
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: September 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 September 17, 2021, Biophytis S.A. published its interim financial report for the first half of 2021 and provided updates on key operational developments and financing transactions SARA-INT. 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 September 17, 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: September 17, 2021

By: /s/ Stanislas Veillet

Name: Stanislas Veillet

Title: Chairman and Chief Executive Officer



Press release

Biophytis reports H1 2021 financial results and provides business update

- SARA-INT: Positive top line results of Phase 2 study demonstrate efficacy of Sarconeos (BIO101) in sarcopenia and support progress into Phase 3
- COVA: DMC second interim analysis shows efficacy results in the promising zone allowing continuation of the phase 2/3 study with Sarconeos (BIO101) in COVID-19. Top line results of the full study are expected in Q1 2022
- Manufacturing scale up signed with a major global CDMO to increase potential supply of Sarconeos (BIO10) in anticipation of COVA positive results
- Biophytis leadership team reinforced with new senior appointments
- Cash on hand increased to €23 million as of June 30th 2021, compared to €18.8 million as of December 31 2020, following successful IPO on Nasdaq in February 2021. In addition, new convertible bond financing of €32 million signed with Atlas

Paris (France), Cambridge (Massachusetts, U.S.), September 17, 2021, 8:00 am. CET – 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 publishes its interim financial report for the first half of 2021 and provides updates on key operational developments and financing transactions.

Stanislas Veillet, CEO of Biophytis, said: *“During the first half of 2021 Biophytis reached a major milestone with positive results from the SARA-INT Phase 2 trial, which demonstrated the efficacy of Sarconeos (BIO101) in sarcopenia. Indeed 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. We are now committed to progressing Sarconeos (BIO101) into phase 3 for this indication either alone or through partnerships with pharmaceutical companies. Moreover, recommendations from DMC a few days ago for our COVA study to continue without any modification, based upon efficacy results in the promising zone following the second interim analysis, are very encouraging. We hope that Sarconeos (BIO101) will become one of the first drug candidates able to restore breathing capabilities for hospitalized patients in severe conditions, and therefore avoiding their admission to ICUs. The whole Company is now focused on the next milestones, ie complete the trial as soon as possible, as well as industrial scaling up and regulatory approvals in Europe, USA and Brazil. We want to be ready for commercialization of our Sarconeos (BIO101) in COVID-19 first half of 2022.*

From a financial perspective, our cash position was strengthened following our successful IPO in the US market. We also closed a new ORNANE contract with Atlas up to 32M€ securing the outlook of the Company's financing.”



Income Statement Summary (*)

(amounts in thousands of euros, except share data)	For the Half Years Ended June 30,	
	2020	2021
Research and development, net of research tax credit	(5,192)	(7,594)
General and administrative expenses	(2,269)	(2,919)
Operating Loss	(7,461)	(10,513)
Net financial expense	(1,999)	(5,352)
Loss before taxes	(9,460)	(15,865)
Net loss	(9,460)	(15,865)
Basic and diluted weighted average number of shares outstanding	37,211,432	110,680,727
Basic and diluted loss per share (€/share)	(0.25)	(0.14)

(*) the interim 2021 consolidated financial statements were subject to limited review by the Statutory Auditors.

Operational Update

- **SARA clinical program in sarcopenia.** On August 2, 2021, Biophytis announced top line results of the SARA-INT phase 2 clinical study with Sarconeos (BIO101) in Sarcopenia.

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. Sarconeos (BIO101) also showed a very good safety profile at the doses of 175 mg bid and of 350 mg bid with no Serious Adverse Events (AE) related to the product.

The results of Sarconeos (BIO101) on the 400MWT as the primary endpoint are promising since no other alternative treatment exists as of today. This paves the way towards an upcoming confirmatory phase 3 study in sarcopenia and allows further development of Sarconeos (BIO101) in this indication.

This is a key milestone for Biophytis after 15 years of research and development with Sorbonne University.

- **Phase 2/3 COVA study for acute respiratory failure associated with COVID-19.** On September 10 2021, the Data Monitoring Committee (DMC) recommended to continue the Phase 2-3 COVA study without any modification of the protocol after the Interim Analysis 2 found efficacy results in the promising zone, based on 155 COVID-19 patients hospitalized with respiratory failure. This recommendation completes previous safety evaluation performed by DMC last August that confirmed the good safety profile of Sarconeos (BIO101).

As of September 15, 35 clinical centers are opened to recruit COVID-19 patients in the USA, Brazil, France and Belgium. 200 patients are randomized in COVA trial to this date.

15 additional sites will be opened to accelerate recruitment in USA, Brazil, France, UK and Belgium, where the COVA study is already approved.

