HOLD
COMPANY UPDATE

Lowering Target Price To $155 On Filgotinib CRL; Calls Into Question Its Potential Differentiation Within The JAK Class

Financial Summary

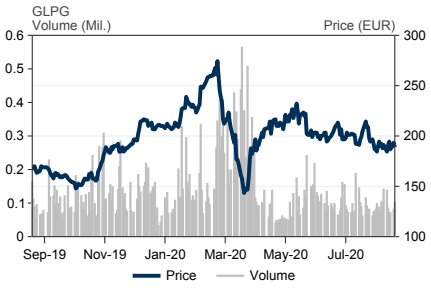
Changes	Previous	Current
Rating	—	Hold
Target Price	$187.00	$155.00
FY20E Revenue	€635.0	€554.0
FY21E Revenue	€670.0	€686.0

Price (08/18/20):	$188.08
52-Week Range:	$274 - $112
Market Cap.(mm):	$12,281.6
Shr.O/S-Diluted (mm):	65.3
Avg Daily Vol (3 Mo):	107,303
Dividend / Yield:	$0.00 / 0.0%
Cash (mm):	€5,567

Revenue	2019A	2020E	2021E
Q1	€40.9	€106.9A	€NE
Q2	€67.6	€117.7A	€NE
Q3	€644.0	€186.0	€NE
Q4	€143.2	€144.0	€NE
FY (Dec)	€895.9A	€554.0	€686.0

EPS IFRS	2019A	2020E	2021E
Q1	(0.89)	(0.78)A	NE
Q2	(0.86)	(1.77)A	NE
Q3	5.83	(0.63)	NE
Q4	(1.82)	(1.54)	NE
EPS IFRS	2.49A	(4.95)	(4.46)

Price Performance



Summary

We are reiterating our Hold rating after GILD/GLPG announced the receipt of a complete response letter (CRL) for filgotinib in rheumatoid arthritis (RA). The company noted the FDA is now requiring data from the ongoing MANTA/MANTA-RAy studies and expressed concerns around the risk/benefit of the 200mg filgotinib dose. Since MANTA/MANTA-RAy results are expected in 1H21, we think this could push approval/launch of filgotinib in RA out to potentially 1H22. With that said, we think the CRL also raises additional questions about filgotinib's potential differentiation, particularly on safety relative to other JAKs, and likely provides a boost to ABBV's (NC, $95.65) Rinvoq and its sales force's ability to counter detail in the future. While filgotinib EU approval is still highly likely, we think sales will likely be modest in the near-term, and we do not view upcoming updates on the clinical front as stock moving. Thus we remain on the sidelines.

Key Points

Management held a call with the analysts where they shared more details on the CRL and the safety concerns raised by the FDA. (1) The FDA is requiring GILD/GLPG to submit data from the MANTA/MANTA-RAy studies to determine filgotinib's impact on sperm parameters. Data from these studies are examining the 200mg dose and results are expected in 1H21; (2) the FDA also raised concerns on the overall risk/benefit profile of the 200mg dose, as it relates to an increase in specific safety signal(s) relative the 100mg dose. GLPG did not disclose what the specific safety signal(s) was, but did note it was one of the *"usual suspects"* for the class. In our transfer/downgrade note (see note here), we had highlighted the risk/benefit profile of the 200mg vs. 100mg as a potential concern, with our bear case label scenario one where only the 100mg dose was approved with a testicular tox warning. While we did not rule out the possibility of a CRL, we thought it was a low probability event but clearly, the FDA continues to take a conservative stance on the JAK class as it relates to safety and it remains to be seen whether the 200mg dose will ultimately gain approval. There continues to be a disparity in how the regulatory agencies approach the JAK class, recall the recent CHMP positive opinion on both doses of filgotinib and the EU commission's approval of both doses of LLY's (NC, $153.11) Olumiant (which only has its low dose approved in the US).

While the company would not provide specific timelines, we think a possible re-submission in the US in mid-2021 for filgotinib in RA makes sense. Recall both the MANTA/MANTA-RAy studies are fully enrolled. GLPG plans to submit 26-week data from both studies along with a safety database from the FINCH and DARWIN datasets (including both 100mg and 200mg doses), which they believe should address the FDA safety concerns. Barring any regulatory hiccup (GLPG does not anticipate the need for another study), we estimate filgotinib could gain US approval in RA in 1H22. This assumes MANTA/MANTA-RAy data are available by the end of 1H21 followed by a GILD resubmission in 3Q21 and a class 2 review — GILD used its priority review voucher this time around — which we estimate could take ~6 months from re-submission.

We think the case for filgotinib's differentiation among the JAKs is even tougher now given the CRL. Since the reason for the CRL lays with issues around safety, we think it's going to be difficult for GILD/GLPG to make a strong case now, and potentially in the future, that this is differentiated on this front. Commercially, we think this likely gives ABBV's Rinvoq even more of a leg-up in the JAK class as they already have a robust commercial footprint in the immunology & inflammation category through its years of marketing Humira and now the ability to counter detail on safety for all the JAKs including filgotinib. For this and factoring the delay due to the CRL, we trim our peak market share for filgotinib in the US. This results in our target price of $155.

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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 $155. This is based on a probability-weighted, risk-adjusted NPV analysis. We assign $39, $3, $10, $2, $5 for filgotinib, GLPG1690, GLPG1972, 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.

