

Equity Research

June 19, 2017

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Biotechnology and Life Sciences

Galapagos N.V.

Clinical Development Outcomes over Next 12-months will Rapidly Evolve Investment Thesis

We initiate coverage of Galapagos (GLPG) with a Buy rating and \$98 Price Target. Galapagos is a biopharma company with a strong history of R&D that is now poised to become a commercial organization over the next several years. Our Buy thesis is based upon three key points, **1)** filgotinib is the main revenue driver of our model, and has demonstrated potential to be a best in class JAK inhibitor, but is also facing fierce competition for auto-immune disorders; **2)** the cystic fibrosis program represents a call-option to our model, with solid looking pre-clinical assay work offset by positive in vivo results from Vertex (VRTX, Not Rated); and **3)** M&A may be a catalyst in the longer term but is unlikely to be near-term until current clinical efforts mature. **We expect the GLPG Analyst Day on June 20th to provide additional insight for our positioning.**

GLPG

\$81.82*

12 month target

\$98.00

BUY

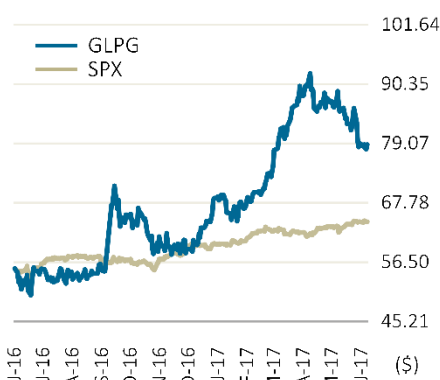
52 week range

\$50.24 - \$92.40

Market Cap (m)

\$3,711

Price Performance



*Source: IDC - price is intraday

- ▶ **Filgotinib stacking up well as a next-generation JAK inhibitor:** Our market model forecasts filgotinib to be first to market in Crohn's Disease relative to AbbVie's JAK inhibitor upadacitinib, but ~12-months behind in RA. Overall we forecast filgotinib sales of ~\$1.8bn by 2022 reaching to ~\$5.7bn by 2026E. Realized sales for GLPG will be lower as the drug is partnered with Gilead (GILD, Not Rated).
- ▶ **Cystic Fibrosis catalysts expected to play-out during 2H2017:** Galapagos/ AbbVie (ABBV, Not Rated) is in a race against Vertex to develop a triplet combination therapy for the treatment of Cystic Fibrosis. Effectively, GLPG needs to have a triple combination therapy started ahead of any potential approval for a triplet therapy from Vertex, to avoid required comparative studies. Both Galapagos and Vertex will have multiple data-readouts during 2H2017, with a discussion culminating at the NAFC conference (early November).
- ▶ **M&A could be a longer-term catalyst, but not near-term:** Given the partnerships on two potential blockbuster efforts, in auto-immune disorders (Gilead) and cystic fibrosis (AbbVie), expanded relationships may be possible as the current development efforts mature.
- ▶ **Valuation:** Our \$98PT values GLPG at ~4.5x EV/ 2022E Sales.

Estimates

	1Q16 A	2Q16 A	3Q16 A	4Q16 A	FY16 A	1Q17 A	2Q17 E	3Q17 E	4Q17 E	FY17 E	FY18 E
Sales	15	34	16	87	152	40	0	0	0	0	0
EBITDA (Adj.)	0	0	0	0	0	(7)	(53)	(57)	(60)	(176)	(235)
Diluted EPS (Adj.)	0.00	0.00	0.00	0.00	0.00	(0.28)	(1.12)	(1.17)	(1.23)	(3.81)	(4.76)

Source: BTIG Estimates and Company Documents (\$ in millions, except per share amount)

Clinical Development Outcomes over Next 12-months will Rapidly Evolve Investment Thesis

