

Galapagos

Upgrade to Buy; Upcoming SELECTION Should Underpin Filgotinib's Broad Potential

30 March 2020

Key Takeaway

We are optimistic upcoming filgotinib Phase III SELECTION ulcerative colitis (UC) data will be positive, potentially informing on filgotinib's broader commercial potential. Cash underpins c.54% of the current share price, which along with our risk-adjusted pipeline NPVs, suggests only c.\$2bn WW peak filgotinib sales are implied, vs GILD cons \$2.6bn 2029E and JEFc \$6bn. This, along with likely assured filgotinib RA approvals & UC data, drives our upgrade to Buy.

Expectations for UC data: Phase III SELECTION data evaluating JAK-1 inhibitor filgotinib in ulcerative colitis (UC) are expected 2Q20E. On a placebo-adjusted basis, we believe positive efficacy for the clinical remission co-primary endpoints would be:

- **Week-10 induction:** c.10%-15%
- **Week-58 maintenance:** c.20%-25%

Data comparisons with other biologics and PFE's Xeljanz (JAK1-3), are challenging given: (1) variable degree of biologic-exposed patients, with higher proportions likely setting a more challenging bar for efficacy; and, (2) different time points and definitions of clinical remission used. However, we suspect filgotinib will be expected to at least be on par with Xeljanz' efficacy, but with a potentially best-in-class safety profile. We forecast \$6bn WW peak sales for filgotinib, with \$3bn in RA, \$600m in Crohn's disease, \$400m in UC, and a \$2bn cumulative contribution for other indications, combined worth c.€94/share (c.45% of NPVs) at 95% probability.

RA approval expected 3Q20E albeit full extent of COVID-19 disruption remains to be seen: US FDA filgotinib approval for rheumatoid arthritis (RA) is expected around the 19 Aug PDUFA date. We understand filgotinib manufacturing facilities have been FDA-approved in the past, which could play in GLPG/GILD's favour given the current travel restrictions postponing FDA foreign facility inspections. Our base case assumption is that there will not be an Advisory Committee meeting ahead of approval, albeit we have heard debate as to whether one could be scheduled given both doses of filgotinib have been filed.

Recruitment into other filgotinib trials has been paused due to COVID-19: This could potentially delay Phase II MANTA male safety data (2020E), plus Phase III Crohn's disease (mid-2021E), psoriatic arthritis and ankylosing spondylitis data (both 1H22E), among others. Recruitment continues for the Phase III GLPG1690 ISABELA lung fibrosis (IPF) trial, but we note that given the already difficult-to-recruit, high-risk population, delays to the planned 1Q21E interim futility analysis and 2022E efficacy data could occur, in our view, with the added risk that potentially higher COVID-19-related event rate and deaths could confound results.

Upgrading to Buy with current share price undervaluing filgotinib: After the stock's recent de-rating, cash alone underpins over half of the current share price, which along with our conservatively risk-adjusted NPVs for the burgeoning pipeline, suggests only c.\$2bn peak filgotinib sales are assumed, vs JEFc \$6bn and below GILD cons risk-adjusted \$2.6bn 2029E sales. With near-term catalysts, filgotinib RA approvals and UC Phase III data, widely anticipated to be positive, we upgrade to Buy. PT -7% to €210.

Rating | Target | Estimate Change

Netherlands | Biotechnology

RATING	↑ BUY
TICKER	GLPG NA
PRICE	€163.80 [^]
PRICE TARGET (PT)	€210.00 (from €225.00)
MARKET CAP	€10.6B / \$11.7B

[^]Prior trading day's closing price unless otherwise noted.

RATING	↑ BUY
TICKER	GLPG
PRICE	\$182.14 [^]
PRICE TARGET (PT)	\$232.00 (from \$243.00)
MARKET CAP	€10.7B / \$11.8B

[^]Prior trading day's closing price unless otherwise noted.

FY Dec				
EUR	2019A	2020E	2021E	2022E
EPS	5.77	(0.31)	↓(3.19)	(3.00)
Prev.			(3.18)	
FY P/E	28.4x	NM	NM	NM

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GALAPAGOS (GLPG NA)

Estimates				
€	2019A	2020E	2021E	2022E
Rev. (MM)	895.9	693.2	634.3	689.1
<i>Previous</i>				
EBIT (MM)	370.3	(43.9)	(242.6)	(231.9)
<i>Previous</i>				
Cash Position	5,780.8	↑ 5,375.8	↑ 4,858.3	↑ 4,346.6
<i>Previous</i>		5,371.8	4,844.0	4,333.1
EPS	5.77	(0.31)	↓ (3.19)	(3.00)
<i>Previous</i>			(3.18)	

Valuation				
	2019A	2020E	2021E	2022E
P/Rev	11.8x	15.3x	16.7x	15.4x
EV/Rev	5.4x	7.0x	7.7x	7.1x
EV/EBIT	13.1x	NM	NM	NM
FY P/E	28.4x	NM	NM	NM

Market Data	
52-Week Range:	€252.90 - €83.38
Total Entprs. Value	€4.9B
Avg. Daily Value MM (USD)	115.75
Float (%)	73.3%

Financial Summary	
Long-Term Debt (MM)	€0.0
Cash & ST Invest. (MM)	€5,780.8

The Long View

Scenarios

Base Case

- Lead product filgotinib underpins much of our valuation and remains the focus. We are encouraged by its competitive profile in the Phase III FINCH RA programme and Phase II FITZROY Crohn's trial. Partner Gilead should be well-placed to maximise its commercial potential.
- Numerous other pipeline programmes could also crystallise value via possible milestones from the broad R&D opt-in alliance with Gilead, in particular in lung fibrosis (IPF) and osteoarthritis. The current share price significantly undervalues filgotinib, which along with likely positive near-term catalysts, dictates our Buy.
- Price Target €210/\$232 per share/ADS largely comprising filgotinib, GLPG1690, and GLPG1972 NPVs plus Net Cash.

Upside Scenario

- Positive initial Toledo proof-of-concept data during 2020E could add c.€4/share
- Positive Phase III ISABELA results for GLPG1690 in idiopathic pulmonary fibrosis during 1Q21E could add around €16/share
- Over a 12-month period, these potential catalysts could boost our NPV derived Price Target to c.€235/\$259 per share/ADS

Downside Scenario

- Safety concerns for filgotinib during 2020E could remove around €64/share from our valuation
- Efficacy and/or safety concerns in the filgotinib Phase III Crohn's or ulcerative colitis during 2020-21E trials could remove up to €30/share
- Discontinuation of or delays to the Toledo programme during 2020-21E could remove c.€4/share
- Efficacy or safety concerns for GLPG1690 in IPF during 1Q21E could remove at least €16/share
- Over a 12-month period, these setbacks could reduce our NPV derived Price Target to c.€95/\$105 per share/ADS

Investment Thesis / Where We Differ

- The c.€5.8bn Cash at 31 December 2019, including the c.\$5bn proceeds from the Gilead deal, should be more than sufficient to fund operations for the foreseeable future.
- If successfully developed, Galapagos could commercialise GLPG1690 itself in Europe for the Orphan Disease IPF, which could provide a potentially lucrative long-term opportunity.

