

## BIOPHYTIS : 2017 Full Year Results

- Launch and progress in the SARA-OBS observational clinical study in the United States, Belgium, France, and Italy;
- Agencies' authorizations of SARA-INT phase 2b interventional clinical study in the United States and Belgium;
- Completion of Macuneos non-clinical regulatory studies prior to the launch of the MACA-PK Phase 1/2a clinical trial;
- Sarconeos proof of concept communication in Duchenne Muscular Dystrophy and design of the clinical plan in this indication;
- Implementation of a €15million bond financing line ("ORNANEBSA") and issue of two tranches of bonds for €6 million;
- Completion of 3 private placements (april 3<sup>rd</sup>, October 10<sup>th</sup>, October 31<sup>st</sup>) for a total amount of €21,3M;
- Cash at year-end 20,0 M€

Paris (France), March 28<sup>th</sup>, 2018, 8:00 am - BIOPHYTIS (Euronext Growth Paris: ALBPS), a biotechnology company specializing in the development of drug candidates for the treatment of degenerative age-related or genetic linked diseases, released its financial results today, and reviewed its activities.

*"In 2017, significant progress has been realized in our two key clinical programs, as described in the development plan presented in 2016 : SARA in sarcopenia, and MACA in AMD ; we also have communicated preclinical results which allow us to consider a second clinical program for Sarconeos. The MYODA program will be developed in Duchenne Muscular Dystrophy, a degenerative disease of genetic origin. The company simultaneously raised the necessary capital to fund its clinical programs" stated Stanislas Veillet, Chairman and CEO of BIOPHYTIS, adding: "2018 will be a year of value creation, as the efficacy of our drug candidates will be tested for the first time in patients with age-related, disabling diseases for which no treatment exists. Sarconeos will be tested in sarcopenic patients in Europe and the United States, as part of the SARA-INT Phase 2b study. Macuneos will be tested in patients with Age-Related Macular Degeneration (dry AMD) in Europe as part of the MACA-PK Phase 1/2a study. In addition, we will prepare the clinical development plans of our drug candidates in orphan secondary indications, Sarconeos in Duchenne myopathy and Macuneos in Stargardt's disease."*

## **2017 KEY HIGHLIGHTS**

### **The different steps of the SARA clinical program followed the program described in 2016, in particular:**

- Clinical data production of SARA-PK study. Their analysis allow to confirm the good pharmacokinetic profile in elderly healthy subjects, to confirm the therapeutic window of the Sarconeos drug candidate, and to specify the doses that will be used for the Phase 2b SARA-INT clinical trial.
- Authorization by the regulatory authorities to launch the SARA-OBS clinical trial in Sarcopenia and to open 9 clinical centers in the United States, Belgium, France and Italy. SARA-OBS is a 6-months observational clinical study involving more than 300 patients with sarcopenia. Patients' mobility and muscular quality will be assessed, based on the following criteria: 6-minute walk test, mobility (SPPB test), muscle strength (grip test), body composition and plasmatic parameters. Data from SARA-OBS will provide a better characterization of the target population for the Sarconeos treatment. Patients in the SARA-OBS study will be included in the phase 2b study of SARA-INT at the end of 6 months, once consent is given.
- Approval of the Food and Drug Agency (FDA) and from the FAMHP (Belgian Regulatory Agency) to launch Phase 2b SARA-INT interventional study in Sarcopenia. SARA-INT's objectives are to assess the safety and efficacy of two doses of BIO101 (175 mg bid and 350 mg bid) orally administered for 26 weeks, against placebo in a population of men and women aged over 65 with a risk of motor disability; and to evaluate the treatment impact, namely the improved physical function and the reduced risk of motor disability, after a six months treatment against placebo in the targeted population. The study should include 334 subjects reporting a loss of physical function in the last 6-12 months and considered at risk of motor disability.

### **A new therapeutic opportunity has been identified for Sarconeos:**

- The abstract entitled : "Sarconeos demonstrates a significant improvement in muscle functions and anti-fibrotic properties in the animal model of Duchenne muscular dystrophy", was presented at the World Muscle Society's International Congress in October in Saint Malo, France. These results demonstrate the efficacy of Sarconeos in improving dystrophic muscle function and preventing the onset of fibrosis. This paves the way for a new therapeutic solution for patients with DMD.
- As a result, Professor Thomas Voit, a specialist in pediatric diseases, joined the Biophytis Scientific Advisory Board to participate in the design of the MYODA clinical program in DMD. Dr. Voit is the Director of the Center for Biomedical Research (BRC) at the Great Ormond Street Children's Hospital NHS Foundation Trust and the Institute of Child Health, University College London. Professor Voit was previously Medical and Scientific Director of the Institute of Myology (La Pitié Salpêtrière Hospital).

