

# Forward Looking Statements

This presentation 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. These forward-looking statements include statements regarding Biophytis' anticipated timing for its various Sarconeos (BIO101) clinical trials and expectations regarding commercialization. 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 including, without limitation, delays in patient recruitment or retention, interruptions in sourcing or supply chain, its ability to obtain the necessary regulatory authorizations, COVID-19-related delays, and the impact of the current pandemic on the Company's clinical trials. The forward-looking statements contained in this presentation 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 refer to the "Risk Factors" section of the Company's 2021 Full Year Financial Report available on BIOPHYTIS website (www.biophytis.com) and to the risks discussed in the Company's registration statement on Form F-1 and other reports filed with the Securities and Exchange Commission (the "SEC"). 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.



# Today's Corporate Highlights



HQ location: Paris, France



Founded: 2006



Employees: 27 (May 30, 2022)



Euronext growth (ALBPS): July 2015



Nasdaq (BPTS): February 2021



Market cap: €9.2 M (December 30, 2022)



Cash: €19.7 M as of June 30, 2022



Key partner: Sorbonne University

## **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.
- Our **small molecules** are aimed at stimulating **biological resilience** to stress during aging.

## Sarconeos (BIO101)

- Our leading drug candidate is administered orally, for the treatment of mobility disability in elderly patients with sarcopenia, with positive results in a Phase 2 clinical study (SARA) completed in the United States and Europe.
- We have also completed **an international Phase 2-3 clinical study** for the treatment of severe respiratory manifestations in **COVID-19 (COVA)** with very encouraging results.
- A pediatric formulation of Sarconeos (BIO101) is being developed with IND granted in the US and Belgium (MYODA) for the treatment of **Duchenne Muscular Dystrophy** (DMD).



## **Executive Team**



#### **Stanislas Veillet - Founder & CEO**

- PhD in genetics, AgroParisTech
- 25+ years in biotech; Pharmacia-Monsanto, Danone Group



### Philippe Rousseau - CFO

- Nearly 15 years of experience in Finance for Pharma & Biotech companies (Genset, Therabron, Cytoo, ExonHit, Vivalis)
- Expertise in cross-border transactions and management of strategic partnerships



#### Pierre Dilda - CSO

- PhD in pharmacology (Paris V)
- 25 years experience in pharmaceutical research, in both academic and industrial settings



### Waly Dioh - COO

- PhD in phytopathology (Paris XI) and MBA
- 21+ years biotech experience in France and the U.S. and R&D at Monsanto



#### **Benoit Canolle-CBO**

- PhD in Neurosciences
   (Aix-Marseille University), execMBA
   (Kedge Business School)
- 17 years experience in Pharma R&D:
   Sanofi & Pierre Fabre

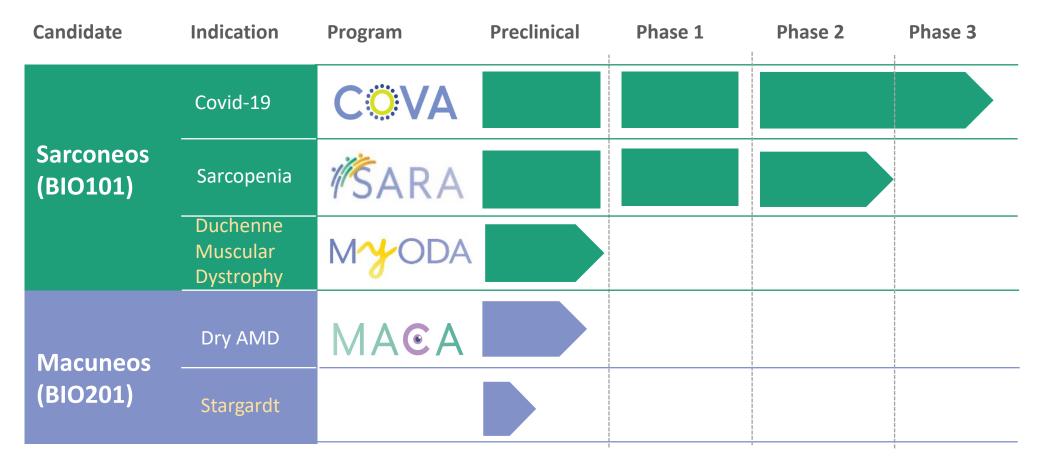


#### Rob van Maanen- CMO

- MD from the University of Ultrech-NL, MBA from UvA Amsterdam-NL
- 20 years of experience in both large pharmaceutical companies and small biotechs (Khondrion, Astellas, Roche, Novartis, Eisai and Organon)



