
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: February 26, 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 February 26, 2021, Biophytis S.A. issued a press release announcing its non-audited financial results for the year ended December 31, 2020, and providing updates on key operational developments and financing transactions.

A copy of the press release is attached as Exhibit 99.1 to this Form 6-K.

The information in this Report on Form 6-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

EXHIBIT LIST

Exhibit	Description
<u>99.1</u>	<u>Press Release dated February 26, 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: February 26, 2021

By: /s/ Stanislas Veillet

Name: Stanislas Veillet

Title: Chairman and Chief Executive Officer



Press Release

Biophytis Reports 2020 Full Year Results

Paris, France, Cambridge (Massachusetts, United States), February 26, 2021 – 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 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 announces its non-audited financial results for the year ended December 31, 2020, and provides updates on key operational developments and financing transactions.

- Major milestones achieved during 2020
 - ✓ Launch of the phase 2-3 COVA trial assessing Sarconeos (BIO101) as a potential treatment for acute respiratory failure linked to COVID-19
 - o global, multicenter, double-blind, placebo-controlled, group-sequential and adaptive design two-part Phase 2-3 study approved in 5 countries: the US, Brazil, France, Belgium and the UK
 - o Patient enrollment for Part 1 completed with 50 patients, and trial moving to Part 2 following approvals from certain Regulatory Authorities
 - o Interim Analysis of Part 1 expected in Q1 2021 and results from the full study (Part 1 and Part 2) expected in Q2 2021, subject to any delays in patient recruitment or retention, interruptions in sourcing or supply chain, regulatory authorizations and procedures, COVID-19-related delays, and the impact of the current pandemic
 - ✓ Treatment completed for the last patient in the Phase 2 SARA-INT trial for the treatment of sarcopenia. Top-line results expected in Q2 2021
 - ✓ Successful completion of four private placements, strengthening significantly company financial resources, with total cash and cash equivalents and other current financial assets amounting to €18.8 million as of December 31, 2020
- Successful IPO on Nasdaq Capital Market closed on February 12, 2021 for total gross proceeds of \$20.1 million

Stanislas Veillet, President and CEO of Biophytis, said: *“2020 marked a turning point for Biophytis. Four successful private placements have allowed us to strengthen our financial situation in order to enter a new and exciting phase in the development of the company. At the same time, we have been making strong progress in clinical operations. We are proud to participate in the world fight against SARS-CoV-2 through the launch of COVA, our phase 2-3 study assessing Sarconeos (BIO101) as a potential treatment for patients with severe respiratory manifestation of COVID-19. The study is now entering Phase 3 in Brazil, the United States, France and Belgium, and full results are expected in Q2 2021. Our last patient completing last visit in the SARA-INT Phase 2 trial in sarcopenia is also an important milestone, and we look forward to top-line results which are also expected in Q2 2021.”*



Press release

The Company's annual 2020 non-audited consolidated financial statements prepared in accordance with IFRS were reviewed by the Company's Board of Directors on February 23, 2021. Audit procedures are being completed, the issuance of the audit report is pending, and will be included in the Company's upcoming 2020 annual financial report and SEC Form 20-F.

Annual 2020 Financial Results

• **Cash and cash equivalents and other current financial assets.** Cash and cash equivalents and other current financial assets as of December 31, 2020 were €18.8 million, an increase of €12 million compared to €6.8 million as of December 31, 2019.

During 2020, cash used in operating activities was €9.9 million. Cash used in investment activities was €12.7 million, of which €12.5 million are linked to fixed term deposit contracts. These uses were offset by €22.1 million of cash provided by financing activities.

• **Research and Development Expenses.** Net research and development expenses were €9.9 million for 2020, an increase of €0.8 million, or 9%, compared to €9.1 million for 2019. This increase is mainly linked to the launch of the COVA program. In parallel, SARA-INT, our Phase 2 trial in Sarcopenia is progressing. Patients recruitment was completed in March 2020, and the last dosing of our last patient was achieved in December 2020.

Net research and development expenses included research tax credits (French '*Crédit Impôt Recherche*', or CIR) and other subsidies totaling €3.3 million in 2020 compared to €2.8 million in 2019.

• **General and Administrative Expenses.** General and administrative expenses were €4 million for 2020 compared to €6.6 million for 2019, a decrease of €2.6 million, or 39%. This significant decrease was primarily linked to the fees and expenses incurred in 2019 in connection with our attempted listing on Nasdaq, and to cost reduction efforts related to personnel and structure expenses in 2020 compared to 2019.

