

BUY
COMPANY UPDATE

Financial Summary

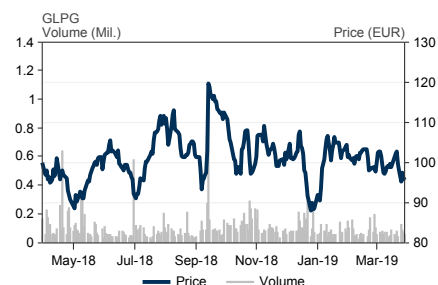
Changes	Previous	Current
Rating	—	Buy
Target Price	\$111.00	\$121.00
FY19E EPS	—	€(4.90)
FY20E EPS	—	€(3.69)
FY19E Revenue	—	€158.0
FY20E Revenue	—	€189.0

Price (03/28/19):	\$96.13
52-Week Range:	\$122 - \$85
Market Cap.(mm):	5,235.7
Shr.O/S-Diluted (mm):	54.5
Avg Daily Vol (3 Mo):	82,223
Dividend / Yield:	\$0.00 / 0.0%

Revenue	2018A	2019E	2020E
Q1	€44.8	€32.0	€NE
Q2	€57.0	€37.0	€NE
Q3	€103.2	€42.0	€NE
Q4	€112.8	€47.0	€NE
FY (Dec)	€317.8A	€158.0	€189.0

EPS	2018A	2019E	2020E
Q1	€(0.73)	€(1.22)	€NE
Q2	€(0.42)	€(1.22)	€NE
Q3	€0.28	€(1.22)	€NE
Q4	€0.27	€(1.24)	€NE
EPS	€(0.56)A	€(4.90)	€(3.69)

Price Performance



Positive Top-Line P3 Filgotinib Results in FINCH 1 & 3 RA Studies; Excellent Safety Profile Differentiated vs. Competition

Summary

Last night after market close, GLPG and partner Gilead announced positive top-line results for the P3 FINCH 1 (MTX-IR) and FINCH 3 (MTX-naive) studies of filgotinib in RA. Both studies met their respective primary endpoints (ACR20 at weeks 12 and 24, respectively) and also demonstrated statistically significant impacts on clinically meaning key secondary endpoints (i.e. ACR50; DAS remission; radiographic progression). Importantly, filgotinib demonstrated an outstanding safety profile, with low rates of key side-effects associated with the JAK inhibitor class, including: serious infections, herpes zoster, DVT/PE, death, malignancy, and MACE. Our early cross-trial comparisons vs. ABBV's competitive JAK1, upadacitinib, suggest that filgotinib appears slightly less effective (Exhibits 3 & 4). However, KOLs suggest that safety remains a key focus for this class of medicines and on this front, filgotinib leads, in our view (Exhibit 1). Based on the positive results, we are increasing our target price to \$121 from \$111.

Key Points

We think filgotinib has best-in-class safety. The FDA has accepted priority review of Abbvie's upadacitinib NDA application for the treatment of adult patients with moderate-to-severe RA. The regulatory decision for upadacitinib is anticipated in 3Q19. In each SELECT P3 studies, upadacitinib met all primary and ranked secondary endpoints. The most frequent SAE were infections. We think upadacitinib will ultimately be approved, following tofacitinib and baricitinib in the JAK class. With today's data, filgotinib will likely be the 4th Jak inhibitor to market (est. 2021) 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 (see Exhibit 1). DVT/PE event is 2 out of 2,203 (0.1%).

Will safety be a class issue for 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 should differentiate it.

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.

Safety summary (see Exhibits 1 & 2). GLPG announced interim safety information from the four studies (24 week results of the ongoing P3 FINCH 1, 2, and 3 trials, and updated Week 156 safety data from the P2b DARWIN 3 long term extension study), that includes 3,452 patients, 2,088 of which received filgotinib. No dose dependent safety effect has been observed in the FINCH studies. P2b DARWIN extension study enrolled 739 patients, receiving filgotinib 100 mg twice daily, 100 mg or 200 mg once daily. DARWIN results represent treatment with filgotinib through 156 weeks or longer and show that filgotinib maintains <0.1 DVTs & PE/PYE. Safety for filgotinib looks favorable vs. other JAKs and this will be an important aspect for positioning given Pfizer's recent tofacitinib post-marketing CV safety study results disclosure.