# Our Clinical Pipeline as of today



XXX: orphan diseases

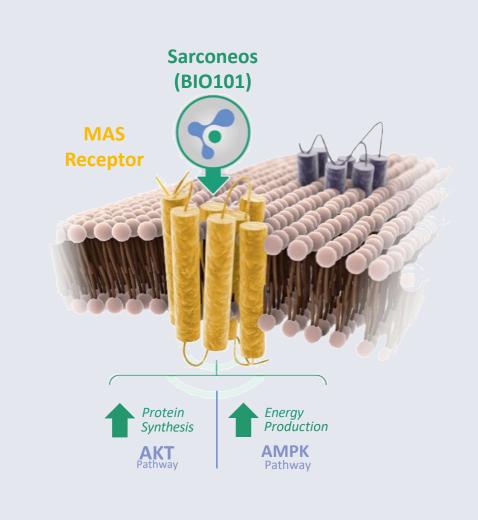


# Sarconeos (BIO101): Mechanism of Action

Sarconeos (BIO101) triggers two important MAS receptor downstream signaling-pathways in myocytes:

- PI3K/AKT/mTOR: Increases protein synthesis
- AMPK/ACC: Stimulates energy production

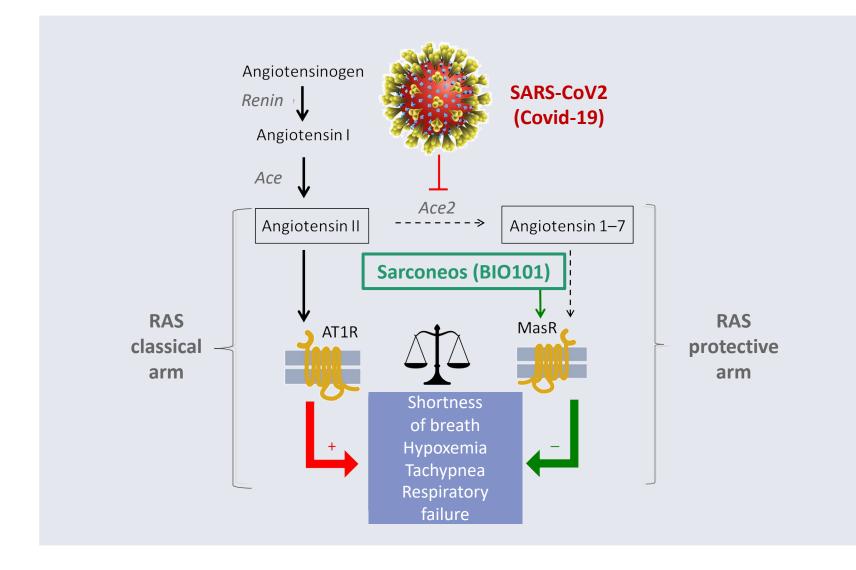
MAS activation in skeletal and smooth muscles stimulates muscle metabolism and strength with a potential impact on mobility and/or respiratory functions





# Sarconeos (BIO101) stimulates respiratory function by activating the MAS receptor, a key component in the renin-angiotensin system, the target of SARS-CoV2

- Sarconeos (BIO101) activates the MAS receptor, a key component of the protective arm of the Renin-Angiotensin System (RAS), involved in the balance of the cardiorespiratory function
- The production of Ang 1-7, the natural ligand of MAS receptor, is impaired by SARS-CoV-2, which uses ACE2 to penetrate the lungs, causing respiratory failures
- Sarconeos (BIO101) by reactivating the RAS protective arm, has the potential to restimulate respiratory capacity in COVID-19 patients







# Sarconeos (BIO101) in COVID-19





# COVA Study: Targeting COVID-19 Hospitalized Patients with Respiratory Failure



Patients **aged 45 and above**, with proven COVID-19, and severe respiratory symptoms:

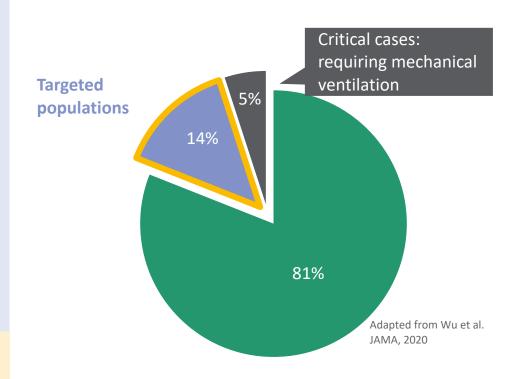
- With evidence of respiratory decompensation
   ≤7 days before start of study medication, meeting one of the following:
  - Tachypnea: ≥ 25 breaths per minute
  - Arterial oxygen saturation 92% or less

Hospitalized patients with respiratory failure estimated to 15-18% of hospitalized patients: ca **500 new patients per day or 180,000 patients/year in the USA** (*CDC data, October 27, 2022*)



#### Allowed medications:

- Antiviral agents such as remdesivir, bamlanivimab, paxlovid
- Anti-inflammatory agents such as dexamethasone



Mild cases: infection without or with mild signs of pneumonia



# International Phase 2-3 COVA clinical trial to evaluate the safety and efficacy COVA of Sarconeos (BIO101) in the treatment of severe forms of COVID-19



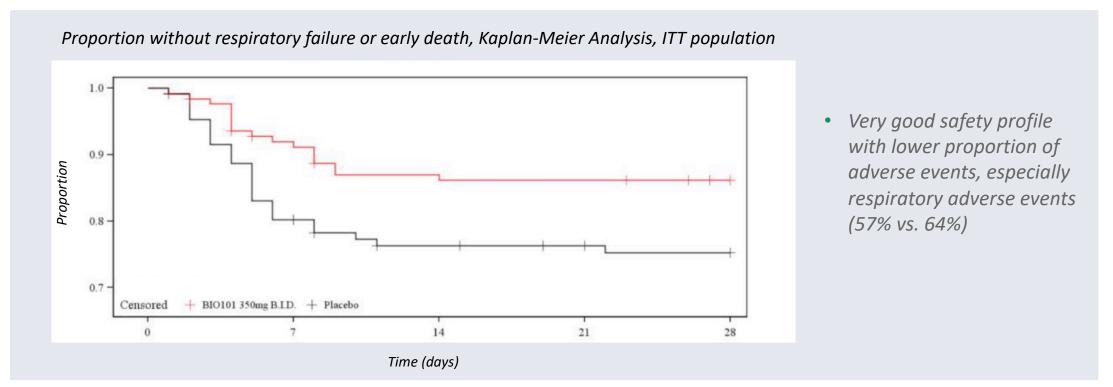
Design	Endpoints & S	tudy Follow-Up	Patient Population		
<ul> <li>Global, multi-center, double-blind, placebo-controlled group Phase 2-3 sequential (2 parts) adaptive design</li> <li>International study including 37 clinical centers in US, Brazil, France &amp; Belgium</li> </ul>	<ul> <li>Secondary endpoints: n discharge at 28 days</li> </ul>	ortion of patients with rly death within 28 days nortality at 28 and 90 days; N=237) after early study	<ul> <li>Age: 45 years old or</li> <li>Hospitalized for seven symptoms and with infection</li> <li>Patients with hypoxed tachypnea (&gt; 25 breector)</li> <li>All authorized Covid or anti-inflammatory</li> </ul>	ere respiratory proven Covid-19 emia (<92%) or aths/min) -19 drugs (anti-viral	
Product	2020	2021	2022	2023	
350 mg b.i.d of Sarconeos (BIO101)	COVA Phase 2-3		E/ (I DIGEII	LRs Commercialization H1 2023	



# Very promising results strongly supporting therapeutic potential of Sarconeos (BIO101) in COVID-19 (1/2)

#### **RESULTS ON RESPIRATORY FAILURE OR EARLY DEATH**

- Reduction in the **risk of early death or respiratory failure by 45% (p=0.037**) in the ITT population and by 53% (p=0.051) in the PP population at day 28
- Post-hoc analyses strongly strengthening the primary analysis that had shown significant differences over 28 days in the Kaplan Meier curves (p=0.034)