Catalysts

- Filgotinib Phase IIb/III SELECTION ulcerative colitis data in 2Q20E for potential filings in 2H20E
- Filgotinib RA approvals and launches across US, EU and Japan from 2H20E
- Phase II data for GLPG1690 in systemic sclerosis (NOVESA) and GLPG1205 in IPF (PINTA) in 3Q20E
- Phase IIb ROCCELLA GLPG1972 osteoarthritis data during 4Q20E
- Toledo GLPG3312 proof-of-concept data in ulcerative colitis potentially during 2H20E
- GLPG1690 Phase III IPF interim futility analysis 1Q21E

Upgrade to Buy; PT -7% to €210

Lead product filgotinib, along with cash, underpins the majority of our €210/share sum-of-the-parts valuation and remains the focus for investors. Gilead licensed global rights in December 2015 providing a partner to maximise the drug's commercial potential, after AbbVie elected to opt-out in favour of prioritising its own JAK inhibitor upadacitinib. We are encouraged by filgotinib's competitive profile based on the Phase IIb DARWIN and Phase III FINCH rheumatoid arthritis (RA) clinical data, with results from the Phase II FITZROY trial also suggesting the drug is effective for inflammatory bowel disease (IBD). We forecast \$6bn global blockbuster potential largely comprising \$3bn in RA. The broad R&D collaboration with Gilead provides external endorsement of Galapagos' largely underappreciated pipeline and discovery capabilities, with Gilead gaining an opt-in for ex-EU rights for all programmes post-Phase II. The pivotal programme for GLPG1690 for lung fibrosis (IPF) is underway, and could have significant commercial potential, with GLPG1205 in Phase II and GLPG3499 preparing for Phase I for the same indication. GLPG1972 with partner Servier for osteoarthritis could also be an underappreciated Phase II asset, in our view. The Gilead collaboration funds will likely be used to accelerate development of the secretive Toledo programme, aiming to secure GLPG's first-mover advantage. The current share price significantly undervalues filgotinib, which along with likely positive near-term catalysts, dictates our Buy.

Filgotinib approaching first regulatory approvals during 2H20E

Selective JAK1 inhibitor filgotinib promises to be a safe and convenient oral treatment for rheumatoid arthritis (RA). Encouraging Phase II data in Crohn's disease (CD) suggest the drug could also have potential in inflammatory bowel disease (IBD), perhaps a greater unmet medical need albeit a smaller eligible patient population. Multiple proof-of-concept studies in other indications are ongoing. Compared to currently approved biologic agents such as TNFs (e.g. Humira), filgotinib is administered orally, targets JAK1 specifically, and has a rapid onset, sustained response and potential for monotherapy use.

- **Peak sales forecast:** \$6bn with \$3bn in RA, \$600m in CD, \$400m in ulcerative colitis (UC), and a \$2bn cumulative contribution for other indications
- **Valuation:** c.€94 per share with a 95% probability of success
- **Next news flow:** Phase IIb/III SELECTION ulcerative colitis data during 2Q20E; regulatory approvals for RA during 2H20E; potential update on timings for the MANTA male safety study during 2020E

Phase III SELECTION UC preview

The Phase IIb/III SELECTION trial was initiated in December 2016, evaluating two doses of filgotinib, 100mg or 200mg, once daily (qd) versus placebo in c.1,300 patients with moderate to severe ulcerative colitis. The study consists of an induction period, after which patients achieving response or remission criteria at week-10 are able to continue into the maintenance study for a further 48 weeks. In addition to biologic-naïve patients, patients included in the trial may have previously demonstrated an inadequate clinical response, loss of response to, or intolerance to at least one biologic (biologic-IR), which may include either an anti-TNF and/or the integrin receptor antagonist Entyvio (vedolizumab).

The co-primary endpoints of the study are clinical remission at week-10 and week-58, for the induction and maintenance periods, respectively, as defined by components of the Mayo score, endoscopy, bleeding and stool (EBS), with specific criteria not disclosed.

This is a modification of the more conventional Mayo score, which also includes a physician global assessment sub-score.

In May 2018, following a pre-planned interim futility analysis conducted after 350 patients had completed the induction period in the Phase IIb portion of the study, the Independent Data Monitoring Committee (IDMC) recommended that the study proceed into Phase III, still utilising both filgotinib doses. The trial completed recruitment in 1Q19, with top-line data expected during 2Q20E.

Expectations for SELECTION data

It is challenging to compare across clinical trials for biologic therapies in ulcerative colitis, particularly given that the degree of biologic-exposure varies between trials and different timepoints and definitions have been used, together confounding fair comparison (Exhibit 1). However, given filgotinib's convenient oral administration and potentially best-in-class safety profile, we believe that the following placebo-adjusted improvements in clinical remission would be viewed positively:

- **Induction of clinical remission at week-10:** 10%-15%
- **Maintenance of clinical remission at week-58:** 20%-25%

We suspect filgotinib will be expected to at least be on par with the efficacy demonstrated by the JAK1-3 inhibitor Xeljanz (tofacitinib) but with a superior safety profile, given precedent set by the RA programme, although we note different timepoints and definitions of clinical remission used between the two trials could limit comparison.

Exhibit 1 - Clinical remission comparison of selected therapies for ulcerative colitis

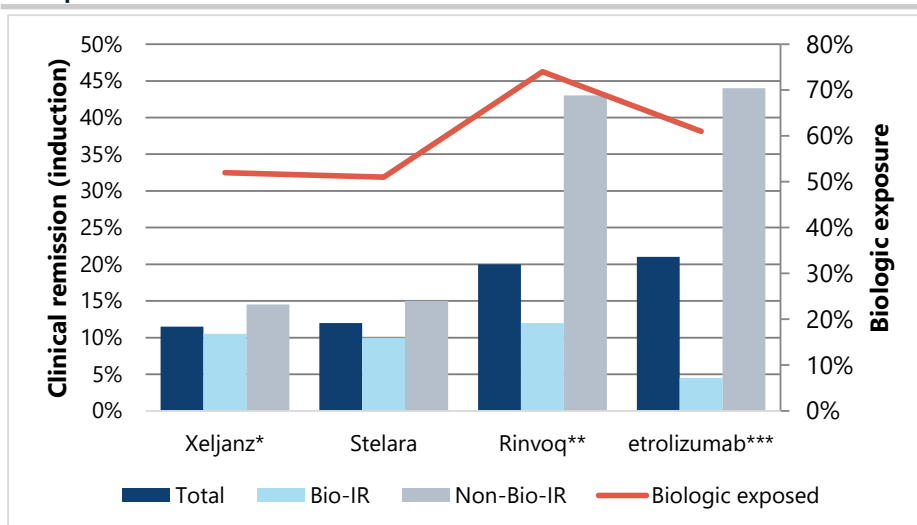
Drug	Mechanism of action	Status	Trial data	Biologic exposure	Arm	Clinical remission - Induction		Clinical remission - Maintenance		Clinical remission - Sustained				
						Week	Pbo-adj	Week	Pbo-adj	Week	Pbo-adj			
Remicade	TNFα	Approved	Phase III	NA	5mg/kg placebo	8	34%-39% 6%-15%	24%-28%	54	35% 17%	18%	8, 30 & 54	20% 7%	13%
Humira	TNFα	Approved	Phase III	TNF-IR c.22%	160/80mg placebo	8	17%-19% 9%	7%-9%	54	17% 9%	9%	8 & 52	9% 4%	4%
Simponi	TNFα	Approved	Phase III	None	200/100mg placebo	6	18% 6%	11%	54	34% 22%	12%	30 & 54	28% 16%	12%
Entyvio	Integrin inhibitor (IRA)	Approved	Phase III	TNF-IR c.39%	300mg placebo	6	17% 5%	12%	52	42% 16%	26%	6 & 52	21% 9%	12%
Xeljanz	JAK1,2,3	Approved	Phase III	TNF-IR c.52%	10mg/5mg placebo	8	17%-18% 4%-8%	10%-13%	52	34% 11%	23%	0, 24 & 52	46% 10%	36%
Stelara	IL12/23	Approved	Phase III	Bio-IR c.51% Dual TNF/IRA-IR c.17%	6mg/kg & 90mg placebo	8	19% 7%	12%	52	45% 26%	19%	8 & 52	66% 36%	30%
Rinvoq	JAK1	Phase III	Phase Ib	Bio-IR c.74%	15mg 30mg 45mg placebo	8	14% 14% 20% 0%	14%-20%*	-	- - - -	-	-	- - - -	-
etrolizumab	Integrin inhibitor (IRA)	Phase III	Phase II	TNF-IR c.61%	100mg 300mg+LD placebo	10	21% 10% 0%	10%-21%	-	- - -	-	-	- - -	-