Continued overleap...

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.

Data summary-FINCH 1: FINCH 1 evaluated filgotinib versus adalimumab or placebo, on a stable background dose of methotrexate in moderately-to-severely active RA patients with prior inadequate response to methotrexate. The study achieved its primary endpoint for both doses of filgotinib in the proportion of patients achieving an ACR20 response vs. placebo at week 12. The proportion of patients achieving ACR50 and ACR70 response was significantly greater for both doses of filgotinib vs. placebo at week 12, as well. The proportions of patients achieving clinical remission (DAS28(CRP) < 2.6) and low disease activity (DAS28(CRP) < 3.2) at week 12 were significantly higher for both filgotinib arms vs. placebo. Filgotinib 200 mg results were non-inferior to adalimumab on a comparison of low disease activity (DAS 28(CRP) < 3.2) at week 12. Filgotinib was not stat. sig vs. adalimumab on DAS remission at week 12. Patients that received 100 mg or 200 mg of filgotinib also had stat. sig reductions in Health Assessment Questionnaire Disability Index (HAQ - DI) at week 12 vs. patients receiving placebo. See Exhibit 3 for placebo-adjusted efficacy data.

Data summary-FINCH 3: FINCH 3 evaluated filgotinib + methotrexate (MTX) and filgotinib monotherapy in MTX-naïve moderate-to-severely active RA patients. The study achieved its primary endpoint of the proportion of patients achieving ACR20 response at week 24. ACR20 response was significantly higher for filgotinib 200 mg + MTX ($p < 0.001$) and filgotinib 100 mg + MTX ($p < 0.05$) vs. MTX alone. The proportion of patients achieving ACR50, ACR70, and clinical remission (DAS28(CRP) < 2.6) at week 24 was also significantly higher for patients receiving once-daily 100 mg or 200 mg filgotinib + MTX vs. MTX alone. Patients receiving filgotinib also experienced greater reduction in the Health Assessment Questionnaire Disability Index (HAQ-DI) vs. MTX alone at week 24. 200 mg monotherapy was not superior vs. MTX on ACR20 response but was nominally superior on ACR50 and ACR70 at week 24. See Exhibit 4 for MTX-adjusted efficacy data.

Changes to model: We increased our filgotinib RA PoS to 95% from 85% and slightly increased our penetration rates into RA to reflect what we believe is best-in-class safety that will drive incremental sales vs. our previous assumptions. These changes increase our TP to \$121 from a prior \$111.

Exhibit 1: Updated DARWIN3 long term safety data in comparison to peers.

Event per 100 PYE	filgotinib	baricitinib	tofacitinib	upadacitinib	tocilizumab	adalimumab
	50-200 mg	2 and 4 mg QD	5 mg BID	6 and 12 mg BID	4 and 8 mg/kg	
Patient year exp.	2,203	6,637	5,278	725	14,994	23,943
Serious infection	1.2	2.9	2.4	2.3	4.5	4.6
herpes zoster	1.5	3.2	3.8	3.7	ND	ND
DVT/PE	0.1	0.5	0.2	0.7	ND	ND
Deaths	0.2	0.3	0.6	0.3	0.6	0.8
Malignancy excluding NMSC	0.5	-	-	-	-	-
MACE	0.1	-	-	-	-	-
Source	DARWIN3 wk156	Genovese <i>et al</i> ACR2017	Wollenhaupt ACR 2017	Genovese ACR2017	Genovese ACR 2012	Burmester 2011

