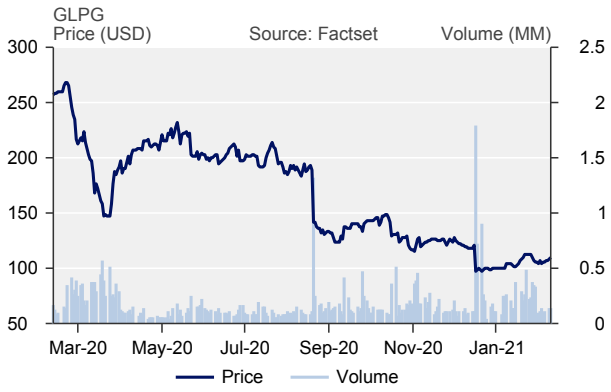
Biotechnology

GLPG - NSQ February 10, 2021

Intraday Price 2/10/21	**$90.60**
Rating:	*(prior Buy)* Hold
12-Month Target Price:	*(prior $140.00)* NA
52-Week Range:	$93.01 - $274.03
Market Cap (M):	5,926.3
Shares O/S (M):	65.4
Float:	100.0%
Avg. Daily Volume (000):	243.5
Debt (M):	$0.0
Dividend:	$0.00
Dividend Yield:	0.0%
Risk Profile:	Speculative
Fiscal Year End:	December

Total Expenses ('000)

	2020E	2021E	2022E
1Q	178,771A	222,784	247,195
2Q	240,570A	230,356	257,942
3Q	208,119A	243,362	279,437
4Q	218,630	250,221	290,185
FY	846,090	946,723	1,074,759
Prior	—	996,917	1,125,956



Galapagos is based in Belgium and is listed in the US under the symbol GLPG and on the Euronext Amsterdam exchange also under the symbol GLPG. All financial data is converted to USD, from Euros.

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Galapagos NV

Hold

Ziritaxestat IPF Program Discontinued – Downgrading Shares to Hold

Summary

- **Galapagos and commercial partner Gilead (GILD - Buy) announced that they will be discontinuing the P3 Pivotal ISABELA Studies of ziritaxestat in idiopathic pulmonary fibrosis (IPF). GLPG shares are down ~18% on the news.**
- **The discontinuation comes following a Data Monitoring Committee review which determined that the risk/benefit profile no longer warrants continued development. As such, Galapagos is also discontinuing the NOVESSA study developing ziritaxestat in systemic sclerosis.**
- **Where does Galapagos go from here? In our view, Galapagos still has several opportunities over the longer term. In particular, GLPG1205 demonstrated positive P2 data and has become the lead asset in IPF, and the Toledo program is early stage but promising, and data is expected over 2021. In addition, filgotinib is also not out of the picture, but the European markets and irritable bowel syndrome in the US are likely to drive more modest sales compared to other inflammatory drugs. The company still has ~$6B in cash and has the time to develop its earlier stage pipeline, but we need to see more data emerge from these programs and gain clarity if/when value drivers emerge. As such, we are stepping to the sidelines, downgrading the shares to Hold, from Buy and removing our prior price target of $140.**

Details

Next steps for Galapagos. The ziritaxestat fail is a major setback to Galapagos' long term value drivers, but the company still has several opportunities on the commercial side and in its earlier stage pipeline. For filgotinib, there is an opportunity for label expansion in EU later this year into UC and the MANTA data in mid-2021, which should highlight the path forward in the US. In the pipeline, Galapagos still has a number of anti-fibrotic assets, including GLPG1205 (GPR84 inhibitor) and GLPG4716 (chitinase inhibitor) moving into P2b and P2 for IPF, respectively. On the inflammatory side, Galapagos has its TYK2 inhibitor GLPG3667, which is reading out P1b data this year as well as initial POC data from the Toledo program, which represents a novel target in inflammation. Also on the inflammatory side, we are watching for P1b data from the knee osteoatritis program, GLPG555 (JAK1). Ultimately, Galapagos still has a promising pipeline and cash to fund operations for several years, and although we remain hopeful, we are stepping to the sidelines as we await more data from these programs.

