

April 8, 2020

Biotechnology

BUY
COMPANY UPDATE

Financial Summary

Changes	Previous	Current
Rating	—	Buy
Target Price	—	\$298.00
FY19A EPS	—	€2.49
FY20E EPS	—	€(1.61)
FY19A Revenue	—	€895.9
FY20E Revenue	—	€643.3

Price (04/08/20):	\$202.70
52-Week Range:	\$274 - \$111
Market Cap.(mm):	13,175.5
Shr.O/S-Diluted (mm):	65.0
Avg Daily Vol (3 Mo):	223,829
Dividend / Yield:	\$0.00 / 0.0%

Revenue	2018A	2019A	2020E
Q1	€44.8	€40.9	€110.0
Q2	€57.0	€67.6	€110.5
Q3	€103.2	€644.0	€111.1
Q4	€112.8	€143.2	€311.7
FY (Dec)	€317.8A	€895.9A	€643.3

EPS	2018A	2019A	2020E
Q1	€(0.73)	€(0.89)	€(0.95)
Q2	€(0.42)	€(0.86)	€(1.06)
Q3	€0.28	€5.83	€(1.21)
Q4	€0.27	€(1.79)	€1.62
EPS	€(0.56)A	€2.49A	€(1.61)

Price Performance

CEO Fireside Chat Recap: Maximizing Execution in COVID-19
Uncertainty; Filgo UC Data On-Deck; Broad Pipeline Progress

Summary

We recently hosted a call with GLPG's CEO Onno van de Stolpe and Elizabeth Goodwin, VP Investor Relations, where we discussed: 1) status of filgo NDA filing for RA; 2) approaching P3 filgo UC data; 3) update on non-filgo pipeline initiatives; 4) anticipated filgo market differentiation; and 5) GLPG EU commercial build. Importantly, management does not anticipate a delay in the filgo RA PDUFA date (Stifel est. August 2020). For filgo in UC (data est. 2Q20), cross trial comparisons with competitors may prove challenging due to subtle differences in trial designs/endpoints, but management thinks Rinvoq is most appropriate (~14-20% pbo-adjusted remission). Non-filgo pipeline, including P3 '1690 and P2 '1205 in IPF, as well as P2b '1972 in OA continue as planned for now, but the situation remains fluid. Street assumes filgo black box given Rinvoq class label, but GLPG internal market research suggests docs will recognize filgo best-in-class safety advantages.

Key Points

GLPG/GILD paused studies with filgotinib; no evidence of delayed approval in RA. Prior to our conversation with management, the Company had 2 updates (March 20th and 22nd) where they acknowledged the impact of the coronavirus on some of its clinical studies, which led to a pause in enrollment of its P2 and P3 studies with filgotinib. We see this as a reasonable step since these patients are immunosuppressed as a result of the therapy. Affected trials include: DIVERSITY (Crhon's), PENGUIN (psoriatic arthritis), a P2 study in uveitis, and both MANTA and MANTA-ray studies. In addition, GLPG said that it now plans to launch a P3 study of filgotinib in AS later this year (prior guidance 1H20). Importantly, management has not seen evidence of a delay in the approval of filgotinib. And while GLPG does not expect an adcom, they did point to the possibility of a virtual adcom, if one were convened.

Filgotinib readout in UC remains on-track for this quarter. Management is bullish, as are we, that the data will be positive given prior success with competing JAKi (PFE's Xeljanz and ABBV's Rinvoq). How positive? We don't know, but GLPG said that it is aiming for filgotinib to fall in line with what Rinvoq has shown (Rinvoq P2b = ~15-20% placebo adjusted remission rate in its P2b and ~10-13% for Xeljanz). Management did caution against cross-trial comparisons given the differences in study designs and slightly different endpoints across JAKs studies. 1) The primary endpoint in the Rinvoq P2b study was clinical remission per adapted Mayo score, which includes PROs. 2) Trials evaluating Rinvoq and Xeljanz used a high dose induction followed by a low maintenance dose. By contrast, the primary endpoint in GLPG/GILD's P3 includes remission based on components of the Mayo Clinic Score, and patients in the treatment arm are randomized to receive either 200 mg or 100 mg of filgotinib.

GLPG forging ahead with PoC studies in the backdrop of COVID-19 disruption. Management was transparent in acknowledging that enrollment in ongoing PoC studies had slowed, but were not prepared to change their guidance (2H20). We outline updates from ongoing studies below:

- **GLPG1690:** Recruitment continues in the ISABELA P3 study in IPF, and remains on track (futility analysis 1H21). However, management is cognizant of the fluidity of the situation (esp. in the US) and acknowledged that things could change. The Company continues to closely monitor patients enrolled in the study to minimize pts drop-offs and missing data points (patients are monitored once a month, to once every 3 mos.) GLPG remains on track to report P2 data with '1690 in SSc (NOVESA) in 2H20.

Continued below...

