First Take

Galapagos NV (GLPG)

July 2, 2019

Price: $130.44; Market Cap (M): $7,124; *7/1/2019 Close*

Rating: Buy; Price Target: $150.00

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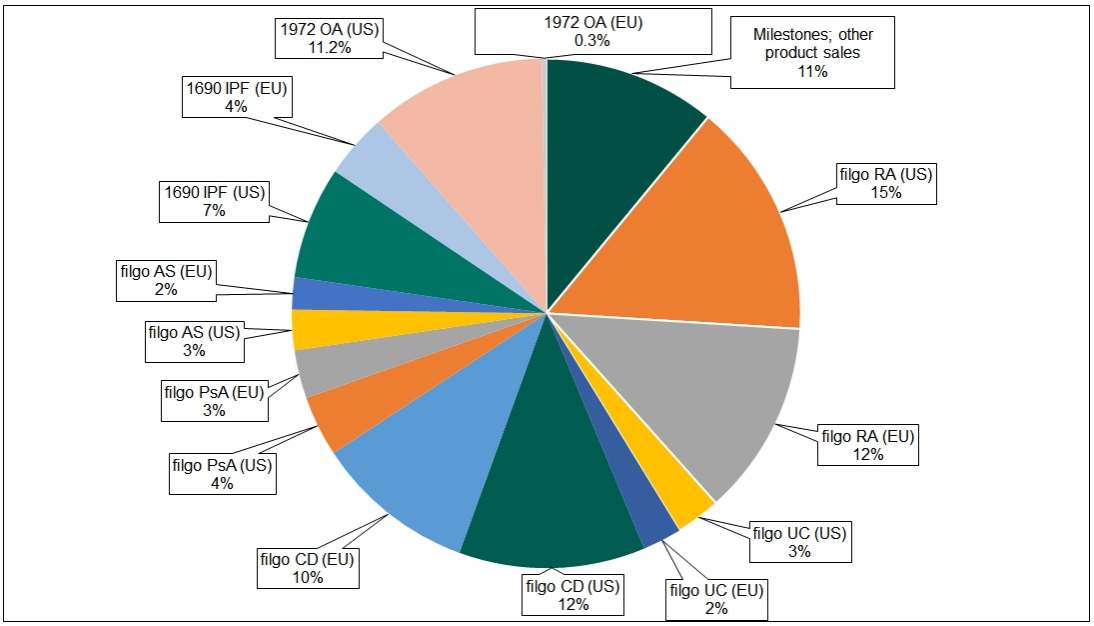
MANTA May Not Have Been the FDA Mantra After All

Filgotinib NDA by YE19 is an upside surprise. As highlighted in our prior notes, it was our position that the MANTA program should not have any bearing on the older RA patient population and remains more relevant to the UC/ Crohn's patients. Hence, the outcome of the post-FINCH program meeting with the FDA, culminating in a potential NDA filing for filgotinib in the U.S., disclosed by partner Gilead (GILD; not rated) on July 1, 2019, after the markets close, while not surprising, should come as a significant relief, by narrowing commercial lead time vs. Abbvie (ABBV; not rated). Beyond the RA-centric launch, the UC Phase 3 program is now fully recruited and there are two filgotinib-centric POC data events during 2H19, including Sjogren's and cutaneous lupus erythematosus. Beyond these, it is all about the maturing pipeline with insights into the ongoing Phase 3 IPF program, and recruitment completion to its 850+ patient Phase 2 program in osteoarthritis (OA). Given the anticipated catalysts over the next 12 to 24 months encompassing multiple Phase 2 and 3 readouts, additional programs advancing into the pivotal-stage, along with enhanced visibility garnered from the likely commercialization of filgotinib, all supported by a robust cash balance of roughly $1.37B, the stock is likely to have multiple value drivers over the near-to-intermediate term, in our view. Beyond filgotinib, which is being investigated in 10-plus indications spanning Phase 3 and 2 programs, we note: (1) an unencumbered IPF franchise spanning two novel compounds in Phase 3 and 2; (2) an 850-plus patient, potentially disease-altering Phase 2 program in OA with GLPG1972 ('1972) for which Galapagos owns the U.S. rights. Other pipeline assets that are likely to deliver clinical news flow include: (1) a partnered Phase 2 program in atopic dermatitis; and (2) 20-plus early-stage programs targeting various inflammation and fibrosis-related maladies, which together we think give Galapagos one of the broadest, yet focused small molecule programs in biotechnology.

