



Biophytis[®]

LIVE HEALTHIER LONGER



January 2021 | Euronext, EPA: ALBPS

Forward Looking Statements

All statements pertaining to future financial and/or operating results, future growth in research, clinical development, and potential opportunities for Biophytis SA and its subsidiaries (the “Company”) and its products, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management constitute forward-looking statements.

Any statements that are not historical fact (including, but not limited to, statements that contain words such as “will,” “believes,” “plans,” “anticipates,” “expects,” “estimates”) should also be considered to be forward-looking statements.

By their nature, forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development or commercialization of potential products, uncertainty in the results of clinical trials or regulatory approvals, need and ability to obtain future capital, and other risks, 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 Euronext Growth of Euronext Paris filed with the AMF, which is available on the AMF website (www.amf-france.org) or on the Company’s website (www.biophytis.com).

Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect the Company's business. Any forward-looking statements that we make in this presentation speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this presentation, except as required by law.

A clinical-stage biotechnology company specialized in age-related diseases



Our goal

Prevent disabilities (muscular, respiratory and vision) and increase **health span** for patients suffering from **age-related diseases**

Our **small molecules** stimulate **biological resilience** and are developed by **reverse pharmacology** from **plant secondary metabolites**



COVID-19 & Neuromuscular diseases

Drug candidate **Sarconeos (BIO101)** in clinical development for :

COVID-19 Phase 2/3
Respiratory Failure resulting from SARS-CoV2 infection

Sarcopenia: Clinical Phase 2
A geriatric chronic muscular dystrophy

Duchenne's Muscular Dystrophy (DMD): IND granted
A pediatric genetic muscular dystrophy



Retinal diseases

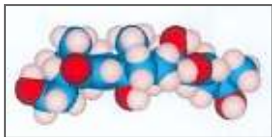
Pre-clinical drug candidate **Macuneos (BIO201)** for diseases of the retina, such as dry **Age-related Macular Degeneration (AMD)** and Stargardt's disease

Modern drug discovery process, inspired by traditional medicine

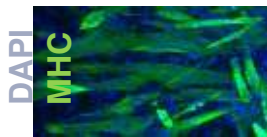
Our technology

Reverse pharmacology for drug candidates in Age Related diseases

Build a proprietary collection of natural molecules & analogs from medicinal plant, produced under biotic or abiotic stress



Screen in cellular models of age related diseases and identification of targets & pathways



Selection of best drug candidates based on animal models of aging or genetic diseases



- Sarconeos (BIO 101)
- Macuneos (BIO201)

- Small molecules: natural and/or NCE (new chemical entity)
- New key target against aging
- Preclinical proof-of-concept & safety
- IP on use, process and composition of matter

Executive team

MONSANTO



Bristol-Myers Squibb



MetaStat



Shire



Stanislas Veillet - Founder & CEO

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



Samuel Agus - CMO

- MD, PhD, Board-certified Neurologist
- 15+ years pharma/biotech experience including Abbott, Shire and Teva Pharmaceuticals



Pierre Dilda - CSO

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



Waly Diah - COO

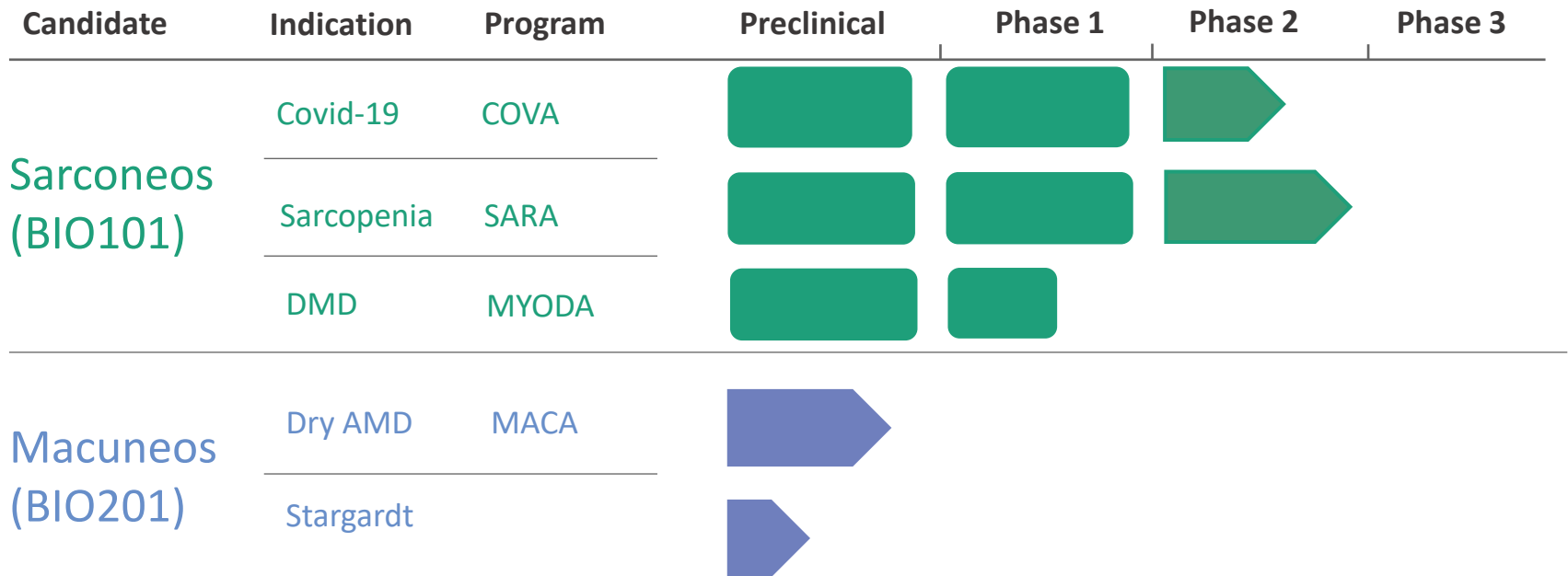
- PhD in phytopathology (Paris XI) and MBA
- 21+ years biotech experience in France and the U.S. and R&D at Monsanto



