Press release

Biophytis Announces 2021 Operational and Financial Results and Gives Updates on 2022 perspectives

- ✓ Success of Nasdaq IPO in February 2021
- ✓ €23.9M of available cash on December 31 2021 and new financing instruments for a total of €42M allowing financial visibility beyond mid 2023
- ✓ Strong growth of operational expenses to €26.8M, mainly reflecting clinical program advancement in COVID-19 (COVA) and in sarcopenia (SARA)
- ✓ Significant milestones reached for COVA and SARA allowing to prepare for future development of the programs

Paris, France, Cambridge (Massachusetts, United States), April 7th, 2022 – 8am CET - Biophytis SA (NasdaqCM: BPTS, Euronext Growth Paris: ALBPS), **("Biophytis" or the "Company"),** a clinical-stage biotechnology company focused on the development of therapeutics that slow the degenerative processes associated with aging, including severe respiratory failure in patients suffering from COVID-19, today announces its non audited financial results for the year ended December 31, 2021, and provides updates on key operational achievements as well as perspectives for 2022.

Stanislas Veillet, President and CEO of Biophytis, declares: "*2021 was a very busy year for Biophytis, both for our financing and for the execution of our clinical studies. We have succeeded in listing the Company on Nasdaq in February 2021, which now allows us to be present in the most important market in the world for investment in Biotech. We also renewed our instruments with historical partners: Atlas and Kreos Capital, for a total of €42M of new financings. Those new instruments, together with our €24 millions of cash at the end of December 2021 should allow a good financial visibility for the development of the Company.*
Regarding the projects, after having launched COVA - our international study in Covid-19 in 2020 - the whole Company was focused in 2021 on patient recruitment. Based on the independent DMC review of our study in September 2021 based on the first 155 patients, Sarconeos (BIO101) was demonstrating efficacy in the "promising zone" for respiratory manifestations linked to COVID-19. This interim result was very important for us to progress the study into its last phase. Since then, the health situation has changed. The number of hospitalized patients has decreased, due to a lower severity from the Omicron variant, and to the strong progression of collective immunization. Therefore, we have taken the decision to early terminate patient enrolment into the COVA study, in order to be able to report results by Q3 2022. In the meantime, we will have the opportunity to bring Sarconeos (BIO101) to some patients in Brazil, in the framework of an Expanded Access Program (EAP) for which we obtained authorization from ANVISA last December 2021.
Lastly, 2021 was also a landmark year for SARA, our phase 2 trial in Sarcopenia. We achieved the study with encouraging results, despite a reduced cohort having performed the full test of our primary endpoint: the 400MWT test, due to restrictions during the pandemic. We are now exchanging with FDA for the preparation our phase 2-3 study and assuming authorizations are obtained, we expect to enroll our first patient in by H2 2022.
In a global very unstable context since two years, we have demonstrated our capacity to adapt, while progressing the development of our main assets. We are still concentrating on the Company key objective, which is to bring to the market the products coming from our research."

Major operational milestones achieved during 2021:

- As regards to our global Phase 2-3 COVA study in COVID-19:
  - ✓ The Data Monitoring Committee (DMC) had recommended in September 2021 from the Interim Analysis 2 the continuation of the COVA study without modification of the protocol based on results showing the efficacy of the treatment with Sarconeos (BIO101) in the promising zone and no futility of the study,
  - ✓ 237 patients have been randomized to date, over a total cohort expected to be between 310 and 465 patients, in 35 clinical centers in France, Belgium, the USA and Brazil

- As regards to our Phase 2 SARA-INT trial for the treatment of Sarcopenia:
  - ✓ Sarconeos (BIO101) at the highest dose of 350 mg bid demonstrated an increase of 0.1 meter per second (m/s) in the PP population (Per Protocol subset of participants that complied to the clinical protocol) of treatment). This result is meaningful as the Minimal Clinically Important Difference (MCID) for the 400MWT in sarcopenia is 0.1 m/s.
  - ✓ However, due to restrictions during the pandemic, only 106 patients could perform the 400m walk test at the end-of-treatment visit, which was the primary endpoint of our study – ie 55% of loss of efficacy data,
  - ✓ Following a type C meeting in January 2022 with the FDA the Company is currently preparing a Phase 2-3 study, with the objective of having a first patient in during H2 2022, pending regulatory authorizations, and depending on the evolution of the pandemic.

