NEW THERAPEUTICS FOR AGING DISEASES

*Press release*

# BIOPHYTIS: Business Update and Consolidated Half-Year Financials as of June 30, 2016

**Romainville, September 29, 2016, 6:00 pm – BIOPHYTIS (Alternext Paris: ALBPS), a biotechnology company specialized in the development of drug candidates to treat ageing diseases, today reports its consolidated half-year financials as of June 30, 2016 and confirms its clinical development strategy.**

**Stanislas Veillet, CEO of BIOPHYTIS, declares:** *"The first months of 2016 were a productive period for Biophytis, with important development milestones on our most advanced drug candidate Sarconeos. Our clinical program, and especially SARA-PK and SARA-OBS studies aimed at preparing the SARA international Phase 2b trial, is in line with the timeline communicated in last April. Positive results of the first phase of SARA-PK have enabled us to launch the MAD phase of the trial, and we are now ready to start SARA-OBS as soon as regulatory approvals are granted."*

## Key first-half 2016 highlights

The Company received the formal scientific advice from the Belgian Federal Agency for Medicines and Health Products (FAMHP) regarding the clinical and regulatory development of Sarconeos (BIO101) aimed at conducting a Phase 2b clinical study in the treatment of Sarcopenia.

The Company announces a significant evolution of its strategy emphasizing the clinical and regulatory development of its drug candidates: Sarconeos (BIO101) and Macuneos (BIO201), simultaneously in the United States and Europe :

- Significant increase in the size of clinical trials: SARA (for Sarcopenia) and MACA (for AMD), with the recruitment of additional patients in the United States, to increase the statistical power, and meet FDA requirements. It is planned to expand the number of patients involved in the studies to 300 patients, spread in 4 countries: France, Belgium, Italy, and United States.
- Performing additional clinical studies on elderly subjects with Sarconeos (SARA-PK and SARA-OBS) and Macuneos (MACA-PK and MACA-OBS), to better characterize these new indications without marketed therapies. In particular, for Sarconeos (BIO101), on one hand, conducting a study in Belgium (the SARA-PK study) in order to determine the pharmacokinetics and the safe use of Sarconeos in healthy elderly volunteers; on the other hand, a pilot characterization study in a pre-selected target population of patients suffering from Sarcopenia (the SARA-OBS study).

## H1 2016 Consolidated Income Statement

| In € thousands – in IFRS standard | 30/06/2016 | 30/06/2015* |
|---|---|---|
| Net research and development | (2,327) | (545) |
| General & Administrative | (1,384) | (1,060) |
| **Operational loss** | **(3,711)** | **(1,605)** |
| Financial result | (9) | (126) |
| **Net loss** | **(3,720)** | **(1,731)** |

** Accounting statements of 2015 first semester have been adjusted. These adjustments are presented in detail in the Financial Report for 2016 first semester, in chapter 3, paragraph 2.4.*

The Company's operating result amounts to €(3,711)K as of June 30, 2016 vs. €(1,605)K as of June 30, 2015. This evolution is mainly due to the Company's development works as part of the Sarconeos project and preparation of the Phase 2b trial.
External expenses increased by €1,723K compared to the first half of 2015, including preclinical studies, submission of regulatory files and production of the clinical batches.
Besides, the Company reinforced its research and development teams during the second half of 2015, with the recruitment of a Head of Research and a Head of Operations. Staff expenses increased by €529K between the first half of 2015 and the first half of 2016.

| In € thousands | 30/06/2016 | 31/12/2015 |
|---|---|---|
| Non-current financial assets (liquidity contract) | 73 | 272 |
| Cash and equivalents | 6,805 | 9,407 |
| Short-term deposits | 5,000 | 9,002 |
| Bank accounts | 1,805 | 407 |
| Bank overdrafts | - | (2) |
| Other receivables * | - | 50 |
| **Available cash position** | **6,878** | **9,729** |

** payments received by the securities manager upon exercise of Warrants*

The cash position amounted to €1,603K as of June 30, 2015. The Initial public offering on Alternext Paris in July 2015 and the private placement realized in August 2015 have enabled to raise a total amount, net of fees, of €10.5M. The funds raised are mainly dedicated to the R&D program. Then, the available cash position was €6,878K as of June 30, 2016.

## Post-closing highlights and outlook

### Conditional advance granted by Bpifrance

Bpifrance grants Biophytis a conditional advance of €1.1M aimed at co-financing the pharmacokinetics study for Sarconeos (SARA-PK)

### SARA-PK study

The SARA-PK MAD portion of the study has been launched. It assesses the safety and pharmacokinetics of Sarconeos in 30 elderly subjects, it will consist in multiple ascending oral administrations daily for 14 days. Data from this second portion of the study will be reported by the end of the year and will be used to select the two doses of Sarconeos for study in Phase 2b SARA-INT trial, which is currently expected to begin in the first half of 2017.

The objective of the SARA-PK study is to assess the safety, tolerability and pharmacokinetic profile of Sarconeos in elderly healthy volunteers (>65 years old). The recently completed SAD portion of the study was aimed at comparing pharmacokinetics in elderly and young volunteers following escalating single dose administrations. No severe adverse event related to Sarconeos was reported following any of the four administrated doses, ranging from 100mg/day up to 1400mg/day, in 24 young or elderly subjects enrolled.

### SARA-OBS study

Submission of regulatory approvals
Regulatory filings have been submitted in France, Italy and Belgium. Authorizations should be available in the coming weeks.

SARA-OBS is a clinical observational study aimed at characterizing a patients' population diagnosed with sarcopenia, that could be ultimately enrolled in the SARA-INT study:

- 300 sarcopenic patients followed for a period of six months,
- 8 clinical centers in Europe and in the United States involved, including Toulouse, Liege, Rome, Gainesville and Boston,
- Recruitment according to the criteria defined by the Foundation for the National Institutes of Health: muscle mass, muscular strength (grip test), 6-minute walk test, body composition and plasmatic parameters.

The results of the study will enrich the clinical and regulatory file for Sarconeos, required for authorization to initiate the Phase 2b SARA-INT clinical study.

The international steering committee set up to oversee the SARA-OBS study is composed of: Pr Roger Fielding, Pr Yves Rolland, Pr Marco Pahore, Pr Olivier Bruyère.

The CRO ICON will be in charge of coordinating and accompanying the 8 clinical centers selected, conducting the dialogue with regulatory agencies in the 4 countries involved, and collecting observational and analytical data. ICON is a highly experienced partner in clinical development in endocrine and metabolic pathologies, with a particular interest in sarcopenia for several years.

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## 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 need. Specifically, the company is advancing two lead products into mid-stage clinical testing next year: Sarconeos (BIO101) to treat sarcopenic obesity and Macuneos (BIO201) to treat dry age-related macular degeneration (AMD). The company was founded in partnership with researchers at the UPMC (Pierre et Marie Curie University) and also collaborates with scientists at the Institute of Myology, and the Vision Institute

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

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

## 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 Alternext of Euronext Paris filed with the AMF, which is available on the AMF website (www.amf- france.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 5 both French and English. In the event of any differences between the two texts, the French language version shall supersede.


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