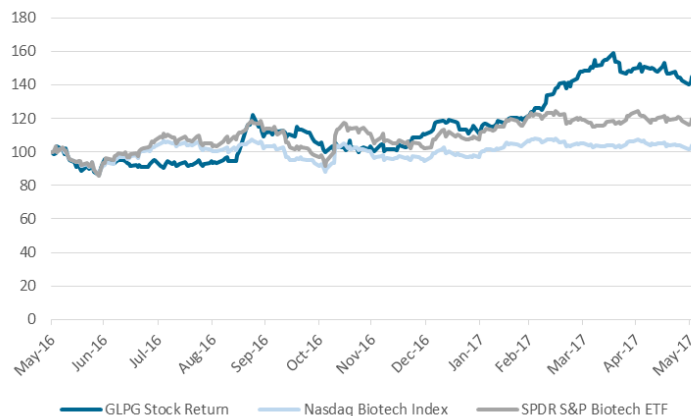
We initiate coverage of Galapagos (GLPG) with a Buy rating and \$98 Price Target. Galapagos is a biopharma company with a strong history of R&D that is now poised to become a commercial organization over the next several years. Our Buy thesis is based upon three key points, **1)** filgotinib is the main revenue driver of our model, and has demonstrated potential to be a best in class JAK inhibitor, but is also facing fierce competition for auto-immune disorders; **2)** the cystic fibrosis program represents a call-option to our model, with solid looking pre-clinical work offset by positive in vivo results from Vertex (VRTX, Not Rated); and **3)** M&A may be a catalyst in the longer term but is unlikely to be near-term catalyst until current clinical efforts mature. **We expect the GLPG Analyst Day on June 20th to provide additional insight for our positioning.**

Filgotinib stacking up well as a next-generation JAK inhibitor: Filgotinib is expected to be approved across a range of auto-immune disorders over the next 5-years, with Rheumatoid Arthritis being the largest opportunity. Our market model forecasts filgotinib to be first to market in Crohn’s Disease relative to AbbVie’s JAK inhibitor upadacitinib, but ~12-months behind in RA. Overall, we forecast filgotinib sales of ~\$1.8bn by 2022 reaching to ~\$5.7bn by 2026E. Realized sales for GLPG will be lower as the drug is partnered with Gilead (GILD, Not Rated).

Cystic Fibrosis catalysts expected to play-out during 2H2017: Galapagos/AbbVie is in a race against Vertex to develop a triplet combination therapy for the treatment of Cystic Fibrosis. Effectively, GLPG needs to have a triple combination therapy started ahead of any potential approval for a triplet therapy from Vertex, to avoid required comparative studies. Both Galapagos and Vertex will have multiple data-readouts during 2H2017, with a discussion culminating at the NAFC conference during early November.

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Figure 1. GLPG shares have outperformed the NBI Index over the past 52-weeks



Source: Company Reports, Bloomberg, FactSet, BTIG Research Estimates, June 2017

An illustrative Fair Value analysis for our current GLPG model would imply a stock price around ~\$98 (Figure 2), or approximately ~4.5x EV our current 2022E sales forecast of ~\$897m. The current EV/ 2022E Sales multiple of GLPG's biopharma peer group is ~4x.

- Given that revenues flowing through our model are mostly net margin payments from partners AbbVie and Gilead, we would generally expect the stock to trade at a premium sales multiple relative to biotech peers.
- Our current model forecasts that the company could reach positive EBITDA by 2022E, although this projection could fall short if management ramps internal development programs.