2022 outlook and perspectives:

- For the COVA study in COVID-19:

To date, 237 patients have been recruited in our COVA study. Due to the evolution of the pandemic in the territories of our studies which are presenting high vaccination and collective immunization rates, provided the predominance of the Omicron variant which involve significantly lower number of hospital cases, patient recruitment has strongly slowed down and then stopped since the first months of 2022. In this context, we have decided to early terminate patient enrollment, and plan to report the results of this trial by Q3 2022.

- For the SARA study in Sarcopenia:

Following the first type C meeting with FDA in January 2022, a second type C meeting is planned in Q3 2022 to discuss the Phase 2-3 protocol. The objective is to have a FPI (First patient In) for this study during H2 2022. We also plan to have discussions with EMA during H2 2022, in order to obtain scientific advice on the Phase 2 results and the progression toward a phase 2-3. These plans remain subject to regulatory authorizations and procedures, any delays in patient recruitment or retention, interruptions in sourcing or supply chain, and to COVID-19-related delays.

- For the MYODA study in Duchenne Muscular Dystrophy (DMD):

After an IND ''may proceed'' letter from the FDA (USA)in December 2019, in March 2021 Biophytis received approval from the Belgian FAMHP to proceed with its clinical investigation of Sarconeos (BIO101) in non-ambulatory patients with DMD. However due to the COVID-19 situation and its impact on our operational

capabilities, the MYODA study has been delayed to end of 2022 or beginning of 2023 depending on the evolution of the pandemic.

Annual 2021 Financial Results

The Company's annual 2021 non-audited consolidated financial statements prepared in accordance with IFRS were reviewed by the Company's Board of Directors on April 4, 2022. Audit procedures are being completed, the issuance of the audit report is pending, and will be included in the Company's upcoming 2021 annual financial report and SEC Form 20-F, respectively to be filed with AMF and SEC.

• **Cash and cash equivalents and short-term deposits included in other current financial assets.** Cash and cash equivalents and short-term deposits included in other current financial assets as of December 31, 2021 were €23.9 million, a significant increase of €5.6 million compared to €18.3 million as of December 31, 2020.

The table below summarizes the non audited profit and loss statement.

(amounts in thousands of euros)	31/12/2020 (*) 12 mos	31/12/2021 12 mos
Research and development expenses, net	(9,921)	(19,665)
General and administrative expenses	(4,020)	(7,150)
Operating loss	**(13,941)**	**(26,815)**
Net Financial expense	**(11,575)**	**(4,432)**
Loss before taxes	**(25,516)**	**(31,247)**
Income taxes benefit	-	-
Net loss	**(25,516)**	**(31,247)**
Attributable to shareholders of Biophytis	*(25,516)*	*(31,246)*
Basic and diluted weighted average number of shares outstanding	59,974,486	**118,282,679**
Basic loss per share (€/share)	**(0.43)**	**(0.26)**
Diluted loss per share (€/share)	**(0.43)**	**(0.26)**

• **Research and Development Expenses**. Net research and development expenses were €19.7 million for 2021, an increase of €9.8 million, compared to €9.9 million in 2020. This increase is mainly reflecting the progression of the COVA program from Phase 1 to Phase 2, the finalization of SARA-INT, our phase 2 trial in Sarcopenia, as well as the scaling up of Sarconeos (BIO101) to prepare for potential registration.
Net research and development expenses included research tax credits (French '*Crédit d'Impôt Recherche*', or CIR) totaling €4 million in 2021 compared to €3.3 million in 2020.

• **General and Administrative Expenses.** General and administrative expenses were €7.2 million for 2021 compared to €4 million for 2020, an increase of €3.2 million, primarily in connection with our listing on Nasdaq, and to higher personnel costs.

