



November 2023 | Euronext: ALBPS – Nasdaq: BPTS

## 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](http://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: 25



Euronext growth (ALBPS) : July 2015



Nasdaq (BPTS): February 2021



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) - in regulatory and clinical phases

- Our leading drug candidate is administered orally:
  - for the treatment of severe respiratory events related to **COVID-19** following **positive results in Phase 2/3 clinical study (COVA)**
  - for the treatment of reduced mobility in elderly patients with **sarcopenia**, with **promising results** in a **Phase 2 clinical study (SARA)** conducted in the United States and Europe
- 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



**Edouard Bieth – CBO**

- Over 18 years' experience in the pharmaceutical industry (Tillotts Pharma, AstraZeneca, Servier, Menarin)
- Master's degree in biology and pharmacology of ageing, training in sales and marketing strategy



**Nicolas Fellmann – CFO**

- Over 25 years' experience in finance (Onxeo, BioAlliance Pharma, Pfizer) after several years as an auditor at E&Y
- Expertise in fund raising, mergers & acquisitions and managing strategic partnerships in Europe, the US and Asia



**Pierre Dilda – CSO**

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



**Waly Diah – COO**

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



**Chiara Baccelli – Director of Pharma Operations & Quality Assurance**

- PharmD from Pisa University, PhD in Pharma and Biomedical Sciences from the CU of Leuven and MBA in Innovation and Strategy from IRIIG in Lyon
- 20+ years' experience in the development and production of pharma products, at UCB, Delpharm and Bioprojet













**Rob van Maanen – CMO**

- MD from the University of Utrecht-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

Candidate	Indication	Program	Preclinical	Phase 1	Phase 2	Phase 3	Regulatory	Market
Sarconeos (BIO101)	Covid-19	COVA						
	Sarcopenia	SARA						
	Duchenne Muscular Dystrophy	MyODA						
Macuneos (BIO201)	Dry AMD	MACA						
	Stargardt							