GLPG Annual P&L Summary
(figures in €m, except per share data)

	2017	2018	1Q19	2Q19	3Q19	4Q19	2019	1Q20	2Q20	3Q20E	4Q20E	2020E	2021E	2022E	2023E	2024E	2025E
Filgotinib EU Sales (JAKi; RA, UC, CD, AS, PsA)	-	-	-	-	-	-	-	-	-	1	3	4	16	60	176	359	626
GLPG1690 EU Sales (Autotaxin; IPF)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	10	31
Total Product Sales	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**1**	**3**	**4**	**16**	**60**	**176**	**368**	**657**
Filgotinib Royalties	-	-	-	-	-	-	-	-	-	-	-	-	-	3	56	262	558
GLPG1690 Royalties	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	11	34
GLPG1972 Royalties (OA)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	23	72
Total Royalties	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**3**	**56**	**295**	**664**
Other Revenues (upfronts, milestones, grants, etc.)	**156**	**318**	**41**	**68**	**644**	**143**	**896**	**107**	**118**	**185**	**141**	**551**	**670**	**470**	**548**	**435**	**247**
Total Revenues	**156**	**318**	**41**	**68**	**644**	**143**	**896**	**107**	**118**	**186**	**144**	**554**	**686**	**533**	**779**	**1,099**	**1,568**
% y/y growth	*3%*	*104%*	*-9%*	*19%*	*524%*	*27%*	*182%*	*161%*	*74%*	*-71%*	*0%*	*-38%*	*24%*	*-22%*	*46%*	*41%*	*43%*
COGs	-	-	-	-	-	-	-	-	-	0	0	0	2	6	18	37	66
% of sales	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*1%*	*2%*	*3%*	*4%*
Gross Income	156	318	41	68	644	143	896	107	118	186	144	554	684	527	761	1,062	1,502
% gross margin	*100%*	*100%*	*100%*	*100%*	*100%*	*100%*	*100%*	*100%*	*100%*	*100%*	*100%*	*100%*	*100%*	*99%*	*98%*	*97%*	*96%*
G&A Expense	24	36	11	18	33	37	74	35	55	40	45	174	130	137	147	157	168
% of sales	*16%*	*11%*	*27%*	*26%*	*5%*	*26%*	*8%*	*32%*	*47%*	*22%*	*31%*	*31%*	*19%*	*26%*	*19%*	*14%*	*11%*
S&M Expense	3	4	-	-	-	-	25	-	-	23	27	50	135	142	149	156	164
% of sales	*2%*	*1%*	*0%*	*0%*	*0%*	*0%*	*3%*	*0%*	*0%*	*12%*	*19%*	*9%*	*20%*	*27%*	*19%*	*14%*	*10%*
R&D Expense	219	323	83	94	121	129	427	117	149	160	174	600	710	732	754	776	800
% of sales	*140%*	*102%*	*203%*	*140%*	*19%*	*90%*	*48%*	*109%*	*127%*	*86%*	*121%*	*108%*	*104%*	*137%*	*97%*	*71%*	*51%*
GILD Profit (Loss) Share Expense, net	-	-	-	-	-	-	-	-	-	(1)	(2)	(3)	(16)	(45)	(38)	41	161
% of sales	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*-1%*	*-2%*	*-1%*	*-2%*	*-8%*	*-5%*	*4%*	*10%*
Operating Income	**(90)**	**(45)**	**(53)**	**(44)**	**491**	**(23)**	**370**	**(45)**	**(86)**	**(36)**	**(100)**	**(267)**	**(275)**	**(439)**	**(249)**	**(68)**	**210**
% operating margin	*na*	*na*	*na*	*na*	*76%*	*na*	*41%*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*13%*
Total financial income (expense)	(26)	16	5	(3)	(146)	(76)	(220)	(6)	(28)	(6)	(6)	(46)	(15)	(10)	(8)	(8)	(8)
Pre-tax income	**(116)**	**(29)**	**(49)**	**(47)**	**344**	**(99)**	**150**	**(50)**	**(115)**	**(42)**	**(105)**	**(313)**	**(290)**	**(449)**	**(257)**	**(76)**	**202**
% pre-trax income margin	*na*	*na*	*na*	*na*	*53%*	*na*	*17%*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*13%*
Tax expense (benefit)	0	0	0	0	(17)	17	0	0	0	-	-	-	-	-	-	-	-
% tax rate	*na*	*na*	*na*	*na*	*-3%*	*na*	*0%*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*0%*
Net income (loss)	**(116)**	**(29)**	**(49)**	**(47)**	**361**	**(115)**	**150**	**(51)**	**(115)**	**(42)**	**(105)**	**(313)**	**(290)**	**(449)**	**(257)**	**(76)**	**202**
% net margin	*na*	*na*	*na*	*na*	*56%*	*na*	*17%*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*13%*
IFRS EPS	**(2.34)**	**(0.56)**	**(0.89)**	**(0.86)**	**5.83**	**(1.82)**	**2.49**	**(0.78)**	**(1.77)**	**(0.63)**	**(1.54)**	**(4.95)**	**(4.46)**	**(6.70)**	**(3.73)**	**(1.08)**	**2.75**
% y/y growth	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*
Weighted Average Diluted Shares	49.5	52.1	54.6	54.8	62.0	63.5	60.1	64.8	65.1	66.9	68.6	63.1	65.0	67.0	69.0	71.0	73.2
% y/y growth	*5%*	*5%*	*7%*	*7%*	*14%*	*17%*	*15%*	*19%*	*19%*	*8%*	*8%*	*5%*	*3%*	*3%*	*3%*	*3%*	*3%*

Source: Company information and Stifel estimates

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Galapagos NV (GLPG) as of August 18, 2020 (in USD)

*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
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The recommendation contained in this report was produced at 18 August 2020 23:03EDT and disseminated at 18 August 2020 23:03EDT.

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