• **Financial results:** Financial loss amounted to €4.4 million in 2021 vs €11.6 million in 2020, a decrease of €7.2 million, resulting majorly from the variation of the fair value as calculated using IFRS 9, for our various

convertible financing instruments, respectively Atlas, Kreos and Negma in 2021 and Atlas & Negma in 2020.

• Net Loss. Net loss was €31.2 million for 2021, as compared to €25.5 million for 2020. Net loss per share (based on weighted-average number of shares outstanding over the period except the treasury shares) was €0.26 in 2021 compared to €0.43 in 2020.

(*) In October 2021, it was determined that the annual consolidated financial statements for the years ended December 31, 2019 and 2020 required correction for the accounting treatment of the convertible notes, as per IFRS 9. Please refer to our press releases dated October 7 and 29, 2021. The details of this restatement is described in our 2021 Annual Financial report, to be filed shortly with AMF.

Appointments:

Biophytis has reinforced its management teams through the nominations of: Benoit Canolle as *Chief Business Officer*, and Rob Van Maanen as *Chief Medical Officer* in 2021, then Philippe Rousseau as *Chief Financial Officer* in April 2022, upon departure of Evelyne Nguyen

At the Board level, Claude Allary serves as Independent Director since July 2021, replacing Jean Franchi.

Reminder of key operational events

(more details are provided in our press releases as available on Biophytis's website: www.biophytis.com)

- Cova Phase 2-3 program in respiratory deficiencies linked to COVID-19:

- On May 12th, the Company announced it has recruited the 155th participant for Part 2 of the study in patients infected with COVID-19, which allowed the independent Data Monitoring Committee (DMC) to conduct its second interim analysis, based on safety and efficacy data, for the continuation of the trial, in case of favourable results.
- On June 30th, Biophytis secured contracts with a major global Custom Development and Manufacturing Organization (CDMO) for the manufacturing of registration batches of Sarconeos (BIO101). These contracts were signed in preparation of the potential filing of the product in COVID-19 for Emergency Use Authorization with FDA, or Conditional Marketing Authorization with EMA.
- On August 16th, the Company announced recommendation by the Data Monitoring Committee (DMC) to continue patient recruitment into part 2 of the COVA study with the protocol unmodified after review of safety data, based on the first 50 patients.
- On September 15th, the Company announced the recommendation by the DMC to continue the COVA study without any modification of the protocol after the interim efficacy data were found in the promising zone. This Interim Analysis 2 was based on 155 COVID-19 patients hospitalized with respiratory failure and has shown no futility, indicating that BIO101 remains a candidate treatment for acute respiratory failure associated with COVID-19.
- In December 2021 we received approval from the ANVISA (Brazilian health authority) to use our product Sarconeos (BIO101) for an Expanded Access Program (EAP) to treat hospitalized patients with severe COVID-19. A maximum of 80 patients who are mechanically ventilated in Intensive Care Unit of Brazilian hospitals will be treated with Sarconeos (BIO101) for up to 28 days to prevent further deterioration and mortality.

- Lastly, the Company has announced today the early termination of patient recruitment provided the evolution of the COVID-19 pandemic, and projects to report results by Q3 2022.

- SARA Phase 2 program in sarcopenia:

- On October 4th, the Company announced full results of the study, showing that Sarconeos (BIO101) at the highest dose of 350 mg bid showed an increase of 0.09 meter per second (m/s) in the FAS population and of 0.10 m/s in the PP population compared to placebo in observed data, for the 400MWT in gait speed, after 6 months of treatment in observed data. The Minimal Clinically Important Difference (MCID) for the 400MWT in sarcopenia is 0.1 m/s.
- The product also showed a very good safety profile at the doses of 175 mg bid and of 350 mg bid with no Serious Adverse Events (SAE) related to the product.
- On January 24, 2022, a type C meeting between the Company and the FDA was held. During the meeting, we discussed conducting additional dose-finding studies, as well as safety and pharmacokinetics data. We also discussed further definition of the proposed population and indication, and CMC (chemistry, manufacturing, and control section) data to be submitted, as well as the regulatory non-clinical plan. We will assess, and address FDA's recommendations in the coming development of our seamless Phase 2-3 program. Based on the comments from FDA, we plan to submit the protocols for our next studies in Q4 2022. We also anticipate discussions with the EMA in the first half of 2022, to get scientific advice including on the results of the Phase 2b study and potential progression into Phase 2-3.