Adam A. Walsh, M.D. | (617) 488-4626 | adamwalsh@stifel.com
Edwin Zhang, PhD | (212) 271-3787 | zhange@stifel.com
Stifel Equity Trading Desk | (800) 424-8870

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Investment Thesis

With the recent GILD partnership, GLPG is well-positioned to capitalize on its core drug discovery and development capabilities. We believe filgotinib has best-in-class safety that will prove a competitive advantage in the market and allow for meaningful penetration despite fourth to market status in RA. We think filgotinib also has significant potential in the IBD space, where oral compounds are likely to dominate the future treatment landscape. GLPG1690 has demonstrated potential in a P2, and P3 is progressing. The Toledo inflammation program remains opaque, but we are optimistic as we expect GILD examined the data in depth as part of its recent due diligence. We view GLPG as a well-funded, R&D productive, corporate partner validated, biotech player with a deep and broad pipeline and multiple significant value-creating milestones on the horizon.

GLPG forging ahead with PoC studies in the backdrop of COVID-19 disruption...continued from above.

- **GLPG1205:** No change – data from the PoC P2 PINTA study in IPF are expected in 3Q20.
- **GLPG 1972:** The Company is in the midst of finishing the P2b ROCCELLA study in OA with data anticipated in 2H20. As a reminder, quantitative MRI assessment of the target knee is required at the end of the study ([NCT03595618](#)), which would require an outpatient visit. Management signaled that the FDA has shown flexibility with respect to study endpoints and protocols. They believe that even if measurements are not taken at the 52 wk time point, and done later, the data points would still be valid.

GLPG sees filgotinib's safety profile as the main differentiator compared to other JAKi. As we have noted previously, one of the debates around filgotinib is whether it will be able to avoid a black box for thromboembolic events (TE), which is likely a class effect. GLPG believes that the drug's safety profile is more favorable when put up against its competitors. Management also pointed to their own market research, which suggests that physicians will be able to analyze the data and spot the benefits of filgotinib. In UC, GLPG sees the MANTA and MANTA-ray testicular tox studies as important given the prevalence of UC in younger individuals compared to RA, which tends to affect the older population. Management said that it plans to release substantial safety data from the UC study, similar to other data releases (i.e. FINCH trial).

Commercialization build in the EU remains focused. GLPG is building up its commercial team in Benelux, France, Italy and Spain, and continue to prepare for the launch of filgotinib in RA. Management recognized that Rinvoq's launch has gone well (which bodes well for JAKs in the EU), and believes that they may have an advantage over ABBV in the current climate since marketing of Rinvoq has been halted – potentially giving GLPG time to catch up. GLPG also highlighted potential for meaningful uptake of filgotinib and other JAKi in the EU due their rapid onset, oral availability vs. biologic, and lack of ADAs.

Target Price Methodology/Risks

We arrive at our 12-month target price of \$298 using a discounted cash flow (WACC 10%, terminal growth 1.5%). We probability-adjust our revenue projections for individual product candidates to reflect clinical, developmental and regulatory risks. We use a 10% WACC, which is in line with industry peers, to reflect inherent risk in biotechnology drug development. Our 1.5% terminal growth rate reflects drug patent expirations, partially offset by assumed new drug approvals to sustain steady-state CF.

Risks include: development, clinical, regulatory, manufacturing, commercial, competitive, financing, political, and volatility inherent to the sector.