Figure 2. Our Fair Value analysis supports a Buy recommendation for GLPG shares

Line	Clinical Program Valuation	Peak Annual Revenue (10yr Forward, \$m)	Risk Discount to Program %	NPV (10-Year Forecast, \$m)
A	Filgotinib (UC, Crohn's)	\$2,019	30%	\$931
	Cystic Fibrosis Program	\$467	60%	\$52
B	Total NPV	-	-	\$983
C	Market Cap @ Fair Value			\$4,722
D	Net Cash			\$1,090
E	Enterprise Value @ Fair Value			\$3,632
F (B minus E)	Stock Premium (+) / Discount (-) Versus NPV \$m			\$2,649
	Stock Premium (+) / Discount (-) Versus NPV %			269%
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G	Revenues 2022E			\$897
H	Large Cap Biotech 2022 EV/ Sales Multiple (Premium)			7.0x
I (G x H)	Valuation using Median Peer Multiple			\$6,281
J (0.5*B + 0.5*I)	Blended Enterprise Valuation (50% NPV + 50% EV/ 2022E Sales)			\$3,632
K	Current Net Cash -1 Year Burn			\$1,090
L	Net Shares Outstanding (mm)			48
M (J + K / L)	Implied Fair Value			\$98
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N	Company	(2022 Sales, \$m)	(Current EV, \$m)	Peer EV/ 2022 Sales
	Vertex (VRTX)	4819	29439	6.1
	Seattle Genetics (SGEN)	1531	8657	5.7
	Tesaro (TSRO)	1855	7212	3.9
	Exelixis (EXEL)	1628	5290	3.2
	Intercept (ICPT)	1912	2692	1.4
	Median			4x

Source: Company Reports, ClinicalTrials.gov, FactSet, Bloomberg, BTIG Research Estimates, June 2017

GLPG Stock Catalysts for 2017

During 2H2017 we expect the most impactful catalysts for Galapagos shares to be data related to their competitive positioning in IBD and Cystic Fibrosis. The focus of investors' attention will be the initial read-outs from the Cystic Fibrosis portfolio as the company aims to stay on a competitive timeline against Vertex for a Triplet Therapy. GLPG is also on a competitive timeline against AbbVie in RA and several of their Phase 3 studies are expected to readout during the back half of 2017. There are minimal catalysts for the GLPG IBD portfolio in 2017, but we think that 2018 will yield significant catalysts as interim data for both Crohn's and UC are expected to readout from the Phase 3 pivotal studies. **Below, we highlight the key datasets expected to be stock catalysts during the remainder of 2017:**

CF Data Expected during 2H2017

- **Galapagos Phase 2 ongoing (ALBATROSS) GLPG2222:** A Study to evaluate GLPG2222 in Ivacaftor-treated Subjects With Cystic Fibrosis (Age +18), N=35, Start Jan '17 (NCT03045523)
- **Galapagos Phase 2 ongoing (FLAMINGO) GLPG2222:** A Phase IIa, Randomized, Double-blind, Placebo-controlled Study to Evaluate Multiple Doses of GLPG2222 in Subjects With Cystic Fibrosis Who Are Homozygous for the F508del Mutation, n=50, Start March 2017 (NCT03119649)
- **Galapagos Phase 1 start Mid-2017:** GLPG2222 (C1) + GLPG2737 (C2) + GLPG2451 (Potentiator QD) / GLPG1837 (Potentiator BID)
- **Vertex Phase 2 triplet data during 2H2017:** Tezacaftor (VX-661) + Ivacaftor + VX-440
- **Vertex Phase 2 triplet data during 2H2017:** Tezacaftor (VX-661) + Ivacaftor + VX-152
- **Vertex Phase 1 triplet data during 2H2017:** Tezacaftor (VX-661) + Ivacaftor + VX-659

Rheumatoid Arthritis Events Expected during 2H2017

- **Lilly's response to the FDA CRL on Baracitinib during 2H2017**
- **Filgotinib presentation of the DARWIN-3 Interim Data at the 2017 ACR Meeting during 2H2017**
- **Upadacitinib readout for SELECT-BEYOND, -COMPARE, and - MONOTHERPY during 2H2017**

IBD Data Expected during 2H2017

- **Ozanimod Phase 2 data in Crohn's during 2H2017:** If the data are superior to mongersen, it could become filgotinib's leading competitor to market although it will trail the launch of filgotinib which is already in Phase 3.
- **Mongersen and Otezla Phase 2 data in Ulcerative Colitis during 2H2017:** The data could set a benchmark for filgotinib's Phase 3 data in UC.