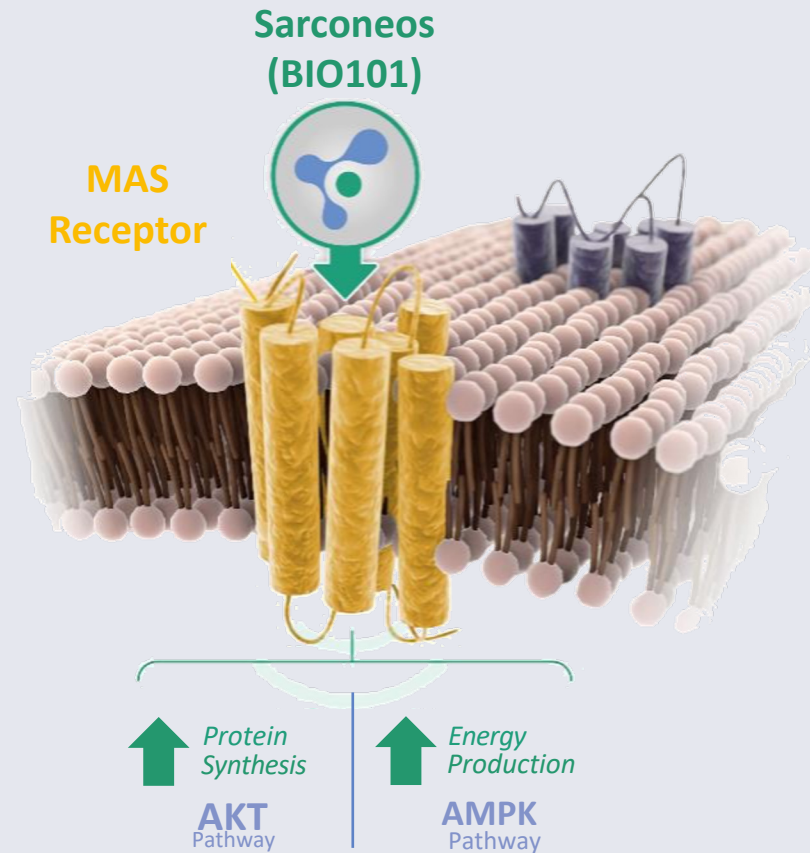
XXX : orphan diseases

## Sarconeos (BIO101): Mechanism of Action

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

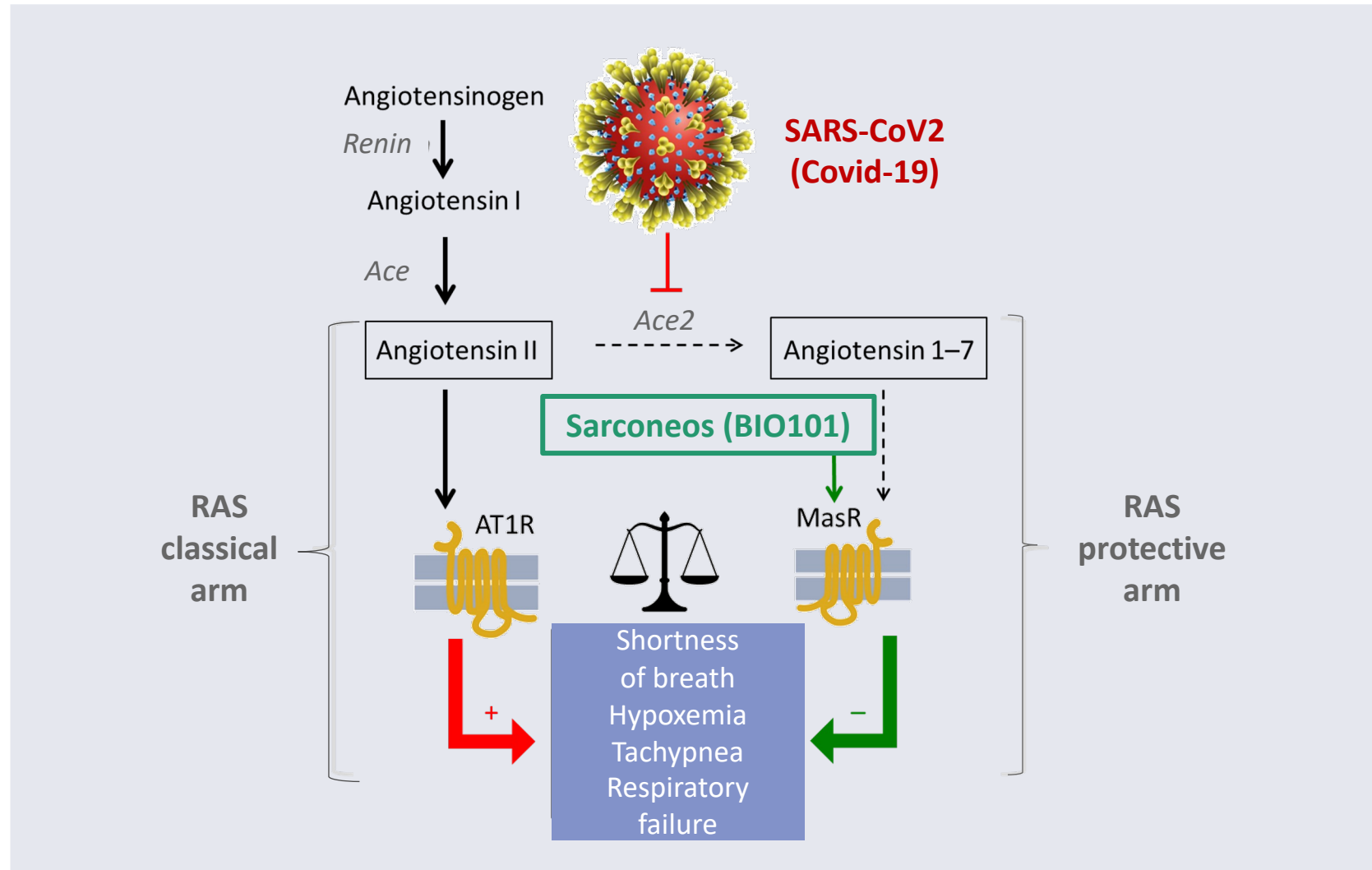
- **PI3K/AKT/mTOR:** Increases protein synthesis
- **AMPK/ACC:** Stimulates energy production

