Biophytis (ALBPS.PA)

Company Update

May 29, 2018

Biophytis Enrolls First Patient in Phase IIb Study for Sarconeos in Sarcopenia, and Receives Orphan Drug Designation in DMD

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Biophytis (Euronext Paris: ALBPS.PA) has announced several recent updates, including the enrollment of the first patient in a Phase IIb trial for lead candidate sarconeos (BIO101) in sarcopenia (SARA-INT), and orphan drug designation for this product in Duchenne muscular dystrophy (DMD). During 2017, the Company received approval from the FDA to initiate the SARA-INT trial, and similar regulatory approval processes for this study continue to progress in various European countries. Concurrently, Biophytis is enrolling patients into the SARA-OBS clinical trial, which is a 6-month observational study designed to better characterize sarcopenia as a patient population, and participants may ultimately opt-in to SARA-INT after completion which should help the pace of enrollment. Recent preclinical data with this asset also support its potential in Duchenne muscular dystrophy (DMD), and a safety and pharmacokinetics study (MYODA-PK) is planned to initiate in the second half of 2018. This candidate has received orphan drug designation for DMD from the FDA and a positive opinion from the EMA. The Company is also progressing with macuneos in dry age related macular degeneration (AMD), with completion of preclinical regulatory studies geared towards launching a Phase I/IIa single-ascending dose trial in H2 2018.

- **First Patient Enrolled in Phase IIb SARA-INT Trial.** Biophytis recently announced the inclusion of the first patient in their SARA-INT study evaluating the safety and efficacy of sarconeos in individuals who suffer from sarcopenia. This is a randomized, double-blind, placebo-controlled Phase IIb study planned to enroll 334 patients across 22 sites in the United States and Europe. Participants will be enrolled to receive either 175 mg sarconeos, 350 mg sarconeos, or placebo, and treatment will be orally administered twice daily over 6 months. The primary endpoint is in change in gait speed measured during a 400-meter walk test, which will be assessed at baseline and 6 months. Secondary endpoints include changes in the patient reported outcome (PRO), raising from a chair, appendicular lean mass (ALM), body composition in dual energy x-ray absorptiometry (DEXA), muscle strength, stair power climbing test, short physical performance battery and 6-minute walk test. Patients must be over the age

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Market Data

Price	$3.43
Market Cap (M)	$46
EV (M)	$24
Shares Outstanding (M)	13.5
Fully Diluted Shares (M)	15.2
Avg Daily Vol	96,060
52-week Range:	$2.82 - $8.86
Cash (M)	$23.0
Net Cash/Share	$1.62
Annualized Cash Burn (M)	$17.0
Years of Cash Left	1.3
Debt (M)	$1.2

Relevant values converted at 1 EUR to 1.15 USD

Financials

FY Dec		2015A	2016A	2017A
EPS	H1	(0.53)A	(0.70)A	(0.82)A
	H2	NA	NA	NA
	FY	(1.25)A	(1.48)A	(1.43)A

of 65 with a reported loss of physical functioning within the last 6 to 12 months, and be considered at risk for mobility disability. About 50% of patients will be recruited from the population of sarcopenia patients in the SARA-OBS study. Biophytis anticipates to complete patient recruitment by year-end 2018, with anticipated preliminary results during summer 2019 and final results around year-end 2019.

- **SARA-OBS Ongoing, Designed to Speed Enrollment of SARA-INT.** Biophytis is currently conducting SARA-OBS, a 6-month observational clinical study designed to better characterize the condition of sarcopenia and optimize recruitment for the Company's interventional study SARA-INT, which is essentially a continuation of SARA-OBS. As such, both trials share inclusion criteria, and primary and secondary endpoints. SARA-OBS is planned to enroll more that 300 sarcopenia patients and evaluate mobility and muscular quality, about half of which will be enrolled into SARA-INT. Assessments include 6-minute walk test, muscle strength via grip test, and body composition. Participants are being enrolled across 9 clinical centers in the United States and Europe, and interim results are anticipated in the first half of 2018.