• **Net Loss.** Net loss was €17.1 million for 2020, as compared to €17.8 million for 2019. Net loss per share (based on weighted-average number of shares outstanding over the period except the treasury shares) was €0.28 in 2020 compared to €1.05 in 2019.

The table below summarizes the non-audited operating results.



Press release

(amounts in thousands euros, except for share data)	2019	2020
Net Research and Development expenses	(9 089)	(9 921)
General and administrative expenses	(6 593)	(4 021)
Operating loss	(15 682)	(13 942)
Net financial loss	(2 134)	(3 112)
Loss before tax	(17 816)	(17 054)
Income tax	28	-
Net loss	(17 788)	(17 054)
Non diluted weighted average number of shares outstanding, except treasury shares	16 882 661	59 974 486
Basic and non diluted loss per share (€/action)	(1,05)	(0,28)

Summary of operational events (more details are provided in the corresponding press releases available on Biophytis's website: www.biophytis.com)

Launch of the Phase 2-3 COVA study in patients with severe respiratory manifestation of COVID-19

- In May 2020, Biophytis received approval from the Belgian Federal Agency for Medicines and Health Products (FAMHP), to proceed with its clinical development program COVA, a two-part study assessing Sarconeos (BIO101) in patients aged 45 and older, hospitalized with severe respiratory manifestations following COVID-19 infection;
- Biophytis received approvals for COVA from the UK Medicines Healthcare Products Regulatory Agency (MHRA) in June 2020, from the United States Food and Drug Administration (FDA) and the French Health Authority (ANSM) in July 2020 and the Brazilian Health Regulatory Agency (ANVISA) in August 2020;
- In August 2020, the first participant for Part 1 of the study was enrolled in Belgium;
- In October 2020, the first US and Brazilian patients were enrolled in COVA, with clinical centers opened and ready to recruit in Belgium, France, Brazil and the US. In December 2020, the first patient was enrolled in France;
- In February 2021, authorization for patient recruitment for Part 2 of COVA was obtained from regulatory authorities in Brazil, the United States, France and Belgium. Part 2 of COVA is a Phase 3 pivotal randomized study investigating the safety and efficacy of Sarconeos (BIO101) on the respiratory function from 310 COVID-19 patients (including the 50 patients from Part 1 of the study).
- The Company expects to report full results (For Part 1 and Part 2) in Q2 2021, subject to any delays in patient recruitment or retention, interruptions in sourcing or supply chain, regulatory authorizations and procedures, COVID-19-related delays, and the impact of the current pandemic.

SARA clinical program in sarcopenia :

- In March 2020, due to COVID-19, Biophytis adapted the protocol of SARA-INT to allow patient follow up to take place at home, based on guidelines from regulators, including the U.S. FDA;
- In March 2020, Biophytis completed enrolment of the 233 patients into SARA-INT;
- In December 2020, the last patient in SARA-INT completed his final on-treatment visit;
- Biophytis expects to report top-line data from SARA-INT in Q2 2021, subject to any delays in patient recruitment or retention, interruptions in sourcing or supply chain, regulatory authorizations and procedures, COVID-19-related delays, and the impact of the current pandemic.



Press release

MYODA clinical program in Duchenne Muscular Dystrophy (DMD):

- After an IND “may proceed” letter from the FDA (USA) in December 2019, in March 2020 Biophytis received approval from the Belgian FAMHP to proceed with its clinical investigation of Sarconeos (BIO101) in non-ambulatory patients with DMD.
- Depending on the evolution of the pandemic and its impact on our operational capabilities, the MYODA study is expected to start in H1 2021.

Financing

1/ Debt financing: Replacement of the convertible ORNANEBSA from Negma by the convertible ORNANE from Atlas:

In April 2020, the Company secured a new line of financing of €24 million from Atlas Special Opportunities LLC, a specialized investment fund based in New York (United States) providing for the issuance of 960 3-year note warrants. The 960 3-year note warrants require their holder to exercise them, at our request, in tranches of 120 warrants each. Each warrant grants its holder the right to one ORNANE. The ORNANE have a par value of €25,000.

In April 2020, the Company formerly notified NEGMA Group LTD of its decision to terminate the contract signed in August 2019. The Negma agreement provided for up to €24 million in financing through the issuance of multiple tranches of convertible notes with attached warrants. This termination has led to litigation between Negma and Biophytis, and legal proceedings are ongoing.