Evelyne Nguyen- CFO

- 25+ years of experience in Corporate Finance for International Pharma & Biotech companies (BMS, LFB)
- Expertise in cross-borders transactions between Europe, US and Asia

Our clinical pipeline for worldwide development



- Second generation drug candidates, BIO103 and BIO203, are life-cycle extension candidates in the preclinical Phase

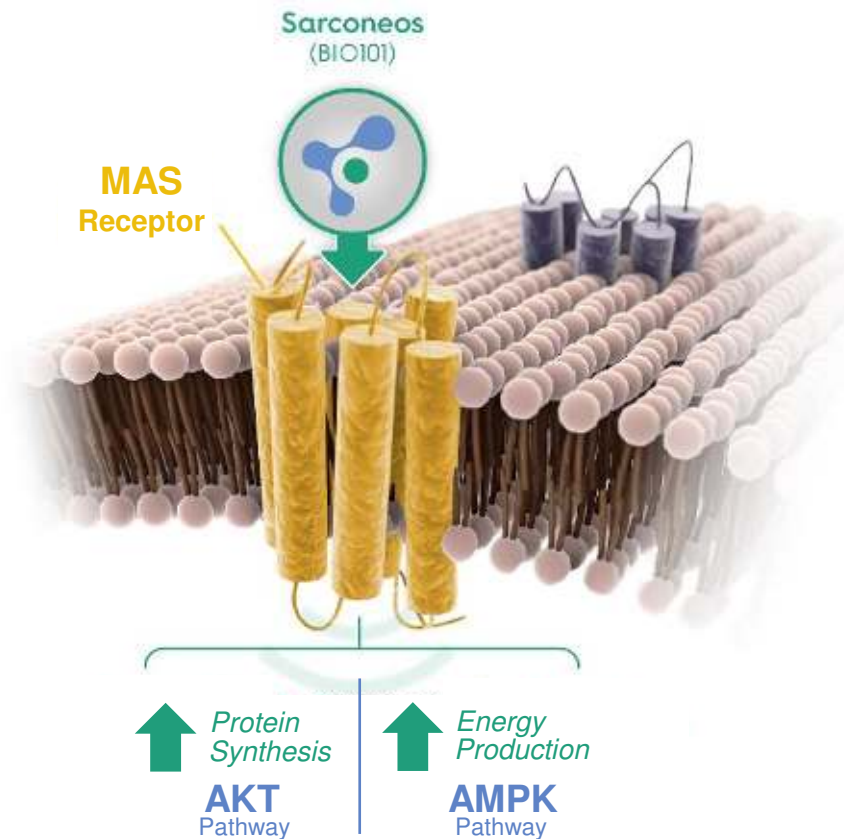


Key milestones

- ✓ COVA (Phase 2/3) started in the Belgium, Brazil, France and US
- ☐ COVA completion of patient enrollment (Part 1) expected in January 2021
- ☐ COVA interim analysis expected in Q1 2021
- ☐ COVA completion of patient enrollment (Part 2) expected in Q1 2021
- ☐ COVA topline results and EUA filing (in US and EU) expected in Q2 2021
- ✓ SARA-INT (Phase2) patient enrollment completed in March 2020
- ✓ SARA-INT last patient out (LPO) completed in Dec 2020
- ☐ SARA-INT topline trial results expected in Q2 2021
- ✓ MYODA (Phase 1 to 3) IND approved in Belgium and US
- ☐ MYODA FPI expected in H1 2021 depending on COVID-19 pandemic evolution

Sarconeos (BIO101) activates MAS receptor, a key factor for muscle and respiratory functions

- MAS receptor: a key component of the Renin-Angiotensin System (RAS)
- Trigger two important downstream pathways in myocytes:

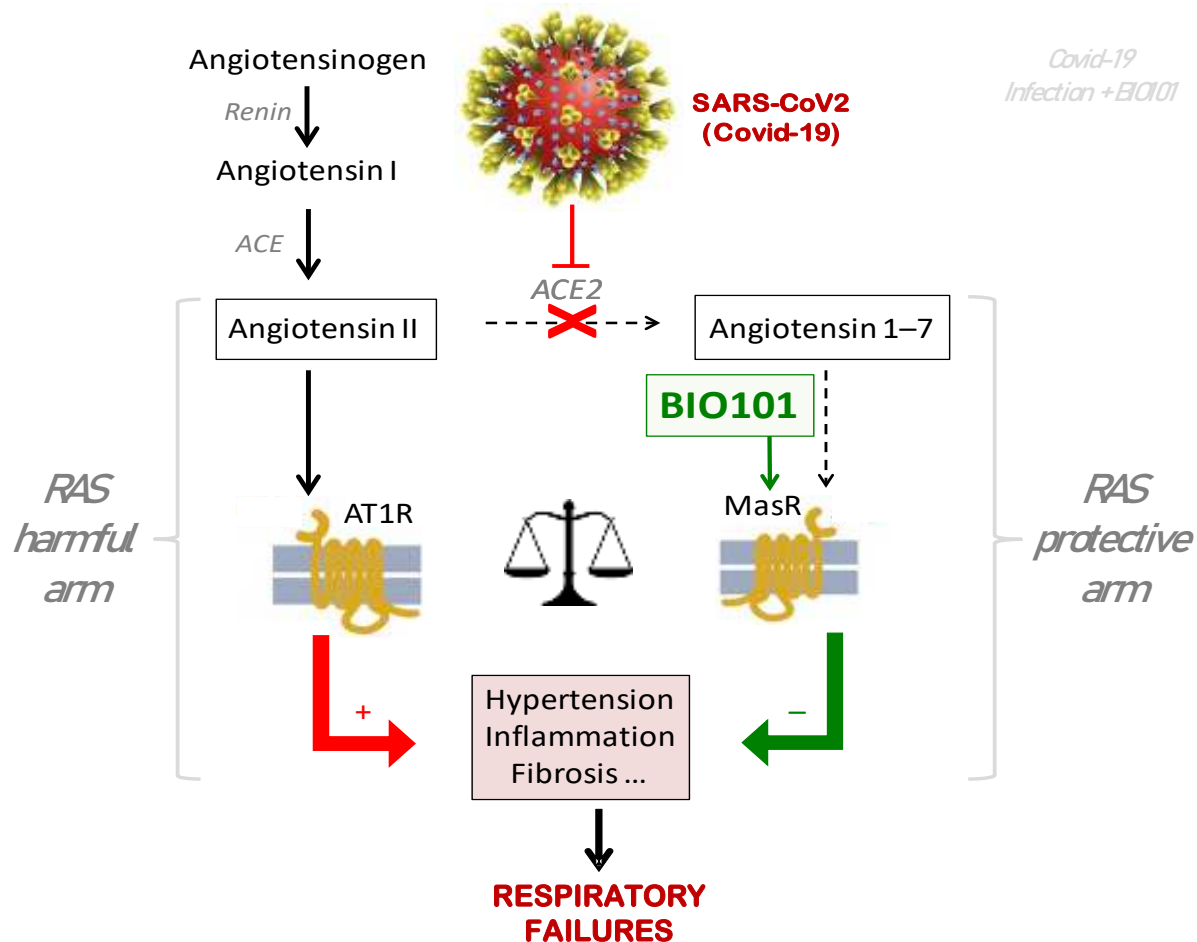


PI3K/AKT/mTOR: Increases **protein synthesis**, preserving muscle mass and increasing **muscle strength**

AMPK/ACC Stimulates **energy production**, increasing muscle strength and **mobility**

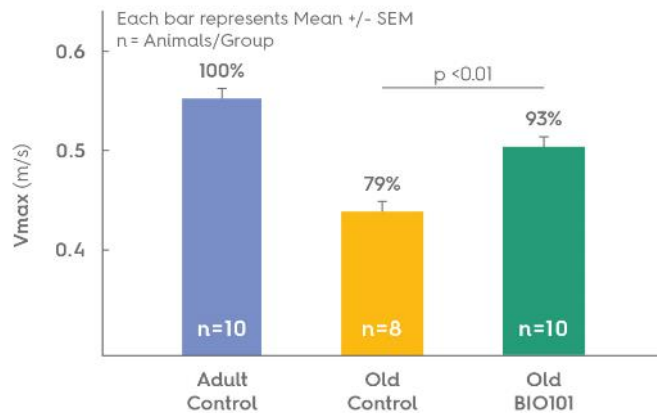
Sarconeos (BIO101) for respiratory failure in COVID-19

- SARS-CoV-2 uses ACE2 to penetrate into the lungs destabilizing RAS system and causing respiratory failures
- Sarconeos (BIO101) activates MAS receptor, a key component of the protective arm of the RAS system, and re stimulates respiratory function



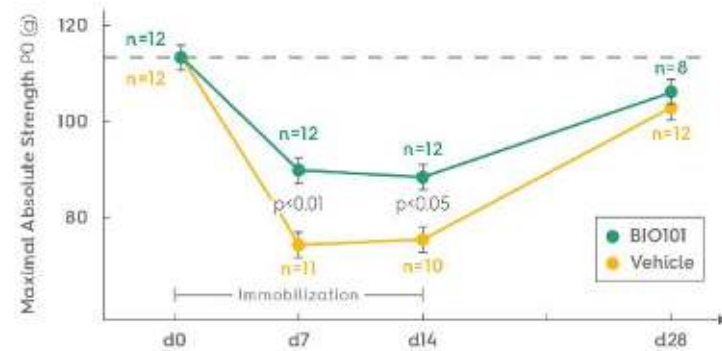
Sarconeos (BIO101) improves muscle strength and mobility in animal model

Beneficial effect on mobility in aged mice fed with high fat diet¹



Administration of 50 mg/kg/day of Sarconeos (BIO101) demonstrated a statistically significant ($p < 0.01$) improvement in maximum running velocity (Vmax) compared to “old” control mice, compensating almost completely for the loss of mobility due to aging

Preservation of muscle strength in immobilized mice

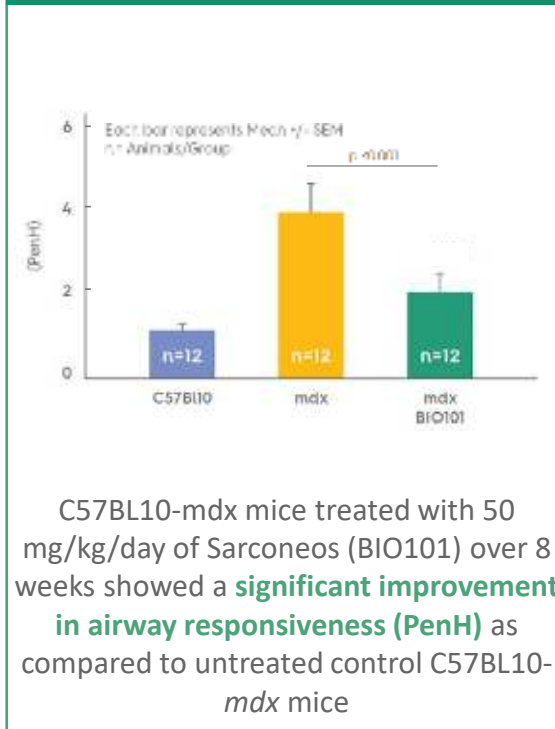


Administration of 50 mg/kg/day of Sarconeos (BIO101) demonstrated a preservation of muscle strength while immobilized (d0-d14) compared to vehicle control in hindlimb-immobilized mice