Figure 3. Catalyst Calendar for Crohn's, Ulcerative Colitis, Rheumatoid Arthritis, and Cystic Fibrosis

Drug	Manufacturer	Target	Phase	Trial Number	Primary Compl. Date	Catalyst
Crohn's						
Mongersen - GED-0301	Celgene	Smad7	3	NCT02596893	2022 - September	YE2018 - Phase 3 Interim Data*
Filgotinib - GLPG-0634	Galapagos	JAK 1	-	-	-	2H2017 - UEGW
Filgotinib - GLPG-0634	Galapagos	JAK 1	3	NCT02914561	2019 - November	YE2018 - Phase 3 Interim Data*
Upadacitinib - ABT-494	AbbVie	JAK 1	2	NCT02365649	2016 - November	YE2017 - Phase 3 Study Starts
SHP647 - formerly PF-00547659	Shire	MAdCAM-1	2	NCT01276509	2014 - February	1H2017 - FDA Decision on Phase 3 Trial
Ozanimod	Celgene	S1-P	2	NCT02531113	2018 - January	2H2017 - Phase 2 Data
Ulcerative Colitis						
Tofacitinib - Xeljanz	Pfizer	JAK 3	3	NCT01458574	2016 - May	1H2017 - NDA Filing
Ozanimod	Celgene	S1-P1/S1-P5	3	NCT02435992	2018 - September	YE2018 - Phase 3 Interim Data
Filgotinib - GLPG-0634	Galapagos	JAK 1	2b/3	NCT02914522	2019 - November	YE2018 - Phase 2b/3 Interim Data
Mongersen - GED-0301	Celgene	Smad7	2	NCT02601300	2016 - September	YE2017 - Phase 2 Data
Otezla	Celgene	PDE4	2	NCT02289417	2017 - December	YE2017 - Phase 2 Data
Upadacitinib - ABT-494	AbbVie	JAK 1	2	NCT02819635	2021 - April	1H2018 - Phase 2 Interim Data
Rheumatoid Arthritis						
Baracitinib	Celgene	JAK 1/JAK 2	NDA Filed			YE2017 - Response to FDA CRL
Filgotinib - GLPG-0634	Galapagos	JAK 1	2	NCT02065700	2019 - May	2H2017 - DARWIN3 Interim Data at ACR
Filgotinib - GLPG-0634	Galapagos	JAK 2	3	NCT02873936	2018 - June	1H2018 - FINCH 2
Upadacitinib - ABT-494	AbbVie	JAK 1	3	NCT02706847	2017 - April	2H2017 - SELECT-BEYOND
Upadacitinib - ABT-494	AbbVie	JAK 1	3	NCT02629159	2017 - August	2H2017 - SELECT-COMPARE
Upadacitinib - ABT-494	AbbVie	JAK 1	3	NCT02706951	2017 - October	2H2017 - SELECT-MONOTHERAPY
Cystic Fibrosis						
GLPG2222	Galapagos	CFTR Corrector	2	NCT03045523	2017 - December	Phase 2 Ongoing (ALBATROSS)
GLPG2222	Galapagos	CFTR Corrector	2	NCT03119649	2018 - March	Phase 2 Ongoing (FLAMINGO)
Tezacaftor (VX-661) + Ivacaftor	Vertex	CFTR Combo	3	NCT02412111	2017 - November	1Q17 - Enrollment Completion
Triplet: GLPG2222 (C1) + GLPG2737 (C2) + GLPG2451 or GLPG1837 (Potentiator QD/BID)	Galapagos	CFTR Triplet	1	N/A	N/A	Mid-2017 - Phase 1 Start
Tezacaftor (VX-661) + Ivacaftor + VX-440	Vertex	CFTR Triplet	2	NCT02951182	2018 - May	2H2017 - Phase 2 Data
Tezacaftor (VX-661) + Ivacaftor + VX-152	Vertex	CFTR Triplet	2	NCT02951195	2017 - October	2H2017 - Phase 2 Data
Tezacaftor (VX-661) + Ivacaftor + VX-659	Vertex	CFTR Triplet	1	NCT03029455	2017 - August	2H2017 - Phase 1 Data