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

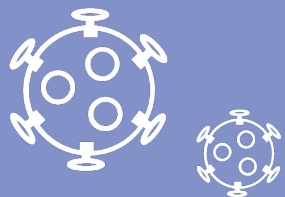




# Sarconeos (BIO101) in COVID-19



# COVA Study: Targeting COVID-19 Hospitalized Patients with severe COVID-19



## 45+



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

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

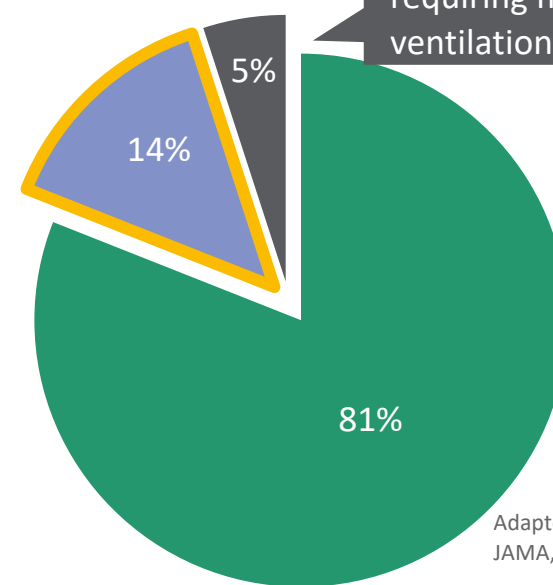
Hospitalized patients with respiratory failure estimated to 15-18% of hospitalized patients: ca **500 new patients per day or 180,000 patients/year in the USA** (CDC data, October 27, 2022)



