STIFEL

Galapagos NV
GLPG – NASDAQ; GLPG – NA

December 15, 2020

Biotechnology

HOLD
Price $119.45 (as of close 12/15/20)

FLASH NOTE

Fil-NOT-inib: GILD Returns EU Rights & Won't Pursue US Approval In RA; Story Remains A Challenge Even At These Levels

Summary

We are reiterating our Hold rating after GLPG announced a restructured development and commercial agreement with GILD (NC, $59.43) for filgotinib (Jyseleca) after GILD's Type A meeting where it determined there is no path forward for the 200mg dose in rheumatoid arthritis (RA) in the US, which is required to be competitive, and is stopping development of other indications. In the revised agreement, GLPG does gain full rights to the EU but, in our view, this will likely necessitate significant increased spend (i.e. S&M) for what we think is a non-differentiated JAK where there is meaningful competition. While GLPG/GILD may continue to see approval for filgotinib in the US for IBD, we doubt investors will assign any value (if there is any remaining) for Jyseleca in the US. We expect the stock to trade down on the news tomorrow ahead of its conference call with investors at 8:00AM ET.

Key Points

Where does the development of filgotinib stand under the new agreement? GLPG communicated that it plans to cease development of filgotinib in PsA, AS and uveitis given that there is no longer a viable path forward for filgotinib in the US. Of note, GILD/GLPG plan on continuing development of the drug in IBD. Here, GILD will retain operational responsibility for current studies in Crohn's disease, while GLPG will take over responsibility of the ongoing trials in UC. The drug is under review by the EMA and GLPG expects to file for approval in UC in Japan in 1H21. Recall that GLPG reported positive data in UC with the 200mg dose of filgotinib earlier this year. The fact that GILD has decided to not advance the drug in RA — in part because they would likely have to run another study in RA — brings the MANTA and MANTA-RAy data into sharp relief in our view. GLPG remains on track to deliver the 26-week MANTA/MANTA-RAy data by mid-2021 and expects to submit data to regulators shortly thereafter for filgotinib's sNDA in UC. In order to complete their review of filgotinib (including indications outside of RA), the FDA now requires up to Week 52 follow-up data from both studies in patients who show >50% decrease in semen parameters by Week 26 and do not recover. We are not sure how many patients that is at the moment, but nonetheless this stretches out timelines for development of filgotnib in UC. GILD/GLPG expect to have more clarity on the development of filgotinib in IBD in the US after they meet with the FDA with MANTA and MANTA-Ray data in hand.

Here's how the commercial responsibilities look now: (1) GLPG assumes the responsibility for commercializing Jyseleca in RA in Europe, as well as all future indications. Recall, the 100mg and 200mg doses are approved in Europe for the treatment of moderate to severe RA. GLPG expects to assume the majority of commercial activities for Europe by the end of 2021; (2) GILD keeps the commercial rights outside of Europe, including Japan; and (3) GLPG will still "fight" for filgotinib's IBD opportunity in the US, pending the MANTA data, which are expected in 1H21. We spoke with IR who said tomorrow they will discuss the peak sales opportunity for Jyseleca in the EU and potential profitability measures. We doubt investors will look to assign credit based on these and this is "show me" story.

Change in economics doesn't help the need for meaningfully increased spend to commercialize filgotinib in the EU and compete with major competitors. All economics for Jyseleca in Europe are now transferring to GLPG with GLPG having sole responsibility for EU commercialization. Previously, the EU economics were a profit split, with each company taking responsibility for certain regions in certain indications. Now, GLPG will owe GILD a tiered royalty of 8-15% on EU net sales, starting in 2024. Further, GILD is no longer responsible for any future milestone payments related to the EU. By our math, there are ~$835 million in potential milestone payments remaining from the previous filgotinib deal though we don't know the break down between development, regulatory, commercial, or regional milestones — we only model about $350 million on a risk adjusted basis, none of which we tied to Europe. In the US, it appears the economics are unchanged (GLPG receives tiered royalties — we model 20-30%) though the only remaining indications are CD and UC. Finally, GILD will pay GLPG €110 million in 2021 and €50 million in 2022. While our model is under review, what we do know is that GLPG will likely need to ramp S&M spend to compete in the EU against pretty sizable competitors, specifically ABBV (NC, $102.82) whose JAK Rinvoq has been ramping very quickly as it leverages its significant immunology footprint. GLPG's opex is currently ~$500-$550 million a year, of which almost all of it is R&D, so we'd expect this to increase meaningfully as the company takes over the EU launch responsibility. If we assume zero credit for filgotinib in the US and $200 million a year in SG&A costs, that represents 20% downside to our $135 target price based on our model, or about $108/share.

Derek C. Archila | (617) 848-2762 | archilad@stifel.com
Bill Grau, PhD | (617) 488-4147 | grauw@stifel.com
Benjamin Porter | (617) 488-4404 | porterb@stifel.com
Jacques Villefranc, PhD | (617) 488-4403 | villefrancj@stifel.com
Stifel Equity Trading Desk | (800) 424-8870

Investment Thesis

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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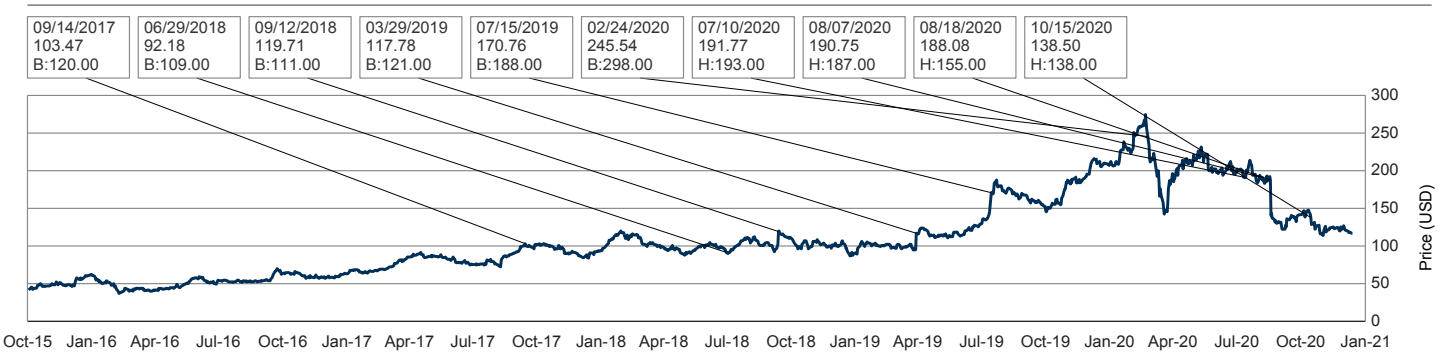
Galapagos NV (GLPG) as of December 14, 2020 (in USD)



*Represents the value(s) that changed.
Buy=B; Hold=H; Sell=S; Discontinued=D; Suspended=SU; Discontinued=D; Initiation=I

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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[1] This rating is only utilised by Stifel Canada.

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