*Estimated

Source: Company Reports, ClinicalTrials.gov, FactSet, Bloomberg, BTIG Research Estimates, June 2017

Filgotinib's Estimates Currently Lag Consensus

Our financial model for GLPG puts us ahead of current consensus estimates for revenues and EBITDA by 2021E (Figure 4). That said, we expect financial forecasts to be volatile over the next 12-months as key datasets for filgotinib and the Cystic Fibrosis program alter assumptions for the next 5-years.

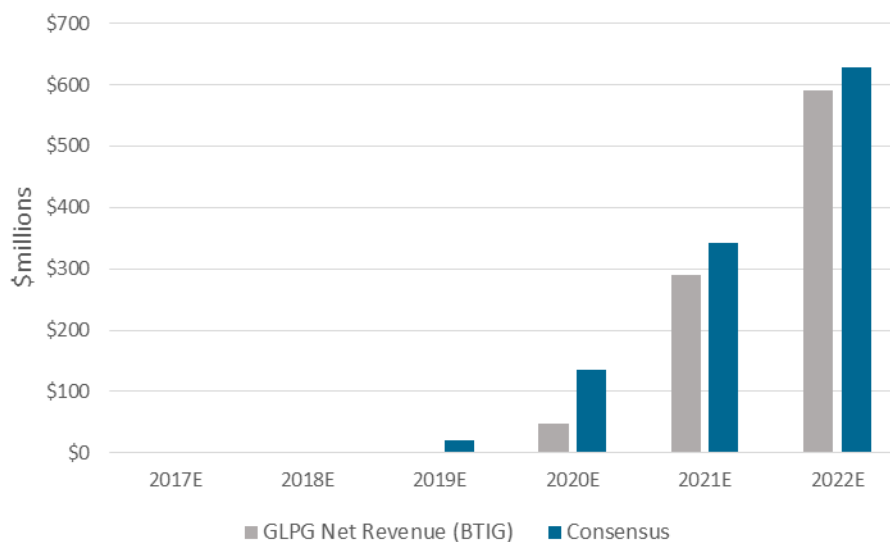
Figure 4. We are €151m ahead of consensus sales estimates for 2021E

Forecast Summary (US\$m/ Per Share)	2017E	2018E	2019E	2020E	2021E
Sales (BTIG)	€177	€177	€238	€223	€460
Sales (Consensus)	€139	€203	€202	€266	€309
Relative	€38	-€27	€36	-€42	€151
EBITDA (BTIG)	-€176	-€235	-€200	-€226	-€24
EBITDA (Consensus)	-€61	-€24	-€62	€46	-€96
Relative	-€116	-€211	-€137	-€271	€72
Diluted EPS (BTIG)	-€3.8	-€4.8	-€3.9	-€4.5	-€0.5
Diluted EPS (Consensus)	-€1.4	-€0.9	-€0.7	-€0.4	€0.3
Relative	-€2.4	-€3.8	-€3.2	-€4.1	-€0.8

Source: Company Data, Bloomberg, FactSet, BTIG Research Estimates, June 2017

Regarding filgotinib's estimates specifically, we are ~\$51m below consensus sales estimates for 2021E (Figure 5) and ~\$38m below for 2022E. Comparability issues may arise as we use net-revenues realized by GLPG, versus total drug sales recorded.

Figure 5. We are -\$51m below 2021E consensus sales estimates for filgotinib



Source: Company Data, Bloomberg, FactSet, BTIG Research Estimates, June 2017