

BUY
COMPANY UPDATE

Financial Summary

Changes	Previous	Current
Rating	—	Buy
Target Price	—	\$121.00
FY19E EPS	—	€(3.77)
FY20E EPS	—	€(3.64)
FY19E Revenue	—	€173.9
FY20E Revenue	—	€189.0

Price (07/01/19):	\$130.44
52-Week Range:	\$131 - \$85
Market Cap.(mm):	7,104.4
Shr.O/S-Diluted (mm):	54.5
Avg Daily Vol (3 Mo):	122,981
Dividend / Yield:	\$0.00 / 0.0%

Revenue	2018A	2019E	2020E
Q1	€44.8	€40.9	€NE
Q2	€57.0	€42.0	€NE
Q3	€103.2	€44.0	€NE
Q4	€112.8	€47.0	€NE
FY (Dec)	€317.8A	€173.9	€189.0

EPS	2018A	2019E	2020E
Q1	€(0.73)	€(0.89)A	€NE
Q2	€(0.42)	€(0.94)	€NE
Q3	€0.28	€(0.94)	€NE
Q4	€0.27	€(1.00)	€NE
EPS	€(0.56)A	€(3.77)	€(3.64)

Price Performance



Filgotinib NDA Submission in RA by YE19; MANTA No Longer Gating

Summary

Galapagos partner GILD announced that a regulatory pathway is established for an NDA submission for filgotinib in rheumatoid arthritis (RA) by YE19. The positive news came out of the recent pre-NDA meeting with FDA. GLPG investors have been concerned that the still-enrolling P2 MANTA (testicular tox) study would be a gating factor for NDA submission. Today's news largely removes this uncertainty. The press release was light on details, and in the meantime we await more clarity. It is likely that MANTA data are still required for review by FDA after NDA submission (rolling). On the competitive front, upadacitinib PDUFA is anticipated in 3Q19. We currently model for filgotinib launch in RA in FY21 (95% PoS) and unadjusted peak revenue to GLPG of \$622M.

Key Points

MANTA no longer in the way for NDA submission. At the pre-NDA meeting, FDA seems to have agreed that GILD/GLPG could submit the NDA in RA for filgotinib in 2019, regardless of MANTA trial status at the time of filing. The ongoing Phase 2 MANTA safety study is to assess semen parameters with filgotinib treatment in men with moderately to severely active ulcerative colitis or Crohn's disease. It has been delayed due to slow patient enrollment and created uncertainty in the filing timeline for filgotinib in RA. Today's news largely removed this overhang. That said, we think the MANTA data are likely still required (on a rolling submission basis) for FDA review. The positive news is that the MANTA trial is no longer a gating factor to NDA submission and the final FDA approval remains in line with our estimate of YE2020. GLPG shares have had a good run in the last 30 days (up +13%) and GLPG market cap is over \$7B now. We think the FDA's green light to the NDA submission of filgotinib in RA will keep the share momentum into July.

Formulary access is key. The commercial success of filgotinib depends upon its label, real-world performance, pricing and payer interactions, all of which will drive the ultimate penetration to the marketplace. Upadacitinib is the major competitor to filgotinib, in our view. *While we believe it may take filgotinib some time to gain meaningful market share in the crowded RA space, we think the target market is sufficiently large to accommodate multiple Jak inhibitors.* Formulary placement will be crucial for filgotinib's ultimate commercial success as well - and while new to the RA field, we expect GILD/GLPG will leverage filgotinib's best-in-class safety to its maximal advantage. Abbvie's upadacitinib will still make for formidable competition, given its Humira experience and long-standing agreements with payers.

Filgotinib best-in-class safety versus class issue for Jak inhibitors. Filgotinib will likely be the 4th Jak inhibitor to market with a differentiated safety profile. The updated DARWIN 3 long term safety study (2,203 patient years) still shows that filgotinib has the best safety profile among the 4 Jak inhibitors. The FDA recently issued an alert that a safety study found an increased risk of blood clots in the lungs and death when a 10mg twice daily dose of tofacitinib (Xeljanz) was used in RA patients (FDA has not approved this 10 mg twice daily dose for RA). Note that both upadacitinib and filgotinib are Jak1 specific inhibitors, which are different from tofa and bari. Based on the data so far, we think it is possible that filgotinib could have favorable label language vs. peers. Nonetheless, safety remains a major concern for clinicians prescribing JAK inhibitors - so filgotinib's best-in-class profile could differentiate and may have a better shot if it can successfully get into formulary.