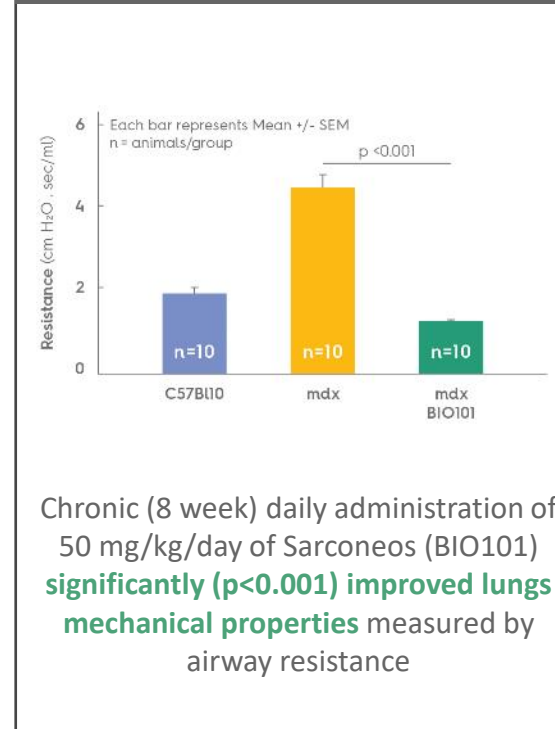
1. Results were presented in a poster at the SCWD conference in December 2016 in Berlin, Germany.

Sarconeos (BIO101) improves respiratory functions in animal model

Improves the time-dependent degradation of respiratory function¹

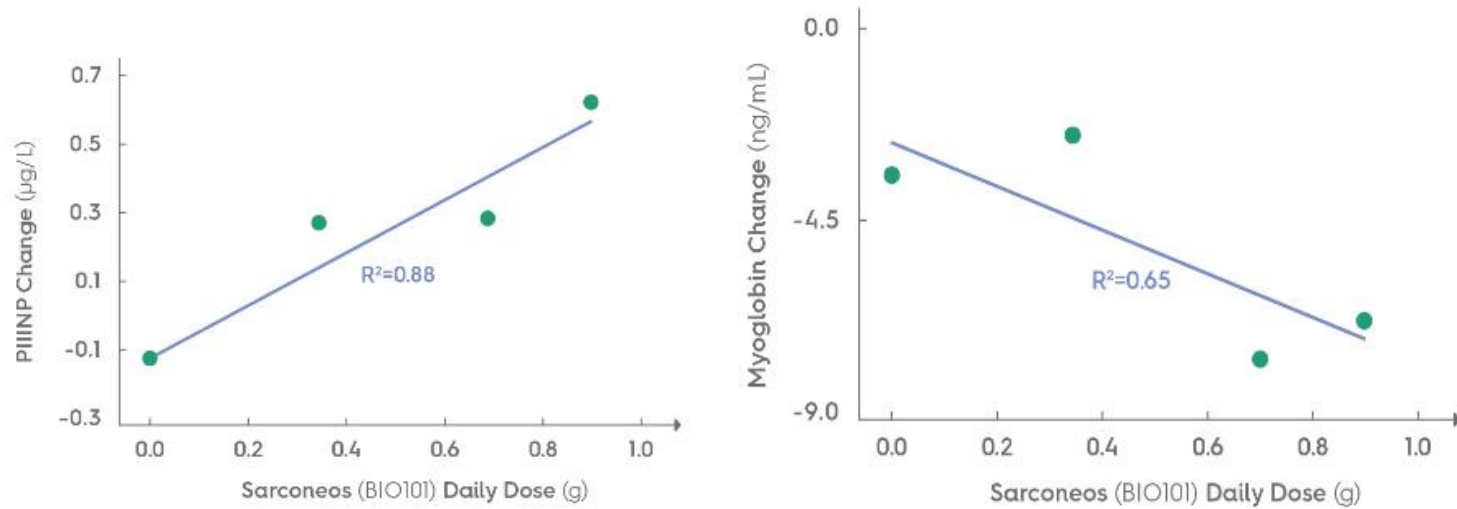


Improves lungs mechanical properties²



1. Results were presented in October 2019 at the WMS conference in Copenhagen, Denmark in a poster presentation;
2. Results were presented in March 2019 at the annual international congress of Myology in Bordeaux, France in a poster presentation.

Sarconeos (BIO101) showed good safety and activity in Phase 1 study (SARA-PK) in elderly healthy volunteers



Sarconeos (BIO101) showed a dose dependent effect on muscle growth and repair (PIIINP) and a dose dependent negative effect on muscle wasting (myoglobin)

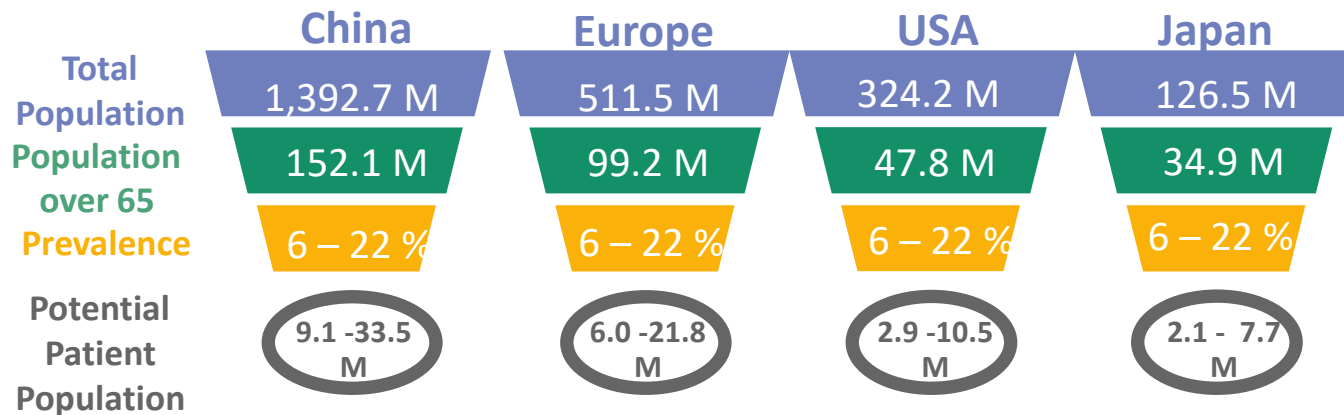
- Single and multiple ascending doses tested in 54 healthy young and elderly (over 65 years) volunteers
- Good safety profile : No Severe Adverse Events
- **Two active doses** (175 & 350 mg b.i.d.) have been selected for the upcoming Phase 2 studies