### Allowed medications:

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

**Severe cases:**  
**hospitalized with hypoxemia,**  
**tachypnea or pneumonia**



Critical cases: ICU  
requiring mechanical  
ventilation

Adapted from Wu et al.  
JAMA, 2020

Mild cases:  
infection without or with mild signs of pneumonia

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



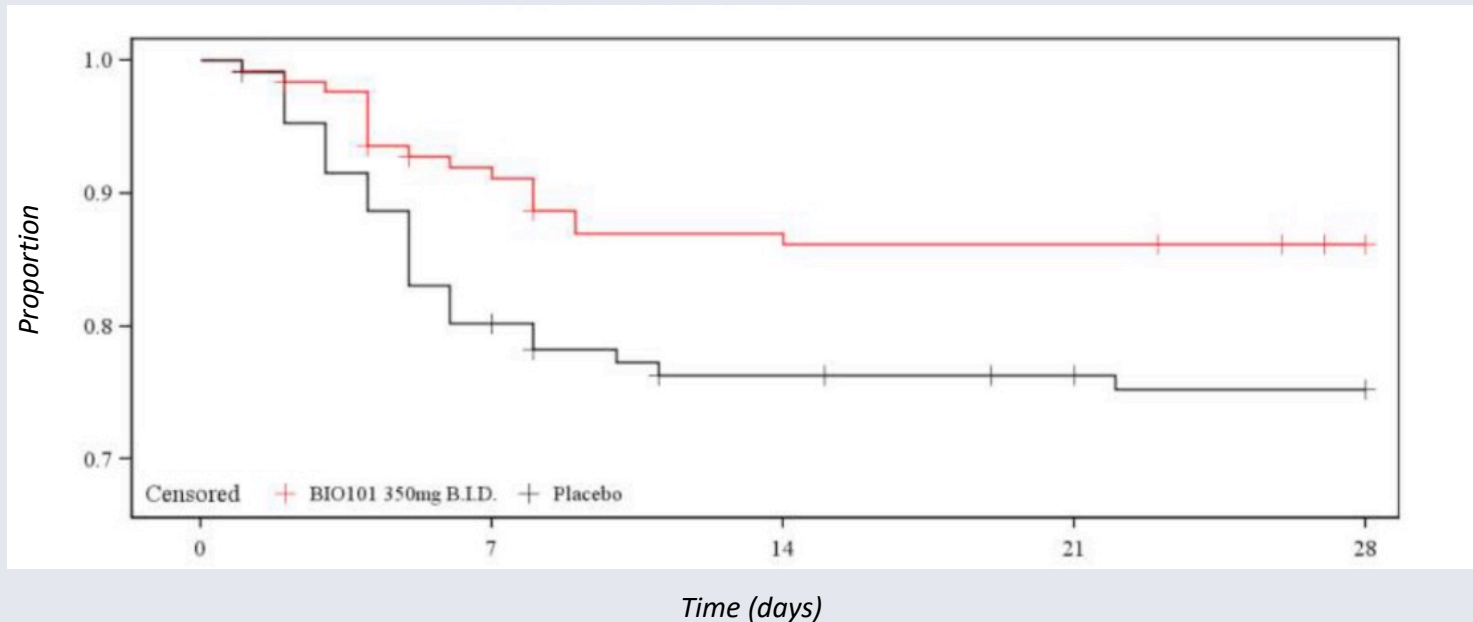
Design	Endpoints & Study Follow-Up		Patient Population		
<ul style="list-style-type: none"> <li>Global, multi-center, double-blind, placebo-controlled group Phase 2-3 sequential (2 parts) adaptive design</li> <li>International study including 37 clinical centers in US, Brazil, France &amp; Belgium</li> </ul>	<ul style="list-style-type: none"> <li>Primary endpoint: proportion of patients with respiratory failure or early death within 28 days</li> <li>Secondary endpoints: mortality at 28 and 90 days; discharge at 28 days</li> <li>End of study: Q2 2022 (N=237) after early study termination</li> </ul>		<ul style="list-style-type: none"> <li>Age: 45 years old or over</li> <li>Hospitalized for severe respiratory symptoms and with proven Covid-19 infection</li> <li>Patients with hypoxemia (&lt;92%) or tachypnea (&gt; 25 breaths/min)</li> <li>All authorized Covid-19 drugs (anti-viral or anti-inflammatory)</li> </ul>		
Product	2020	2021	2022	2023	
350 mg b.i.d of Sarconeos (BIO101)	COVA Phase 2-3		★ EAP Brazil	★ Final results	★ EAP France (pending)

# Positive results strongly supporting therapeutic potential of Sarconeos (BIO101) in severe COVID-19: respiratory failure or early death

## RESPIRATORY FAILURE OR EARLY DEATH : THE STUDY MET PRIMARY ENDPOINT

- Reduction in the risk of early death or respiratory failure at day 28 by 44% ( $p=0.043$ , CMH test)
- Time to early death or respiratory failure over 28 days was lower ( $p=0.022$ , Kaplan Meier analysis)
- Post hoc analysis confirmed the reduction in the **risk of early death or respiratory failure** in the ITT population and in the PP population

*Proportion without respiratory failure or early death, Kaplan-Meier Analysis, ITT population*

