

GALAPAGOS NV (GLPG-NASDAQ)

Biotechnology

Dane Leone, CFA | (212) 856-4374 | dane.leone@raymondjames.com

Steven Seedhouse, Ph.D. | (212) 885-1837 | steve.seedhouse@raymondjames.com

Bowen Wu, Res. Assoc. | (212) 856-4381 | bowen.wu@raymondjames.com

Type A Let Them Know: US FDA Did the Heisman on Filgo

RECOMMENDATION

On Tuesday post market-close, Galapagos and Gilead announced a shift in the partnership agreement between the two companies as it relates to filgotinib (Jyseleca). The change in the partnership agreement comes as a result of a Type A meeting with the US FDA regarding the Complete Response Letter (CRL) that was received for the NDA submission of filgotinib for the treatment of Rheumatoid Arthritis (RA) ([see here](#)). Based upon commentary from the management team ([Link to CEO Blog](#)), the Type A meeting made it clear that the US FDA would not approve the 200mg dosage of filgotinib. Gilead has made the decision that it would not be productive to commercialize filgotinib for RA without the 200mg dosage within the US (which is in-line with feedback from the rheumatology community). As a result, Gilead has returned commercial rights for filgotinib to Galapagos for Western Europe in exchange for a royalty on sales (previously 50 – 50 partnership). Both companies remain committed to ongoing programs for ulcerative colitis and Crohn’s disease. We reiterate our **Market Perform**, and have made compensatory changes to our GLPG model as a result of the alteration in partnership along with the updated regulatory outlook – we now forecast \$1.1bn in filgotinib global sales during 2027. The Galapagos management team will host an investor call tomorrow, 16 December 2020, at 14:00 CET / 8 AM ET, which will also be webcasted.

Under the amended agreement, development of filgotinib varies depending on indication:

- in RA, Galapagos will assume sole operational responsibility;
- in psoriatic arthritis (PsA), ankylosing spondylitis (AS), and non-infectious uveitis, both companies will stop the trials and development over the coming months
- Gilead and Galapagos will remain co-partners for evaluating filgotinib in IBD, and specifically, Gilead will remain operational responsibility for the current Crohn’s disease trial, and Galapagos will take operational responsibility for the ongoing UC trials.
- As part of the updated financial agreements, Galapagos regains developmental and commercialization rights for filgotinib in Europe, with the transfer of rights completed by December 31, 2022. Beginning January 1, 2021, Galapagos will be solely responsible for the development costs for certain trials, while remaining 50/50 with Gilead for other trials (see Figure 1). Commercial rights on filgotinib moving fully back to Galapagos as of January 1, 2022 will be subject to payment of tiered royalties of 8-15% of net sales in Europe to Gilead, starting during 2024.
- With the amended agreement, Gilead will pay Galapagos €160 million, split between a €110 million payment during 2021 and a €50 million payment during 2022, and is subject to certain adjustments for higher than budgeted development costs - Gilead will fully recognize these payments under R&D expenses during 4Q2020.

DECEMBER 15, 2020 | 6:31 PM EST
COMPANY COMMENT

Market Perform 3 Target Price NM

Suitability High Risk/Speculation

MARKET DATA

Current Price (Dec-15-20)	\$119.45
Market Cap (mln)	\$7,813
Current Net Debt (mln)	\$(6,189)
Enterprise Value (mln)	\$1,624
Shares Outstanding (mln)	65.4
30-Day Avg. Daily Value (mln)	\$18.0
Dividend	\$0.00
Dividend Yield	0.0%
52-Week Range	\$112.00 - \$274.03

KEY FINANCIAL METRICS

	1Q	2Q	3Q	4Q
EBITDA (mln) (\$, Dec FY)				
2019A	(53)	(44)	491	(23)
2020E	(45)	(86)	(32)	(116)
new	(45) A	(86) A	(32) A	(108)
2021E	(107)	(115)	(122)	(133)
new	(110)	(106)	(102)	(92)
2022E	(90)	(72)	(71)	(67)
new	(73)	(70)	(66)	(62)

	2019A	2020E	2021E	2022E
EBITDA (mln) (\$, Dec FY)				
old	370	(279)	(477)	(301)
new	370	(271)	(410)	(271)
GAAP EPS (\$, Dec FY)				
old	2.49	(5.57)	(7.31)	(4.61)
new	2.49	(5.45)	(6.27)	(4.15)
Revenue (mln) (\$, Dec FY)				
old	896	416	224	438
new	896	424	288	492

Source: Thomson One, Raymond James & Associates. Quarterly figures may not add to full year due to rounding.