Sarcopenia: a large unmet medical need with no 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

Sarconeos (BIO101):

- ✓ Only drug candidate currently being tested in Phase 2 for sarcopenia
- ✓ Myostatin inhibitors halted for lack of efficacy in neuromuscular diseases



SARA-INT: on going Phase 2 clinical trial in sarcopenia

- Global, multicenter, double-blind, randomized, placebo-controlled trial: NCT03452488
- Recruitment completed March 2020 for 233 elderly patients with sarcopenia at risk of mobility disability over 22 centers in the US and Belgium

Objectives	Key Endpoints	Inclusion Criteria
<ul style="list-style-type: none"> • Assess safety and efficacy of two doses of Sarconeos (BIO101) administered orally with a meal over 26 weeks, compared to placebo • Treatment effect on improvement of physical function and on decrease of risk of mobility disability 	<p>Primary</p> <ul style="list-style-type: none"> • 400-meter walk test (400MWT) - 0.05 m/s is considered the minimal meaningful change <p>Key secondary</p> <ul style="list-style-type: none"> • Handgrip strength • 400MWT responder analysis • Patient reported outcomes (PRO) 	<ul style="list-style-type: none"> • Age (≥ 65 or over) • Low mobility measured by Short Performance Physical Battery (SPPB) ≤ 8 out of 12 • DEXA body composition as measured by ALM/BMI (appendicular lean mass/ body mass index) • Able to exercise for 30 minutes per day 5 days per week

SARA-INT: topline results expected in Q2 2021



"The SARA-INT Phase 2 trial is investigating a new treatment for sarcopenia, a disease of aging which is characterized by loss of muscle mass and function."

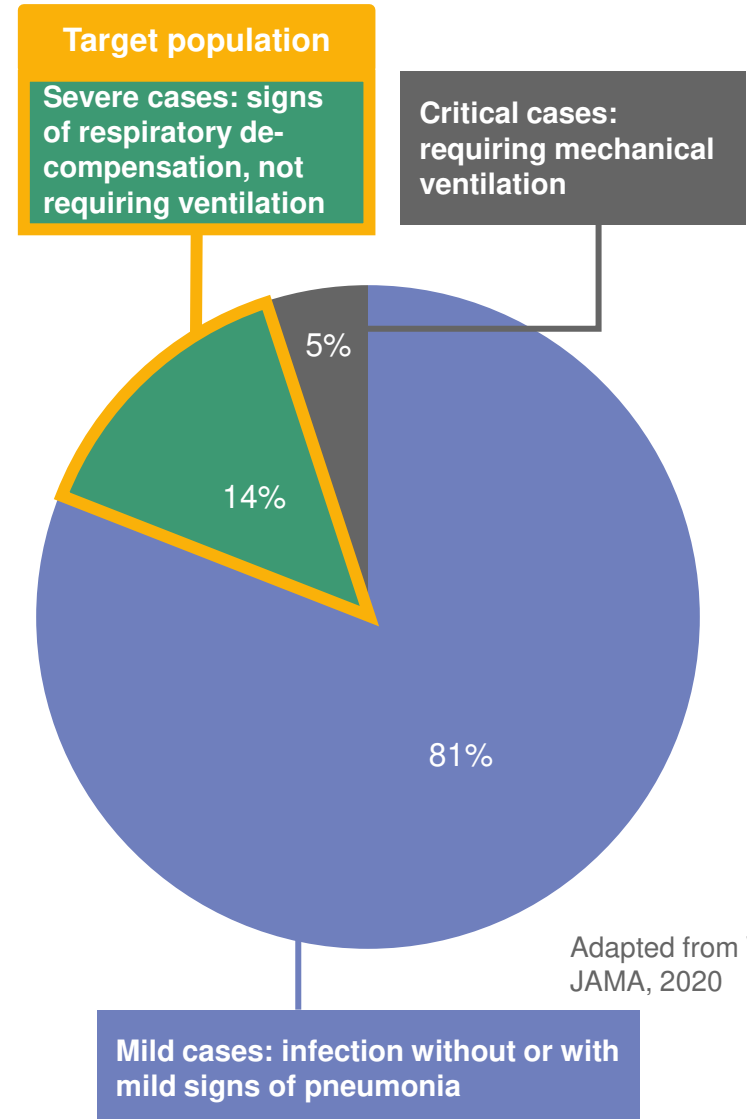
Dr. Roger Fielding, PhD, Director of the Nutrition, Exercise Physiology & Sarcopenia Laboratory at **Tufts University** in Boston and Principal Investigator of SARA-INT trial

Product	2019	2020	2021
175 & 350 mg b.i.d of Sarconeos (BIO101)	SARA-INT Phase 2		

- **No safety issue** to date, with multiple DSMB Meetings with the conclusion that the benefit – risk ratio is positive.
- **Last patient out in December 2020** with 196 patients having completed the study.
- **Topline trial results** expected in **Q2 2021**.

