

GALAPAGOS NV (GLPG-NASDAQ)

Biotechnology

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ROCCELLA Update, Endpoint Not Met

On Thursday, after market close, Galapagos NV and partner Servier announced that the Phase 2 ROCCELLA trial of GLPG1972/SR01086 for knee osteoarthritis (OA) did not meet the primary endpoint of reducing cartilage loss of central medial tibiofemoral compartment of the target knee. The primary endpoint did not show efficacy compared to placebo, as the change from baseline to week 52 in cartilage thickness, in mm (SD) was -0.116 (0.27) for the placebo group and -0.068 (0.20), -0.097 (0.27), and -0.085 (0.22), for the low, medium, and high doses of GLPG1972, respectively. Galapagos reported that statistically significant difference versus placebo was not reached for the primary or secondary endpoints, for any of the treated groups. GLPG1972 was generally well-tolerated by patients in the trial. Galapagos is conducting additional analyses of the results, and will present them at upcoming medical conferences. **We had not incorporated GLPG1972 into our model, and thus make no changes to our estimates.**

Expctations were based on ARGS reduction from a previous Phase 1b trial: GLPG1972/S201086 is a highly selective inhibitor of ADAMTS-5, a key aggrecanase and a cartilage degrading enzyme, which in a Phase 1b trial, demonstrated a greater than 50% reduction in ARGS neopeptide in serum, over a four week period. The Phase 2 ROCCELLA trial was a global, double-blind, placebo-controlled, dose ranging trial to evaluate the efficacy and safety of three different once-daily oral doses of GLP1972. The trial recruited 932 patients, with a mean 63 years old, mean disease duration of 7 years, and a key endpoint of a 75% reduction versus control in knee cartilage loss after 52 weeks of treatment, as evaluated by MRI (management estimated on average 100 microns of cartilage are lost per year for knee OA). Considering the failure of the trial today, Gilead will most likely not exercise its option to license GLPG1972.

OCTOBER 15, 2020 | 5:48 PM EDT
COMPANY BRIEF

Market Perform 3

Suitability High Risk/Speculation

MARKET DATA

Current Price (Oct-15-20)	\$138.50
Market Cap (mln)	\$9,050
Current Net Debt (mln)	\$(6,224)
Enterprise Value (mln)	\$2,826
Shares Outstanding (mln)	65.3
30-Day Avg. Daily Value (mln)	\$20.3
Dividend	\$0.00
Dividend Yield	0.0%
52-Week Range	\$112.00 - \$274.03

KEY FINANCIAL METRICS

	1Q	2Q	3Q	4Q
EBITDA (mln) (\$, Dec FY)				
2019A	(53)	(44)	491	(23)
2020E	(45) A	(86) A	(139)	(139)
2021E	(129)	(137)	(145)	(156)
2022E	(114)	(96)	(95)	(92)
	2019A	2020E	2021E	2022E
EBITDA (mln) (\$, Dec FY)	370	(408)	(567)	(396)
GAAP EPS (\$, Dec FY)	2.49	(6.82)	(8.73)	(6.10)
Revenue (mln) (\$, Dec FY)	896	312	224	438

Source: Thomson One, Raymond James & Associates. Quarterly figures may not add to full year due to rounding.

COMPANY DESCRIPTION

Galapagos NV is a clinical-stage biotechnology company that is researching and developing novel small molecules to treat indications such as rheumatoid arthritis and inflammation. It was founded in 1999, and is headquartered in Mechelen, Belgium. Its diverse pipeline consists of multiple programs that are in Phases 1-3, and also has preclinical developments. Its most advanced program is filgotinib, a selective JAK1 inhibitor, which is targeting multiple indications including rheumatoid arthritis, ulcerative colitis, and Crohn's disease. Besides filgotinib, Galapagos has four current primary areas of interest: IPF, atopic dermatitis, OA, and inflammation fibrosis.



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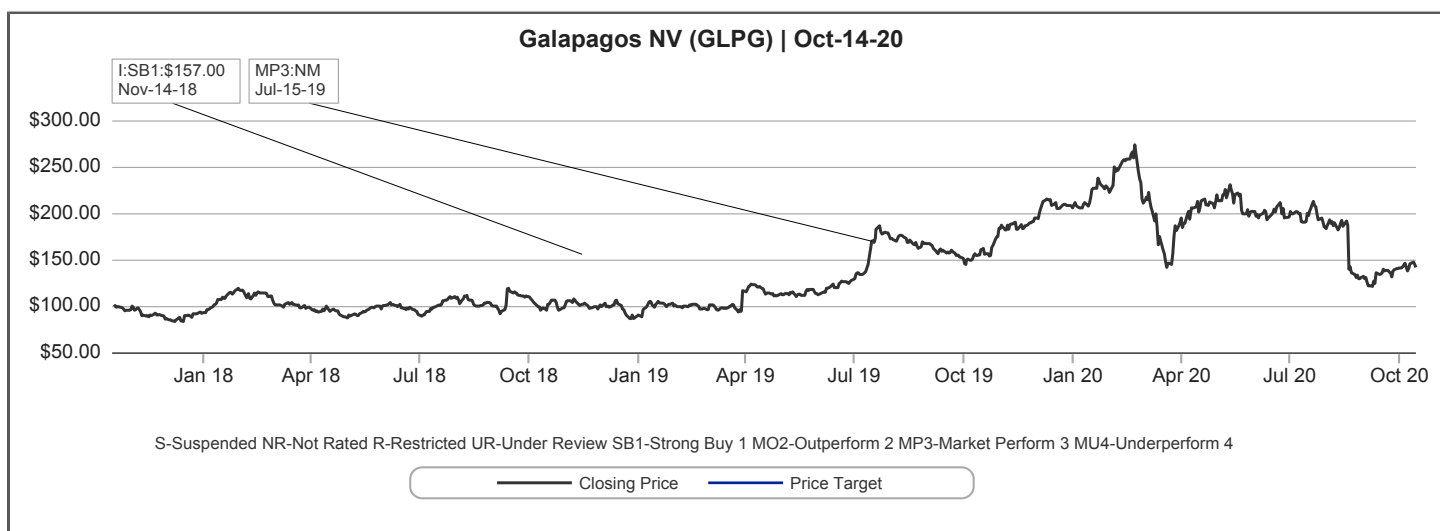
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Valuation Methodology

Galapagos NV

We value based on 5 year forward EV/sales.

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Company Specific Risk Factors

Galapagos NV

We assign a **High Risk/Speculation Suitability** rating as the company is currently not profitable, and is not anticipated to be profitable for a number of years. As such, if the company is unable to secure financing for its activities, it could cease operations.

Stronger data from competitors to filgotinib could reduce our optimism for the program, along with our current commercial sales estimates.

Filgotinib may not be approved by the U.S. FDA for rheumatoid arthritis, which could significantly alter our revenue forecasts for the company, and endanger the Gilead partnership.

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Company Name

Galapagos NV

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