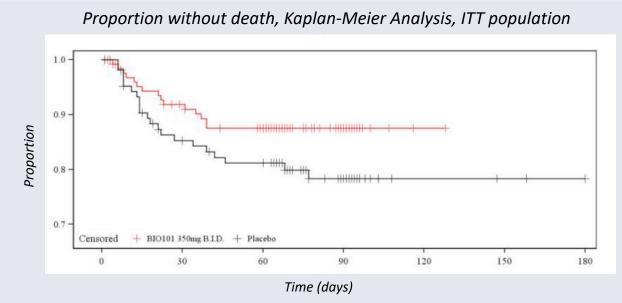




# Very promising results strongly supporting therapeutic potential of Sarconeos (BIO101) in COVID-19 (2/2)

#### **RESULTS ON MORTALITY FOLLOW-UP OVER 90 DAYS**

- Reduction in the risk of death at day 90 of 43% (p=0.076) in the ITT population and 70% (p=0.016) in the PP population
- Post-hoc analyses strengthening the trend shown in the primary analysis with similar reduction of risk of death at day 28 which was not significant
- The reduction in the risk of death at day 90 reflects the effect of Sarconeos (BIO101) on early death and respiratory
  failure during the maximum 28 days treatment period that translates efficiently and in the same proportion into a
  reduction in the risk of death later on



 Lower proportion of patients with severe adverse events compared to placebo (25% vs. 31%)





# Sarconeos (BIO101) in Sarcopenia





# SARA project: Treatment for Sarcopenia, A Large Unmet Medical Need

#### NO CURRENTLY APPROVED DRUGS

- Age-related degeneration of skeletal muscle characterized by a loss of muscle mass, strength and functional issues such as the ability to stand and/or walk
- A major cause of mobility disability, resulting in a loss of independence and increased risk of adverse events (for example falls),
   which can shorten life expectancy
- Prevalence estimated between 6-22% in the elderly (defined as over 60 years of age), a population expected to double from approximately 962 million in 2017 to 2.1 billion by 2050<sup>1</sup>

## Sarconeos (BIO101):

- ✓ First drug candidate to complete Phase 2 (SARA-INT) with clinically meaningful outcome on mobility
- ✓ On track to prepare the Phase 3 program
- ✓ Myostatin inhibitors halted for lack of effectiveness in neuromuscular diseases

<sup>1</sup>United Nations' World Population Prospects: 2017 Revision





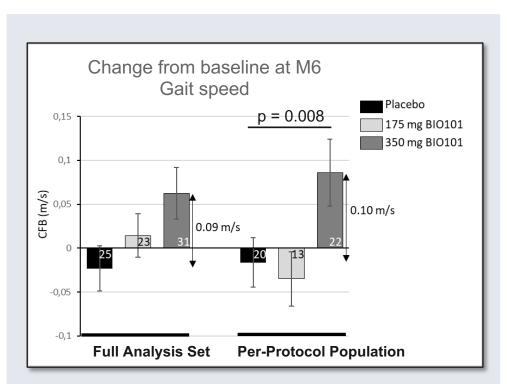
# SARA-INT: Phase 2 Trial Overview

Design		Endpoints		Patient Population	
<ul> <li>Global, double-blind, placebo-controlled to NCT03452488</li> <li>Assess safety and eff doses of Sarconeos (administered orally vover 26 weeks, as coplacebo</li> <li>Treatment effect on of physical function (and on on decrease of mobility disability</li> </ul>	rial: ficacy of two BIO101) with a meal mpared to fimprovement figait speed)	0.05 mean	meter walk test (400MWT m/s is considered the min ningful change	nimal	<ul> <li>Age: 65 years old or over</li> <li>Low mobility measured by Short Performance Physical Battery (SPPB) ≤8 out of 12</li> <li>DEXA body composition as measured by ALM/BMI (appendicular lean mass / body mass index)</li> <li>Able to exercise for 30 minutes per day 5 days per week</li> </ul>
Product	2019		2020	2	2021 2022
175 & 350 mg b.i.d of Sarconeos (BIO101)			SARA-INT Phase 2		TLRs meetings preparation Q4 2022 and FPI H1 2023



# Preparations for phase 3 have started based on the positive results of the SARA-INT phase 2 trial

# Sarconeos (BIO101) significantly improves the gait speed in the 400 MWT, the primary endpoint of SARA-INT Phase 2 trial, in the PP population after 6 months of treatment



⇒ TREATMENT EFFECT IS STATISTICALLY SIGNIFICANT IN PP POPULATION AT M6 (P = 0.008)