COVID-19 : targeting hospitalized patients with respiratory failure, not intubated

- Patients **aged 45 and above**, with proven COVID-19, respiratory symptoms:
 - With evidence of respiratory decompensation ≤ 4 days before start of study medication, meeting one of the following:
 - Tachypnea: ≥ 25 breaths per minute
 - Arterial oxygen saturation $\leq 92\%$
- Allowed medications: antimalarial, antibacterial and antiviral agents, anti-inflammatory agents and ACE inhibitors / ARB

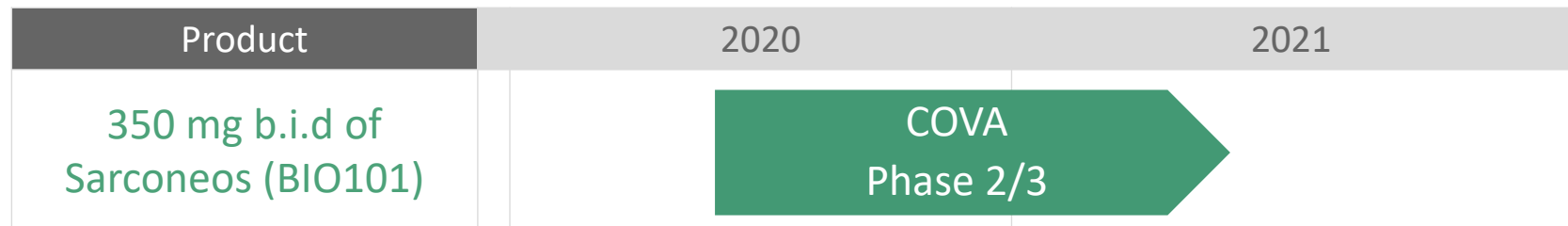


Adapted from Wu et al. JAMA, 2020

COVA : Sarconeos (BI0101) to prevent respiratory deterioration linked to COVID-19

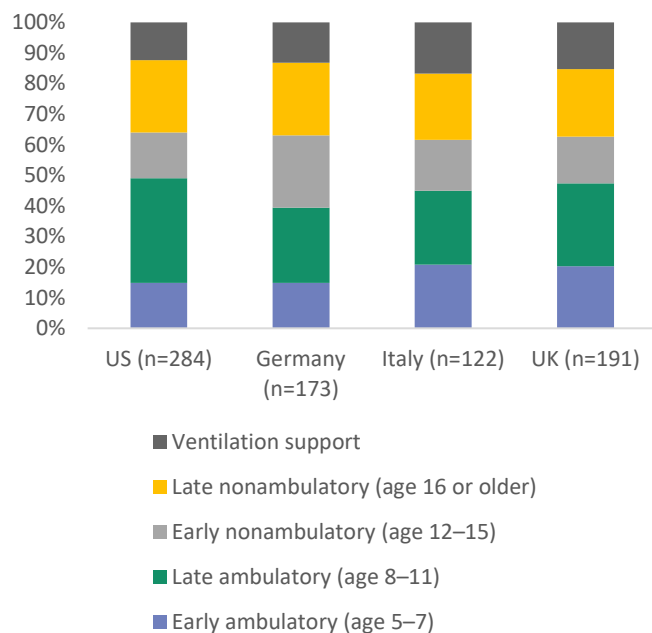


	Part	Goal	Analysis by the DMC	Number of participants
<ul style="list-style-type: none"> • A Phase 2/3 study • Multinational, multi-centric • Double-blind, placebo controlled • Group sequential (2 parts), adaptive design • Sarconeos (BI0101) 350mg BID vs. placebo 	1	1. Obtain safety and tolerability data on (BI0101)	IA1: 1 st interim analysis Decide on the beginning of part 2 recruitment	50 1:1 randomization
		2. Obtain an indication of activity for BIO101	Assess indication of activity of BIO101	
	2	Re-assess the sample size for step 2	IA2: 2 nd interim analysis to confirm sample size for Part 2	155 (an addition of 105 participants) 1:1 randomization
		Confirmation of the effect of BIO101 in preventing further respiratory deterioration	Final analysis	310-465 (an addition of 155-310 participants) 1:1 randomization



DMD: No cure and limited treatment options

Proportion of ambulatory class in DMD¹



- 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.

MYODA: IND granted by FDA to start Phase 2/3 clinical study



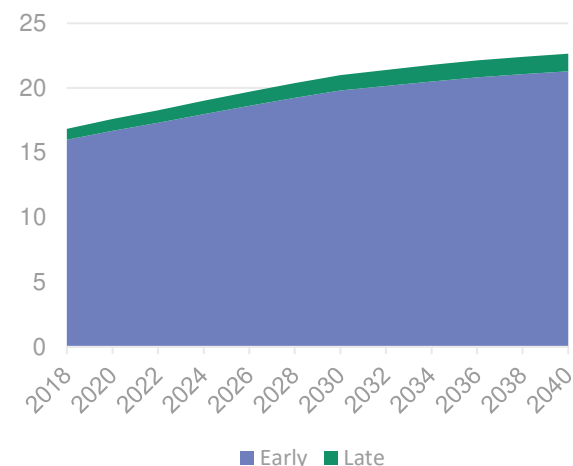
Product	2020	2021	2022	2023
Sarconeos (BIO101)				

Design	Patients	Regulatory Status
<ul style="list-style-type: none"> Global, multicenter, double-blind, placebo-controlled, seamless, Phase 1-2-3 clinical trial Part 1: Safety, tolerability & PK (initial 7 days of dosing of escalating dose of Sarconeos BIO(101)) Part 2: Efficacy of Sarconeos (Respiratory function after dosing for 52 weeks) Part 3: Efficacy of Sarconeos (Respiratory function after dosing for 52 weeks) 	<ul style="list-style-type: none"> Non-ambulatory DMD patients: <ul style="list-style-type: none"> Part 1: 18 participants Part 2: an addition of 30 participants Part 3: up to 200 participants Interim analysis at the end of parts 1 and 2 Enrollment in the U.S. and EU Patient advocacy group support <ul style="list-style-type: none"> AFM Téléthon in France 	<ul style="list-style-type: none"> Orphan drug designation in US and Europe granted in 2018 FDA IND and CTA in Belgium granted in 2020

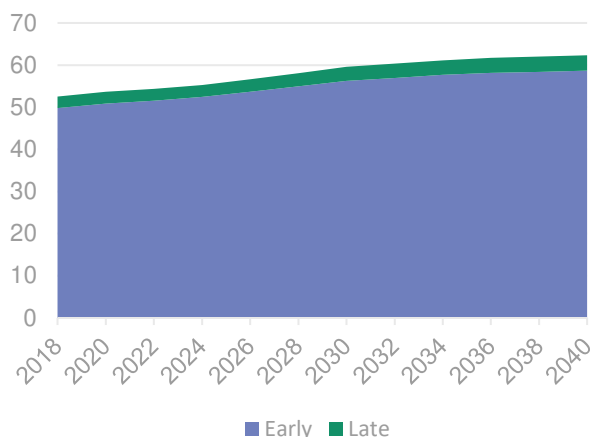
Dry AMD is an unmet medical need with no approved drugs