Please read domestic and foreign disclosure/risk information beginning on page 3 and Analyst Certification on page 4.

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Figure 1 - Amended filgotinib development plan

Indication	Development, commercialization, and associated costs now led by	Affiliated Trials	Key Upcoming Catalysts
Rheumatoid Arthritis	Galapagos	DARWIN3, FINCH4, FILOSOPHY, MANTA, MANTA-RAY	Week 26 MANTA and MANTA-RAY data during mid-2021
Psoriatic Arthritis	Galapagos	PENGUIN 1 + 2, EQUATOR 2	These trials are expected to be discontinued in coming months
Ankylosing Spondylitis		SEALION 1 + 2	
Uveitis		HUMBOLDT	
Ulcerative Colitis	Galapagos and Gilead (Galapagos assumes operational responsibility in ongoing trials)	SELECTION, SELECTION-LTE	Under review by EMA, Japan regulatory filing during 1H2021, US FDA filing guidance after MANTA and MANTA-RAY data
Crohn's Disease	Galapagos and Gilead (Gilead retains operational responsibility)	DIVERSITY + LTE, DIVERGENCE 1 + 2 (and LTEs)	-

Source: Raymond James Research

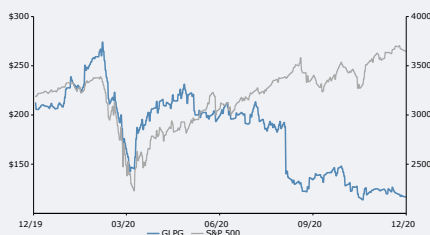
Figure 2 - GLPG Income Statement

Galapagos NV, Income Statement	EUR € mm																										
	2015A	2016A	2017A	2018A	2018A	Mar-20	Jun-20	Sep-20	Dec-20	2020E	Mar-21	Jun-21	Sep-21	Dec-21	2021E	Mar-22	Jun-22	Sep-22	Dec-22	2022E	2023E	2024E	2025E	2026E	2027E		
Total Revenue	60,560	152	156	318	896	107	118	144	55	424	57	66	75	89	288	110	118	127	137	492	634	631	778	857	938		
Product Revenues	0	0	0	0	0	0	15	15	15	17	26	35	49	128	70	78	87	97	332	474	551	698	777	858			
Reimbursement Revenues	40	130	127	289	845	88	104	132	40	376	40	40	40	40	160	40	40	40	40	160	160	80	80	80	80		
Other Income	21	22	29	29	51	9	14	12		35				0	0	0	0	0	0	0	0	0	0	0	0		
Cost of Goods Sold	0.00	0	0	0	0	0	0	0.0	-0.8	-1	-0.9	-1.3	-1.7	-1.5	-0	-3.5	-3.8	-4.3	-4.8	-17	-14	-17	-21	-23	-20		
Gross Profit	61	152	156	318	896	107	118	144	56	425	58	67	76	92	294	113	122	131	142	509	649	647	799	880	964		
Gross Margin %						99%	99%	99%	99%	99%	93%	93%	93%	93%	99%	93%	93%	93%	93%	95%	97%	97%	97%	97%	97%		
Operating Expenses	-150.0	-163.1	-265.7	-362.7	-525.6	-152	-204	-176	-164	-645.3	-168	-178	-178	-184	-703.7	-186	-192	-198	-204	-779.6	-828.4	-868.2	-900.8	-952.7	-1006.2		
Research and Development	-130	-140	-219	-323	-427	-117	-159	-132	-130	-534	-139	-142	-146	-150	-577	-151	-153	-154	-156	-614	-639	-665	-695	-720	-749		
Research and Development % of Sales	-21.8%					-10.9%	-13.5%	-9.2%	-9.1%	-12.6%	-24.4%	-21.5%	-21.5%	-21.5%	-20.0%	-13.7%	-13.0%	-15.4%	-14.6%	-13.5%	-10.1%	-8.8%	-8.8%	-8.3%	-8.1%		
General and administrative expenses	-19	-22	-24	-37	-74	-25	-38	-27	-29	-118	-29	-31	-32	-34	-127	-35	-38	-43	-45	-160	-180	-204	-209	-233	-257		
General and administrative % of Sales	-3.1%					-23.3%	-32.2%	-18.8%	-24.6%	-27.8%	-50.9%	-46.7%	-46.7%	-46.7%	-44.1%	-31.8%	-32.2%	-33.9%	-32.9%	-26.4%	-28.4%	-31.7%	-24.9%	-27.1%	-27.5%		