- Sarconeos (BIO101) at the highest dose of 350 mg bid showed a clinically meaningful improvement of 0.09 m/s in the FAS population (not significant) and of 0.10 m/s in the PP population (significant, p=0.008) compared to placebo for the 400MWT in gait speed after 6 months of treatment
- Clinical Relevance: the Minimal Clinically Important Difference (MCID) in sarcopenia (0.1 m/s) is known to be associated with a reduction in mobility disability and mortality in elderly
- Sarconeos (BIO101) showed a very good safety profile at the doses of 175 mg bid and of 350 mg bid with no Serious Adverse Events (AE) related to the product
- Based on these encouraging results, a phase 2/3 protocol is currently being discussed with the FDA and the EMA with the aim of having a first patient in for this study at the end of the first half of 2023



# SARA – Phase 3 development plan, pending FDA & EMA CTA advice and approval

Design		Endpoints		Patient Pop	ulation	
<ul> <li>Global, double-blind phase 3 placebo-con</li> <li>Assess safety and eff Sarconeos (BIO101) administered orally of 52 weeks, as companied to the companient of the rist disability</li> </ul>	ficacy 350 mg BID over at least red to placebo	<ul> <li>Primary</li> <li>Major Mobility Disability (MMD)     assessed by the inability to     complete the 400 meter walk test     (400MWT) within 15 min</li> <li>Secondary</li> <li>Handgrip Strength (HGS)</li> <li>Patient Reported Outcomes (PRO)</li> </ul>		<ul> <li>Age: 65 years old of the control of t</li></ul>	sured by Short ical Battery ngth (HGS < 20 ale and male)	
Product	2023		2024		2025	2026
350 mg b.i.d of Sarconeos (BIO101)	SARA Phase 3 (partnership)  Filing for Marketing Authorization					





# Sarconeos (BIO101) in DMD





# MYODA: Treatment Overview for Duchenne Muscular Dystrophy (DMD)



Rare, genetic neuromuscular disease in male children characterized by accelerated degeneration of muscles, responsible for loss of mobility, respiratory failure and cardiomyopathy, leading to premature death.

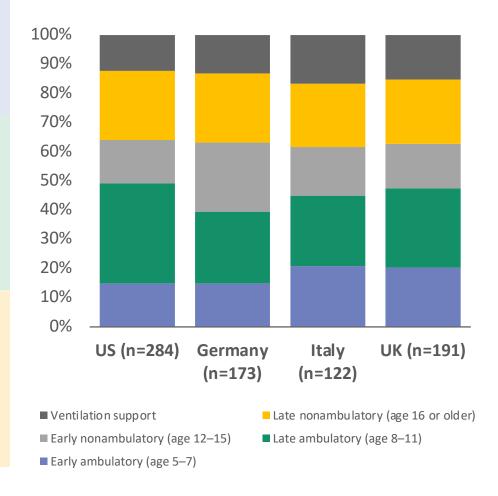


No known cure and limited treatment options, including corticosteroids and targeted therapies (exon-skipping in U.S. & stop codon in EU) that treat approximately 13% of DMD patients with specific genetic mutations.



We received **orphan drug designation (ODD)** in 2018 from the FDA and EMA for Sarconeos (BIO101) in DMD.

## Proportion of ambulatory class in DMD<sup>1</sup>







# MYODA: Overview of Clinical Trial Aimed to Start H1 2023\*

FDA IND in the USA and CTA in Belgium in 2020

Design		Endpoints	Patient Population		
<ul> <li>A Randomized, Double-Bl Phase 1-2 Study</li> <li>Evaluate the Safety, Efficace Pharmacokinetics, and Phase Sarconeos (BIO101) in Nor Patients with Respiratory I</li> <li>Pedriatric oral formulation Sarconeos (BIO101)</li> </ul>	cy, armacodynamics of n-Ambulatory DMD Deterioration.	<ul> <li>Primary: change from baseline on Peak Expiratory Flow (PEF)</li> <li>Secondary: The Forced Vital Capacity (FVC), Performance of Upper Limbs (PUL) scale, Grip strength (MyoGrip)</li> <li>Part 1 (N=18): Safety, tolerability &amp; PK - 7 days of dosing of escalating dose</li> <li>Part 2 (N=48): Safety and efficacy on respiratory function (PEF) after dosing for 52 weeks</li> </ul>	<ul> <li>Age: ≥12 years old</li> <li>Non-ambulatory DMD patients</li> <li>Patients at risk of respiratory failure</li> </ul>		
Product	2020	2021	2022	2023	
Sarconeos (BIO101)	ODD in the USA a	MYODA			