### **The company's financial situation has been considerably strengthened:**

- On April 3<sup>rd</sup>: a capital increase subscribed by several private investors and management, amounting to €3.7M, was realized by the issue of 1,310,431 new shares at a unit price of €2.85,
- Simultaneously: set up of a financing line that can go up to €15 million, with Bracknor Fund, in the form of 5 tranches of €3M of Redeemable Bonds in cash or in New or Existing Shares with BSA (ORNANEBSA) ,
- In May: drawdown of the first tranche of bond warrants redeemable in cash and/or in new and/ or existing shares with a par value of €3M; the totality of the bonds has been converted,
- In July: drawdown of a second tranche of bond warrants redeemable in cash and/or in new and/or existing shares with a par value of €3M; the totality of the bonds has been converted,
- October 10: completion of a €10.4M capital increase through a private placement and the issuance of 1,989,000 new ordinary shares at a unit price of €5.25 subscribed by qualified investors,
- October 31: completion of a €7.5M capital increase through a private placement and the issuance of 1,513,000 new ordinary shares at a unit price of €5.00 subscribed by qualified investors.

## 2018 PERSPECTIVES

In the continuity of its development plan, Biophtis has set three major objectives for the current year :

- Pursuit of the SARA clinical plan in sarcopenia with the conduct of the SARA-INT Phase 2b interventional study: regulatory approvals have been granted in Belgium and the United States, and the granting process is continuing in other countries. Based on patients already selected for the SARA-OBS study, the company plans to include the first patient in the second quarter of 2018. More than 150 patients will have spent 6 months under observation and approximately another 150 will be recruited specifically in SARA-INT. Accordingly, the administration period could end in the first half of 2019, followed by the publication of preliminary results in the summer of 2019.
- Pursuit of the MACA clinical plan in AMD with the launch of the MACA-PK Phase 1/2a study in Europe: the regulatory approval process is underway and the Single Ascending Dose (SAD) phase of the study could begin this summer. The results of the SAD phase are expected before the end of the year.
- Preparatory work for the MYODA clinical program (in Duchenne Muscular Dystrophy): the clinical plan of Sarconeos in DMD is being developed with the clinicians and the CRO. It is planned to start with a first safety and pharmacokinetics validation, MYODA-PK, of the drug candidate in young patients with DMD (aged 2 to 18 years). MYODA-PK could be launched in the second half of 2018. An application for Orphan Drug designation has also been filed with the European Medicines Agency.

## FINANCIAL HIGHLIGHTS

The Group's Income Statement, Consolidated Balance Sheet and Statement of Cash Flows have been drawn up in accordance with IFRS. The consolidated financial statements have been audited. The financial statements for the year ended December 31, 2017 were approved by the Board of Directors on March 26, 2018. The certification report has been issued on March 27, 2018.

**Net loss of €11.4 million, up by €3.4 million mostly due to investments in the clinical program and the financial charge linked to the convertible bonds issuance.**

The table below summarizes the key figures of the income statement:

In € thousands	2017	2016
Net Research and Development Costs	(7,043)	(5,121)
Research and Development Costs	(9,593)	(6,788)
Grants	2,550	1,667
General and administrative expenses	(2,865)	(2,820)
<b>Operating income</b>	<b>(9,908)</b>	<b>(7,942)</b>
Financial income	(1,501)	(13)
<b>Net Income</b>	<b>(11,409)</b>	<b>(7,954)</b>

The increase in development costs (launch and development of SARA-OBS, non-clinical regulatory studies for MACA) was the main reason for the significant increase in R&D expenses.

However, general and administrative expenses remain stable on the period.

Financial expenses are mainly due to the effect of the recognition at fair value of the Redeemable in Cash or New or Existing Shares with Subscription Warrants ("ORNANEBSA"), issued by the company in May 2017 and July 2017. This charge has no impact on the Company's cash position.