Sales and marketing expenses	-1	-2	-3	-3	-25	-10	-17	-17		-44					0	0	0	0	0	0	0	0	0	0	0		
Sales and marketing % of Sales	-0.2%					-9.3%	-14.5%	-11.8%	-19.1%	-10.4%	-7.7%	-7.7%	-7.7%	-7.7%	-1.4%	-1.7%	-1.7%	-1.7%	-1.7%	-0.0%	-0.0%	-0.0%	-0.0%	-0.0%	-0.0%		
Operating Profit	-89	-11	-90	-45	370	-44,585	-86	-32	-108	-271	-110	-104	-102	-92	-410	-73	-70	-66	-62	-271	-180	-221	-102	-72	-43		
Operating Profit Margin %	-148%	-6%	-58%	-14%	41%	-40.5%	-27%	-22%	-19%	-64%	-19%	-15%	-13%	-10%	-14%	-66%	-59%	-52%	-45%	-55%	-28%	-33%	-12%	-8%	-5%		
Fair value re-measurement of Share Sub Agreement	-31	57	0	0	-182	-20.53	-0.59	13.03		-8				0	0	0	0	0	0	0	0	0	0	0	0		
Other financial income	2	10	5	23	21	39.72	-25.44	-0.20		14				0	0	0	0	0	0	0	0	0	0	0	0		
Other financial expenses	-2	-2	-31	-8	-60	-24.87	-2.43	-01.99		-89				0	0	0	0	0	0	0	0	0	0	0	0		
Prestax Income	-120	94	-116	-29	150	-50	-115	-82	-108	-354	-110	-106	-102	-92	-410	-73	-70	-66	-62	-271	-180	-221	-102	-72	-43		
Income Tax Provision	1	0	0	0	0	-0.54	-0.37	-0.39		-1				0	0	0	0	0	0	0	0	0	0	0	0		
Tax Rate																											
Net Income	-119	94	-116	-29	150	-51	-115	-82	-108	-355	-110	-106	-102	-92	-410	-73	-70	-66	-62	-271	-180	-221	-102	-72	-43		
Basic Shares Outstanding						64.82	65.00	65.34	65.34	65.12	65.34	65.34	65.34	65.34	65.34	65.34	65.34	65.34	65.34	65.34	65.34	65.34	65.34	65.34	65.34		
Diluted Shares Outstanding						64.82	65.00	65.34	65.34	65.12	65.34	65.34	65.34	65.34	65.34	65.34	65.34	65.34	65.34	65.34	65.34	65.34	65.34	65.34	65.34		
Basic EPS		46.99	49.48	53.00	58.48																						
Diluted EPS		1.16	-2.34	-0.61	2.48	-0.78	-1.77	-1.25	-1.65	-5	-1.69	-1.62	-1.56	-1.40	-6	-1.32	-1.07	-1.02	-0.95	-4	-3	-3	-1	-1	-1		
Diluted EPS Growth % YoY																											
Performance Metrics																											
EBITDA	0.00	-8.17	-86.20	-41.97	370.29	-44.59	-86.21	-32.38	-107.53	-270.69	-110.16	-105.97	-101.94	-91.74	-408.81	-72.91	-69.61	-66.38	-62.24	-271.15	-179.06	-221.10	-102.25	-72.25	-42.51		

Source: Raymond James Research

COMPANY DESCRIPTION

Galapagos NV is a clinical-stage biotechnology company that is researching and developing novel small molecules to treat indications such as rheumatoid arthritis and inflammation. It was founded in 1999, and is headquartered in Mechelen, Belgium. Its diverse pipeline consists of multiple programs that are in Phases 1-3, and also has preclinical developments. Its most advanced program is filgotinib, a selective JAK1 inhibitor, which is targeting multiple indications including rheumatoid arthritis, ulcerative colitis, and Crohn's disease. Besides filgotinib, Galapagos has four current primary areas of interest: IPF, atopic dermatitis, OA, and inflammation fibrosis.

