### UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

# FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

Date of report: July 11, 2024

Commission File Number: 001-38974

# **BIOPHYTIS S.A.**

(Translation of registrant's name into English)

Stanislas Veillet
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(Address of principal executive office)

(Address of principal executive office)		
Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:		
☑ Form 20-F □ Form 40-F		
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): □		
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): □		

On July 11, 2024, Biophytis S.A. issued a press release announcing that Biophytis obtains IND approval from the FDA to start its phase 2 OBA study in obesity. A copy of the press release is attached as Exhibit 99.1 to this Form 6-K.

## EXHIBIT LIST

Exhibit		Description
<u>99.1</u>	Press Release dated July 11, 2024.	

### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

## BIOPHYTIS S.A.

Date: July 11, 2024 By: /s/ Stanislas Veillet

Name: Stanislas Veillet

Title: Chairman and Chief Executive Officer



Press release

# Biophytis obtains IND approval from the FDA to start its phase 2 OBA study in obesity

Paris (France) and Cambridge (Massachusetts, USA), July 11, 2024 – 07:00am CET – Biophytis SA (Euronext Growth Paris: ALBPS), ("Biophytis" or the "Company"), a clinical-stage biotechnology company specialized in the development of therapeutics for age-related diseases, today announced that it has received Investigational New Drug (IND) approval from the Food and Drug Administration (FDA) for its phase 2 OBA clinical study in obesity with BIO101 (20-hydroxyecdysone).

The primary objective of the study is to measure the improvement in muscle strength in the lower limbs, as assessed by knee extension test. Secondary endpoints will include analysis of mobility (via the 6-minute walk test) and body composition (assessment of fat and lean mass). A world-renowned medical expert in the field of obesity and President-elect of the American Obesity Society, Marc-André Cornier, Professor of Medicine and Director of the Endocrinology, Diabetes and Metabolic Diseases Unit at the Medical University of South Carolina, will be the principal investigator of the phase 2 OBA study.

Professor Marc-André Cornier commented: "I am very happy that the IND for the phase 2 OBA clinical study with BI0101 (20-hydroxyecdysone) has been approved by the FDA. It is critical for us to study the safety and efficacy of new therapies designed to reduce the risk of muscle mass loss and resulting muscle weakness with functional consequences that may be associated with incretin-based therapies. Additionally we might observe further weight loss over and above that obtainable with a GLP-1 RA."

The multicenter study is due to start mid-2024 in the USA and could be extended to Europe. Preliminary results on the efficacy of BIO101 (20-hydroxyecdysone) are expected in 2025. Biophytis is seeking funding and partnerships to complete this study.

Stanislas Veillet, CEO de Biophytis, stated: "Obesity represents a major medical challenge and a significant growth opportunity for Biophytis. The obesity treatment market, estimated at \$6 billion in 2023, is expected to reach \$100 billion by 2030, with an average annual growth rate of 42%. Obtaining an IND from the FDA is a crucial step that will enable us to make rapid progress in this indication and attract new pharmaceutical partners. We are convinced that BIO101 could become a reference treatment for preserving muscle mass, strength and function in obese patients treated with GLP-1 RAs. This development has convinced our partner Blanver in Latin America, and we are convinced that it will attract new ones in other regions of the world where obesity is a major health issue."

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#### **About BIOPHYTIS**

Biophytis SA is a clinical-stage biotechnology company specializing in the development of drug candidates for age-related diseases. BIO101 (20-hydroxyecdysone), our lead drug candidate, is a small molecule in development for muscular (sarcopenia, phase 3 ready and Duchenne muscular dystrophy, phase 1-2 study to be started, respiratory (Covid-19, phase 2 completed) and metabolic diseases (obesity, phase 2 to be started). The company is based in Paris, France, and Cambridge, Massachusetts. The Company's ordinary shares are listed on Euronext Growth (Ticker: ALBPS -ISIN: FR0012816825). For more information, visit <a href="https://www.biophytis.com">www.biophytis.com</a>





#### Forward-looking statements

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 in such forward-looking statements will be verified, which are subject to various risks and uncertainties. The forward-looking statements contained in this press release are also subject to risks not yet known to Biophytis or not currently considered material by Biophytis. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. Please also refer to the "Risk and uncertainties the Company is to face» section from the Company's 2023 Financial Report available on BIOPHYTIS website (www.biophytis.com) and as exposed in the "Risk Factors" section of form 20-F as well as other forms filed with the SEC (Securities and Exchange Commission, USA). We undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as required by law.

#### **Biophytis contacts**

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