Source: Company data; Jefferies research. Note: *Clinical remission assessed with a modified Mayo (EBS) score

We highlight three caveats to consider when comparing SELECTION data to prior UC datasets:

- **Harder to show benefit in biologic-IR patients:** With three different classes of biologic therapies approved for moderate-to-severe UC, recruiting biologic-naïve patients is challenging, particularly at sites within the US and Western Europe. It stands to reason that demonstrating benefit is more challenging in biologic-exposed patients, as demonstrated in the induction data from the Xeljanz, Stelara, Rinvoq and etrolizumab trials (Exhibit 2). Hence, the higher the proportion of biologic-IR patients included in the trial, the more challenging it could be to demonstrate differentiated efficacy, albeit we are encouraged by Phase III FINCH-2 data which demonstrate efficacy of filgotinib in RA patients who have previously failed a biologic. Furthermore, the SELECTION trial includes patients which may have failed Entyvio (integrin receptor antagonist), not just anti-TNFs, or potentially both. These refractory patients likely create a more difficult setting to demonstrate efficacy, in our view.

Exhibit 2 - Induction clinical remission rates overall and between biologic exposed/naive patients



Source: Company data, Jefferies research; Note: Timing and remission definitions variable; *averaged across trials; ** 45mg dose only; ***100mg dose only

- **Severity of disease:** Like the Phase IIb trial of fellow JAK1 Rinvoq (upadacitinib), the SELECTION trial uses a modified Mayo Score for patient assessment at baseline and for the primary endpoint of clinical remission. Galapagos has not disclosed inclusion criteria, but we suspect it could be similar to that used for the Rinvoq trials, i.e. a modified Mayo score of 5-9. With other Phase III trials adopting a Mayo score of 6-12 for inclusion, and the etrolizumab Phase II a score ≥ 5 , this could mean that baseline severity could potentially be different.
- **Clinical remission definition:** Similarly, the SELECTION trial's definition of clinical remission utilises the EBS score, rather than the more traditional Phase III endpoint of assessment utilising the Mayo score, which could limit comparison to competitors.

Other endpoints

Our general expectations for the other efficacy parameters:

- **Response rate:** A consistent 20%-30% response rate throughout the entire study would be comparable, in our view,
- **Endoscopic remission:** the comparable data points are sparse but a 10%-25% remission rate during the initial 10-week induction period would appear comparable to Pfizer's Xeljanz and AbbVie's Rinvoq, both of which are JAK inhibitors.

JAKs could offer convenience advantages over other biologics

As a once-daily oral treatment, JAK inhibitors offer potential convenience advantages over competitor biologics which often require physician visits for intravenous administration. We note that a subcutaneous formulation of Entyvio for maintenance treatment has been filed with regulators, with US FDA issuing a Complete Response Letter in December but European approval likely after a positive CHMP decision in February 2020.

As small molecules, an added advantage of JAK inhibitors is the lack of anti-drug antibodies, which may increase the likelihood of sustained responses, versus the loss of response which can occur with biologics, as well as enabling intermittent treatment for disease flares, which is generally not advisable for biologics.

Safety in focus

Safety will be a key focus for the SELECTION trial, given the concerns related to the JAK inhibitor class overall, but could potentially act as confirmation of filgotinib's differentiated safety profile. Notably, in July 2019 FDA issued new warnings about an increased risk of blood clots and death with the 10mg twice daily (bid) dose of Xeljanz, and recommended reserving use for patients who have failed or are intolerant of anti-TNFs, avoiding use in patients at high risk of thrombosis and limiting the use of the 10mg bid dosage to the shortest duration needed. Europe's EMA followed suit in November 2019, advising that Xeljanz should be used with caution in patients at high risk of blood clots and limiting use in patients >65 years.

Potentially differentiated safety profile

Other JAK inhibitors have been shown to produce a range of side effects, including abnormalities in platelets, low density lipoprotein (LDL), cholesterol, red blood cell count and NK (natural killer) cell count, raising concerns about risk of serious infections and venous thromboembolism (VTE). We believe filgotinib has more JAK1 selectivity than any other JAK inhibitor, which could result in an improved safety profile.

In keeping with this, the Phase II DARWIN and Phase III FINCH RA programmes confirmed filgotinib's potentially best-in-class safety profile, in our view, with rates of VTE, serious infection, opportunistic infection, malignancy, major adverse cardiovascular events and death broadly in-line or below placebo rates.

An added potential benefit of filgotinib for inflammatory bowel disease (IBD) is the lack of adverse effect on haemoglobin levels demonstrated in trials to-date, with an actual increase in levels of up to 4% in the DARWIN trial. This compares favourably to Xeljanz, which carries a warning requiring haemoglobin monitoring and dose-adjustment depending on levels. This is particularly important for IBD, with up to one-third of patients suffering from recurrent anaemia, and could potentially be a differentiating factor for filgotinib, in our view.

MANTA studies ongoing

Recall, FDA has previously had issues regarding use of the highest 200mg/day filgotinib dose in male patients, based on concerns over toxicity to the male reproductive system relating to rat/dog toxicology studies. Consequently, despite the fact the Phase II DARWIN trials confirmed no clinically meaningful changes in male hormone levels, US males taking part in the Phase III SELECTION UC and Phase III DIVERSITY Crohn's disease studies are only eligible to receive the higher 200mg/day dose if they have failed at least one prior biologic.