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 Income Statement (in 000s, except per share data)	FY 2016A	FY 2017A	FY 2018A	Mar 1Q19A	Jun 2Q19A	Sep 3Q19A	Dec 4Q19A	FY 2019A	Mar 1Q20E	Jun 2Q20E	Sep 3Q20E	Dec 4Q20E	FY 2020E	FY 2021E	FY 2022E	FY 2023E	FY 2024E	FY 2025E
POS																		
Rheumatoid Arthritis (Filgotinib)	95%													57,748	219,495	519,772	838,672	911,704
Crohn's disease (Filgotinib)	50%													-	-	-	11,340	114,446
Ulcerative colitis (Filgotinib)	75%													-	-	8,583	68,331	123,993
Psoriatic arthritis (Filgotinib)	50%													-	-	6,079	23,105	54,713
Ankylosing spondylitis (Filgotinib)	40%													-	-	2,133	7,079	14,169
IPF (Autotaxin)	20%													-	-	7,578	13,759	20,235
Osteoarthritis (OA)	15%													-	-	-	7,767	15,955
Upfront/milestone pmts/other income	151,612	155,917	317,845	40,919	67,590	643,954	143,427	895,890	110,000	110,550	111,103	311,658	643,311	460,000	557,000	450,000	450,000	450,000
Total Revenue €	€ 151,612	€ 155,917	€ 317,845	€ 40,919	€ 67,590	€ 643,954	€ 143,427	€ 895,890	€ 110,000	€ 110,550	€ 111,103	€ 311,658	€ 643,311	€ 517,748	€ 793,290	€ 1,087,204	€ 1,617,518	€ 1,875,255
Total Revenue \$	\$163,826	\$185,541	\$378,235	\$46,238	\$76,377	\$727,668	\$162,072	\$1,012,356	\$121,000	\$121,605	\$122,213	\$342,824	\$707,642	\$616,120	\$944,015	\$1,293,773	\$1,924,847	\$2,231,553
COGS	-	-	-	-	-	-	-	-	-	-	-	-	-	5,775	23,629	63,720	116,752	142,525
Gross profit	151,612	155,917	317,845	40,919	67,590	643,954	143,427	895,890	110,000	110,550	111,103	311,658	643,311	511,973	769,661	1,023,484	1,500,766	1,732,729
R&D	139,573	218,502	322,876	83,195	94,372	120,680	129,073	427,320	137,050	143,903	152,537	163,214	596,703	626,539	651,600	677,684	704,771	725,914
SG&A	23,529	27,218	39,776	10,966	17,586	32,643	37,083	98,278	37,100	38,213	40,124	42,531	157,968	164,286	169,215	174,291	179,520	184,906
Income from co-promotion activities	-	-	-	-	-	-	-	-	-	-	-	-	-	15,168	75,890	188,386	320,833	376,554
Restructuring & integration costs	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Operating Expense	163,102	245,720	362,652	94,161	111,958	153,323	166,156	525,598	174,150	182,116	192,660	205,745	754,671	805,993	896,705	1,040,341	1,205,124	1,287,373
Operating income (loss) €	11,491	(89,802)	(44,807)	(53,242)	(44,367)	490,631	(22,730)	370,292	(64,150)	(71,566)	(81,558)	105,913	(111,360)	(263,684)	24,736	359,914	937,309	1,198,463
Operating income (loss) \$	(\$15,651)	(\$106,864)	(\$53,320)	(\$60,163)	(\$50,135)	\$554,413	(\$25,685)	\$418,430	(\$70,565)	(\$78,722)	(\$89,713)	\$116,504	(\$122,496)	(\$313,784)	\$29,436	\$428,297	\$1,115,398	\$1,426,171
Fair value share of subscription agreement	57,479	-	-	-	-	(142,349)	(39,295)	(181,644)	-	-	-	-	-	-	-	-	-	-
Financial income	9,950	3,663	18,335	6,999	(1,349)	34,755	(18,923)	21,482	4,500	4,410	4,322	4,235	17,467	45,023	40,018	37,254	36,971	40,992
Financial expense	(1,692)	(29,368)	(2,737)	(2,345)	(1,472)	(38,631)	(17,623)	(60,071)	(2,500)	(2,525)	(2,550)	(2,576)	(10,151)	(10,202)	(10,253)	(10,304)	(10,356)	(10,407)
Net income (loss) before taxes	54,246	(115,507)	(29,209)	(48,588)	(47,188)	344,405	(98,570)	150,059	(62,150)	(69,681)	(79,786)	107,573	(104,044)	(228,863)	54,502	386,864	963,924	1,229,048
Income tax provision	(235)	(198)	50	68	61	(16,828)	16,913	214	100	100	100	100	400	3,706	26,307	65,547	83,575	
Net income (loss) from continuing operations €	54,012	(115,704)	(29,259)	(48,656)	(47,249)	361,233	(115,483)	149,845	(62,250)	(69,781)	(79,886)	107,473	(104,444)	(228,863)	50,795	360,557	898,377	1,145,473
Net income (loss) from continuing operations \$	\$57,714	(\$137,688)	(\$34,818)	(\$54,981)	(\$53,392)	\$408,193	(\$130,496)	\$169,325	(\$68,475)	(\$76,759)	(\$87,875)	\$118,220	(\$114,888)	(\$272,347)	\$60,447	\$429,063	\$1,069,069	\$1,363,113
Net income from discontinued operations	-	(62)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Translation differences, other	-	(569)	-	-	-	238	-	238	-	-	-	-	-	-	-	-	-	-
Total comprehensive income (loss) to owners of the parent €	54,012	(116,336)	(29,259)	(48,656)	(47,249)	361,471	(115,483)	150,083	(62,250)	(69,781)	(79,886)	107,473	(104,444)	(228,863)	50,795	360,557	898,377	1,145,473
EPS - continuing operations €	€ 1.14	(€ 2.34)	(€ 0.56)	(€ 0.88)	(€ 0.86)	€ 5.83	(€ 1.79)	€ 2.49	(€ 0.86)	(€ 1.06)	(€ 1.21)	€ 1.62	(€ 1.61)	(€ 3.38)	€ 0.73	€ 5.02	€ 12.14	€ 15.02
EPS - continuing operations \$	\$1.22	(\$2.78)	(\$0.68)	(\$1.01)	(\$0.97)	\$6.59	(\$2.02)	\$2.59	(\$1.05)	(\$1.17)	(\$1.33)	\$1.78	(\$1.77)	(\$4.02)	\$0.87	\$5.97	\$14.44	\$17.88
Shares outstanding (weighted average)	47,308	49,479	52,769	54,615	54,823	61,954	64,667	60,179	65,184	65,575	65,969	66,365	65,773	67,746	69,779	71,872	74,028	76,249

Source: Stifel estimates and reported company data

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Galapagos NV (GLPG) as of April 07, 2020 (in USD)



*Represents the value(s) that changed.

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