

Galapagos NV

GLPG - NASDAQ; GLPG - NA

October 27, 2020

Biotechnology

HOLD

Price \$127.27

FLASH NOTE

TOLEDO Program Reveal Not Thesis Changing; Still Very Much A "Show Me" Story

Summary

We are reiterating our Hold rating on shares after the company hosted its TOLEDO R&D roundtable where they officially disclosed the target and mechanism of action. While we find the target interesting and management seems *very* optimistic (CEO called it a "once in a lifetime opportunity"), we don't think this changes the sentiment on the stock in the near-to-medium term. Given the setback with filgotinib in the US and the recent failure of GLPG1972 in knee osteoarthritis, we don't think investors are in a rush to assign more value for GLPG's R&D engine/pipeline, particularly when management is setting the bar very high for TOLEDO ahead of signal finding study results in 2021-2022. Beyond its pipeline, we think upside for shares largely relies on US approval of filgotinib in RA and whether its profile will even be competitive vs. the incumbent JAKs, the latter we aren't very confident in.

Key Points

Though the targets of the TOLEDO program are now public — there are still many questions to answer and a lot of derisking to be done. The targets are salt-inducible kinases (SIK1/2/3) that management believes are master regulators of the balance between inflammatory and immunoregulatory functions. The key point that management continues to highlight about the TOLEDO program is that inhibition of these targets seem to generate a balanced effect: down regulation of "pro-inflammatory" functions and upregulation of "immune modulating" functions. This mechanism is unique — nearly all other approved or late-stage anti-inflammatory therapies to-date inhibit pro-inflammatory processes. The CSO highlighted some high-level data demonstrating the breadth of efficacy SIK inhibition. Those results appeared to demonstrate that SIK inhibition is efficacious across numerous inflammatory and fibrotic disease models with a range of etiologies from innate immune overactivity to adaptive immune overactivity and everything in between. In our view, at the extremes there are two ways to interpret these results: first, (and management's view) is that this is a once in a lifetime mechanism of action; second, is that SIK inhibition may be a "jack of all trades, master of none." Remember, corticosteroids are oral therapies with incredible breadth of efficacy and activity but, due to this pleiotropy, come with a litany of side effects. Improving on the profile of corticosteroids (via more selective therapies) has been the primary goal of immunological drug development for decades. We think it is really too early to take a strong position at either end of this spectrum. At this point our concern is what it will ultimately cost for clarity about whether SIK inhibition is clinically differentiated and where it is clinically differentiated; based on the clinical development plan, management is expected to put a lot of human capital and investment behind the program but it's not clear if the company's initial signal finding studies will offer

When will we begin to see data from TOLEDO? The company plans to employ a similar development strategy as it has with other compounds in its pipeline, which leverages biomarker, initial efficacy and safety data from small signal finding, proof-of-concept studies with the idea to move right into Phase 2 or Phase 3 studies if data are positive. While this is a fair approach and one that has the potential of accelerating development timelines & path to market, while potentially reducing costs, it is also not without risk. We can look to the recent failure of GLPG1972 in knee OA as an example where very early data from a small study did not translate to positive results in a large Ph2. Management offered up its development timelines for TOLEDO as follows: (1) in 2020 - GLPG will initiate five proof-of-concept, signal finding studies. Three of these are already recruiting - the Phase 1 CALOSOMA study (n=25) in psoriasis, the Phase 2 SEA TURTLE study (n=30) in ulcerative colitis (UC), and the Phase 2 LADYBUG study (n=25) in rheumatoid arthritis (RA); (2) in 2021 - GLPG expects top-line data from these first three studies to readout after which, Phase 2b dose-ranging studies will begin in RA, UC, and psoriatic arthritis (PsA) assuming data are positive. The company will also begin proof of concept Phase 2 studies in Sjögren's and systemic lupus erythematosus (SLE) in early 2021; and (3) in 2022 - ideally, the results of the Sjögren's and SLE studies will read out, along with the Phase 2b studies in RA, UC and PsA. After which, they would conduct Phase 3 trials. These could be pretty aggressive timelines and again, we may not see differentiating data for this program until 2022 - thus we are not eager to assign more credit.

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Investment Thesis

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Our thesis is predicated on: (1) the chance of it receiving a meaningfully differentiated label within the JAK class is low; (2) we are cautious on GILD/GLPG's ability to deliver filgotinib sales ahead of consensus estimates between 2020-2025, which to us seem high; and (3) while we are positive on GLPG's pipeline and its long-term prospects, we don't see any major, near-term catalysts from the pipeline that would sufficiently offset our commercial concerns. While there is a lot to like here, given GLPG's meaningful cash position and robust R&D engine, we would seek a better entry point.

Target Price Methodology/Risks

Our target price for GLPG shares is \$138. This is based on a probability-weighted, risk-adjusted NPV analysis. We assign \$34, \$2, \$1, \$5 for filgotinib, GLPG1690, Other revenue, Other pipeline, respectively. We assign \$96 of value for cash.

Risks: Underperforming filgotinib consensus sales, failures from the pipeline, delays from the pipeline, competition.

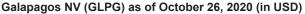
Company Description

Galapagos is a clinical-stage biotechnology company specialized in the discovery and development of disease modifying, small molecule medicines with novel mechanisms of action. The pipeline includes clinical candidates focused on rheumatoid arthritis, inflammatory bowel disease, idiopathic pulmonary fibrosis, osteoarthritis, and atopic dermatitis. Lead assets include filgotinib (partnered with Gilead), GLPG1690 in IPF, and GLPG1972 in OA. Galapagos recently signed a transformational deal with Gilead that brought in significant cash and should allow for accelerated R&D. The Galapagos group, including fee-for-service subsidiary Fidelta, has approximately 460 employees, operating from its Mechelen, Belgium headquarters and facilities in The Netherlands, France and Croatia.



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*Represents the value(s) that changed.

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For a price chart with our ratings and target price changes for GLPG go to http://stifel2.bluematrix.com/sellside/Disclosures.action?ticker=GLPG

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