In contrast, the FINCH RA programme, approved by a different FDA division, allowed inclusion of the 200mg/day dose, but included a dedicated male UC patient testicular safety study, MANTA, which could finally lay safety concerns to rest, in our view. During 2019, a second study, MANTA-RAY was initiated, with more relaxed inclusion criteria and including patients with other rheumatic diseases, in order to speed up recruitment, albeit enrolment into both studies has now been paused due to the COVID-19 outbreak. Unblinded data from these male safety studies will be made available to FDA as part of the RA filing, however Galapagos and partner Gilead remain unforthcoming regarding the timing of headline data.

Broad applicability means multi-blockbuster potential

We forecast peak sales of \$3bn in RA, \$600m in CD and \$400m in UC. We understand Gilead and Galapagos aim to pursue development of filgotinib in 10 to 14 indications, not including the Crohn's sub-populations. Given this extensive programme, we include a \$2bn WW peak sales contribution reflecting filgotinib's potential use in other indications

beyond RA and IBD. We note Humira was not the first anti-TNF α biologic to be approved but it is now the most commercially successful, in part due to its regulatory approvals for numerous indications. Currently, we believe 35%-40% of Humira's global sales are from its use in indications other than RA and IBD, hence we estimate a 30%-35% contribution from these diseases for filgotinib representing around \$2bn at peak.

Galapagos receives 20%-30% tiered royalties on sales from partner Gilead and a 50:50 profit-share on co-promotion in EU5 and Benelux. Galapagos is also eligible to receive up to \$1.27bn in milestones, of which \$600m are dependent on achieving sales targets. However, as part of the broad collaboration with Gilead, Galapagos is responsible for funding 50% of R&D spend.

Pipeline gaining attention

Gilead has an option for exclusive ex-European rights to all of Galapagos' current and future programmes. Galapagos is responsible for all discovery and development of programmes until the end of Phase II, following which Gilead has the right to opt-in to co-development, and after which costs will be shared equally. With the exception of GLPG1690 and GLPG1972, Gilead will pay \$150m opt-in per programme, with Galapagos eligible for tiered royalties ranging from 20%-24%.

GLPG1690: novel mechanism of action for fibrosis

- **Peak sales forecast:** \$1.85bn WW in IPF assuming 2023E launches
- **Valuation:** c.€16 per share with a 40% probability of success
- **Next news flow:** Phase IIa NOVESA systemic sclerosis data during 3Q20E; Phase III ISABELA IPF futility analysis during 1Q21E, with efficacy data from 2022E

Phase IIa GLPG1690 idiopathic pulmonary fibrosis (IPF) [FLORA data were encouraging](#). Importantly, there was a signal suggesting that GLPG1690 may stabilise lung function, which, if confirmed in the ongoing ISABELA studies, could be a significant benefit given currently approved drugs Esbriet (pirfenidone) and Ofev (nintedanib) only slow the rate of disease progression. Autotaxin inhibitor GLPG1690 has Orphan Drug designation for IPF in both the US and Europe.

The Phase III ISABELA programme initiated in December 2018, consisting of two identical double-blind placebo-controlled trials evaluating two doses of GLPG1690, 200mg or 600mg once-daily on top of standard of care (pirfenidone, nintedanib, or prior) versus placebo on top of standard of care over 12 months. The primary endpoint is the rate of forced vital capacity (FVC) decline at 12 months, with secondary endpoints including respiratory-related hospitalisations, overall survival, quality of life and safety. A futility analysis will be performed once 30% of patients have completed 12 months treatment, which is expected to occur 1Q21E, with data then expected from 2022E.

Galapagos splits global development costs 50:50 with Gilead, and is eligible for a \$325m milestone on potential US FDA approval of GLPG1690, and 20%-24% royalties on US sales. We forecast \$1.25bn WW peak sales based on a modest 15% penetration of mild-moderate IPF patients. Note 2016 sales of Esbriet and Ofev combined were c.\$1.3bn after only around two years on the US market.

IPF is a core area of focus for Galapagos, with GPR84 antagonist GLPG1205 currently in the Phase IIa PINTA trial for data 1H20E, and GLPG3499 in preclinical development.

GLPG1690 is also in the Phase II NOVESA trial in systemic sclerosis (SSc), for which we expect first data during 3Q20E. Given the high-risk indication, we do not currently ascribe any value to GLPG1690 for SSc.

GLPG1972: high-risk but potentially high-reward

- **Peak sales forecast:** \$3bn WW in osteoarthritis assuming 2025E launches; Servier has ex-US rights
- **Valuation:** c.€5.5 per share with a 20% probability of success
- **Next news flow:** Phase II ROCCELLA data during 4Q20E triggering Gilead opt-in decision.

GLPG1972 is a novel potent and selective oral ADAMTS-5 inhibitor in development for osteoarthritis (OA). The ADAMTS (A Disintegrin And Metalloproteinase with Thrombospondin motifs) enzymes, in particular ADAMTS-5, have been implicated in the degradation of aggrecan. Aggrecan is a core component of the articular cartilage extracellular matrix and key for cartilage function. Increased aggrecanase activity initiating a loss of aggrecan is recognised as a trigger factor for OA, preceding more severe cartilage destruction that is characteristic of OA.

In Phase I trials GLPG1972 was safe and well-tolerated, but importantly was also shown to lead to a dose-dependent reduction in blood levels of ARGS neoepitope fragments by up to 50% over a 2-4 week period. ARGS is a biomarker for cartilage breakdown, released on cleavage of aggrecan by ADAMTS-5.

The Phase IIb ROCCELLA trial initiated in June 2018, evaluating three once-daily oral doses of GLPG1972 versus placebo in c.850 patients with knee OA for 52 weeks. The primary endpoint is change in cartilage thickness at week 52 as assessed by qMRI imaging of the central medial tibiofemoral compartment. Recruitment completed around six months ahead of schedule in June 2019, with headline data expected during 4Q20E.

GLPG1972 was discovered as part of an OA alliance between Galapagos and Servier, with Servier exercising its ex-US option in July 2017. On completion of the ROCCELLA study, Gilead has the option to pay \$250m for US rights, plus up to an additional \$200m if certain endpoints are met, and up to a further \$550m in regulatory and commercial milestones. Galapagos will contribute 50% of development costs for the US. We currently forecast \$3bn WW peak sales, for a c.€5.5/share NPV at 20% probability. GLPG1972 was granted FDA Fast Track designation in November 2018.

Toledo: full steam ahead advancing secretive programme

- **Peak sales forecast:** \$3bn WW for the broad programme across autoimmune diseases
- **Valuation:** c.€4 per share with a 15% probability of success
- **Next news flow:** Initial GLPG3312 Phase I data potentially 1Q20E; GLPG3970 began Phase I in 3Q19 with multiple Phase II proof-of-concept studies in inflammatory conditions expected to start by YE2020E.

The Toledo programme aims to improve upon disease control rates achieved with current standard of care, with applicability across a number of inflammatory diseases. The programme employs a novel mechanism of action, targeting the interplay between dendritic (sensory) cells and epithelial cells. Preclinical data in a number of inflammatory bowel disease (IBD) models and a rheumatoid arthritis (RA) model suggests substantial reductions in disease activity indexes, superior to other drug classes studied, including JAK-inhibitors.