2/ Equity raising:

In 2020, the Company successfully raised capital through several transactions:

- Public offering of share subscription warrants:

In April 2020, the Company closed a public offering of warrants to purchase ordinary shares, allowing shareholders registered as of April 8, 2020 to benefit from a non-negotiable and non-transferable subscription priority period and then new shareholders, to subscribe for warrants to purchase ordinary shares. Demands exceeded three times the number of available warrants. A total of 7,475,708 warrants were subscribed for total proceeds of €448 thousand.

- Private placement transactions :

The Company successfully closed four private placement transactions which strengthened significantly its equity position. In February, June, July and October 2020, the Company issued shares to institutional investors totaling €3.3 million, €4 millions, €6.1 million and €10 million, respectively, and for a total of €23.4 million.

Appointments:

In January 2020, Biophytis appointed Evelyne Nguyen as Chief Financial Officer in replacement of Daniel Schneiderman.



Press release

2021 Outlook:

Programs:

The COVA study: The full results (Part 1 and Part 2) are expected in Q2 2021. Subject to any COVID-19 related delays, the Company anticipates applying for Emergency Use Authorization from FDA, and Conditional Market Approval from EMA in Q2 2021.

The SARA -INT study: Following the last visit completion of the last patient in December 2020, the Company is preparing to release top-line results of this Phase 2 trial during Q2 2021.

The MYODA study: Depending on the evolution of the COVID-19 pandemic, the Company is intending to start in H1 2021 the Phase 1-3 MYODA trial.

These plans remain subject to any delays in patient recruitment or retention, interruptions in sourcing or supply chain, regulatory authorizations and procedures, COVID-19-related delays, and the impact of the current pandemic.

Nasdaq IPO:

On February 12, 2021, the Company closed its previously announced initial public offering on the Nasdaq Capital Market by way of a capital increase of 12,000,000 ordinary shares represented by 1,200,000 American Depositary Shares (“ADSs”), with each ADS representing 10 ordinary shares, at a price of \$16.75 per ADS. Total gross proceeds were approximately \$20.1 million. The Company received net proceeds of approximately \$16.35 million or €13.5 million, after deducting underwriting discounts and commissions, management fee and estimated offering expenses payable by the Company. Since February 10, 2021, Biophytis ADSs are listed on Nasdaq Capital Market (US trading ticker: BPTS)

Coronavirus Statement

We are closely monitoring how the spread of COVID-19 is affecting our employees, business, preclinical and clinical studies. As part of our COVID-19 pandemic response, most of our employees have transitioned to working remotely and travel has been restricted. During the pandemic, we instructed our employees to work remotely as much as possible except for essential and required activities that needed to be performed in laboratories. Such access and work must comply with social distancing and other local government and facility requirements and policies were implemented during initial and subsequent waivers of COVID-19. While we have substantially completed enrollment dosing of Sarconeos (BIO101) in our SARA-INT study, limitations on in-office visits due to study site closures during the initial COVID-19 wave required adaptation of the study protocol including closing on-site activities, organizing patient follow-ups to take place at home, and expanding treatment from six to nine months for some patients. All such changes to the protocol were submitted to, reviewed and approved by reviewing IRBs. Despite these impediments, the last patient completed his final on treatment visit in December 2020.

However, the impact of continued and prolonged disruptions caused by the COVID-19 pandemic may result in further difficulties or delays in initiating, enrolling, conducting or completing our ongoing and planned clinical trials, which could result in additional unforeseen costs. The impact of COVID-19 on our future clinical research and development progress will largely depend on future developments of the pandemic. These future COVID-19 developments are highly uncertain and cannot be predicted with confidence, and include issues such as: the rate and ultimate geographic spread of the disease; the duration of the pandemic; travel restrictions and social distancing requirements in the U.S., Brazil, the UK, France and other countries; business disruptions and closures; impact on financial markets and the global economy; and the effectiveness of actions taken to contain, treat and prevent the disease.

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Press release

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 common shares are listed on the Euronext Growth Paris market (Ticker: ALBPS - ISIN: FR0012816825), and ADSs 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. These forward-looking statements include statements regarding Biophytis' anticipated timing for its Interim Analysis of Part 1 and release of full study results. 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 including, without limitation, delays in patient recruitment or retention, interruptions in sourcing or supply chain, its ability to obtain the necessary regulatory authorizations, COVID-19-related delays, the impact of the current pandemic on the Company's clinical trials and other risks described in our filings with the U.S. Securities and Exchange Commission. 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. In France, please also refer to the "Risk Factors" section of the Company's Annual 2019 Report and the Company's Half Year 2020 Report available on BIOPHYTIS website (www.biophytis.com). 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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Press release

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