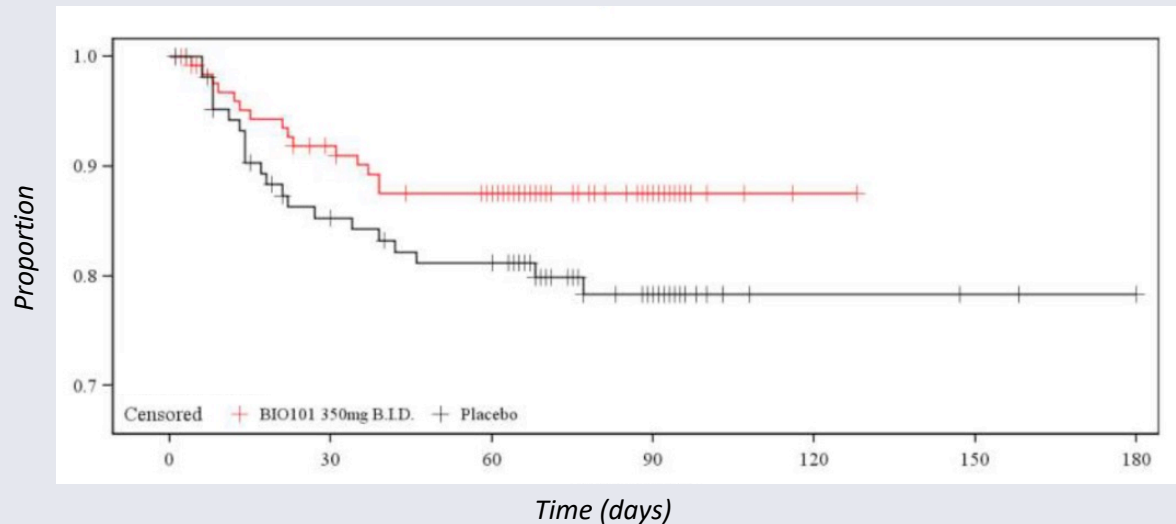


# Positive results strongly supporting therapeutic potential of Sarconeos (BIO101) in sever COVID-19: mortality and safety

## MORTALITY FOLLOW-UP OVER 90 DAYS AND SAFETY

- Kaplan Meier post hoc analysis showed a **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

*Proportion without death, Kaplan-Meier Analysis, ITT population*



- Very good safety profile with lower proportion of adverse events, especially respiratory adverse events (57% vs. 64%)*
- Lower proportion of patients with severe adverse events compared to placebo (25% vs. 31%)*

# Biophytis initiates market access processes for Sarconeos (BIO101) treatment of severe forms of COVID-19



## Early access

- EAP in France: application for early access will be re-submitted in Q1 2024
- EAP in Brazil: EAP program authorized in 2022 by ANVISA, put on hold at the end of the phase 2-3 COVA study. Application to lift the hold to be filed in H2 2023

## Market access

- Preparation of the conditional marketing authorization application in Europe and in the United States
- Following pre-submission meeting requests with the EMA and the FDA, scientific advice will be requested in Q4 2023



# 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

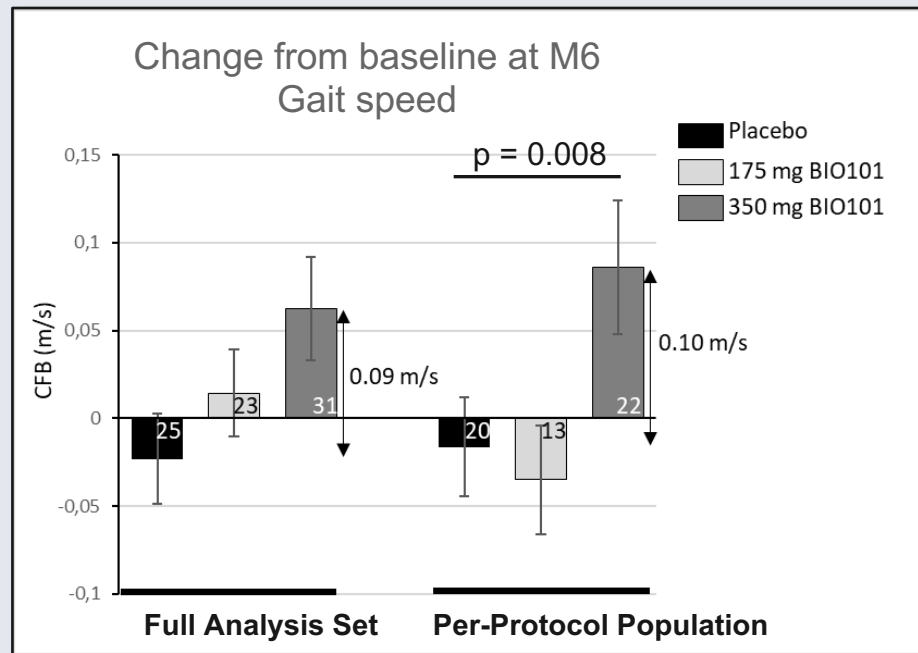
<sup>1</sup>United Nations' World Population Prospects: 2017 Revision

