**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: April 18, 2023**

**Commission File Number: 001-38974**

# BIOPHYTIS S.A.

**(Translation of registrant's name into English)**

**Stanislas Veillet**
**Biophytis S.A.**
**Sorbonne University—BC 9, Bâtiment A 4ème étage**
**4 place Jussieu**
**75005 Paris, France**
**+33 1 44 27 23 00**
**(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 April 18, 2023, Biophytis S.A. issued a press release announcing 2022 Financial Results and 2023 Perspectives. 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 April 18, 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: April 18, 2023

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

**Exhibit 99.1**

**Press release**

**Biophytis Announces 2022 Financial Results and 2023 Perspectives**

- ✓ **€11.1M of available cash and equivalents on December 31, 2022, and financing instruments for a total of €22M allowing financial visibility beyond mid 2024**
- ✓ **Positive results of the Phase 2-3 COVA study for the treatment of severe COVID-19 with Sarconeos (BIO101)**
- ✓ **Early Access Program (EAP) submission in France by June 2023 while preparing filing for conditional marketing authorization in the USA and Europe for Sarconeos (BIO101) in COVID-19**

**Paris, France, Cambridge (Massachusetts, United States), April 18th, 2022 – 8am CET** - Biophytis SA (NasdaqCM: BPTS, Euronext Growth Paris: ALBPS), **("Biophytis" or the "Company"),** 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 its financial results for the year ended December 31, 2022, and provides updates on key perspectives for 2023.

Stanislas Veillet, President and CEO of Biophytis, stated: "*In a difficult economic and financial environment, 2022 was a crucial year for Biophytis. We were able to complete the Phase 2-3 COVA clinical trial and report positive results from the study demonstrating the effect of Sarconeos (BIO101) in the treatment of severe forms of COVID-19. The statistically significant 44% reduction in the risk of respiratory failure or early death is a very important result for patients as COVID-19 continues to be a major health problem, with over 40,000 deaths in 2022 according to Santé Publique France. Confident in the therapeutic potential of Sarconeos (BIO101), we have pursued the implementation of an EAP, with the objective of providing access to Sarconeos (BIO101) to a few thousand COVID-19 patients hospitalised in Brazil and France in the second half of 2023. In parallel, we are preparing for the filing of a conditional marketing authorisation (CMA) in Europe and an emergency use authorisation (EUA) in the US.*

*The end of the clinical development phase and the start of the regulatory process of this COVA project in COVID-19 means that our financing needs are decreasing. We are now entering a new era, with the opportunity to generate the first revenues from our research investment as early as the second half of 2023. In parallel, we will continue to carry on the company's other projects (sarcopenia - SARA, Duchenne muscular dystrophy - MYODA and AMD - MACA) while remaining frugal with our financial and human resources. In a global context that remains very challenging for biotech companies, we will continue to be highly adaptive to pursue the development of our pipeline of drug candidates with very limited resources, without losing sight of our main objective which is to obtain conditional marketing approvals for Sarconeos (BIO101) in the treatment of Covid-19 and to generate our first revenues in the early access program as early as 2023."*

**Major operational milestones achieved in 2022:**

**The company focused its human and financial resources on completing the COVA phase 2-3 study in COVID-19, reporting its results and preparing an early access programme for Sarconeos (BIO101)**

- As regards to our global Phase 2-3 COVA study in COVID-19
  - ✓ Enrolment of the study stopped in April 2022 after the 237th patient had been enrolled;
  - ✓ Discharge of the last COVA patient in June 2022, locking of the clinical database and analysis of results in August 2022;
  - ✓ Reporting of promising first trial results in September 2022;
  - ✓ Reporting of the positive post-hoc analysis of the phase 2-3 COVA study strongly supporting the therapeutic potential of Sarconeos (BIO101) in severe forms of COVID-19 in November 2022;
  - ✓ Publication of positive final study results in February 2023 demonstrating that the clinical study met the primary endpoint with a 44% reduction in the risk of early death and respiratory failure.

- As regards to the preparation of the early access program for Sarconeos (BIO101) for the treatment of hospitalized COVID-19 patients
  - ✓ Obtaining early access approval in February 2022 for critical COVID-19 patients in Brazil;
  - ✓ Preparing the industrialization of Sarconeos (BIO101) in view of the early access program in Brazil and France.

- Scientific communication in international congresses of the main results of the SARA (Sarcopenia) and MYODA (Duchenne Muscular Dystrophy) programs.
  - ✓ SARA: Presentation of the main clinical results of phase 2 SARA-INT at the ICFSR in Boston, USA, in April 2022 and of the possible design of phase 3 at the SCWD in Lisbon, Portugal, in June 2022
  - ✓ MYODA: Presentation of new preclinical efficacy data for Sarconeos (BIO101) in SMA (Spinal Muscular Atrophy) at the SMA Cure 2022 conference in Anaheim, California, U.S.

**2023 outlook and perspectives:**

- **For the COVA study in COVID-19:**

The Company has initiated the regulatory development process with a view to marketing Sarconeos (BIO101) in severe forms of COVID-19.

To accelerate the availability of this treatment, an early access program has been initiated in France and Brazil. In France, a pre-filing meeting with the French Health Authority was held in March and the Company plans to file this application in the second quarter of 2023, with the objective of starting this program in the second half of this year. In Brazil, the Company continues to re-initiate the early access program, which was suspended at the end of the COVA clinical trial in mid-2022, pending final efficacy and safety results. These programs should enable the treatment of a few thousand COVID-19 patients in hospital and thus generate the first revenues for the company from 2023 on.