Galapagos plans to start a Phase II with the first generation Toledo compound GLPG3312 in ulcerative colitis during 2020E. This is despite an undisclosed toxicity with GLPG3312 that prevents oral-systemic delivery. Galapagos expects second-generation compound GLPG3970 to be better tolerated should data from a planned Phase I trial confirm its preclinical profile, then enabling development for a broader range of

inflammatory diseases. As the target is likely to be revealed upon Phase II initiation, management is keen to maintain its development timeline advantage, planning up to eight proof-of-concept Phase II studies by YE2020E, some of which could be dose-finding.

Galapagos is very enthusiastic about the programme. Toledo is now the biggest discovery project, with c.40% of discovery efforts for new compounds.

Price Target €210

Our €210/\$232 per share/ADS Price Target is based on a sum-of-the-parts valuation largely comprising probability-adjusted NPVs for filgotinib, GLPG1690 in IPF, GLPG1972 in osteoarthritis and the broad Toledo programme, together with Net Cash.

Exhibit 3 - Galapagos Sum-of-the-Parts Valuation

	Indication	Peak Sales (\$mn)	Value (EURmn)	Prob.	Adj. Value (EURmn)	EUR per share
filgotinib	RA, Crohn's, Ulcerative Colitis & Others	6,000	6,385	95%	6,066	93.6
CF Collaboration	Cystic fibrosis	2,000	890	15%	134	2.1
GLPG1690	Idiopathic pulmonary fibrosis	1,850	2,532	40%	1,013	15.6
GLPG1972	Osteoarthritis	3,000	1,780	20%	356	5.5
Toledo	Autoimmune diseases	3,000	1,860	15%	279	4.3
Net Cash/(Debt)			5,772	100%	5,772	89.0
Valuation			19,220		13,620	210.1
Potential Dilution for Funding					0	0.0
Potential Diluted Valuation						210.1

Source: Jefferies estimates

Exhibit 4 - Galapagos Sources of Potential Upside and Downside Risks

	Upside	EUR per share	Downside	EUR per share
filgotinib regulatory approvals in RA	Major approvals in 2H20E	4.9	Safety concerns	(64.0)
filgotinib Phase III in Crohn's & Ulcerative colitis	Positive data confirm profile	0.0	Efficacy and/or safety concerns	(29.6)
Toledo initial proof-of-concept data	Positive efficacy & safety	4.3	Discontinued or delayed	(4.3)
GLPG1690 Phase III ISABELA in IPF	Positive efficacy & safety	15.6	Efficacy and/or safety concerns	(15.6)
Potential Upside/(Downside)		24.9		(113.5)
Potential Valuation		235.0		96.6

Source: Jefferies estimates

Exhibit 5 - Galapagos catalysts

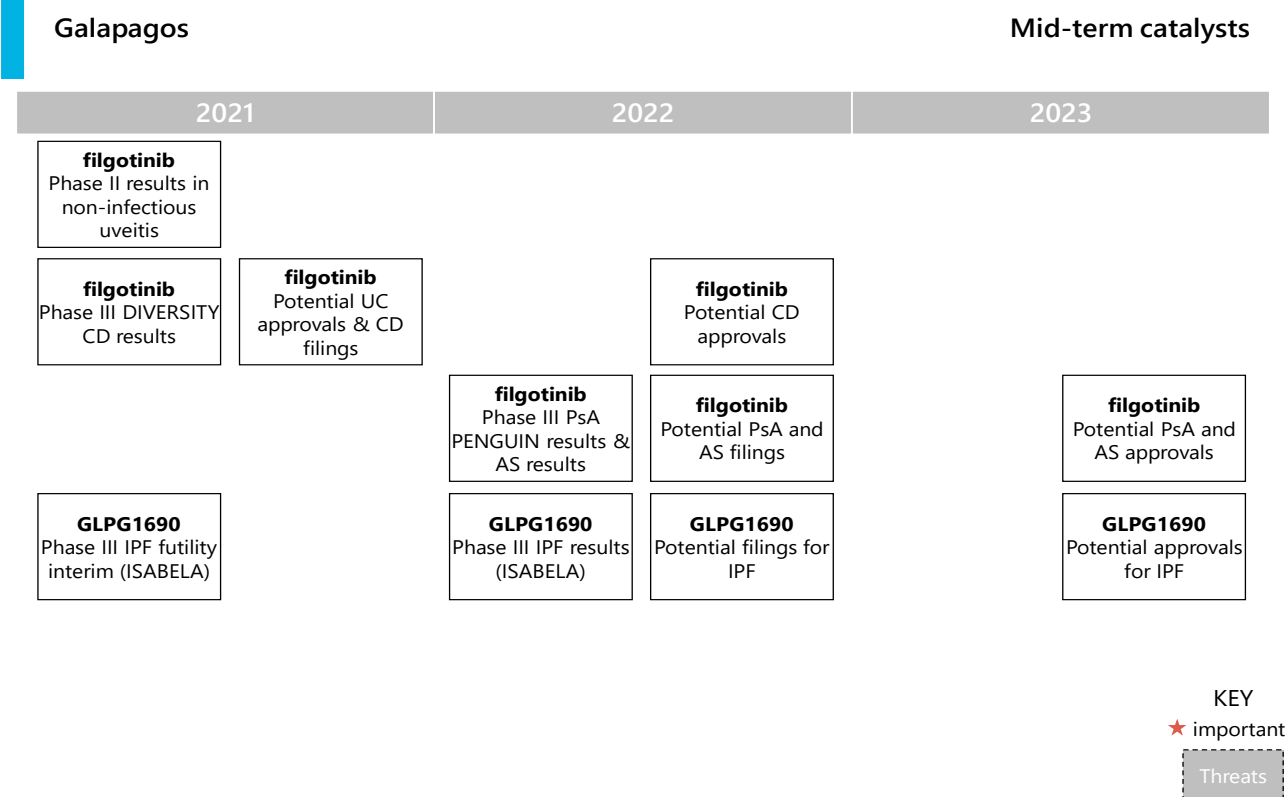
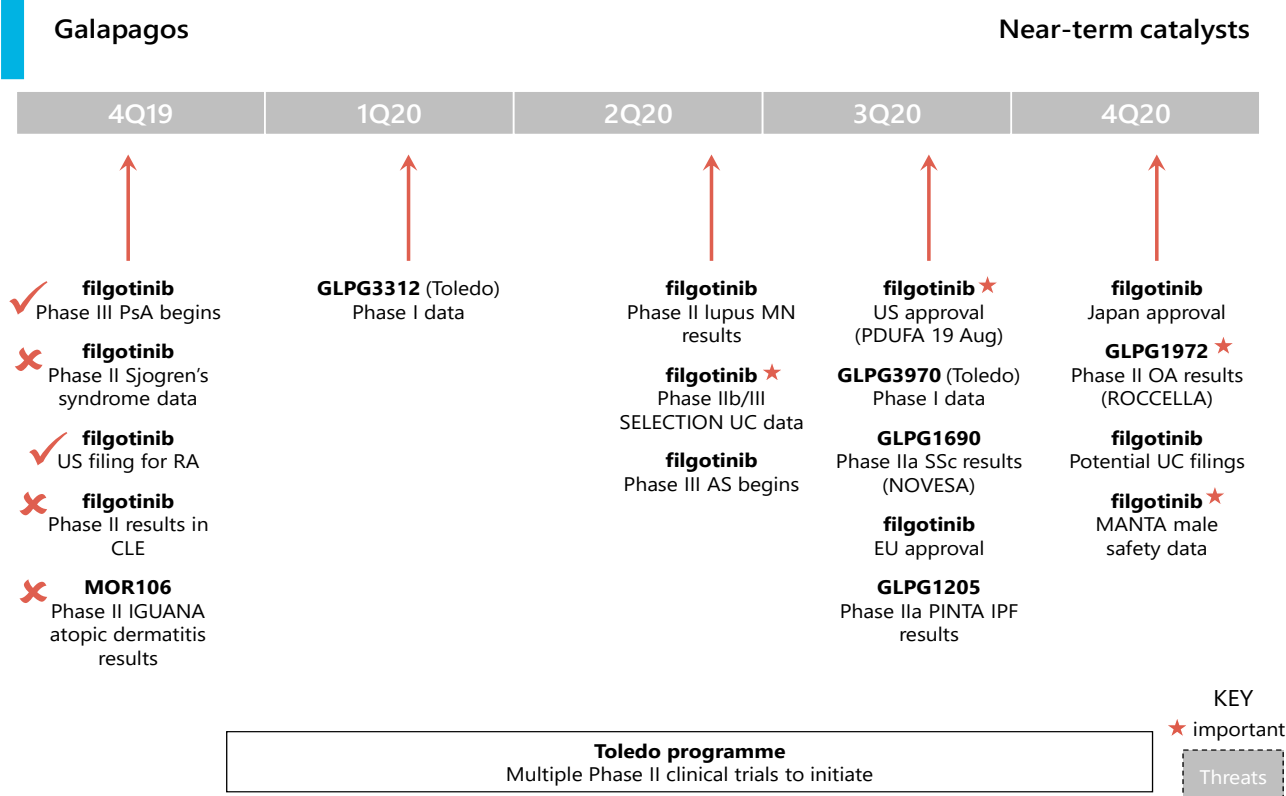