**The Company increased its cash position to €20.0 million at December 31, 2017, following various capital increases during the year.**

The table below summarizes the key figures for Company cash:

in € thousands	2017	2016
Non-current financial assets (liquidity contract)	190	98
Cash and cash equivalents	19,858	3,036
Short-Term deposits	9,857	2,001
Bank accounts	10,001	1,065
<b>Available Cash</b>	<b>20,048</b>	<b>3,134</b>

The company completed several private placements by issuing new shares generating a capital increase of €21.7 million, as follows:

In April 2017 :

- a €3.2 million private placement by issuing 1,117,449 new shares at a unit price of €2.85.
- a €550,000 capital increase subscribed by the Company's management through the issuance of 192,982 new shares at a unit price of €2.85.

In October 2017 :

- a €10.4 million private placement by issuing 1,989,000 new shares at a unit price of €5.25.
- a €7.6m private placement by issuing 1,513,000 new shares at a unit price of €5.

In May and July 2017, the company issued two convertible bonds tranches ("ORNANEBSA") for €3 million each. The Company has the option to issue 900 additional bond warrants, which allows the company to draw a maximum additional amount of €9 million.

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### About SARCONEOS

Sarconeos is a first-in-class drug candidate based on the activation of the MAS receptor (major player of the renin-angiotensin system) restoring muscular anabolism, inhibiting myostatin, and that had demonstrated meaningful activity in animal models of muscular dystrophies. Sarconeos is developed in the treatment of sarcopenia, an age-related degeneration of skeletal muscle, leading to loss of mobility in elderly people. This condition, for which no medical treatment currently exists, was first described in 1993 and has entered the International Classification of Diseases (M62.84) in 2016. It affects more than 50 million people worldwide.

### About MACUNEOS:

Macuneos is the first representative of a new class of drug candidates, agonists of nuclear receptor PPAR. Macuneos protects retinal pigment epithelium: Biophytis has shown in animal models a protection of retinal cells against phototoxic effects of A2E in the presence of blue light (oxidative stress), a reduction in accumulation of A2E, and eventually a slowdown of the degenerative process of the retina. Macuneos is a drug candidate against the dry form of AMD: AMD affects the central part of the retina, called the macula, causing severe visual impairment and irreversible loss of central vision beyond 60 years old. Macuneos is in tablet form (once per day), containing 100 mg or 350 mg of active Pharmaceutical Ingredient (API).

### About BIOPHYTIS

Biophytis SA ([www.biophytis.com](http://www.biophytis.com)), founded in 2006, develops drug candidates targeting diseases of aging. Using its technology and know-how, Biophytis has begun clinical development of innovative therapeutics to restore the muscular and visual functions in diseases with significant unmet medical needs. Specifically, the company is advancing two lead products into mid-stage clinical testing this year: Sarconeos (BIO101) to treat sarcopenic obesity and Macuneos (BIO201) to treat dry age-related macular degeneration (AMD).

The business model of BIOPHYTIS is to ensure the conduct of the project until clinical activity in the patient is proven, then to license the technologies in order to continue the development in partnership with a pharmaceutical laboratory.

The company was founded in partnership with researchers at the UPMC (Pierre and Marie Curie University) and also collaborates with scientists at the Institute of Myology, and the Vision Institute.

BIOPHYTIS is listed on the Euronext Growth market of Euronext Paris (ALBPS; ISIN: FR0012816825).

For more information: <http://www.biophytis.com>

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BIOPHYTIS is eligible for the SMEs scheme



### Disclaimer

This press release contains certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. For a discussion of risks and uncertainties which could cause the Company's actual results, financial condition, performance or achievements to differ from those contained in the forward looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the Listing Prospectus upon the admission of Company's shares for trading on the regulated market Euronext Growth of Euronext Paris filed with the AMF, which is available on the AMF website ([www.amf-france.org](http://www.amf-france.org)) or on BIOPHYTIS' website ([www.biophytis.com](http://www.biophytis.com)).

This press release and the information contained herein do not constitute an offer to sell or a solicitation of an offer to buy or subscribe to shares in BIOPHYTIS in any country. Items in this press release may contain forward-looking statements involving risks and uncertainties. The Company's actual results could differ substantially from those anticipated in these statements owing to various risk factors which are described in the Company's prospectus. This press release has been prepared in both French and English. In the event of any differences between the two texts, the French language version shall prevail.

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