## SARA-INT: Phase 2 trial overview

Design	Endpoints	Patient Population
<ul style="list-style-type: none"> <li>Global, double-blind, randomized, placebo-controlled trial: NCT03452488</li> <li>Assess safety and efficacy of two doses of Sarconeos (BIO101) administered orally with a meal over 26 weeks, as compared to placebo</li> <li>Treatment effect on improvement of physical function (gait speed) and on decrease of risk of mobility disability</li> </ul>	<p><b>Primary</b></p> <ul style="list-style-type: none"> <li>400-meter walk test (400MWT) - 0.05 m/s is considered the minimal meaningful change</li> </ul> <p><b>Secondary</b></p> <ul style="list-style-type: none"> <li>Handgrip muscle strength</li> <li>Patient reported outcomes (PRO)</li> </ul>	<ul style="list-style-type: none"> <li>Age: 65 years old or over</li> <li>Low mobility measured by Short Performance Physical Battery (SPPB) <math>\leq 8</math> 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>

## Positive results obtained in 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)

- Global, double-blind, randomized, placebo-controlled trial in patients with aged-related sarcopenia at risk of mobility disability to evaluate safety and efficacy of Sarconeos (BIO101)
- At the highest dose of 350 mg bid: clinically meaningful improvement 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
- This level 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

## SARA-31 – Phase 3 development plan

Design	Endpoints		Patient Population	
<ul style="list-style-type: none"><li>Global, double-blind, randomized, phase 3 placebo-controlled trial</li><li>Assess safety and efficacy Sarconeos (BIO101) 350 mg BID administered orally over at least 52 weeks, as compared to placebo</li><li>Treatment effect based on estimation of the risk of mobility disability</li></ul>	<p><b>Primary</b></p> <ul style="list-style-type: none"><li>Major Mobility Disability (MMD) assessed by the inability to complete the 400 meter walk test (400MWT) within 15 min</li></ul> <p><b>Secondary</b></p> <ul style="list-style-type: none"><li>Handgrip Strength (HGS)</li><li>Patient Reported Outcomes (PRO)</li></ul>	<ul style="list-style-type: none"><li>Age: 65 years old or over</li><li>Low mobility measured by Short Performance Physical Battery (SPPB) <math>\leq 7</math></li><li>Low Handgrip Strength (HGS <math>&lt; 20</math> and <math>&lt; 35</math> kg in female and male)</li><li>Slow walkers (gait speed <math>&lt; 0.8</math> m/s)</li></ul>		

Product	2023	2024	2025	2026
350 mg b.i.d of Sarconeos (BIO101)	 CTA in Europe/US	SARA-31 Phase 3 (depending on partnership)		