Exhibit 7 - Galapagos Revenue Model

(EUR millions Dec YE)	2020E									
	2019A	1Q20E	2Q20E	3Q20E	4Q20E	2020E	2021E	2022E	2023E	2024E
R&D Revenue	845.0	106.0	106.0	191.0	239.7	642.7	557.9	535.2	623.0	428.7
Other Income	50.9	12.7	11.8	5.9	16.7	47.0	36.0	32.4	29.2	26.2
filgotinib Royalties	0.0	0.0	0.0	0.3	3.2	3.5	40.5	121.5	248.8	385.1
filgotinib Revenues for EU5-Benelux Profit Share	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	15.2	107.8
Discontinued Operations	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Group Revenue (Prob. Adjusted)	895.9	118.7	117.8	197.2	259.6	693.2	634.3	689.1	916.1	947.8
% Change Year over Year										
R&D Revenue	192.5%	220.8%	80.5%	(69.9%)	101.0%	(23.9%)	(13.2%)	(4.1%)	16.4%	(31.2%)
Other Income	75.5%	61.2%	32.7%	(41.1%)	(31.1%)	(7.7%)	(23.4%)	(10.0%)	(10.0%)	(10.0%)
filgotinib Royalties	n/a	n/a	n/a	n/a	n/a	n/a	1043.1%	200.1%	104.8%	54.8%
Total Group Revenue (Prob. Adjusted)	181.9%	190.1%	74.2%	(69.4%)	81.0%	(22.6%)	(8.5%)	8.6%	32.9%	3.5%

Source: Jefferies estimates, company data

Exhibit 8 - Galapagos Margin Analysis

	2020E									
	2019A	1Q20E	2Q20E	3Q20E	4Q20E	2020E	2021E	2022E	2023E	2024E
Gross Margin	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Sales & Marketing Expenses	2.7%	10.1%	11.0%	7.4%	6.4%	8.1%	11.4%	12.8%	9.9%	9.9%
General & Admin. Expenses	8.2%	16.9%	19.5%	15.2%	10.4%	14.4%	20.5%	21.1%	17.3%	17.7%
R&D Expenses	47.7%	117.3%	120.7%	73.5%	59.2%	83.7%	105.2%	99.0%	76.8%	80.2%
Operating Income	41.3%	(44.3%)	(51.4%)	3.8%	23.8%	(6.3%)	(38.2%)	(33.7%)	(4.0%)	(7.9%)
Pretax Profit	16.7%	(39.3%)	(46.3%)	6.8%	26.2%	(2.9%)	(32.9%)	(28.7%)	(0.3%)	(4.3%)
Net Income	16.7%	(39.3%)	(46.3%)	6.8%	26.2%	(2.9%)	(32.9%)	(28.7%)	(0.3%)	(4.3%)

