

R&D Day Highlighted by Positive Filgotinib DARWIN 3 Results and Early Pipeline; P2 CF Triple Combo Delayed

Yesterday, we attended the Galapagos R&D day which highlighted positive and differentiating safety/efficacy results in the filgotinib DARWIN 3 extension trial as well as solid progress on the earlier-stage pipeline - but these high notes were somewhat overshadowed by a two-quarter delay in the start of the P2 CF triple combo trials. New 60-week data from the filgotinib DARWIN 3 extension study confirmed filgotinib's longer-term safety profile as consistent with that of previously reported studies, while demonstrating sustained improvement in signs and symptoms of active RA, irrespective of dosing regimen (QD/BID) or background treatment (+MTX/MONO). In addition, filgotinib's differentiated profile (good lipid profile, increases in hemoglobin, lowering of platelet count, no impact on NK cells) was further confirmed in the DARWIN 3 extension. We are not surprised by launch delay for P2 triple combo studies (4Q17 vs. prior guidance of mid-16) given the aggressive approach - the gating factor now being discussions with UK regulatory authorities and the potential for them to request 3-month chronic toxicity studies. On the CF upside, Galapagos will run multiple P2s with a variety of triple combinations, providing multiple shots on goal in CF. For the remainder of the year, we expect investors to focus primarily on CF and the earlier stage pipeline, given late-stage filgotinib data (RA; IBD) are not expected until 2018. Near-term CF milestones include: P2 ALBATROSS (2222 + Kalydeco in gating) results in 2H17; P2 FLAMINGO (2222 monotherapy in F508del homozygous) patients in 1Q18; P2 2737+ Orkambi results in 2Q18; and mid-18 first P2 triple combo (2451+2222+2737) results in F508del homozygotes and het-min CF patients. P2a FLORA (IPF) and P1b MOR106 (atopic dermatitis) results due in 2H17 provide significant optionality, in our view, as positive results for either one would add a significant new leg to the story for indications we do not currently include in our model. Net-net, we remain bullish on filgotinib, cautious on the CF triple combo, and are warming to earlier pipeline initiatives. Reiterate Hold and \$83 TP.

Strong interim DARWIN 3 results: We remain encouraged by the solid interim efficacy and safety data from the DARWIN3 P2 extension study in RA patients. Patients who completed DARWIN 1 or 2 and enrolled in DARWIN 3 (N=739) received filgotinib 200mg once daily or 100mg twice daily, depending on prior treatment assignment. A total of 559 patients completed week 60. Results demonstrated that an impressive 84%, 65%, 44%, and 51% of patients reached ACR20, ACR50, ACR70 and DAS28 (CRP) remission at Week 60 respectively. Safety was in line with DARWIN 1 and 2 studies and there were no clinically meaningful changes to male reproductive hormones. The next DARWIN 3 update at 84 weeks may come at ACR.

GLPG cross-trial comparisons still favor filgotinib: Consistent with prior GLPG cross-trial comparisons, DARWIN 3 results continue to support filgotinib's differentiated profile vs. competitive drugs (i.e. Xeljanz, baricitinib, ABT-494) on multiple metrics, including: lipid profile, increases in hemoglobin, lowering of platelet count, and no impact on NK cells. The obvious caveat is that these are not head-to-head trials. Nevertheless, we believe increasing evidence suggests filgotinib's profile may be best-in-class.

P2 triple combo trial launch delayed: Galapagos now plans to launch the first P2 triple trial (2451+2222+2737) in 4Q17, a two-quarter delay vs. prior guidance.

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Changes	Previous	Current
Rating	—	Hold
Target Price	—	\$83.00
FY17E Revenue	—	€79.8
FY18E Revenue	—	€78.2
FY17E EPS	—	€(2.96)
FY18E EPS	—	€(3.53)

Price (06/20/17):	\$78.86
52-Week Range:	\$95 – \$49
Market Cap.(mm):	3,647.8
Shr.O/S-Diluted (mm):	46.3
Avg Daily Vol (3 Mo):	209,415
Dividend(\$ / %)	\$0.00 / 0.0%
S&P Index	2,437.03

Revenue	2016A	2017E	2018E
FY Dec	€151.6A	€79.8	€78.2

EPS	2016A	2017E	2018E
FY Dec	€1.14A	€(2.96)	€(3.53)



