

## Biophytis Reports H1 2020 Financial Results and Provides Business Update

- ✓ *COVA: Initiation of the Phase 2/3 study for the treatment of COVID-19 related respiratory failure in five countries: France, Belgium, UK, USA and Brazil. First patient dosed in Belgium, and active opening of new investigation centers.*
- ✓ *SARA-INT: Treatment period extended by 3 months based on favorable risk profile of Sarconeos (BIO1010) in sarcopenia Phase 2b study. Last patient out expected by end 2020.*
- ✓ *Cash on hand increased to €12.2 million as of June 30<sup>th</sup> 2020, and to €18 million as of July 3 2020 following the last capital increase.*
- ✓ *Call for the next Extraordinary General Assembly on May 10, 2021.*

Paris (France), Cambridge (Massachusetts, U.S.), September 18, 2020, 08:00 CET - Biophytis SA (Euronext Growth Paris: ALBPS), a clinical-stage biotechnology company specialized in the development of drug candidates for treatment of age-related diseases, including neuromuscular diseases, today publishes its interim financial report for the 1<sup>st</sup> half of 2020 and provides a business update. The half year financial report is available on the Company's website.

**Stanislas Veillet, Chief Executive Officer**, stated: *"Biophytis, like many other companies, has experienced some disruptions due to the COVID-19 pandemic. I would like to thank all Biophytis teams and our service providers for their remarkable work in helping us adapt to this health crisis. The pandemic and subsequent lockdowns have resulted in a delay on the Sarconeos (BIO101) clinical trial in sarcopenia. However, we were able to adapt the protocol to ensure safety of our patients and the continuity of the SARA-INT trial and we remain confident that our last patient will exit the study by the end of this year, allowing us to report the first results by mid-2021.*

*We have responded rapidly to the COVID-19 situation over the past few months to leverage our scientific know-how and join the global effort to fight the SARS-CoV-2 virus and its effects.*

*In April we launched COVA, an international Phase 2/3 clinical study with Sarconeos (BIO101) as a potential treatment for acute respiratory failure associated with COVID-19. We are committed to providing an improved and differentiated treatment option that can help patients with COVID-19, and especially those in vulnerable categories who are most at risk of suffering from severe respiratory complications. The first patient has already been recruited in Belgium and we expect centers in France, the United States and Brazil to start enrolling patients in the coming weeks.*

*Investors have recognized and supported our strategy and development programs, through three successful private placement transactions for a total of €13.4 million, allowing the Company to significantly strengthen its cash and equity positions."*



## Income Statement Summary (\*)

(amounts in thousands of euros, except share data)	For the Half Years Ended June 30,	
	2019	2020
Research and development, net .....	(4,828)	(5,192)
General and administrative expenses .....	(4,789)	(2,269)
<b>Operating Loss</b> .....	<b>(9,617)</b>	<b>(7,461)</b>
Net financial expense .....	(581)	(1,999)
<b>Loss before taxes</b> .....	<b>(10,198)</b>	<b>(9,460)</b>
Income taxes benefit .....	-	-
<b>Net loss</b> .....	<b>(10,198)</b>	<b>(9,460)</b>
Basic and diluted weighted average number of shares outstanding .....	13,366,218	37,211,432
<b>Basic and diluted loss per share (€/share)</b> .....	<b>(0.76)</b>	<b>(0.25)</b>

(\*) the interim 2020 consolidated financial statements were subject to limited review by the Statutory Auditors.

## Operational Update

- **SARA clinical program in sarcopenia.** On February 11, 2020, the Belgian and American health authorities agreed to amend the SARA-INT study protocol reducing the number of patients needed in the clinical trial from 334 to 231.

On March 24, 2020, the company announced that it had completed patient recruitment for its Phase 2b study in sarcopenia.

Due to COVID-19 and subsequent lockdowns in Belgium and several American states (California and New York in particular) the progress of SARA-INT has been impacted. In order to preserve the health of patients and given governments and health authorities measures to restrict movement, Biophytis had to adapt the SARA-INT protocol in order to ensure the continuity of the trial, in particular by:

- closing all on-site activities and
- organizing patient follow-up to take place at home.

As a result of these protocol changes, and depending on the evolution of the pandemic, the last patient out from the SARA-INT study is now expected at the end of 2020. The initial results are expected by mid- 2021.

- **New Phase 2/3 COVA study for acute respiratory failure associated with COVID-19.** On April 7, 2020, Biophytis announced the launch of COVA, a new study against Acute Respiratory Distress Syndrome (ARDS) linked to the SARS-CoV-2 virus, with its most advanced drug candidate: Sarconeos (BIO101).

COVID-19 can cause ARDS by disrupting the renin-angiotensin system (RAS), which has a key role in regulating respiratory function. It is believed that SARS-CoV-2 enters cells in various tissues using the Angiotensin 2 Converting Enzyme (ACE-2), a key enzyme in the RAS, thus inhibiting the system's protective arm.

Sarconeos (BIO101) could activate the MAS receptor, a key component of the protective arm of the RAS, and has been shown to restore respiratory function in several preclinical models.



The COVA clinical program is an international Phase 2/3, randomized, double-blind, placebo-controlled, adaptive and group sequential study assessing Sarconeos (BIO101) in patients infected with SARS-CoV-2. At the time of writing the half-yearly report, the study has been authorized in 5 countries: France, the USA, Brazil, Belgium and the UK. The clinical trial started in Belgium with the inclusion of the first patient on September 1, 2020.

The company has also announced the reopening of its subsidiary in Brazil in order to conduct the clinical trial there.