- AMD is a common eye disorder among people over 50 that affects the central part of the retina, known as the macula
- Can impair functions such as reading, driving, and facial recognition, and has a major impact on QoL and the ability to live independently
- Multifactorial disease that we believe is mainly caused by accumulation of A2E (a byproduct of the visual pigment cycle) that leads to retinal degeneration

Projection of AMD prevalence in North America (in M, mean projection)¹



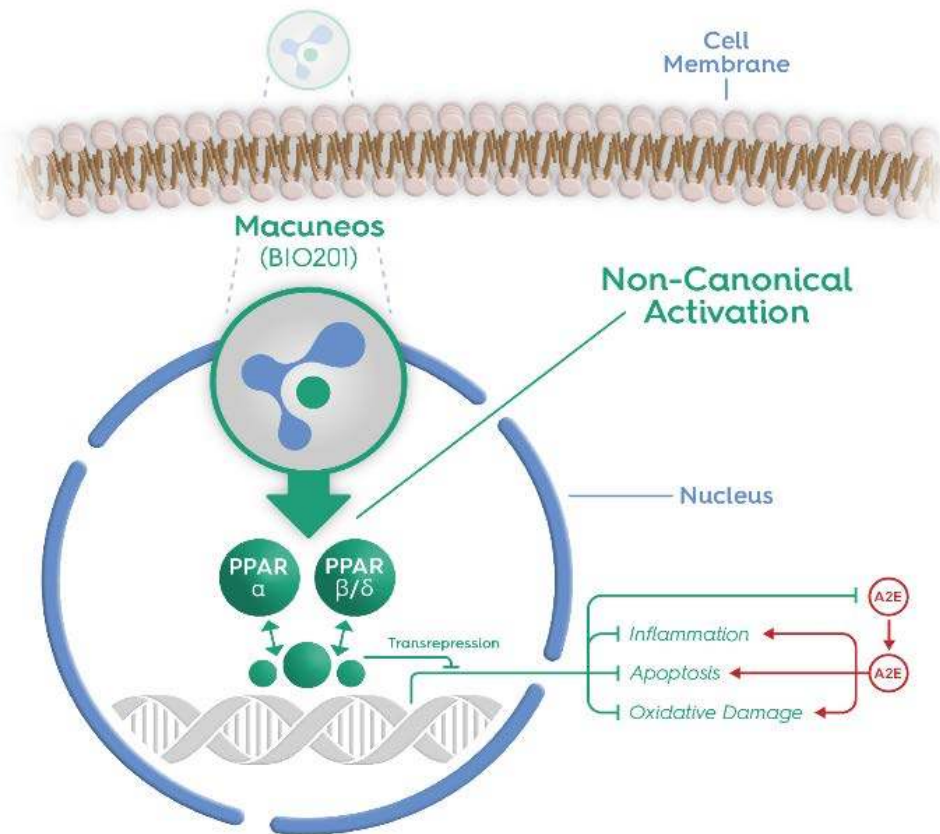
Projection of AMD prevalence in Europe (in M, mean projection)¹



- 85 - 90% of AMD patients have dry AMD in some form; either early, intermediate or late stage, known as geographic atrophy (GA)
- No approved treatments for any stage of dry AMD, including GA
- We are developing Macuneos to treat patients with intermediate dry AMD to prevent the development to advanced stages (wet AMD + GA), which lead to severe vision loss

Macuneos (BIO201) mechanism of action: Non-canonical activation of PPARs

- We believe Macuneos potentially counteracts the phototoxic effects of A2E by selective non-canonical activation of the transrepressive activity of PPAR α and PPAR β/δ in the retina
- Most other PPAR ligands mainly exhibit canonical activity and are associated with side effects



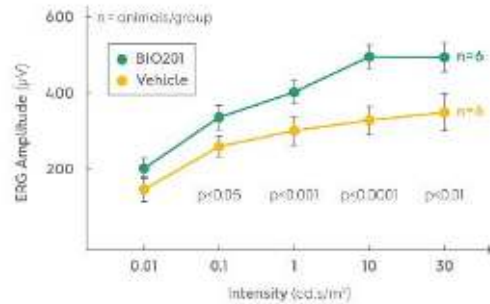
Anti-inflammatory activity (promotes the expression of anti-inflammatory genes)

Anti-oxidant activity (promotes the expression of anti-oxidant genes)

Anti-apoptotic activity (enables pathways that prevent cell death)

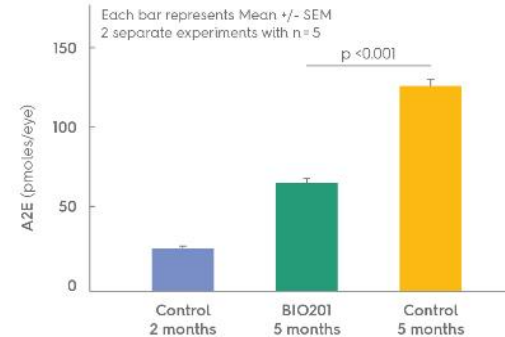
Macuneos (BIO201) protects the retina in rodent models of dry AMD and Stargardt disease

Preservation of visual function in mice



Chronic oral administration of Macuneos for 3 and 6 months **increases ERG amplitude** in ABCA4^{-/-} RDH8^{-/-} mice

Reduced A2E accumulation in mice



Chronic oral administration of Macuneos decreased A2E accumulation by **approximately 45%** in Abca4^{-/-} Rdh8^{-/-} mice as compared to vehicle control mice

Results were presented in May 2016 at the ARVO conference in Seattle, WA in a poster presentation and published in PLoS ONE (Fontaine *et al.*; 2016).