Source: Jefferies estimates, company data

Exhibit 9 - Galapagos Profit and Loss Model

(EUR millions except EPS Dec YE)	2020E					2020E	2021E	2022E	2023E	2024E
	2019A	1Q20E	2Q20E	3Q20E	4Q20E					
Revenue	895.9	118.7	117.8	197.2	259.6	693.2	634.3	689.1	916.1	947.8
Cost of Sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Gross Profit	895.9	118.7	117.8	197.2	259.6	693.2	634.3	689.1	916.1	947.8
Total Operating Expenses	(525.6)	(171.2)	(178.1)	(189.5)	(197.2)	(736.0)	(869.5)	(916.1)	(952.9)	(1,022.4)
Sales & Marketing Expenses	(24.6)	(12.0)	(13.0)	(14.5)	(16.5)	(56.0)	(72.0)	(88.0)	(90.9)	(93.9)
General & Admin. Expenses	(73.7)	(20.0)	(23.0)	(30.0)	(27.0)	(100.0)	(130.0)	(145.6)	(158.7)	(168.2)
R&D Expenses	(427.3)	(139.2)	(142.1)	(145.0)	(153.7)	(580.0)	(667.5)	(682.5)	(703.3)	(760.3)
o/w Acquisition-related Amortisation/Write-down	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other Operating Income	0.0	(0.1)	(0.2)	(0.3)	(0.5)	(1.1)	(7.5)	(4.9)	0.0	0.0
Operating Exceptionals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Operating Income	370.3	(52.6)	(60.6)	7.4	61.9	(43.9)	(242.6)	(231.9)	(36.8)	(74.6)
Adjusted Operating Income	370.3	(52.6)	(60.6)	7.4	61.9	(43.9)	(242.6)	(231.9)	(36.8)	(74.6)
EBITDA	382.7	(48.8)	(56.7)	11.2	65.7	(28.5)	(225.9)	(212.6)	(14.5)	(57.5)
Adjusted EBITDA	382.7	(48.8)	(56.7)	11.2	65.7	(28.5)	(225.9)	(212.6)	(14.5)	(57.5)
Net Financial Income	(38.6)	6.0	6.0	6.0	6.0	24.0	34.0	34.0	34.0	34.0
Exceptionals	(181.6)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Income from Associates & JVs	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pretax Profit	150.1	(46.6)	(54.6)	13.4	67.9	(19.9)	(208.6)	(197.9)	(2.8)	(40.6)
Adjusted Pretax Profit	331.7	(46.6)	(54.6)	13.4	67.9	(19.9)	(208.6)	(197.9)	(2.8)	(40.6)
Taxation	(0.2)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Minority Interests	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income from Continuing Operations	149.8	(46.6)	(54.6)	13.4	67.9	(19.9)	(208.6)	(197.9)	(2.8)	(40.6)
Net Income from Discontinued Operations	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income	149.8	(46.6)	(54.6)	13.4	67.9	(19.9)	(208.6)	(197.9)	(2.8)	(40.6)
Adjusted Net Income	331.5	(46.6)	(54.6)	13.4	67.9	(19.9)	(208.6)	(197.9)	(2.8)	(40.6)
WA Basic Shares (mn)	57.6	64.9	64.9	64.9	64.9	64.9	65.4	65.9	66.4	66.9
WA Shares Diluted (mn)	60.1	64.9	64.9	66.5	66.5	64.9	65.4	65.9	66.4	66.9
EPS (EUR)	2.6	(0.7)	(0.8)	0.2	1.0	(0.3)	(3.2)	(3.0)	(0.0)	(0.6)
Adjusted EPS (EUR)	5.8	(0.7)	(0.8)	0.2	1.0	(0.3)	(3.2)	(3.0)	(0.0)	(0.6)
Diluted EPS (EUR)	2.5	(0.7)	(0.8)	0.2	1.0	(0.3)	(3.2)	(3.0)	(0.0)	(0.6)
Diluted Adjusted EPS (EUR)	5.5	(0.7)	(0.8)	0.2	1.0	(0.3)	(3.2)	(3.0)	(0.0)	(0.6)
Adjusted ADR EPS (\$)	6.4	(0.8)	(0.9)	0.2	1.2	(0.3)	(3.5)	(3.3)	(0.0)	(0.7)
% Change Year over Year										
Revenue	181.9%	190.1%	74.2%	(69.4%)	81.0%	(22.6%)	(8.5%)	8.6%	32.9%	3.5%
Cost of Sales	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Gross Profit	181.9%	190.1%	74.2%	(69.4%)	81.0%	(22.6%)	(8.5%)	8.6%	32.9%	3.5%
Total Operating Expenses	44.9%	81.8%	59.1%	23.6%	18.7%	40.0%	18.1%	5.4%	4.0%	7.3%
Sales & Marketing Expenses	492.8%	587.3%	235.5%	255.6%	10.9%	127.9%	28.6%	22.2%	3.3%	3.3%
General & Admin. Expenses	106.8%	116.9%	67.7%	5.0%	21.6%	35.7%	30.0%	12.0%	9.0%	6.0%
R&D Expenses	32.3%	67.3%	50.6%	20.2%	19.1%	35.7%	15.1%	2.2%	3.0%	8.1%
Operating Income	926.4%	1.2%	(36.5%)	(98.5%)	372.3%	(111.8%)	(453.0%)	4.4%	84.1%	(102.5%)
Adjusted Operating Income	926.4%	1.2%	(36.5%)	(98.5%)	372.3%	(111.8%)	(453.0%)	4.4%	84.1%	(102.5%)
Pretax Profit	613.7%	4.1%	(15.6%)	(96.1%)	168.9%	(113.2%)	(949.9%)	5.1%	98.6%	(1329.6%)
Adjusted Pretax Profit	1235.6%	4.1%	(15.6%)	(97.2%)	214.5%	(106.0%)	(949.9%)	5.1%	98.6%	(1329.6%)
Net Income	612.1%	4.2%	(15.4%)	(96.3%)	158.8%	(113.3%)	(949.9%)	5.1%	98.6%	(1329.6%)
Adjusted Net Income	1232.9%	4.2%	(15.4%)	(97.3%)	189.1%	(106.0%)	(949.9%)	5.1%	98.6%	(1329.6%)
EPS (EUR)	563.2%	19.5%	2.8%	(96.7%)	157.3%	(111.8%)	(941.9%)	5.8%	98.6%	(1318.9%)
Adjusted EPS (EUR)	1124.8%	19.5%	2.8%	(97.6%)	186.9%	(105.3%)	(941.9%)	5.8%	98.6%	(1318.9%)

Source: Jefferies estimates, company data

Exhibit 10 - Galapagos Cash Flow Model

(EUR millions Dec YE)	2019A	2020E	2021E	2022E	2023E	2024E
Operating Income	370.3	(43.9)	(242.6)	(231.9)	(36.8)	(74.6)
Depreciation and Amortisation	12.4	15.3	16.8	19.3	22.4	17.1
EBITDA	382.7	(28.5)	(225.9)	(212.6)	(14.5)	(57.5)
Other Adjustments and Exceptionals	2.3	50.0	57.0	61.6	65.3	68.5
Decrease/(Increase) in Inventories	0.0	0.3	0.0	0.0	0.0	0.0
Decrease/(Increase) in Receivables	(67.3)	1.6	3.2	(3.0)	(12.4)	(1.7)
Increase/(Decrease) in Payables	79.9	(15.3)	22.0	7.6	7.8	12.7
Increase/(Decrease) in Deferred Income	2,804.2	(423.6)	(413.5)	(408.5)	(388.5)	(288.8)
Change in WC	2,816.9	(437.0)	(388.3)	(403.9)	(393.1)	(277.8)
Taxation Paid	(0.1)	(0.1)	0.0	0.0	0.0	0.0
Interest Paid	6.7	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)
Net Cash Flow from Operating Activities	3,208.6	(416.6)	(558.2)	(556.0)	(343.3)	(267.8)
Purchase of Tangible Fixed Assets	(22.4)	(24.3)	(22.2)	(24.1)	(32.1)	(33.2)
Proceeds from Sale of PP&E	0.0	0.0	0.0	0.0	0.0	0.0
Purchase of Intangible Assets	(23.3)	0.0	0.0	0.0	0.0	0.0
(Purchase)/Sale of Investments	(0.1)	0.0	0.0	0.0	0.0	0.0
(Acquisitions)/Disposals of Subsidiaries	0.0	0.0	0.0	0.0	0.0	0.0
Dividends Received from Associates	0.0	0.0	0.0	0.0	0.0	0.0
Interest Received	0.0	25.0	35.0	35.0	35.0	35.0
Net Cash Flow from Investing Activities	(3,764.7)	(24.3)	(22.2)	(24.1)	(32.1)	133.2
Management of Liquid Resources	(3,718.9)	0.0	0.0	0.0	0.0	166.4
Capital Changes	1,340.8	22.1	33.0	38.5	38.5	38.5
Debt Changes	(5.1)	(11.3)	(5.1)	(5.1)	(5.1)	(4.3)
Equity Dividends Paid	0.0	0.0	0.0	0.0	0.0	0.0
Other Financing Cash Flows	0.0	0.0	0.0	0.0	0.0	0.0
Net Cash Flow from Financing Activities	1,335.8	35.8	62.9	68.4	68.4	69.2
Effect of FX on Cash and Cash Equivalents	(10.0)	0.0	0.0	0.0	0.0	0.0
Increase in Cash	769.7	(405.1)	(517.5)	(511.7)	(307.0)	(65.3)
Change in Net Debt	(4,503.7)	393.8	512.4	506.6	301.9	227.5
(Cash Burn)	3,162.8	(440.9)	(580.4)	(580.1)	(375.4)	(301.0)