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...While Galapagos reported that P1 results for individual components 2451, 2222 and 2737 showed each to be safe and tolerable, it now appears the company plans to forego P1 triple combo studies in healthy volunteers, and instead proceed directly into P2 in CF patients - which we view as an aggressive approach that may also speed development timelines, if successful. The company plans to start the regulatory review process in Europe next month by obtaining scientific advice from the UK to ensure broad acceptance of trial design across various EU countries. If all goes smoothly, this should allow for the first triple combo study in CF patients to begin in Q4 2017 (2451+2222+2737). Galapagos plans to launch two additional triple studies in 2018: 3067+2222+2737 and 3067+2222+3221. Data from the three trials are expected in mid-18, 2H18, and 1H19, respectively.

Preferred potentiator unclear: Galapagos disclosed that 2451 has a surprisingly long ~1-month half-life for the active metabolite, which raises the potential for drug accumulation without modification of the dosing schedule. In addition, the planned triple combo studies appear to favor the less well characterized potentiator 3067 (P1 MAD still ongoing), with one study featuring 2451, and two others featuring 3067. We believe this adds to confusion regarding the ultimate makeup of the triple and we can't help but wonder whether Galapagos is having potentiator issues (recall original potentiator 1837 was previously abandoned).

Expectations for ALBATROSS, FLAMINGO, and 2737 + Orkambi: ALBATROSS is testing GLPG first-gen corrector 2222 + Vertex' (VRTX; Buy) Kalydeco in CF patients with gating mutations. Results are expected by YE17. We look for FEV1 improvement in the range of 15% (incremental 5% improvement over Kalydeco monotherapy). FLAMINGO is a monotherapy study with 2222 in F508del homozygous patients. Data are expected 1H18. We expect FEV1 improvement to be low, in range of 2% to 4%, given that a first-gen corrector tested alone in these patients would be unlikely to generate significant benefit. The trial testing 2737 as an add-on to Orkambi is expected to start by YE17 with data around mid-18. Based on preclinical assays, GLPG would expect to triple FEV1 improvement over Orkambi alone (9 to 12%).

Early pipeline intriguing, progressing: We are eager to see P2a proof of concept data from the FLORA study evaluating 1690 (autotaxin inhibitor) in idiopathic pulmonary fibrosis, expected 3Q17. While the primary endpoints are safety, tolerability, and PK/PD, secondary endpoints should provide potential evidence of efficacy (FVC, QoL, FRI, biomarkers). Likewise, P1 data for MOR106 (human MAb targeting IL-17C) in osteoarthritis due in 2H17 should help to define the potential clinical value of this emerging compound via exploratory endpoints of efficacy (EASI and IGA scores).

Filgotinib: The ongoing late-stage clinical studies in RA and IBD are progressing as planned, with results expected in FY18. New P2 POC trials are also underway in small bowel and fistulizing Crohn's disease, Sjögren's syndrome, cutaneous lupus erythematosus, psoriatic arthritis and ankylosing spondylitis, with additional P2 POC studies expected to be announced throughout 2017. The FDA/EMA required testicular tox study is expected to start imminently, but no guidance was provided on timing of results.

Target Price Methodology/Risks

We arrive at our 12-month target price of \$83 using a discounted cash flow (WACC 9%, terminal growth 1%). We probability-adjust our revenue projections for individual product candidates to reflect clinical, developmental, and regulatory risks. We use a 9% WACC, which is in line with industry peers, to reflect inherent risk in biotechnology drug development. Our 1% 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 in mid-2017, with results expected in 1H18. 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.

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Income Statement

(€ 000s, except per share data)