Reminder of key financial events

- IPO on Nasdaq in February 2021:
  On February 12, 2021, the Company closed its previously announced initial public offering on the Nasdaq Capital Market by way of a capital increase of 12,000,000 ordinary shares represented by 1,200,000 American Depositary Shares ("ADSs"), with each ADS representing 10 ordinary shares, at a price of $16.75 per ADS. Total gross proceeds were approximately $20.1 million. The Company received net proceeds of approximately $16.35 million or €13.5 million, after deducting underwriting discounts and commissions, management fee and offering expenses payable by the Company. Since February 10, 2021, Biophytis ADSs are listed on Nasdaq Capital Market (US trading ticker: BPTS)

- ORNANE convertible line with Atlas capital:
  In October 2021 the Company signed a new line of financing through Bonds Redeemable in Cash and New and Existing Shares (ORNANE) with Atlas, a specialized investment fund based in New York – USA, for €32 million. The new financing instrument allows the issuance of 1280 bonds with an option for exchange in cash and/or conversion into new or existing shares (ORNANE). The €32 million total financing can be drawn by Biophytis over the next three years, without obligation, through 8 successive tranches of €4 million each, subject to the issuance of the last tranche under the previous Atlas Contract. This last tranche occurred in December 2021.

  At the beginning of April 2022, the Company has drawn a first tranche of €4 million from this contract. As of April 5th 2022, based on 147 541 024 outstanding shares, assuming conversion on this day and a conversion price equal to 96% of the pricing period VWAP of €0.22, dilution is reflected as follows:

Impact on a shareholder's 1% stake in the Company's capital prior to the transaction	Non diluted	Diluted
Before issuing of new ORNANE	1.00 %	0.94 %
Upon conversion of the ORNANE from tranche 1 of the 2021 Atlas contact: issuing of 18 117 202 additional shares	0.89 %	0.84 %

- Financing line with Kreos Capital:
  In November 2021, the Company as secured a €10 million total loan with Kreos Capital comprising of four tranches of respectively €2.5 million, €3.0 million, €2.5 million and €2.0 million. The two first tranches were drawn upon signing of the contract on November 19, 2021. Besides the loan, Kreos Capital will receive Biophytis' share warrants ("bons de souscription d'action" or "BSA") for a total of approximately €1 million.
  Over the €10 million total bonds, €7.75 million were in straight bonds, and €2.25 million were in convertible bonds to be fully repaid after 36 months. Interest shall accrue on the outstanding principal at fixed interest rates of respectively 10.00 % and 9.50% per annum.

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About BIOPHYTIS

Biophytis SA is a clinical-stage biotechnology company specialized in the development of therapeutics that are aimed at slowing the degenerative processes associated with aging, including severe respiratory failure in patients suffering from COVID-19. Sarconeos (BIO101), our leading drug candidate, is a small molecule, administered orally,) just achieved its phase 2 development as a treatment for sarcopenia in the United States and Europe (SARA-INT). It is also being studied in a clinical two-part Phase 2-3 study (COVA) for the treatment of severe respiratory manifestations of COVID-19 in Europe, Latin America, and the US. A pediatric formulation of Sarconeos (BIO101) is being developed for the treatment of Duchenne Muscular Dystrophy (DMD). 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 ADS (American Depositary Shares) are listed on Nasdaq (Ticker BPTS – ISIN: US09076G1040).

For more information visit www.biophytis.com

Disclaimer

This press release contains forward-looking statements. Forward-looking statements include all statements that are not historical facts. In some cases, you can identify these forward-looking statements by the use of words such as "outlook," "believes," "expects," "potential," "continues," "may," "will," "should," "could," "seeks," "predicts," "intends," "trends," "plans," "estimates," "anticipates" or the negative version of these words or other comparable words. Such forward-looking statements are based on assumptions that Biophytis considers to be reasonable. However, there can be no assurance that the statements contained

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