# Sarconeos (BIO101) in DMD

# 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.

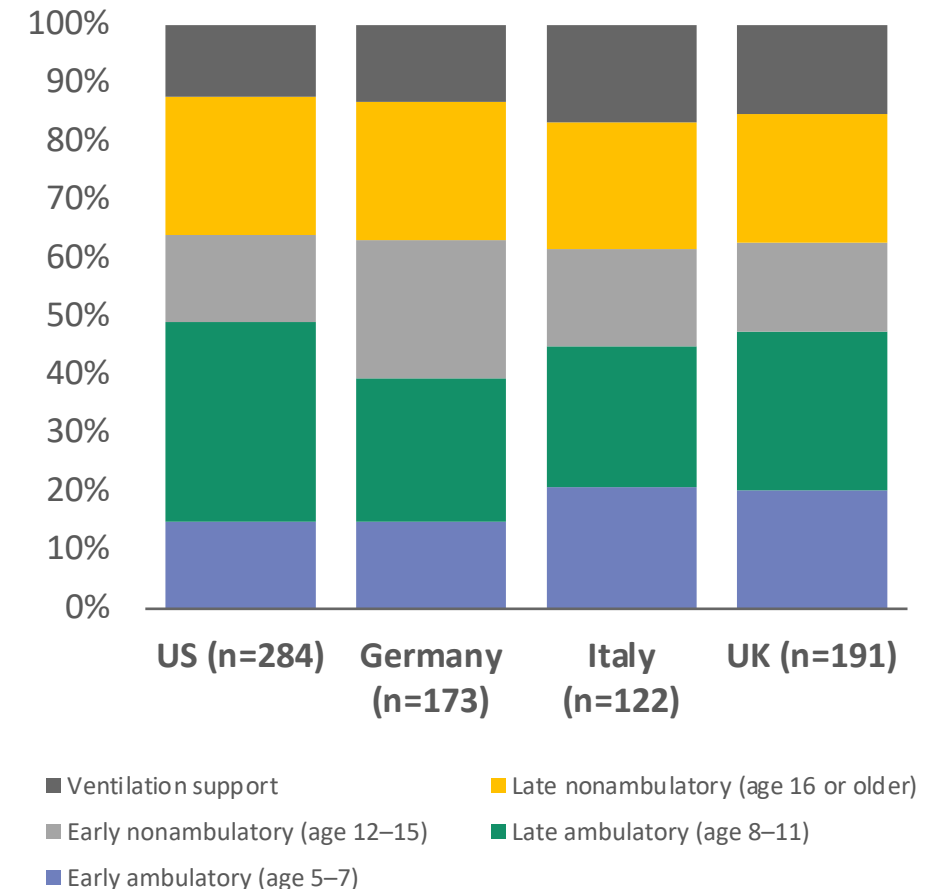


No known cure and limited treatment options, including corticosteroids and targeted therapies (exon-skipping in U.S. & stop codon in EU) that treat approximately 13% of DMD patients with specific genetic mutations.



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>





## Preparing to start phase 1-2 clinical study in DMD

Design	Endpoints		Patient Population	
<ul style="list-style-type: none"><li>A Randomized, Double-Blind, multi-center Phases 1-2 Study</li><li>Evaluate the Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Sarconeos (BIO101) in Non-Ambulatory DMD Patients with Respiratory Deterioration.</li><li>Pediatric oral formulation (powder sachet) of Sarconeos(BIO101)</li></ul>	<ul style="list-style-type: none"><li><b>Primary:</b> change from baseline on Peak Expiratory Flow (PEF)</li><li><b>Secondary:</b> The Forced Vital Capacity (FVC), Performance of Upper Limbs (PUL) scale, Grip strength (MyoGrip)</li><li>Part 1 (N=15): Safety, tolerability &amp; PK - 7 days of dosing of escalating dose</li><li>Part 2 (N=45): Safety and efficacy on respiratory function (PEF) of one dose during 48 weeks</li></ul>		<ul style="list-style-type: none"><li>Age: ≥12 years old</li><li>Non-ambulatory DMD patients</li><li>Patients at risk of respiratory failure</li></ul>	
Product	2023	2024	2025	2026
Sarconeos (BIO101)	★ Amendment to CTA approval		Phases 1-2 study	

