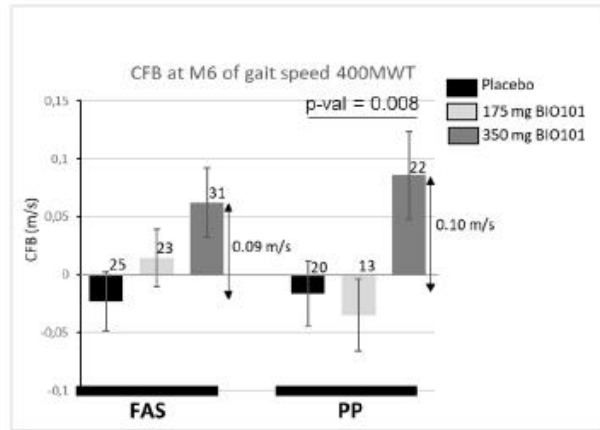
Paris (France), Cambridge (Massachusetts, United States), Oct 4th, 2021, 08 am CEST – Biophytis SA (NasdaqCM: BPTS, Euronext Growth Paris: ALBPS), a clinical-stage biotechnology company focused on the development of therapeutics that slow the degenerative processes associated with aging and improve functional outcomes for patients suffering from age-related diseases, including severe respiratory failure in patients suffering from COVID-19, today announces the full results from the SARA-INT Phase 2 trial of Sarconeos (BIO101) in Sarcopenia that have been presented at the International Congress on Frailty and Sarcopenia Research (ICFSR) on September, 30th. ICFSR is the key international scientific event on Frailty and Sarcopenia and is attended by leading researchers, physicians and Biotech/Pharma in this field.

The results of SARA-INT, with safety and efficacy endpoints including subgroup analysis and secondary endpoints, have been presented by Cendrine Tourette, PhD Biophytis SARA Project Leader and discussed during a dedicated session, moderated by Waly Diouh PhD, Biophytis Chief Operations Officer and Roger A. Fielding, PhD, Principal Investigator of the SARA-INT trial, who heads the Nutrition, Exercise Physiology & Sarcopenia team at Tufts University in Boston.

Stanislas Veillet, CEO of Biophytis said: “Based on the good SARA-INT results, especially the significant effect of Sarconeos (BIO101) on the primary endpoint of the study in PP populations as well as in subpopulations of severe patients, Biophytis can now prepare the phase 3 study through interactions with regulatory agencies. We are committed to progress Sarconeos (BIO101) into phase 3 through partnerships. With the completion of Phase 2 and the preparation of Phase 3, Sarconeos (BIO101) remains the drug candidate with the potential to become the first drug approved for the treatment of Sarcopenia”.

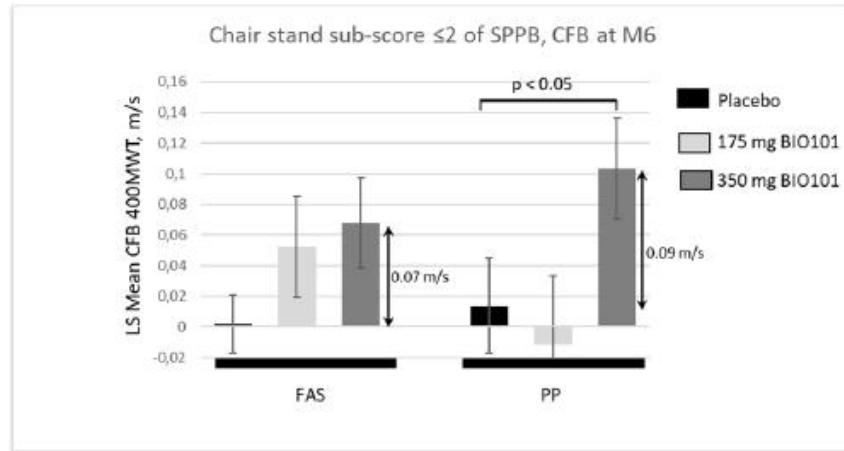
Key highlights presented and discussed during the ICFSR are presented below:

- The effect of two doses of Sarconeos (BIO101), 175 mg bid and 350 mg bid, have been compared to placebo in the Full Analysis Dataset (FAS) and in the Per-Protocol population (PP, subset of participants that complied to the clinical protocol), as well as in sub-populations of patients.
- Sarconeos (BIO101) at the highest dose of 350 mg bid showed a clinically meaningful improvement of 0.09 m/s in the FAS population (not significant) and of 0.10 m/s in the PP population (significant, $p=0.008$) compared to placebo (observed data), for the 400MWT in gait speed after 6 months of treatment. This effect is close to the Minimal Clinically Important Difference (MCID) in sarcopenia (0.1 m/s) known to be associated with a reduction in mobility disability and mortality in elderly.



Effect of Sarconeos (BIO101) on the 400 MWT gait speed in the FAS and PP populations

- Sarconeos (BIO101) at 350mg bid showed very promising treatment effect on the 400MWT gait speed in sub-population at higher risk of mobility disability such as slow walkers (0.07 m/s, $p = 0.015$ in PP population), obese subgroup (0.09 m/s, $p= 0.004$ in PP population), chair stand sub-score ≤ 2 of the SPPB (0.09 m/s, $p= 0.004$ in PP population).



Effect of Sarconeos (BIO101) on the 400MWT gait speed in sub-population with higher risk of mobility disability (chair stand subscore ≤2)

- A trend towards a dose-dependent effect, although not significant, was observed, on the following secondary endpoints: Handgrip Strength and 6-Minute Walk Distance (6MWD) test. Further analyses, e.g. on correlations between clinical endpoints and other parameters, biomarkers and actimetry are ongoing and will be communicated later in scientific congresses.
- Sarconeos (BIO101) showed a very good safety profile after up to 9 months of dosing, with no significant differences between treatment arms and placebo for Adverse Events, Serious Adverse Events, biliary imaging studies, safety laboratory parameters and vital signs including ECG. A tabulated summary of safety data is presented below:

| Events | Placebo | 175 mg BIO101 | 350 mg BIO101 |
|---|-----------|---------------|---------------|
| # participants | 81 | 75 | 74 |
| Adverse Events (% of total events) | 119 (36%) | 123 (37%) | 89 (27%) |
| Number of subjects with any AE | 52 | 51 | 44 |
| Serious Adverse Events (% of total events) | 15 (45%) | 14 (42%) | 4 (12%) |
| Number of subjects with any SAE | 10 | 10 | 4 |
| Treatment Emergent Adverse Events (% of total events) | 107 (38%) | 101 (36%) | 70 (25%) |
| Number of participants with any TEAEs | 48 | 45 | 38 |
| Treatment related TEAEs (% of total events) | 24 (44%) | 15 (27%) | 16 (29%) |
| Number of participants with any treatment related TEAEs | 13 | 10 | 10 |
| Treatment related Serious TEAEs | 2 (100%) | 0 | 0 |

Adverse Events, Serious Adverse Events and Treatment Emergent Adverse Events in the Placebo, 175 mg bid and 350 mg bid groups in the SARA-INT study



Press release

- The COVID-19 pandemic and its related restrictions had a significant impact on the conduct of the study, with 55% of total participants not allowed to perform their on-site End of Study visit, despite the extension of their treatment period. This situation had an impact on the power of the study, can largely explain high level of variability observed and the difficulty to reach statistical significance for secondary endpoints, especially in the FAS population.

Based on preliminary discussions with Key Opinion Leaders during the ICFSR conference, Biophytis is now preparing to start a phase 3 program in 2022 with Sarconeos (BIO101) at the highest dose (350 mg bid), targeting a population of sarcopenic patient at high risk of mobility disability similar to SARA-INT population, with similar endpoints, including the 400 MWT gait speed as primary end-point. The proposed program will be discussed with FDA and EMA, including during **end-of-phase 2 meetings to be held later this year.** Sarconeos (BIO101) has the **potential** to become the **first drug to be approved for the treatment of Sarcopenia.**

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 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 2020 Annual 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.



Press release

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