In parallel, the Company is preparing the conditional marketing authorizatioń application in Europe and due to the health emergency in the United States that we expect to submit in 2023, depending on the feedback from regulatory agencies. In addition, the Company has started the industrialization of the production of Sarconeos (BIO101) in order to complete the regulatory file for the marketing authorization application and with a view to commercialization in 2024.

**For the SARA study in Sarcopenia:**

Following the first Type C meeting with the FDA in January 2022, a scientific advice meeting was held with the EMA to discuss the Phase 3 protocol, targeting a similar population and endpoints as the Phase 2 study. We have continued to engage with the FDA and EMA throughout 2022 and have defined the protocol for the Phase 3 study. We now plan to seek approval to initiate a Phase 3 clinical trial in Europe and the US from the relevant regulatory authorities (EMA and FDA) in the second quarter of 2023. We are also actively seeking industrial partners interested in co-developing Sarconeos (BIO101) in this indication.

**For the MYODA study in Duchenne Muscular Dystrophy (DMD):**

Following the receipt of an "Authorization to Proceed" (IND - Investigational New Drug) letter from the FDA (USA) in December 2019, Biophytis received authorization from the Belgian FAMHP in March 2021 to continue its Sarconeos (BIO101) clinical study in non-ambulatory patients with DMD. However, due to the COVID-19 crisis and its impact on our operational capabilities, the MYODA study was postponed. We have thoroughly revised the protocol and propose a phase 1/2 study for non-ambulatory DMD patients with signs of deteriorating lung function. We expect to submit this new protocol to the competent authorities in the second half of 2023.

**Annual 2022 Financial Results**

The Company's annual 2022 non-audited consolidated financial statements prepared in accordance with IFRS were reviewed by the Company's Board of Directors on April 14, 2023. Audit procedures are being completed, the issuance of the audit report is pending, and will be included in the Company's upcoming 2022 annual financial report and SEC Form 20-F, respectively to be filed with AMF and SEC.

• **Cash and cash equivalents and short-term deposits included in other current financial assets.** Cash and cash equivalents and short-term deposits included in other current financial assets as of December 31, 2022 were €11.1 million, a significant decrease of €12.8 million compared to €23.9 million as of December 31, 2021.

The table below summarizes the key figures of financial statements.

| (Amounts in thousands of euros, except for stock data) | 31/12/2021 12 months (as restated) [1] | 31/12/2022 12 months |
|---|---|---|
| Revenues | - | - |
| Cost of sales | - | - |
| **Gross margin** | **-** | **-** |
| | | |
| Research and development costs, net | (19,665) | (16,034) |
| General and administrative costs | (7,150) | (7,237) |
| **Operating profit** | **(26,815)** | **(23,272)** |
| | | |
| Financial result | (2,517) | (2,564) |
| Tax income (expense) | 24 | 983 |
| Change in fair value of derivative liability | (1,856) | 637 |
| **Financial Results** | **(4,349)** | **(944)** |
| | | |
| **Results before tax** | **(31,164)** | **(24,216)** |
| | | |
| Tax income | - | - |
| **Net results (loss)** | **(31,164)** | **(24,216)** |
| | | |
| *To Biophytis' shareholders* | | |
| *Non controlling interests* | *(31,163)* | *(24,216)* |
| | *(1)* | - |
| | | |
| Weighted average number of outstanding shares (not including own shares) | 118,282,679 | 174,839,276 |
| **Earning per share (€/share)** | **(0.26)** | **(0.14)** |
| **Diluted earning per share (€/share)** | **(0.26)** | **(0.14)** |

• **Research and Development Expenses**. Net research and development expenses were €16.0 million for 2022, a decrease of €3.6 million, compared to €19.7 million in 2021. This decrease is mainly reflecting the end of the Phase 2-3 clinical trial of the COVA program, as well as the end of the SARA-INT study in 2021. Net research and development expenses included research tax credits (French '*Crédit d'Impôt Recherche*', or CIR) totaling €3.3 million in 2022 compared to €4.0 million in 2021. Net R&D costs represent 69% of operating expenses in 2022, compared to 73% in 2021.

• **General and Administrative Expenses.** General and administrative expenses were €7.2 million for 2022 compared to €7.2 million for 2021, a very slight increase between the two years.

• **Financial results:** Financial loss amounted to €1.0 million in 2022 vs €4.4 million in 2021, a decrease of €3.4 million as of 31 December 2021. Resulting majorly from the variation of the fair value as calculated using IFRS 9, for our various convertible financing instruments, respectively Atlas and Kreos.

• **Net Loss.** Net loss was €24.2 million for 2022, as compared to €31.2 million for 2021. Net loss per share (based on weighted-average number of shares outstanding over the period except the treasury shares) was €0.14 in 2022 compared to €0.26 in 2021.

(1) In October 2022, it was determined that the annual consolidated financial statements for the years ended December 31, 2021 required correction for the accounting treatment of the financing agreement with Kréos, as per IFRS 9. Please refer to our press releases dated October 1, 2022 and January 31 2023.

* * * *

**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). In addition, Sarconeos (BIO101) has been demonstrated to be active on severe COVID-19 patients, in a positive Ph2-3 study (COVA) with results released Q1 2023. 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 Half Year 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.

**Biophytis Contact for Investor Relations**
Philippe Rousseau, CFO
Investors@biophytis.com

**Media Contacts**

Antoine Denry : antoine.denry@taddeo.fr – +33 6 18 07 83 27
Agathe Boggio : agathe.boggio@taddeo.fr – +33 7 62 77 69 42