Filgotinib update. The filgotinib launch in Japan and Europe is currently underway for rheumatoid arthritis (RA), and an EMA decision on ulcerative colitis (UC) is expected in 2H21 (CHMP in 1H21). With the DIVERSITY study reading out in 1H22, there may be potential for a Crohn's disease (CD) filing in 2H22. **What about the US?** In the US, Gilead has terminated development for filgotinib in all indications besides inflammatory bowel disease (IBD). The next step on this front is the MANTA safety study. MANTA is required for approval in UC, and following the Type A meeting, the FDA requested an increased 52-week follow-up from the 26-week primary endpoint (expected mid-2021) for any patients who display >50% decrease in semen parameters and do not recover at 26 weeks. The data will remain blinded, except to a specific team responsible for reviewing the data and conducting discussions with regulators. While it is possible that the company will be able to file before the 52-week endpoint (no signals on hormone levels have been detected across trials, which should correlate with semen parameter), semen parameters can be highly variable, so filing will likely have to wait until the full data is available.

IPF Update. IPF has been a significant long term opportunity for Galapagos, and the ziritaxestat fail pushes back entry into that market considerably. The company's second asset, GLPG1205, demonstrated positive data in P2. (*continued on page 2)*

On the primary endpoint, change in forced vital capacity (FVC) from baseline over the 26 weeks, a difference of 42mL was observed for GLPG1205 compared to placebo (-34mL vs. -76mL). The result was consistent across patients regardless of background regimen. Additionally, change in pulmonary lobar volume, as measured by functional respiratory imaging, correlated with the FVC decline observed, further validating the result. Full data from this study is expected in the near future, and the company plans to move into a P2b dose ranging study in 2021. We also note that the company has a Chitinase program (GLPG4716) moving into a P2, potentially this year. Though the design for those studies has not been finalized, we anticipate potential approval timelines to be on a 2024 timeframe. In terms of earlier stage compounds, Galapagos is developing two Toledo compounds which target macrophages, similarly to GLPG1205 and GLPG4716, and GLP4586 which targets fibroblast activation (as well as two undisclosed early development target programs).

Toledo Program. Toledo is a codename for a novel target class discovered by Galapagos for development in multiple inflammatory diseases. The platform targets salt-inducible kinase (SIK), which acts to rebalance the immune response (increasing anti-inflammatory markers and reducing pro-inflammatory markers, rather than just reducing suppressing the immune system). As more information and data emerges for this platform, we expect to see a compelling value proposition as immunosuppression is responsible for most of the severe side effects associated with anti-inflammatories. Three proof of concept studies are ongoing across psoriasis, UC, and RA and two more are expected to start in the near future in lupus and Sjögren's syndrome, with topline data expected across all 5 by mid-2021.

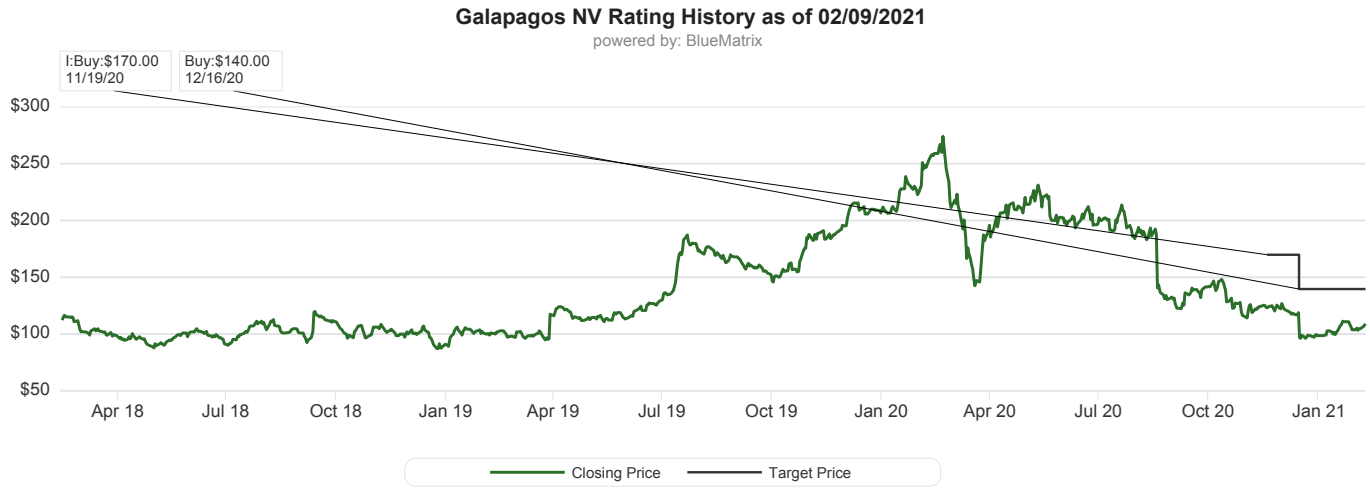
Commercial opportunity in Europe. Though the market opportunity for inflammatory disease in Europe is comparatively modest vs. the US, it is still significant. Currently, the EU5 inflammatory market (68% of total EU market) is worth ~$7B (€5.7B), and breaks down to $3.9B (€3.2B) in RA, $2.1B (€1.7B) in Crohn's disease (CD), and $1B (€0.8B) in UC. Galapagos is targeting peak sales of ~$0.6B (€0.5B), or an 8%-12% market share for IBD + RA. This could increase if they decide to continue development for some of the smaller indications like AS, PsA and uveitis. As for the transition process, Galapagos is expected to take over responsibility for the EU5 ASAP in 2021, and take over the Alpine, Nordic countries, and Ireland by YE21. The filgotinib launch in Europe is currently under way for RA, and an EMA decision on UC is expected in 2H21 (CHMP in 1H21). With the DIVERSITY study reading out in 1H22, there may be potential for a CD filing in 2H22.

