

Biophytis releases its half-yearly accounts as of 30 June 2023 and provides an update on its operations

- **Start of industrial development of Sarconeos (BIO101) with a view to market access in severe forms of Covid-19 (COVA)**
- **Approvals to start the Phase 3 trial in the United States and Belgium in sarcopenia (SARA), a world first, opening up the prospect of partnerships**
- **Cash position and secured financing giving visibility of over 12 months**

Paris (France) and Cambridge (Massachusetts, USA), September 27, 2023 – 11:15 pm CET – Biophytis SA (Nasdaq CM : BPTS, Euronext Growth Paris : ALBPS), («Biophytis»), 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 respiratory failure in patients with COVID-19, publishes its half-year accounts as of 30 June 2023 and provides an update on the progress of its R&D projects over the 1st half of the year and the last few months.

Stanislas Veillet, Chairman and CEO of Biophytis, stated:

"During the first half of 2023, we achieved key milestones in the development of our main drug candidate, Sarconeos (BIO101), with a view to partnerships and market access in 2024, despite a particularly challenging financial environment.

Pursuant to an accelerated development over the last two years, we have obtained positive results from our phase 2-3 COVA. Biophytis is one of the few European companies to have obtained proof of efficacy in patients with severe forms of COVID-19. We are pursuing the pharmaceutical and regulatory development of Sarconeos (BIO101), and are currently in discussions with European and American regulatory agencies to define the conditions for market access.

In addition, thanks to the encouraging results obtained with the SARA-INT phase 2b study, Biophytis has received authorizations from the US and Belgian agencies to start the clinical SARA-31 study, which will be the first phase 3 study ever launched in sarcopenia.

Finally, the Company has strengthened its management team over the last few months, notably in pharmaceutical operations, finance and business development, in order to forge strategic partnerships for the development of Sarconeos (BIO101). With the progress made in its pipeline, Biophytis is confirming its pioneering position in the development of treatments for age-related diseases, generating a strong medical need that is set to grow very rapidly in the years ahead."

Financial information

| (amounts in thousands of euros) | 06.30.2022 | 06.30.2023 |
|--|-----------------|----------------|
| Research and development costs | (6,867) | (3,763) |
| <i>Of which other purchases and external charges</i> | <i>(6,435)</i> | <i>(3,099)</i> |
| <i>Of which personnel costs</i> | <i>(2,950)</i> | <i>(1,443)</i> |
| <i>Of which research tax credit</i> | <i>2,614</i> | <i>922</i> |
| General and administrative expenses | (5,053) | (2,761) |
| <i>Of which other purchases and external charges</i> | | |
| <i>Of which personnel costs</i> | | |
| Operating profit | (11,920) | (6,524) |
| Net financial income | (478) | (1,241) |
| Tax expenses | - | - |
| Net profit (loss) | (12 398) | (7 764) |

- As in the previous year, Biophytis did not record any revenues in the first half of 2023. Operating expenses fell sharply as a result of:
 - Lower R&D expenses related to the completion of clinical trials for the COVA and SARA programs in the second half of 2022. Residual costs relating to clinical development have been booked in 2023, but most R&D expenditure in the first half of the year concerned various preclinical studies on the Company's different programs and operations relating to the production of BIO101.
 - A reduction in personnel costs, mainly due to the valuation of instruments giving access to capital, amounting to €322 thousand in the first half of 2023, compared with €3,533 thousand in the first half of 2022.
- The change in net financial expense is mainly due to the valuation of financial liabilities in accordance with IFRS 9.
- As a result of the above, the half-year loss has been significantly reduced, from €12.4 million at 30 June 2022 to €7.8 million at 30 June 2023.
- Consolidated cash and cash equivalents at 30 June 2023 were €5.8 million. The Company received new financing during the first half, in the form of convertible bonds for €2 million and equity financing combining a private placement and a public offering for €2.3 million. Considering the registered direct offering finalized in July on Nasdaq for a gross amount of \$3.8 million, as well as the bond financing facility in place with Atlas, which may give rise to additional financing of €20 million, the Company can ensure the continuity of its operations for at least the next twelve months.

Outlook and next steps

- COVA program
 - H2/2023: discussions with the European Agency for the Evaluation of Medicinal Products (EMA) and the US Food and Drug Administration (FDA) in the context of scientific advice to clarify the additional information to be submitted as part of marketing authorization applications, in particular the protocol for a confirmatory phase 3 clinical study. Biophytis will also present to the agencies the possibility of extending the scope of its indication to respiratory viral diseases other than COVID-19, in particular influenza.
 - H2/2023: request for reactivation of the authorization for the early access program in Brazil, granted in early 2022.
 - Q1/2024: resubmission to the HAS of an application for authorization of an early access program in France.
- SARA program

Following the authorizations received from the Belgian and US agencies to conduct a phase 3 trial, the Company will actively pursue its search for partners with a view to initiating the trial

in 2024, in collaboration with global or regional pharmaceutical companies under a licensing agreement.

- MYODA program
 - H1/2024 : start of a phase 1-2 trial.
- MACA program
 - Continuing pre-clinical development work on Macuneos (BIO201) and its back-up BIO203 and preparing for clinical development in dry AMD.

About BIOPHYTIS

Biophytis SA is a clinical-stage biotechnology company specializing in the development of drug candidates for age-related diseases. Sarconeos (BIO101), our lead drug candidate, is a small molecule in development for age-related neuromuscular (sarcopenia and Duchenne muscular dystrophy) and cardiorespiratory (Covid-19) diseases. Promising clinical results were obtained in the treatment of sarcopenia in an international phase 2 study, enabling the launch of a phase 3 study in this indication (SARA project). The safety and efficacy of Sarconeos (BIO101) in the treatment of severe COVID-19 were studied in a positive international phase 2-3 clinical trial (COVA project). A pediatric formulation of Sarconeos (BIO101) is currently being developed for the treatment of Duchenne Muscular Dystrophy (DMD, MYODA project). 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 ADSs (American Depositary Shares) are listed on Nasdaq Capital Market (Ticker BPTS - ISIN: US09076G1040).

For more information, visit www.biophytis.com

Disclaimer

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