- **MYODA clinical program in Duchenne muscular dystrophy (DMD).** On March 30, 2020, Biophytis received approval from the Belgian regulatory agency, Federal Agency for Medicines and Health Products (FAMHP), to start the clinical study of its product Sarconeos (BIO101) in non-ambulatory patients with DMD.

The planned MYODA clinical program is based on a 3-part, randomized, double blind, adaptive seamless Phase 1 to 3 clinical study, to evaluate the safety and efficacy of a pediatric formulation of Sarconeos (BIO101) in non-ambulatory patients with DMD and evidence of respiratory deterioration. FAMHP also cleared a protocol adjustment that changed respiratory function to the primary endpoint.

This protocol also obtained IND clearance with the USA Food and Drug Administration (FDA) in December 2019.

Depending on the evolution of the pandemic, this trial might start by the end of 2020.

### **Governance Update and convening of the next EGM**

- The combined General Meeting was held on May 11, 2020. In the absence of a sufficient quorum, ordinary and extraordinary resolutions could not be put to a vote. A second combined General Meeting was convened on May 28, 2020 during which all of the resolutions relating to the combined General Assembly were approved by a large majority, and in particular those ratifying the delegations of powers to the board of directors at the effect of deciding on the issue of shares and / or securities and the authorizations to be granted to the board of directors for the purpose of deciding the exercise of various financial instruments.
- As the company's net equity is now less than 50% of Biophytis' share capital and in accordance with French regulations, shareholders are invited to a new Extraordinary General Meeting which will be held on May 10, 2021. The modalities of the EGM will be announced in the coming weeks depending on the evolution of the pandemic.

### **Interim 2020 Financial Results**

- **Cash and Cash Equivalents.** Cash and cash equivalents as of June 30, 2020 were €12.2 million, an increase of €5.8 million as compared to €6.3 million as of December 31, 2019. During the 1<sup>st</sup> half of 2020, cash used in operating activities and investing activities were close to 0, while cash provided by financing activities amounted to €5.8 million.
- **Research and Development Expenses.** Net research and development expenses were €5.2 million for the 1<sup>st</sup> half of 2020, an increase of €0.4 million as compared to €4.8 million for the 1<sup>st</sup> half of 2019. This increase in net research and development expenses was primarily related to the advancement of our



lead drug candidate, Sarconeos (BIO101), in the SARA-INT program, and preliminary expenses for the launch of the COVA program.

- **General and Administrative Expenses.** General and administrative expenses were €2.3 million for the 1<sup>st</sup> half of 2020, a decrease of €2.5 million as compared to €4.8 million for the 1<sup>st</sup> half of 2019. This decrease in general and administrative expenses was primarily related to the absence of the one-time costs associated with the postponed Nasdaq listing in the USA during the same period in 2019, as well as staff downsizing.
- **Net Loss.** Net loss was €9.5 million for the 1<sup>st</sup> half of 2020, as compared to €10.2 million for the 1<sup>st</sup> half of 2019. Net loss per share (based on weighted-average number of shares outstanding over the period) was €0.25 for the 1<sup>st</sup> half of 2020 and €0.76 for the 1<sup>st</sup> half of 2019.

Despite the loss realized in the first half of 2020 amounting to € 9.5 million, the Board of Directors approved the accounts assuming continuity of operation.

The cash and cash equivalents available as of June 30, 2020 amounted to €12.2 million, and to €18 million following the completion of a capital increase by private placement of €6.1 million on July 3, 2020 (see Note 21). 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.

Upon termination of the Negma ORNANEBSA contract, that led to a litigation procedure currently on going, the Company has signed a new ORNANE contract with Atlas Capital for a total of €24 million. Following the drawing of the 3rd tranche from Atlas, the possible use of this convertible line (see Note 12.2) may provide an additional financing of €15 million for the Company.

The share capital of Biophytis is comprised of 67 227 789 ordinary shares outstanding as of September 18, 2020.

## About BIOPHYTIS

Biophytis SA is a clinical-stage biotechnology company specialized in the development of drug candidates to slow down degenerative processes and improve functional abilities in patients with age-related diseases, including neuromuscular diseases.

Sarconeos (BIO101), our leading drug candidate, is a small molecule, administered orally, currently in clinical Phase 2b in sarcopenia (SARA-INT) in the United States and Europe. A pediatric formulation of Sarconeos (BIO101) is being developed for the treatment of Duchenne Muscular Dystrophy (DMD). The company plans to start the clinical development (MYODA) in H2 2020.

Sarconeos (BIO101) is also being developed as a treatment for patients with COVID-19 related respiratory failure in a Phase 2/3 clinical study (COVA) in the United States, Europe and Latin America.

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). For more information visit [www.biophytis.com](http://www.biophytis.com)

## Disclaimer



This press release contains forward-looking statements. While the Company considers its projections to be based on reasonable assumptions, these forward-looking statements may be called into question by a number of hazards and uncertainties, so that actual results may differ materially from those anticipated in such forward-looking statements. For a description of the risks and uncertainties likely to affect the results, BIOPHYTIS' financial position, performance or achievements and thus cause a change from the forward-looking statements, please refer to the "Risk Factors" section of the Company's 2020 Annual Report available on BIOPHYTIS website ([www.biophytis.com](http://www.biophytis.com)).

This press release, and the information contained in it, does not constitute an offer to sell or subscribe, nor the solicitation of a purchase or subscription order, of BIOPHYTIS shares in any country. The elements contained in this communication may contain forward-looking information involving risks and uncertainties. The Company's actual achievements may differ materially from those anticipated in this information due to different risk and uncertainty factors. This press release was written in French and English; if there is a difference between the texts, the French version will prevail.

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