Continued---GLPG catalyst table.

Adam A. Walsh, M.D. | (617) 488-4626 | adamwalsh@stifel.com
 Edwin Zhang, PhD | (212) 271-3787 | zhange@stifel.com
 Neil Carnahan | (617) 488-4403 | neil.carnahan@stifel.com
 Stifel Equity Trading Desk | (800) 424-8870

Investment Thesis

We are bullish on the prospects for key pipeline asset filgotinib in multiple diseases. Recent positive POC data for GLPG1690 in IPF compel us to include it in our model with 15% POS. The rest of the pipeline is early and we await additional clinical data to assess its value. Galapagos is well financed with >\$1B cash on the balance sheet.

Compound	Event	Timing
Filgotinib	Topline P2 proof of concept data in Sjogren and cutaneous lupus (Partnered with GILD)	2H19
	Expected NDA submission in RA	YE19
	Data from P3 SELECTION study in UC	2Q20
	Complete enrollment of DIVERSITY study in CD	3Q20
	Estimated data readout of Phase 3 DIVERSITY trial in CD	1Q22
MOR106	Data from P1b bridging study in AD	2H19
	Complete enrollment of P2 GECKO trial in AtD (s.c)	YE19
	Data from IGUANA Phase 2 study in AD (i.v)	1H20
GLPG-1972	Complete enrollment of US P2 ROCCELLA trial in osteoarthritis (OA)	YE19
	Estimated data from P2 ROCCELLA trial in osteoarthritis	1Q21
GLPG-1205	Complete enrollment of P2 PINTA trial in IPF (ex-US)	YE19
	Estimated data readout of PINTA trial in IPF	3Q20
GLPG-1690	Readout of P3 ISABELA studies	2022
GLPG-3312	Initiate P2 proof-of-concept study of the first Toledo compound (Study design TBD)	YE19