Source: Jefferies estimates, company data

Exhibit 11 - Galapagos Balance Sheet Model

(EUR millions Dec YE)	2019A	2020E	2021E	2022E	2023E	2024E
Non-current Assets	202.7	211.6	217.0	221.9	231.5	247.6
Intangible Assets	24.9	23.4	21.9	20.3	18.8	17.3
Property, Plant and Equipment	66.1	76.5	83.5	89.8	101.0	118.6
Investments	14.1	14.1	14.1	14.1	14.1	14.1
Other Long-term Assets	97.6	97.6	97.6	97.6	97.6	97.6
Current Assets	5,865.9	5,459.0	4,938.3	4,429.6	4,135.1	3,905.1
Inventories	0.3	0.0	0.0	0.0	0.0	0.0
Trade Accounts Receivable	39.6	38.0	34.8	37.8	50.2	51.9
Other Current Assets	45.2	45.2	45.2	45.2	45.2	45.2
Cash and Cash Equivalents	5,780.8	5,375.8	4,858.3	4,346.6	4,039.6	3,807.9
Total Assets	6,068.6	5,670.6	5,155.3	4,651.5	4,366.6	4,152.7
Current Liabilities	571.8	549.4	566.4	554.0	461.2	409.5
Trade Accounts Payable	142.5	118.6	141.4	148.2	153.0	165.3
Other Current Liabilities	2.0	2.0	2.0	2.0	2.0	2.0
Accrued Expenses	0.9	9.5	8.7	9.4	12.5	13.0
Deferred Income	414.3	413.5	408.5	388.5	288.8	228.5
Short-term Debt	6.2	0.0	0.0	0.0	0.0	0.0
Leasing Obligations	5.8	5.8	5.8	5.8	5.0	0.7
Non-current Liabilities	2,621.2	2,193.2	1,779.6	1,386.0	1,093.0	864.5
Long-term Debt	0.0	0.0	0.0	0.0	0.0	0.0
Leasing Obligations	19.6	14.5	9.4	4.3	0.0	0.0
Deferred Tax Liabilities	0.0	0.0	0.0	0.0	0.0	0.0
Deferred Income	2,586.3	2,163.5	1,755.0	1,366.5	1,077.8	849.3
Long-term Provisions	15.3	15.3	15.3	15.3	15.3	15.3
Total Shareholders' Equity	2,875.7	2,927.9	2,809.3	2,711.4	2,812.3	2,878.7
Share Capital	287.3	287.3	287.3	287.3	287.3	287.3
Share Premium Account	2,703.6	2,725.7	2,758.7	2,797.2	2,835.7	2,874.2
Other Reserves and Adjustments	(6.0)	(6.0)	(6.0)	(6.0)	(6.0)	(6.0)
Retained Earnings	(109.2)	(79.1)	(230.7)	(367.0)	(304.6)	(276.7)
Minority Interests	0.0	0.0	0.0	0.0	0.0	0.0
Total Liabilities and Shareholders' Equity	6,068.6	5,670.6	5,155.3	4,651.5	4,366.6	4,152.7

Source: Jefferies estimates, company data

Company Description

Galapagos

Galapagos is a Belgian biotech company focusing on drug discovery using cells taken from patients with diseases of interest; typically musculoskeletal, CNS and inflammatory disorders plus orphan indications. The company's most advanced product is filgotinib, a JAK1 inhibitor, which has completed Phase III for rheumatoid arthritis and is also in development for Crohn's disease and ulcerative colitis partnered with Gilead. The company has a broad R&D collaboration with Gilead and also has active collaborations with Servier and MorphoSys.

Company Valuation/Risks

Galapagos

Our Price Target is based on a sum-of-the-parts valuation largely comprising probability-adjusted NPVs for filgotinib, GLPG1690 in IPF, GLPG1972 in osteoarthritis, and Toledo in autoimmune disorders, plus Net Cash. Risks include: (1) regulatory setbacks for filgotinib; (2) upcoming late-stage pipeline catalysts are high risk; and (3) clinical trial failures.

Gilead Sciences, Inc.

Our PT is based on a pipeline-adjusted DCF and multiple of our 2020 EPS estimate. Risks: competition, pipeline disappointments, and worse-than-expected sales.

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Investment Recommendation Record

(Article 3(1)e and Article 7 of MAR)

Recommendation Published March 29, 2020 , 17:35 ET.
Recommendation Distributed March 30, 2020 , 00:00 ET.

Company Specific Disclosures

Jefferies LLC is acting as a financial advisor to Kite Pharma (KITE) on the sale of the company to Gilead Sciences (GILD).

Jefferies Group LLC makes a market in the securities or ADRs of Galapagos.

Jefferies Group LLC makes a market in the securities or ADRs of Gilead Sciences, Inc.

Explanation of Jefferies Ratings

Buy - Describes securities that we expect to provide a total return (price appreciation plus yield) of 15% or more within a 12-month period.

Hold - Describes securities that we expect to provide a total return (price appreciation plus yield) of plus 15% or minus 10% within a 12-month period.

Underperform - Describes securities that we expect to provide a total return (price appreciation plus yield) of minus 10% or less within a 12-month period.

The expected total return (price appreciation plus yield) for Buy rated securities with an average security price consistently below \$10 is 20% or more within a 12-month period as these companies are typically more volatile than the overall stock market. For Hold rated securities with an average security price consistently below \$10, the expected total return (price appreciation plus yield) is plus or minus 20% within a 12-month period. For Underperform rated securities with an average security price consistently below \$10, the expected total return (price appreciation plus yield) is minus 20% or less within a 12-month period.

NR - The investment rating and price target have been temporarily suspended. Such suspensions are in compliance with applicable regulations and/or Jefferies policies.

CS - Coverage Suspended. Jefferies has suspended coverage of this company.

NC - Not covered. Jefferies does not cover this company.

Restricted - Describes issuers where, in conjunction with Jefferies engagement in certain transactions, company policy or applicable securities regulations prohibit certain types of communications, including investment recommendations.

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Valuation Methodology

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Other Companies Mentioned in This Report

- Gilead Sciences, Inc. (GILD: \$72.85, BUY)

Rating and Price Target History for: Galapagos (GLPG NA) as of 03-26-2020



Rating and Price Target History for: Galapagos (GLPG) as of 03-26-2020



Rating and Price Target History for: Gilead Sciences, Inc. (GILD) as of 03-26-2020



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Notes: Each box in the Rating and Price Target History chart above represents actions over the past three years in which an analyst initiated on a company, made a change to a rating or price target of a company or discontinued coverage of a company.

Legend:

- I: Initiating Coverage
- D: Dropped Coverage
- B: Buy

H: Hold

UP: Underperform

Distribution of Ratings

Distribution of Ratings						
			IB Serv./Past12 Mos.		JIL Mkt Serv./Past12 Mos.	
	Count	Percent	Count	Percent	Count	Percent
BUY	1288	54.28%	114	8.85%	12	0.93%
HOLD	935	39.40%	34	3.64%	3	0.32%
UNDERPERFORM	150	6.32%	1	0.67%	0	0.00%

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