Appendix



Scientific advisory board



University of Pittsburgh



School of
Medicine



Pr. Jean Mariani, Chairman

- 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

Board of directors

MONSANTO 



genzyme



DRONE VOLT



Stanislas Veillet - Founder & CEO

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



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



Jean M. Franchi

- Independent Director,
- ReplImmune CFO
- 30+ years as finance director, including 15 years at Genzyme



Dimitri Batsis

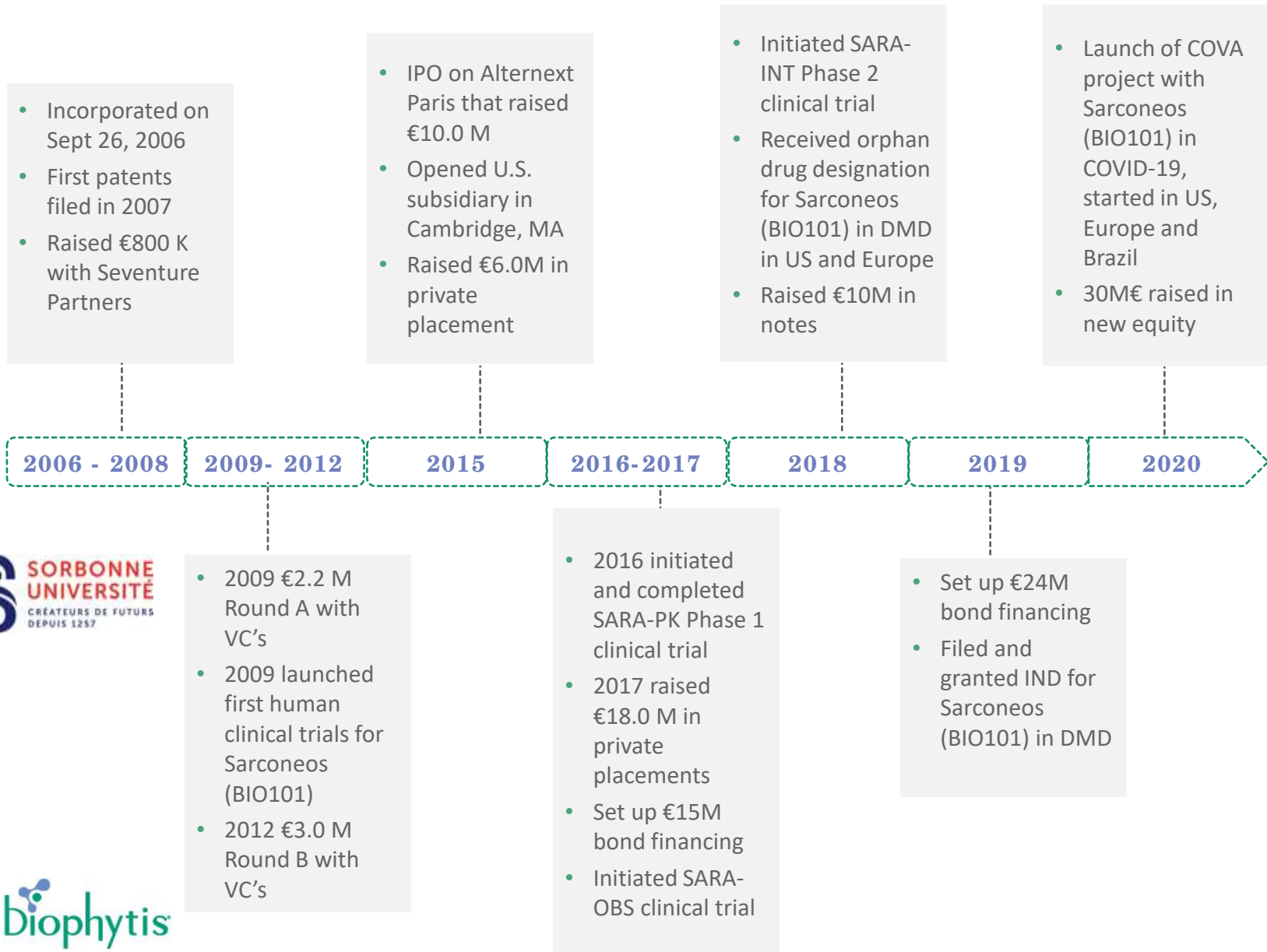
- Independent Director
- Entrepreneur, Founder of Zeni Corporation, Drone Volt
- 20 years in the High-Tech sector



Nadine Coulm

- Independent Director
- 20 years of experience as CFO in charge of IR & Financing with Korian, FNAC, Darty Danone & Casino

From a Sorbonne University spin-off to a successful clinical-stage biotechnology company: 90M€ raised to date



Intellectual Property portfolio – Neuromuscular & respiratory diseases

- We hold exclusive commercial rights through licenses of each of our drug candidates.
- IP is jointly owned with Sorbonne University & sometimes with other academic research institutions¹.
- Patent portfolio covers 10 patent families, including a total of 24 co-owned issued patents and a total of 26 co-owned patent applications.
- Issued patents: 5 European, 2 U.S., and 17 in ROW, including **China, Japan**.
- Pending applications: 2 European, 5 U.S., and 19 in ROW, including **China, Japan, South Korea**



Neuromuscular and respiratory diseases

10 families of patents covering production process, second generation compounds and various applications such as sarcopenia, myopathies (DMD), disuse atrophy, spinal muscular atrophy, respiratory function and COVID-19

Intellectual Property portfolio – Retinal Diseases

- We hold exclusive commercial rights through licenses of each of our drug candidates.
- IP is jointly owned with Sorbonne University & sometimes with other academic research institutions.
- Patent portfolio covers 5 patent families, including a total of 16 co-owned issued patents and a total of 10 co-owned patent applications.
- Issued patents: 4 European, 3 U.S., and 9 in ROW, including **China, Japan**.
- Pending applications: 10 in ROW, including **China, Japan, South Korea**.



Retinal diseases

5 families of patents covering 2 classes of compounds and their applications for dry age-related macular degeneration (AMD) and Stargardt disease

CONTACTS:

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Thank you

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