

Biophytis SA (ALBPS.PA)
Rating: Buy

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Sarcopenia Phase 2 Interventional Study Starting Enrollment in Coming Weeks; Reiterate Buy

Stock Data	03/09/2018
Price	€3.60
Exchange	PSE
Price Target	€10.00
52-Week High	€7.70
52-Week Low	€2.44
Enterprise Value (M)	€44.7
Market Cap (M)	€48
Public Market Float (M)	6.2
Shares Outstanding (M)	13.4
3 Month Avg Volume	160,318

Balance Sheet Metrics	
Cash (M)	€4.4
Total Debt (M)	€1.1
Total Cash/Share	€0.33
Book Value/Share	€0.99

General: Biophytis reports semiannually; we show our projections quarterly.

EPS Diluted	2016A	2017E	2018E
Full Year - Dec			
1Q	--	--	€(0.28)
2Q	€(0.60)	€(0.71)A	€(0.28)
3Q	--	€(0.28)	€(0.30)
4Q	€(0.68)	€(0.23)	€(0.29)
FY	€(1.28)	€(1.16)	€(1.16)



SARA-INT Phase 2b trial to start enrollment imminently. The FDA has authorized Biophytis to conduct the SARA-INT Phase 2b trial, which could start enrollment imminently. SARA-INT is a six-month interventional study to evaluate Sarconeos' effect on improvement of physical function vs. placebo in patients over 65 suffering from sarcopenia and considered at risk of mobility disability. SARA-INT is slated to enroll a total of 334 patients at study centers located in the U.S., Belgium, Italy and France. Per protocol, patients are to be orally dosed of Sarconeos at 175mg BID and at 350mg BID vs. placebo. The primary endpoint is the gait speed at the 400-meter walking test. Top-line results from SARA-INT could be reported in 1H 2019, in our view. We reiterate our Buy rating and €10 price target on Biophytis shares.

Sarconeos preclinical data presented. Earlier this month, Biophytis presented preclinical data of Sarconeos for the treatment of sarcopenia at the 8th International Conference on Frailty & Sarcopenia Research in Miami, FL. We note that Sarconeos is a pharmaceutical-grade preparation (97%) of the ecdysteroid 20-hydroxyecdysone, purified from the plant *Stemmacantha carthamoides*. In preclinical models, Sarconeos treatment induced a significant increase in myofiber diameter (+24%, $p < 0.001$) consistent with rapid and significant activation of AKT/mTOR and MAPK signaling pathways involved in muscle anabolism. A significant decrease in myostatin gene expression (-45%; $p < 0.01$) was also observed. Myostatin inhibits myogenesis (muscle cell growth and differentiation). Sarconeos also stimulated mitochondrial function, particularly in increasing mitochondrial spare respiratory capacity (+23%, $p < 0.05$). Under glucose starvation and in the presence of fatty acids, Sarconeos stimulated basal respiration (+37%, $p < 0.001$), suggesting increased flexibility in energy metabolism. Sarconeos treatment also lowered reactive oxygen species levels in cells subjected to oxidative stress in accordance with AMPK activation, a key player in mitochondrial biogenesis and antioxidant systems. These *in vitro* and *in vivo* data show that Sarconeos enhances muscle function through both anabolic and mitochondrial effects, i.e., increase in muscle mass as well as energy production. In our view, increase in muscle mass alone, though important, may not be sufficient to effectively treat sarcopenia patients, who typically have limited strength and mobility. The fact that Sarconeos can activate energy production alongside muscle cell growth suggests that it could generate positive clinical data in sarcopenia and improve patients' lives, in our view.

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SARA-OBS observational study currently ongoing. Biophytis currently has the SARA-OBS study ongoing, which is a six-month observational clinical study conducted in the EU and in the U.S. Participants are asked to wear a connected device over the entire duration of the study to continuously record data on daily physical activity. The collected data are used to analyze the pattern of physical activity, e.g., a sedentary life style and its relationship with the patient reported difficulty in physical function, assessed by auto-evaluation questionnaires and with established functional tests, e.g. 400-meter walking test and electronically recorded patient-reported outcomes (ePROs). We believe this study may have enrolled close to 90 patients.

Valuation and risks. Our price target is derived from a market value of the firm at \$165M, which includes a discounted cash flow based asset value for Sarconeos and Macuneos, with a 15% discount rate, 0% terminal growth rate and 20% probability of success. Investment risks include: (1) failure of Sarconeos and/or Macuneos in clinical trials; (2) failure of Sarconeos and/or Macuneos to secure regulatory approval; (3) failure of Sarconeos and/or Macuneos to achieve commercial success due to market size, penetration rate, and/or competition; and (4) dilution risk.