€/ \$

	FY 2016A	Mar 1Q17A	Jun 2Q17E	Sep 3Q17E	Dec 4Q17E	FY 2017E	FY 2018E	FY 2019E	FY 2020E	FY 2021E	FY 2022E	FY 2023E	FY 2024E	FY 2025E
POS														
Rheumatoid Arthritis (Filgotinib)									9,205	44,364	103,106	165,014	199,975	213,407
Crohn's disease (Filgotinib)									4,414	34,608	57,348	82,420	130,877	152,953
Ulcerative colitis (Filgotinib)									954	7,478	12,717	18,761	30,617	36,692
Psoriatic arthritis (Filgotinib)										708	3,529	8,474	14,432	18,183
Ankylosing spondylitis (Filgotinib)									1,246	4,006	7,140	11,006	17,072	20,646
Cystic fibrosis (Triple)									10,696	36,797	52,445	53,593	57,970	59,268
IPF (Autotaxin)														
Upfront/milestone prmts/cost reimbursements	151,612	39,863	13,317	13,317	13,317	53,267	78,183	130,267	170,942	22,500	117,300	-	-	87,000
Total Revenue €	€ 151,612	€ 39,863	€ 13,317	€ 13,317	€ 13,317	€ 79,813	€ 78,183	€ 130,267	€ 197,457	€ 150,461	€ 353,586	€ 339,320	€ 450,943	€ 588,149
Total Revenue \$	\$163,826	\$42,644	\$14,796	\$14,796	\$14,796	\$87,033	\$86,870	\$144,741	\$219,397	\$167,179	\$392,873	\$377,022	\$501,048	\$653,499
COGS	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Gross profit	151,612	39,863	13,317	13,317	13,317	79,813	78,183	130,267	197,457	150,461	353,586	339,320	450,943	588,149
R&D	139,573	44,930	45,664	45,312	54,541	190,447	221,276	155,402	140,663	105,497	109,151	117,883	123,777	129,966
SG&A	23,529	6,159	6,510	6,800	7,083	26,552	28,411	32,673	45,742	47,114	48,998	50,958	52,997	55,117
Income from co-promotion activities									834	6,923	18,984	44,177	70,070	95,855
Restructuring & integration costs														
Operating income (loss) €	€ 11,491	(€ 11,226)	(€ 38,857)	(€ 38,795)	(€ 48,308)	(€ 137,186)	(€ 171,504)	(€ 57,808)	€ 11,886	€ 4,773	€ 214,420	€ 214,656	€ 344,239	€ 498,922
Operating income (loss) \$	(\$15,651)	(\$12,009)	(\$43,175)	(\$43,106)	(\$53,675)	(\$151,965)	(\$190,560)	(\$64,231)	\$13,207	\$5,303	\$238,245	\$238,506	\$382,488	\$554,357
Fair value share of subscription agreement	57,479	-	-	-	-	-	-	-	-	-	-	-	-	-
Financial income	9,950	894	882	832	803	3,411	3,083	2,644	2,580	2,075	2,441	2,744	3,483	5,179
Financial expense	(1,692)	(3,274)	-	-	-	(3,274)	-	-	-	-	-	-	-	-
Net income (loss) before taxes	54,246	(13,606)	(37,976)	(37,963)	(47,505)	(€ 137,049)	(168,421)	(55,164)	14,467	6,847	216,861	217,400	347,723	504,100
Income tax provision	(235)	-	-	-	-	-	-	-	-	-	14,747	14,783	23,645	34,279
Net income (loss) from continuing operations €	€ 54,012	(€ 13,605)	(€ 37,976)	(€ 37,963)	(€ 47,505)	(€ 137,048)	(€ 168,421)	(€ 55,164)	€ 14,467	€ 6,847	€ 202,114	€ 202,616	€ 324,077	€ 469,821
Net income (loss) from continuing operations \$	\$57,714	(\$14,554)	(\$42,195)	(\$42,181)	(\$52,783)	(\$151,713)	(\$187,134)	(\$61,294)	\$16,074	\$7,608	\$224,571	\$225,129	\$360,086	\$522,024
Net income from discontinued operations	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Translation differences, other	-	31	-	-	-	31	-	-	-	-	-	-	-	-
Total comprehensive income (loss) to owners of the parent €	54,012	(13,574)	(37,976)	(37,963)	(47,505)	(137,017)	(168,421)	(55,164)	14,467	6,847	202,114	202,616	324,077	469,821
EPS - continuing operations €	€ 1.14	(€ 0.29)	(€ 0.82)	(€ 0.82)	(€ 1.02)	(€ 2.96)	(€ 3.53)	(€ 1.12)	€ 0.27	€ 0.12	€ 3.45	€ 3.29	€ 5.02	€ 6.93
EPS - continuing operations \$	\$1.22	(\$0.31)	(\$0.91)	(\$0.91)	(\$1.14)	(\$3.29)	(\$3.92)	(\$1.25)	\$0.30	\$0.14	\$3.83	\$3.66	\$5.57	\$7.70
Shares outstanding	47,308	46,256	46,302	46,349	46,395	46,325	47,715	49,147	54,174	55,799	58,589	61,518	64,594	67,824

