



# Biophytis: interim results 2018 and perspective on activity

Paris (France), October 22, 2018, 6.00pm - BIOPHYTIS (Euronext Growth Paris: ALBPS), a biotechnology company specializing in the development of drug candidates to fight age-related degenerative diseases, announces the publication of its interim financial report and communicates the perspective on its activity until year-end.

**Stanislas Veillet, CEO of BIOPHYTIS**, stated: "In the first half of 2018, key steps in the clinical programs of our drug candidate Sarconeos were completed, with the opening of the first clinical centers of the phase 2b study SARA-INT in Sarcopenia, and the Orphan Drug Designation for Duchenne Muscular Dystrophy. The Company which had €14 million of cash on June 30<sup>th</sup> and has signed a €10 million loan with Kreos Capital in September, has the adequate financial resources to conduct SARA-INT and obtain the regulatory approvals for the MYODA clinical program in DMD."

The financial report can be downloaded at: http://www.biophytis.com/en/action/document/

# Key highlights of 2018's first semester

In the first semester 2018, Biophytis pursued the SARA clinical program for the drug candidate Sarconeos in sarcopenia. All 11 clinical centers of the SARA-OBS clinical study (a study of observation and pre-recruitment without administration) have been opened: 3 in the United States, 1 in Belgium, 3 in France, 4 in Italy. As of June 30<sup>th</sup>, 162 patients were enrolled in the study. At the same time, Biophytis continued the regulatory work to obtain the authorisations and the opening of clinical centers for the phase 2b of SARA-INT study, which allowed the opening of the first clinical center in Belgium in May.

Also, the Company launched preparatory work for the MYODA program in Duchenne Muscular Dystrophy, which resulted in the obtention of Orphan Drug status for Sarconeos with the Food and Drug Agency (FDA) and European Medicines Agency (EMA).

Finally, the research efforts have been maintained. The Company filed a new patent, the 7<sup>th</sup> to date, concerning the research platform for MAS receptor activator for muscle and metabolism pathologies. Four scientific works were presented at the 8<sup>th</sup> International Conference on Frailty & Sarcopenia Research in Miami. Finally, one poster was presented at the annual congress of the Association for Research in Vision and Ophtalmology (ARVO) in Honolulu, Hawai, in May. The presented results demonstrate the strong potential of Macuneos in the treatment of Age-Related Macular Degeneration (AMD).

#### **Interim financial results 2018**

In € thousands	H1 2018	H1 2017
Net Research and Development Costs	(4,136)	(2,912)
General and administrative expenses	(1,542)	(1,247)
Operating income	(5,678)	(4,159)
Financial income	(12)	(855)

The operating income at end of June 2018 was (5,678) k€ versus (4,159) k€ at end of June 2017. This change is mainly due to :

- An increase of 653 k€ in third-party research and development expenses versus the same period in 2017, mainly due to the combination of conducting simultaneously the last part of the SARA-OBS study and the launch of the SARA-INT study;
- Increase in personnel expenses of 928 k€ versus the same period in 2017, mainly due to the increase of overall staff;

The financial result of (12)  $k \in at$  end of June 2018 versus (855)  $k \in at$  end of June 2017, significantly improved as in 2017 the company was bearing the financial charges of convertible bonds which was no longer the case in 2018.

in € thousands	H1 2018	2017
Non-current financial assets (liquidity contract)	119	190
Cash and cash equivalents	14,121	19,857
Short-Term deposits	10,000	10,001
Bank accounts	4,121	9,856
Available Cash	14,240	20,047

At end of June 2018, the company held two short-term deposit accounts of respectively 7,000 k€ and 3,000k€.

### **Post-closing events**

On September 10<sup>th</sup>, the Company entered into a venture loan agreement with Kreos Capital V (UK) LTD (« KREOS ») by signing a Bonds Issue Agreement for up to 10 M€, with issuance of 442 477 warrants attached to the Tranche A (BSA2018-KREOS), and a pledge on part of the Company's goodwill in favour of KREOS.

o The agreement allows for raising up to 10 M € by an issue of non-convertible Bonds for a total nominal amount of up to 10 M€ with a par value of 1€ per bond, divided into 4 tranches of 2,5 M € each. The issue dates are established as at the contract signature date: the first two tranches shall be issued by September 30<sup>th</sup> 2018, the third and fourth tranches shall be issued in the 4<sup>th</sup> quarter of 2018 and first quarter of 2019, with the possibility to postpone one of the issues to the second quarter of 2019. The nominal interest rate of each tranche is 10% per annum. The tranches shall be repaid in accordance with a 36-months amortisation schedule, following the nominal amount grace period, starting from April 2019. Tranches A and B were issued on 10th September.

- o Each warrant (BSA2018-KREOS) issued in favour of KREOS in the Tranche A scope gives the right to subscribe to one new share of the Company. The warrants are exercisable within a 7 years period starting from their emission date, at an exercise price of 2,67 €.
- o A pledge on part of the Company's goodwill has been granted on September 10<sup>th</sup>.

# Perspective on the activity to come

The company will continue to advance its three clinical programs:

Development of Sarconeos in sarcopenia: Phase 2B clinical study, SARA-INT

The double-blind, placebo-controlled Phase 2b SARA-INT study will include approximately 334 patients. 7 centres are already opened in the United States and in Belgium, and the company is awaiting the authorizations from the French and Italian regulatory agencies. More than 200 patients have already been recruited in the SARA-OBS study, which includes 11 clinical centres in Europe (Belgium, France and Italy) and in the United States. 60 have completed the observational study and are ready to enter the interventional study. The remaining patients will be recruited in 11 additional clinical centres. The company forecasts to complete recruitment in S1 2019.

Development of Sarconeos in Duchenne Muscular Dystrophy: MYODA clinical program Sarconeos has already received the orphan drug status granted by the FDA and the EMA (European Medicines Agency) in the Duchenne Muscular Dystrophy. This status will allow Biophytis to benefit from numerous incentives for the development of its drug candidate, including a marketing exclusivity of 10 years in the European Community and 7 years in the USA. The company has requested the scientific advice from FDA and EMA regarding the clinical program, and expects to obtain regulatory approvals for the MYODA-PK study of safety and pharmacokinetics in patients in S1 2019.

Development of Macuneos in AMD: Phase 1/2a clinical study, MACA-PK

The company is currently conducting the industrial scale-up of the clinical lots of the Macuneos drug candidate. It intends to request the scientific advice from FDA and EMA in Q1 2019, and to obtain regulatory approvals for the MACA-PK study of safety and pharmacokinetics in healthy volunteers in S1 2019.

#### **About BIOPHYTIS**

Biophytis SA (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.

Based on the Sorbonne Université campus, Biophytis collaborates with expert scientists from several Sorbonne Université institutes such as the Paris Seine Biology Institute, 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.amffrance.org) or on BIOPHYTIS' website (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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