<sup>1.</sup>Independent Data Safety Monitoring Board

<sup>\*</sup>Study should start beginning of 2023, depending on the evolution of the pandemic



Phases 1-2

# Key milestones in the development of Sarconeos (BIO101)

	Achieved over the last months	Anticipated in the next 12 months
COVA	<ul> <li>Interim analysis for Part 2 (155 patients) in Q3 2021</li> <li>Early Access Program (EAP) authorization in Brazil in February 2022</li> <li>Early termination of patient enrolment in April 2022</li> <li>Very promising results in November 2022</li> </ul>	<ul> <li>Expand EAP in France and other territories</li> <li>Application for conditional marketing authorisation in Europe and Emergency Use Authorisation (EUA) in the US and Brazil</li> </ul>
SARA	<ul> <li>Positive topline study results in August 2021</li> <li>Full study results communicated during ICFSR in September 2021</li> </ul>	<ul> <li>Regulatory agency meetings (FDA, EMA)</li> <li>Start of Phase 3 study with 1st patient enrolled</li> </ul>
MYODA	<ul> <li>US and Belgian IND regulatory approvals in Q1 2020</li> <li>Clinical batch production in 2021</li> </ul>	Study to start in 2023



# Scientific Advisory Board



#### Pr. Jean Mariani

- Professor of neuroscience and biology of aging and Director of Charles Foix Institute of Longevity at Sorbonne University
- Emeritus Professor (PU-PH) at the Sorbonne University's School of Medicine



#### **Dr. Roger Fielding**

- Professor of Medicine, Tufts University School of Medicine
- Director and Sr. Scientist Jean Mayer USDA Human Nutrition Research Center on Aging



#### René Lafont

- Co-Founder & Professor emeritus and former Dean of the life sciences department at Sorbonne University
- 185 scientific articles + 59 reviews and book chapters



#### **Dr. Thomas Voit**

- Professor, University College London
- Director of the Research Centre of the Great Ormond Street Hospital for Children



#### Pr. Jose-Alain Sahel

- Chair of the department of ophthalmology at University of Pittsburgh School of Medicine and director of the UPMC eye center
- Founder and director of the Vision Institute in Paris and professor at the Sorbonne's medical school



#### Dr. Ivana Kim

- Associate Professor Harvard Medical School, Massachusetts Eye and Ear
- Co-Director of the Harvard Medical School
   Department of Ophthalmology AMD Center of Excellence; Associate Scientist, Massachusetts
   Eye and Ear



## Financial data

Key financial figures Listing Euronext- ALBPS : July 2015

Listing Nasdaq (ADRs) - BPTS: February 2021

Cash position : €19.7m (June 30, 2022)

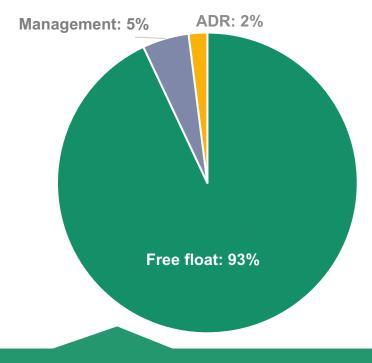
Market cap : €9.2m (Dec. 30, 2022)

Amount raised to date: ca €150m

# Analyst Coverage

- H.C. Wainwright Joe Pantginis, Ph.D.
- Kepler Chevreux Arséne Guekam
- Invest Securities Jamila ELBougrini, Ph.D.

## Shareholding structure



Number of shares: 203,965,750 (October 31st, 2022) 1 ADR = 10 shares





# **THANK YOU**

#### **Contacts:**

Stanislas Veillet – CEO <a href="mailto:stanislas.veillet@biophytis.com">stanislas.veillet@biophytis.com</a>

Philippe Rousseau – CFO <a href="mailto:philippe.rousseau@biophytis.com">philippe.rousseau@biophytis.com</a>

Benoît Canolle –CBO benoit.canolle@biophytis.com

Investor relations: investors@biophytis.com

www.biophytis.com