Margin Analysis

R&D	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	31%	35%	27%	22%
SG&A	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	14%	15%	12%	9%
Operating margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	61%	63%	76%	85%
Tax rate	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	6.8%	6.8%	6.8%	6.8%
Net margin (continuing operations)	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	57%	60%	72%	80%

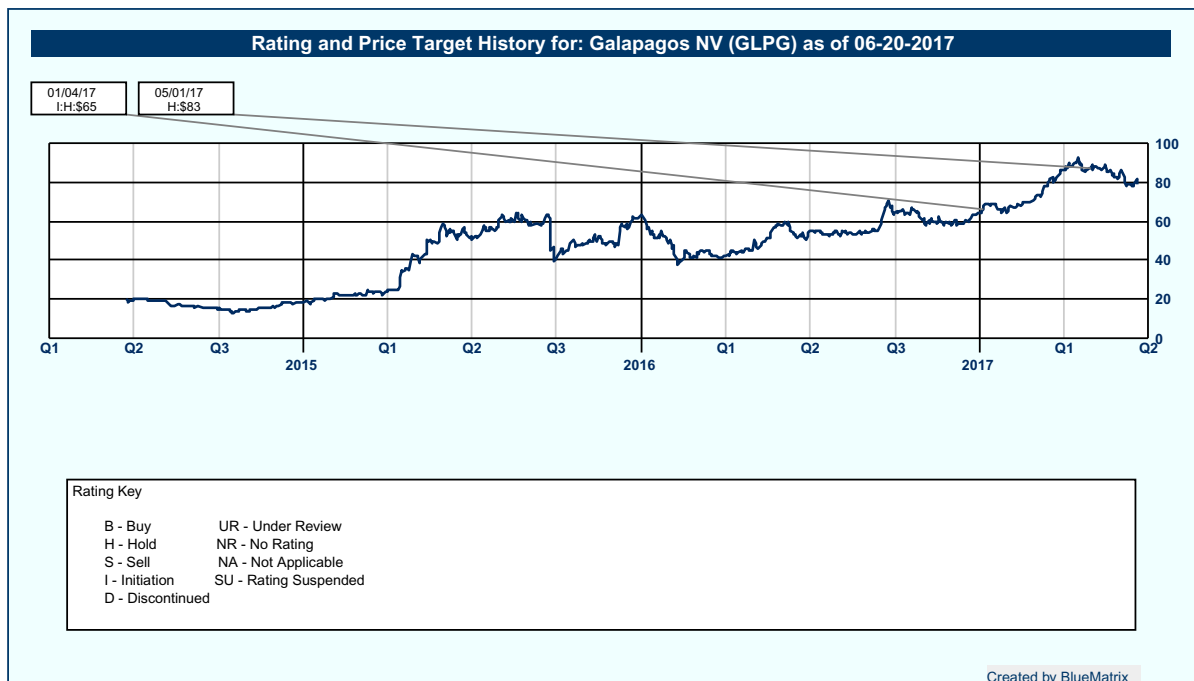
% Change Y/Y

Rheumatoid Arthritis (Filgotinib)	nm	nm	nm	nm	nm	nm	nm	nm	nm	382%	132%	60%	21%	7%
Crohn's disease (Filgotinib)	nm	nm	nm	nm	nm	nm	nm	nm	nm	684%	66%	44%	59%	17%
Ulcerative colitis (Filgotinib)	nm	nm	nm	nm	nm	nm	nm	nm	nm	684%	70%	48%	63%	20%
Cystic fibrosis (Triple)	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	244%	43%	2%	8%
IPF (Autotaxin)	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
Total revenue											-24%	135%	-4%	33%
R&D	nm	nm	32.0%	32.0%	27.3%	36.4%	16.2%	-29.8%	-9.5%	-25.0%	3.5%	8.0%	5.0%	5.0%
SG&A	nm	nm	3.2%	11.8%	5.0%	12.8%	7.0%	15.0%	40.0%	3.0%	4.0%	4.0%	4.0%	4.0%
Operating income	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	0%	60%	45%
Net income	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	0%	60%	45%
EPS	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	-5%	52%	38%
Shares outstanding	nm	nm	nm	nm	nm	nm	-2.1%	3.0%	3.0%	3.0%	3.0%	5.0%	5.0%	5.0%

Source: Stifel estimates and reported company data

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