- **Orphan Drug Designation for Sarconeos in DMD Obtained from FDA, with Positive Opinion from EMA.** Biophytis has recently announced the reception of orphan drug designation for sarconeos in the treatment of Duchenne muscular dystrophy (DMD) from the FDA, and reception of a favorable opinion from the EMA (which is sent to the EU commission for approval). This represents progress with lead asset sarconeos in a secondary indication, along with the benefits of orphan drug designation. In the EU, these include 10-year marketing exclusivity, allocation of drug development credits, and assistance in trial design. In the US, orphan drug designation qualifies companies for 7 years of marketing exclusivity, tax credits for clinical trials costs, and relief from certain fees.

  At the World Muscle Society's 2017 meeting, the Company presented results of a preclinical study titled "Sarconeos demonstrates a significant improvement in muscle functions and anti-fibrotic properties in the animal model of Duchenne muscular dystrophy (DMD)". Findings highlight the potential of this program in DMD, and as such, Biophytis is currently finalizing plans for clinical studies with sarconeos in DMD, which includes a Phase I/IIa pharmacokinetic study expected to begin in the second half of 2018, and a Phase II/III trial planned to begin in 2019.

- **Details of Macuneos' Clinical Program for Dry AMD.** Biophytis' planned clinical program for macuneos consists of a pharmacokinetics study (MACA-PK), observational study (MACA-OBS), and interventional study (MACA-INT). The Company is currently completing pre-clinical studies to enable clinical trial authorization (CTA) for a single-ascending dose Phase I/IIa clinical study (MACA-PK) to evaluate the safety, pharmacokinetics, and pharmacodynamics of this asset. The Company plans to initiate this trial during the second half of 2018, with results expected in the first half of 2019. Biophytis also intends to initiate MACA-OBS in the second half of 2018, which is a study geared towards better characterizing dry AMD and preselect potential patients for the interventional trial.

- **Financial Results for FY2017.** Earlier this year Biophytis reported full year results for the period ended December 31, 2017. Research and development expenses for 2017 totaled $7.6 million as compared to $5.4 million in 2016. The increase is primarily due to launch and development expenses for the SARA clinical program and non-clinical regulatory studies for MACA. General and administrative expenses were $3.1 million for full year 2017, compared to $3.0 million in 2016. Biophytis reported a net loss of $12.4 million in 2017, as compared to a net loss of $8.5 million in 2016. The Company completed 3 private placements that cumulatively raised $26 million during 2017, and issued

2 tranches of bonds for $7.4 million (total facility is 5 tranches for up to $18.5 million). As of December 31, 2017, the Company had cash and equivalents of $23 million.

Expected Upcoming Milestones

- Q2 2018 – Expected interim results from SARA-OBS in sarcopenia patients.
- H2 2018 – Anticipated initiation of the MYODA-PK trial with sarconeos in DMD.
- H2 2018 – Anticipated initiation of the MACA-PK trial for macuneos.
- H2 2018 – Expected initiation of MACA-OBS Phase IIb study with macuneos in dry AMD.
- H1 2019 – Results from the MACA-PK trial for macuneos in dry AMD.
- Summer 2019 – Expected preliminary results from the SARA-INT study with sarconeos in sarcopenia.
- 2019 – Anticipated initiation of the Phase II/III MYODA-INT trial with sarconeos in DMD.
- Year-end 2019 – Expected preliminary results from the SARA-INT study with sarconeos in sarcopenia.
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Risk to Investment

We consider an investment in Biophytis to be a high-risk investment. Biophytis is currently in clinical-stage development and does not have any marketed or approved products. The Company has not entered Phase III clinical trials for any program. Failure to show convincing results in future clinical studies or failure to reach FDA or EMA approval could adversely affect Biophytis's stock price. Regulatory approval to market and sell a drug does not guarantee that the drug will penetrate the market, and sales may not meet expectations. As a clinical-stage company, Biophytis is not profitable and may need to seek additional financing from the public markets, which may result in dilution of existing shareholder value.

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