Source: Company report

Exhibit 2: Safety summary of FINCH 1, 2 and 3 studies

	Placebo/ csDMARD N= 1039 No. (%)	Adalimumab + MTX 40mg EOW N=325 No. (%)	Filgotinib 100 mg +MTX/csDMARD N=840 No. (%)	Filgotinib 200 mg +MTX/csDMARD N=1038 No. (%)	Filgotinib 200 mg N=210 No. (%)	Filgotinib Total N=2088 No. (%)
Serious infections&	10 (1.0)	8 (2.5)	13 (1.5)	13 (1.3)	3 (1.4)	29 (1.4)
Herpes zoster&	4 (0.4)	2 (0.6)	5 (0.6)	6 (0.6)	1 (0.5)	12 (0.6)
DVT/PE&	3 (0.3)	0 (0)	0 (0)	1 (0.1)μ	0 (0)	1 (<0.1)
Death@	2 (0.2)	0 (0)	1 (0.1)	3 (0.3)	0 (0)	4 (0.2)
Malignancy excluding NMSC&	4 (0.4)	1 (0.3)	1 (0.1)	0 (0)	0 (0)	1 (<0.1)
MACE&	5 (0.5)	1 (0.3)	2 (0.2)	2 (0.2)	1 (0.5)	5 (0.2)

Source: Company report

Exhibit 3: Efficacy comparison between filgotinib, upadacitinib and tofacitinib in RA patients with inadequate response to methotrexate

RA with Inadequate Response to Methotrexate		
Filgotinib (FINCH 1)	Week 12	
(RA with Inadequate Response to Methotrexate)	100mg	200mg
Placebo-adjusted	(n=480)	(n=475)
ACR 20 (%)	20	27
ACR 50 (%)	17	27
ACR 70 (%)	12	20
DAS 28(CRP) ≤ 3.2 (Low disease activity) (%)	15	26
DAS 28(CRP) < 2.6 (Clinical remission) (%)	15	25

Upadacitinib (SELECT-COMPARE)		
	Week 12	Week 26
(RA with Inadequate Response to Methotrexate)	15mg	15mg
Placebo-adjusted	(n=651)	(n=651)
ACR 20 (%)	34	32
ACR 50 (%)	30	33
ACR 70 (%)	20	25
DAS 28(CRP) < 3.2	31	37
DAS 28(CRP) < 2.6	23	37

Tofacitinib (Study-IV)				
	Week 12		Week 24	
MTX Inadequate Responders	5mg	10mg	5mg	10mg
Placebo-adjusted	(n=321)	(n=316)	(n=321)	(n=316)
ACR 20 (%)	28	40	25	37
ACR 50 (%)	21	29	23	35
ACR 70 (%)	8	14	13	22

Source: Company Reports and Stifel

Exhibit 4: Efficacy comparison between filgotinib and upadacitinib in RA patients naive to methotrexate

Filgotinib (FINCH 3)			
	Week 24		
Naive to MTX Therapy	200mg Mono	100mg + MTX	200mg + MTX
MTX-adjusted	(n=210)	(n=207)	(n=416)
ACR 20 (%)	7	9	10
ACR 50 (%)	12	11	16
ACR 70 (%)	14	14	18
DAS 28(CRP) < 2.6 (Clinical remission) (%)	13	13	25

Upadacitinib (SELECT-EARLY)				
	Week 12		Week 24	
Naive to MTX Therapy	15mg	30mg	15mg	30mg
MTX-adjusted	(n=317)	(n=314)	(n=317)	(n=314)
ACR 20 (%)	22	23	20	19
ACR 50 (%)	24	28	27	33
ACR 70 (%)	18	23	26	32
DAS 28(CRP) < 2.6 (Clinical remission) (%)	22	27	30	32
LDA (DAS 28(CRP) < 3.2)	25	27	28	33

Source: Company Reports and Stifel

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 Fdelta, has approximately 460 employees, operating from its Mechelen, Belgium headquarters and facilities in The Netherlands, France and Croatia.