Target Price Methodology/Risks

We arrive at our 12-month target price of \$121 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 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, cystic fibrosis, idiopathic pulmonary fibrosis, osteoarthritis, and atopic dermatitis. Lead assets include filgotinib (partnered with Gilead) and a suite of CF potentiators and correctors (partnered with AbbVie). Multiple late stage trials are underway with filgotinib in RA and IBD, with results expected between mid-2018 and 2H19. The CF assets are progressing through multiple P1 and P2 trials, with the goal of launching a triple combo P2 trial around YE17, with results expected in mid-18. 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	Mar 1Q18A	Jun 2Q18A	Sep 3Q18A	Dec 4Q18A	FY 2018A	Mar 1Q19A	Jun 2Q19E	Sep 3Q19E	Dec 4Q19E	FY 2019E	FY 2020E	FY 2021E	FY 2022E	FY 2023E	FY 2024E	FY 2025E
Rheumatoid Arthritis (Filgotinib) POS 95%													-	23,938	90,275	213,987	345,476	375,320
Crohn's disease (Filgotinib) 50%													-	-	5,087	51,365	83,565	83,565
Ulcerative colitis (Filgotinib) 60%													-	-	3,083	24,562	44,692	65,365
Psoriatic arthritis (Filgotinib) 40%													-	-	2,016	7,602	18,020	29,093
Ankylosing spondylitis (Filgotinib) 25%													-	-	1,333	4,424	8,856	13,494
IPF (Autotaxin) 15%													-	-	-	27,064	49,138	72,267
Upfront/milestone prmts/cost reimbursements	151,612	155,917	44,838	57,034	103,208	112,765	317,845	40,919	42,000	44,000	47,000	173,919	188,983	170,085	153,076	137,769	123,992	111,593
Total Revenue €	€ 151,612	€ 155,917	€ 44,838	€ 57,034	€ 103,208	€ 112,765	€ 317,845	€ 40,919	€ 42,000	€ 44,000	€ 47,000	€ 173,919	€ 188,983	€ 194,023	€ 249,783	€ 420,496	€ 641,539	€ 750,697
Total Revenue \$	\$163,826	\$185,541	\$50,667	\$64,448	\$116,625	\$127,424	\$378,235	\$46,238	\$47,460	\$49,720	\$53,110	\$206,964	\$224,890	\$230,887	\$297,241	\$500,390	\$763,431	\$893,329
COGS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	2,706	4,914	7,227
Gross profit	151,612	155,917	44,838	57,034	103,208	112,765	317,845	40,919	42,000	44,000	47,000	173,919	188,983	194,023	249,783	417,789	636,625	743,470
R&D	139,573	218,502	69,765	81,680	80,314	91,117	322,876	83,195	86,523	86,955	91,303	347,976	365,375	379,990	395,190	401,118	407,134	413,241
SG&A	23,529	27,218	7,110	9,104	10,623	12,939	39,776	10,966	11,185	11,521	11,982	45,654	47,480	49,379	52,836	54,421	56,054	57,735
Income from co-promotion activities	-	-	-	-	-	-	-	-	-	-	-	-	-	-	5,994	29,891	73,718	126,198
Restructuring & integration costs	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Operating Expense	163,102	245,720	76,875	90,784	90,937	104,056	362,652	94,161	97,708	98,476	103,285	393,630	412,855	435,364	477,916	529,257	589,386	619,058
Operating income (loss) €	11,491	(89,802)	(32,036)	(33,750)	12,271	8,709	(44,807)	(53,242)	(55,708)	(54,476)	(56,285)	(219,711)	(223,872)	(229,353)	(168,352)	35,969	299,635	420,575
Operating income (loss) \$	(\$15,651)	(\$106,864)	(\$36,201)	(\$38,138)	\$13,866	\$9,841	(\$53,320)	(\$60,163)	(\$62,950)	(\$61,558)	(\$63,602)	(\$261,456)	(\$266,408)	(\$272,930)	(\$200,339)	\$42,803	\$356,565	\$500,484
Fair value share of subscription agreement	57,479	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Financial income	9,950	3,663	1,610	6,499	2,558	7,668	18,335	6,999	5,500	4,000	2,000	18,499	4,043	3,129	2,508	2,049	2,102	3,256
Financial expense	(1,692)	(29,368)	(6,794)	5,553	(467)	(1,028)	(2,737)	(2,345)	(1,200)	(1,320)	(1,452)	(6,317)	(3,500)	(3,501)	(3,502)	(3,503)	(3,504)	(3,505)
Net income (loss) before taxes	54,246	(115,507)	(37,221)	(21,698)	14,362	15,349	(29,209)	(48,588)	(51,408)	(51,796)	(55,737)	(207,529)	(223,330)	(229,725)	(169,347)	34,515	298,233	420,326
Income tax provision	(235)	(199)	62	75	(480)	392	50	68	90	100	120	375	-	-	(11,516)	2,347	20,280	28,582
Net income (loss) from continuing operations €	54,012	(115,704)	(37,283)	(21,773)	14,841	14,956	(29,259)	(48,656)	(51,498)	(51,896)	(55,857)	(207,907)	(223,330)	(229,725)	(157,831)	32,168	277,953	391,744
Net income (loss) from continuing operations \$	\$57,714	(\$137,688)	(\$42,130)	(\$24,603)	\$16,771	\$16,900	(\$34,818)	(\$54,981)	(\$56,193)	(\$58,643)	(\$63,118)	(\$234,935)	(\$265,762)	(\$273,372)	(\$187,819)	\$38,279	\$330,764	\$466,175
Net income from discontinued operations	-	-	(62)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Translation differences, other	-	(569)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total comprehensive income (loss) to owners of the parent €	54,012	(116,336)	(37,283)	(21,773)	14,841	14,956	(29,259)	(48,656)	(51,498)	(51,896)	(55,857)	(207,907)	(223,330)	(229,725)	(157,831)	32,168	277,953	391,744
EPS - continuing operations €	€ 1.14	(€ 2.34)	(€ 0.73)	(€ 0.42)	€ 0.28	€ 0.27	(€ 0.56)	(€ 0.89)	(€ 0.94)	(€ 0.94)	(€ 1.00)	(€ 3.77)	(€ 3.64)	(€ 3.64)	(€ 2.43)	€ 0.48	€ 4.03	€ 5.51
EPS - continuing operations \$	\$1.22	(\$2.78)	(\$0.83)	(\$0.48)	\$0.32	\$0.31	(\$0.68)	(\$1.01)	(\$1.06)	(\$1.06)	(\$1.13)	(\$4.26)	(\$4.34)	(\$4.33)	(\$2.89)	\$0.57	\$4.79	\$6.56
Shares outstanding (weighted average)	47,308	49,479	50,973	51,338	54,299	54,465	52,769	54,615	54,888	55,217	55,769	55,122	61,296	63,135	65,029	66,980	68,989	71,059

Source: Self estimates and reported company data

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Galapagos NV (GLPG) as of July 01, 2019 (in USD)



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