With this new network of 50 sites, top line results of the study are expected in Q1 2022, depending on the evolution of the pandemic.



On June 30, 2021, Biophytis announced it had secured contracts with a major global Custom Development and Manufacturing Organization (CDMO) for the manufacturing of registration batches of Sarconeos (BIO101). These contracts were signed in preparation of the potential filing of the product in COVID-19 for Emergency Use Authorization with the FDA, and/or Conditional Marketing Authorization with the EMA.

- **MYODA clinical program in Duchenne muscular dystrophy (DMD).** Following Biophytis' receipt of the Investigational New Drug Application obtained from the FDA and authorization from the Belgian authorities in early 2020, the study was delayed due to the COVID-19 pandemic.

Biophytis now intends to resume preparations for launching the MYODA phase 1/2 clinical trial of Sarconeos (BIO101) in Duchenne muscular dystrophy, which will now be initiated in 2022, depending on the evolution of the pandemic.

- **New senior appointments reinforce Biophytis' leadership teams.** On July 8, 2021, Biophytis announced the appointment of Claude Allary as Board member. Claude Allary has 40 years of experience with pharmaceuticals industries and was co-founder of Bionest Partners.

The Company also hired new experienced healthcare executives:

- Benoit Canolle, was appointed Chief Business Officer. Benoit brings extensive background in R&D and business development, mostly from Sanofi and Pierre Fabre,

- Rob van Maanen MD, MBA, FFPM, was named new Chief Medical Officer. Rob was previously CMO of Khondrion, a Dutch clinical-stage company, and has held several senior positions, leading Medical Affairs in numerous global pharma companies: Astellas, Eisai, Novartis and Organon.

The appointment of these highly experienced healthcare executives strengthens Biophytis' leadership teams at an important time in the development of the Company.

Financial update

- **Nasdaq IPO successfully closed in February 2021.** On February 12, 2021, Biophytis closed its announced initial public offering (IPO) 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 fees and estimated offering expenses payable by the Company. Since February 10, 2021, Biophytis ADSs are listed on the Nasdaq Capital Market (US trading ticker: BPTS).
 - **New convertible bond financing signed with Atlas.** On June 18, 2021, Biophytis announced a new ORNANE contract with Atlas Capital for €32 million (the "2021 Atlas Contract"). This line of financing can be drawn by Biophytis over the next three years, without obligation, through 8 successive tranches of €4 million each. This facility will allow to secure the Company treasury in order to continue the development of its clinical activities, in particular the further development of Sarconeos (BIO101).
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Interim 2021 Financial Results

- **Cash and Cash Equivalents.** Cash and cash equivalents as of June 30, 2021 were €23 million, an increase of €4.7 million as compared to €18.3 million as of December 31, 2020, and an increase of €10.8 million vs €12.2 million as of June 2020.

During the 1st half of 2021, cash used in operating activities and investing activities amounted to €-0.9 million, compared to 0 last year. Cash provided by financing activities amounted to €18.1 million for the first half of 2021, compared to €5.8 million last year.

- **Research and Development Expenses.** Net research and development expenses were €7.6 million for the 1st half of 2021, an increase of €2.4 million as compared to €5.2 million for the 1st half of 2020. This increase was primarily related to the advancement of our lead drug candidate, Sarconeos (BIO101), in the COVA phase 2-3 program, and activities related to the final completion of our SARA-INT phase 2 program.
- **General and Administrative Expenses.** General and administrative expenses were €2.9 million for the 1st half of 2021, an increase of €0.6 million as compared to €2.3 million for the 1st half of 2020 linked to our Nasdaq listing.
- **Financial loss.** Our financial loss increased from €2.0 million last year to €5.4 this year, reflecting the accrual of financial costs incurred by Biophytis following the execution of the judgment rendered on July 16, 2021, by the Paris Judicial Court in the proceedings between Biophytis and Negma Group Ltd.
- **Net Loss.** Net loss was €15.9 million for the 1st half of 2021, as compared to €9.5 million for the 1st half of 2020. In addition to clinical costs ramping up linked to our COVA development, net loss was highly impacted by financial loss (re above). Net loss per share (based on weighted-average number of shares outstanding over the period) was €0.14 for the 1st half of 2021 and €0.25 for the 1st half of 2020.

The cash and cash equivalents available as of June 30, 2021, amounted to €23 million. The Company believes that this amount, supplemented by existing lines of credit, is sufficient to cover the Company's cash requirements for the next 12 months.

The share capital of Biophytis is comprised of 125 762 242 ordinary shares outstanding as of September 16, 2021.

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.

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