NASDAQ: GLPG

Income Statement

GLPG Income Statement		FY	FY	Mar	Jun	Sep	Dec	FY	Mar	Jun	Sep	Dec	FY	FY
(in 000s, except per share data)		2016A	2017A	1Q18A	2Q18A	3Q18A	4Q18A	2018E	1Q19E	2Q19E	3Q19E	4Q19E	2019E	2020E
	POS													
x	Rheumatoid Arthritis (Filgotinib)													-
x	Crohn's disease (Filgotinib)													-
x	Ulcerative colitis (Filgotinib)													-
x	Psoriatic arthritis (Filgotinib)													-
x	Ankylosing spondylitis (Filgotinib)													-
x	IPF (Autotaxin)													-
	Upfront/milestone pmts/cost reimbursements	151,612	155,917	44,838	57,034	103,208	112,765	317,845	32,000	37,000	42,000	47,000	158,000	188,983
	Total Revenue €	€ 151,612	€ 155,917	€ 44,838	€ 57,034	€ 103,208	€ 112,765	€ 317,845	€ 32,000	€ 37,000	€ 42,000	€ 47,000	€ 158,000	€ 188,983
	Total Revenue \$	\$163,826	\$185,541	\$50,667	\$64,448	\$116,625	\$127,424	\$378,235	\$36,160	\$41,810	\$47,460	\$53,110	\$188,020	\$224,890
	COGS	-	-	-	-	-	-	-	-	-	-	-	-	-
	Gross profit	151,612	155,917	44,838	57,034	103,208	112,765	317,845	32,000	37,000	42,000	47,000	158,000	188,983
	R&D	139,573	218,502	69,765	81,680	80,314	91,117	322,876	92,500	96,200	100,048	105,050	393,798	346,543
	SG&A	23,529	27,218	7,110	9,104	10,623	12,939	39,776	13,000	13,260	13,658	14,204	54,122	75,771
	Income from co-promotion activities	-	-	-	-	-	-	-	-	-	-	-	-	-
	Restructuring & integration costs	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total Operating Expense	163,102	245,720	76,875	90,784	90,937	104,056	362,652	105,500	109,460	113,706	119,255	447,920	422,313
	Operating income (loss) €	11,491	(89,802)	(32,036)	(33,750)	12,271	8,709	(44,807)	(73,500)	(72,460)	(71,706)	(72,255)	(289,920)	(233,330)
	Operating income (loss) \$	(\$15,651)	(\$106,864)	(\$36,201)	(\$38,138)	\$13,866	\$9,841	(\$53,320)	(\$83,055)	(\$81,880)	(\$81,028)	(\$81,648)	(\$345,005)	(\$277,663)
	Fair value share of subscription agreement	57,479	-	-	-	-	-	-	-	-	-	-	-	-
	Financial income	9,950	3,663	1,610	6,499	2,558	7,668	18,335	7,000	5,500	4,000	2,000	18,500	2,638
	Financial expense	(1,692)	(29,368)	(6,794)	5,553	(467)	(1,028)	(2,737)	(600)	(660)	(726)	(799)	(2,785)	-
	Net income (loss) before taxes	54,246	(115,507)	(37,221)	(21,698)	14,362	15,349	(29,209)	(67,100)	(67,620)	(68,432)	(71,053)	(274,205)	(230,692)
	Income tax provision	(235)	(198)	62	75	(480)	392	50	80	90	100	120	390	-
	Net income (loss) from continuing operations €	54,012	(115,704)	(37,283)	(21,773)	14,841	14,956	(29,259)	(67,180)	(67,710)	(68,532)	(71,173)	(274,595)	(230,692)
	Net income (loss) from continuing operations \$	\$57,714	(\$137,688)	(\$42,130)	(\$24,603)	\$16,771	\$16,900	(\$34,818)	(\$75,913)	(\$76,512)	(\$77,441)	(\$80,426)	(\$310,292)	(\$274,523)
	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)	(67,180)	(67,710)	(68,532)	(71,173)	(274,595)	(230,692)
	EPS - continuing operations €	€ 1.14	(€ 2.34)	(€ 0.73)	(€ 0.42)	€ 0.28	€ 0.27	(€ 0.56)	(€ 1.22)	(€ 1.22)	(€ 1.22)	(€ 1.24)	(€ 4.90)	(€ 3.69)
	EPS - continuing operations \$	\$1.22	(\$2.78)	(\$0.83)	(\$0.48)	\$0.32	\$0.31	(\$0.68)	(\$1.38)	(\$1.38)	(\$1.38)	(\$1.41)	(\$5.54)	(\$4.40)
	Shares outstanding (weighted average)	47,308	49,479	50,973	51,338	54,299	54,465	52,769	55,010	55,560	56,116	57,238	55,981	62,456

Source: Stifel estimates and reported company data

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Galapagos NV (GLPG) as of March 28, 2019 (in USD)



*Represents the value(s) that changed.

Buy=B; Hold=H; Sell=S; Discontinued=D; Suspended=SU; Discontinued=D; Initiation=I

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