**Company Citations**

Company Name	Ticker	Exchange	Closing Price	RJ Rating	RJ Entity
Galapagos NV	GLPG	NASDAQ	\$250.00	MP3	Raymond James & Associates

Prices are as of the most recent close on the indicated exchange. See Disclosure section for rating definitions. Stocks that do not trade on a U.S. national exchange may not be registered for sale in all U.S. states. NC=not covered.

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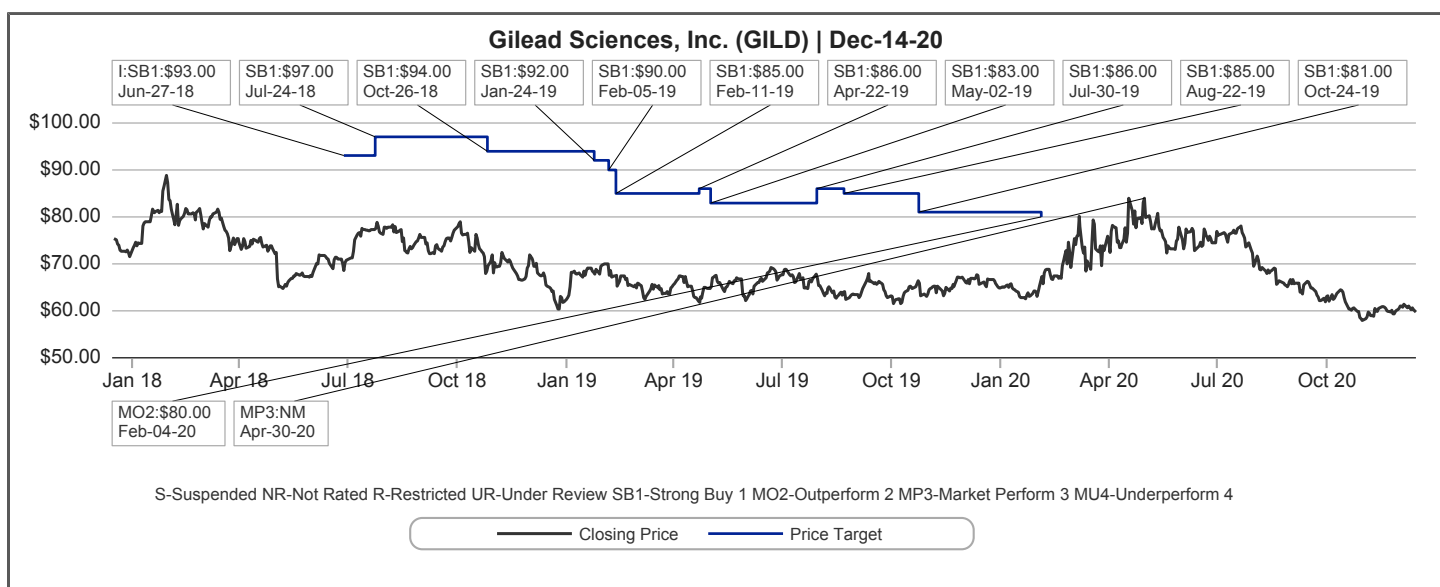
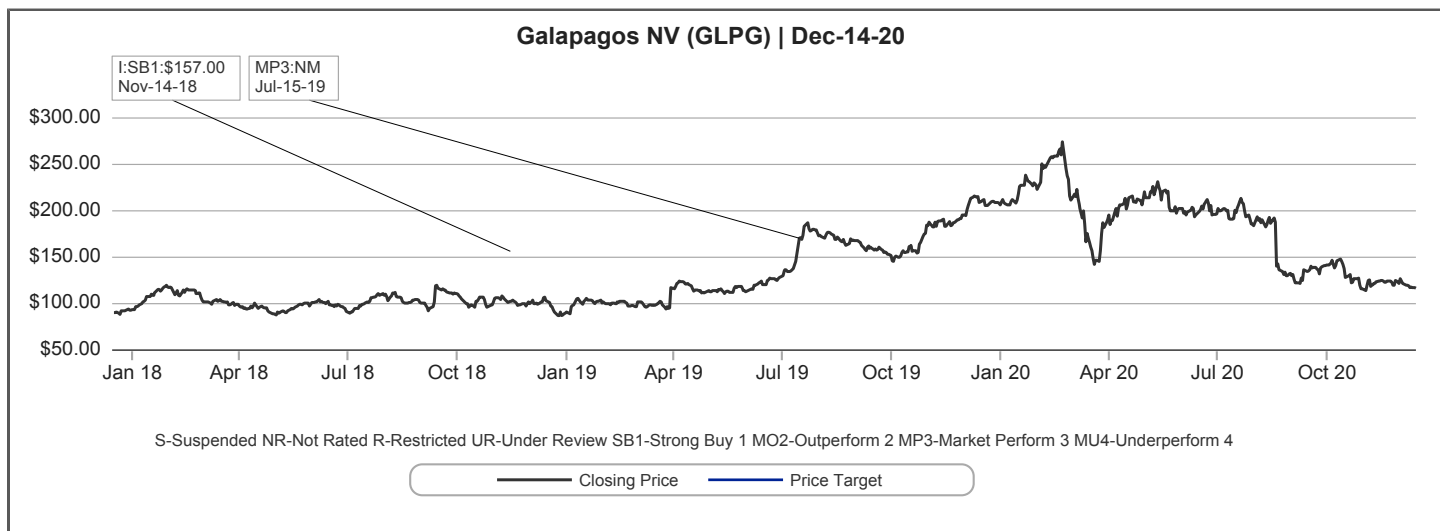
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Valuation Methodology