## Key milestones in the development of Sarconeos (BIO101)

### *Achieved in the last 12 months*

### *Anticipated in the next 12 months*

<b>COVA</b>	<ul style="list-style-type: none"><li>• Positive results of phase 2-3 COVA study</li></ul>	<ul style="list-style-type: none"><li>• Launch of Early Access programs in France and Brazil</li><li>• Application for conditional marketing authorisation in Europe and in the US</li></ul>
<b>SARA</b>	<ul style="list-style-type: none"><li>• Authorisation to start phase 3 SARA-31 study in Belgium and the US</li></ul>	<ul style="list-style-type: none"><li>• Start of phase 3 SARA-31 study depending on financial resources and partnership</li></ul>
<b>MYODA</b>	<ul style="list-style-type: none"><li>• Preparation of an amended protocol to regulatory agencies (FDA, EMA)</li></ul>	<ul style="list-style-type: none"><li>• Submission of an amended protocol to regulatory agencies (FDA, EMA)</li><li>• Start of phases 1/2 study</li></ul>

## 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



**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



**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. Roger Fielding**

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



**Dr. Thomas Voit**

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



**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

### Key financial figures

Listing Euronext (ALBPS) and Nasdaq (BPTS)

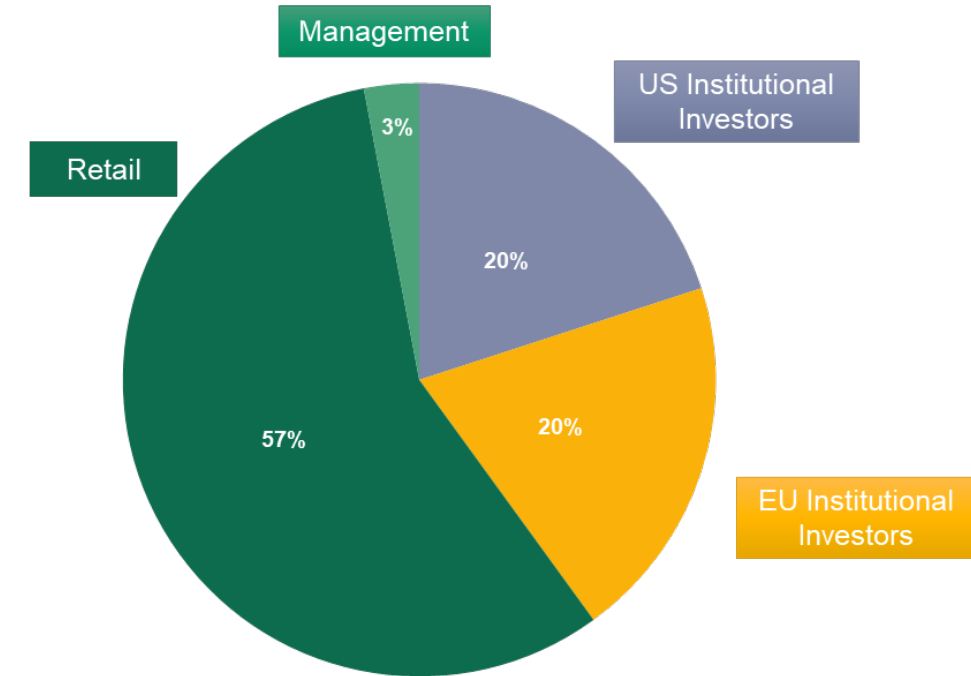
Cash position:

- €5.8m (June 30, 2023)
- €5.1m raised and €2m in convertible bonds drawn down in 2023
- Ongoing fundraising for a minimum guaranteed amount of €2m

### Analyst Coverage

- H.C. Wainwright – *Joe Pantginis, Ph.D.*
- Kepler Cheuvreux – *Nicolas Pauillac*
- Invest Securities – *Jamila El Bougrini, Ph.D.*

## Shareholding structure



Number of shares: 749,276,280 (September 31, 2023)  
1 ADR = 100 shares





# THANK YOU

## Contacts:

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