Valuation and risks to our investment thesis. Our 12-month, $150 price target on shares of Galapagos is derived from a 13-year DCF-based, sum-of-the-parts analysis. Our DCF is driven by: beta of 1.34, terminal growth rate of -3.0%, risk premium of 4.93%, calculated WACC of 9.3%, and tax rate of 20% beginning in FY 2025. Filgotinib (66%), GLPG1690 (11%), GLPG1972 (11%) together make up 88% of our value, with the remainder derived from the probability-adjusted, filgotinib-associated milestone payments. For filgotinib, we assume POS in the range of: 75% (upped from 65% previously) for RA based on the FINCH 1 and 3 clinical updates released post close on March 28, 2019, 65% for UC, and 60% for CD, PsA and AS each, whereas for '1690 and '1972, we assign a 35% and 10% POS, respectively. Note, filgotinib, in our view, did not materially underperform upadacitinib in the FINCH 1 and 3 studies, which we assigned a low probability outcome due to its competitive profile, along with our $2.9B in 2027 sales estimate for the RA segment. Other key risks include: emergence of safety concerns, clinical risks, regulatory risks, and financial risks. Furthermore, regulatory and commercial strategy for filgotinib is under the control of partner, Gilead, not an established player in autoimmune indications. Hence, Gilead may not be able to drive rapid adoption of filgotinib, especially if the overall profile is relatively undifferentiated from AbbVie's upadacitinib, in our view. Hence, our estimates could be negatively impacted if AbbVie successfully leverages its market positioning with Humira during the launch of upadacitinib, which is likely to be a year ahead of filgotinib. The next two value drivers for Galapagos are GLPG1690 and GLPG1972 programs, both of which are high-risk, high-reward programs given the checkered history of drug development of each target. Hence, there are significant clinical risks associated with these programs, which we believe are adequately reflected in our POS assumptions.

Exhibit 1: Weighted Contribution of Individual Disease Segments to Target



Source: H.C. Wainwright & Co. estimates.

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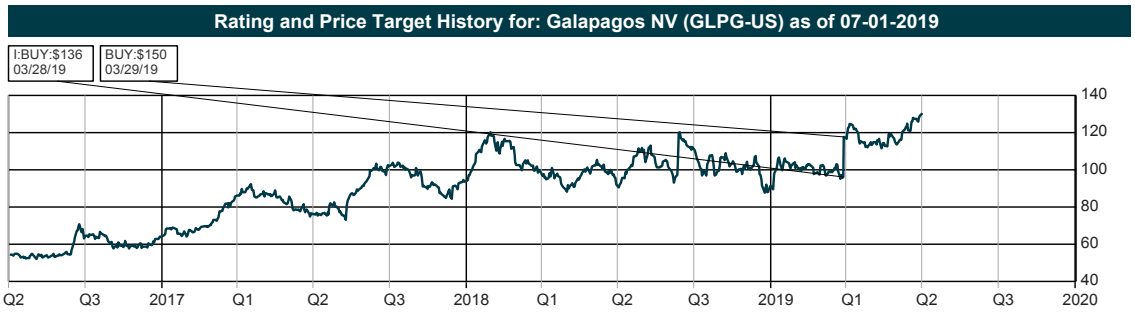

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Distribution of Ratings Table as of July 1, 2019				
			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
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Neutral	25	6.94%	4	16.00%
Sell	0	0.00%	0	0.00%
Under Review	2	0.56%	0	0.00%
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