Gilead Sciences, Inc.

Our valuation is based on our discounted cash flow (DCF) analysis.

Galapagos NV

We value based on 5 year forward EV/sales.

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Company Specific Risk Factors

Gilead Sciences, Inc.

Generic Competition and Loss of Exclusivity: Key Gilead products are coming off patent in the U.S. and EU and will continue to come off patent over the next 10-15 years. If loss of market share and pricing power is greater than we currently model, there is risk to our and Street's estimates. Moreover, Gilead (like all biotech companies) is potentially subject to litigation risk (including inter partes reviews) which can affect patent life for key products.

HCV Competitive Risk: If AbbVie's Mavyret continues to take market share from Gilead or new competitors enter and drive pressure to market share and net pricing, there is risk to our HCV estimates. Every ~\$1B in annual HCV revenue in out years on a recurring basis is worth about ~\$3/share in our model.

HIV Competitive Risk: HIV is a highly competitive field and competitors continue to develop new HIV treatments (e.g., GSK's two drug combination pills, MRK's Delstrigo). If competitors generate favorable clinical data or are able to gain a commercial advantage via pricing or marketing, our HIV estimates could be at risk.

CAR-T Commercial and Development Risk: The field of CAR-T therapies for cancer is relatively new. Any difficulties as it relates to reimbursement or ability to effectively sell the therapies to a wide enough group of treatment centers could create risk to consensus estimates. Moreover, next generation CAR-T approaches including allogeneic treatments and CAR-Ts for solid tumors are less proven and may not yield successes. If the development and commercial headwinds for CAR-T therapies are not navigated, Gilead may not be able to get an appropriate return on its ~\$12B acquisition of KITE.

Risk of Pipeline Assets Failing (Filgotinib/Yescarta/Magrolimab): Gilead has several assets in potentially registrational trials including filgotinib in inflammatory diseases such IBD, Yescarta in 2L DLBCL, and magrolimab in high-risk MDS. In general, revenues for late stage assets are reflected in our and consensus estimates. Therefore, failure of any or all of the ongoing registrational programs represents a risk to estimates.

Sector Risk: Gilead is a large cap biotech company with many commercialized products in both the U.S. and worldwide. Political headlines and sentiment related to drug developers or drug companies, in particular as it relates to drug pricing, could have an adverse effect on Gilead's market valuation.

High Risk Suitability. We assign a High Risk/Growth suitability rating given the unpredictability and volatility of the biotech space.

Galapagos NV

We assign a **High Risk/Speculation Suitability** rating as the company is currently not profitable, and is not anticipated to be profitable for a number of years. As such, if the company is unable to secure financing for its activities, it could cease operations.

Stronger data from competitors to filgotinib could reduce our optimism for the program, along with our current commercial sales estimates.

Filgotinib may not be approved by the U.S. FDA for rheumatoid arthritis, which could significantly alter our revenue forecasts for the company, and endanger the Gilead partnership.

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