Model update. We have pushed out revenues for IPF to 2025, from 2023 and have increased our risk adjustment to 50%, from 30%, based on the earlier stage of development of GLPG1205 compared to ziritaxestat. We have also reduced expenses for 2021 to $947M, from $997M, and for 2022 to $1,075M from $1,126M.

.: Income Statement ($000)														
.: YE December 31	2017A	2018A	2019A	1Q20A	2Q20A	3Q20A	4Q20E	2020E	2021E	2022E	2023E	2024E	2025E	2026E
Revenue:	-													
	-													
Filgotinib Sales (EU) - Rheumatoid Arthritis	-				-	-	5,710	5,710	67,325	230,738	274,354	295,428	334,091	356,857
Filgotinib Sales (EU) - Inflammatory Bowel Disease	-			-	-	-	-	-	-	31,622	92,024	173,229	211,297	239,007
GLPG1205 Sales (EU) - Idiopathic Pulmonary Fibrosis										-	-	-	60,544	247,759
	-													
Net revenue	-	-	-	-	-	-	5,710	5,710	67,325	262,360	366,378	468,657	605,932	843,623
Collaborative revenue:	-													
Revenues	149,963	340,826	997,082	115,844	122,248	155,543		393,635		325,000				
Other Income	34,019	34,231	60,068	10,317	16,590	14,397		41,304	-	-	-	-	-	-
Milestones								-	129,800	59,000				
Filgotinib Royalties (Japan) - Rheumatoid Arthritis	-	-	-		-	-	1,905	1,905	27,337	40,033	67,713	100,964	140,153	173,290
Filgotinib Royalties (US + Japan) - Inflammatory Bowel Disease				-	-	-	-	-	-	20,490	100,754	225,362	300,148	384,560
GLPG1205 Royalties (US) - Idiopathic Pulmonary Fibrosis										-	-	-	41,164	88,701
	-	-	-					-	-	-	-	-	-	-
Total Collaborative Revenue	**183,982**	**375,057**	**1,057,150**	**126,161**	**138,838**	**169,940**	**1,905**	**436,843**	**157,137**	**444,523**	**168,467**	**326,326**	**481,465**	**646,551**
Total Revenue	**183,982**	**375,057**	**1,057,150**	**126,161**	**138,838**	**169,940**	**7,615**	**442,553**	**224,463**	**706,883**	**534,845**	**794,983**	**1,087,396**	**1,490,174**
Gross Margins:														
Cost of Goods Sold				-	-	-	1,142	1,142	12,119	39,354	43,965	46,866	60,593	84,362
%Gross Margin							80%	80%	82%	85%	88%	90%	90%	90%
Gross Profit	183,982	375,057	1,057,150	126,161	138,838	169,940	6,473	441,411	212,344	667,529	490,880	748,117	1,026,803	1,405,812
Operating Expenses:														
Research and Development	257,832	380,993	504,238	137,780	175,955	156,063	157,624	627,422	639,970	652,770	665,825	679,142	692,725	706,579
%R&D														
General and Administrative	28,810	42,045	86,967	29,384	44,454	31,775	36,541	142,155	149,263	179,115	188,071	191,832	195,669	199,582
%G&A														
Sales and Marketing	3,308	4,892	29,001	11,606	20,161	20,281	23,323	75,371	145,371	203,520	223,872	235,066	246,819	259,160
%S&M														
Operating Expenses	289,950	427,929	620,206	178,771	240,570	208,119	218,630	846,090	946,723	1,074,759	1,121,733	1,152,905	1,195,805	1,249,683
Operating Income (Loss)	(105,968)	(52,872)	436,945	(52,610)	(101,733)	(38,179)	(211,015)	(403,537)	(722,260)	(367,876)	(586,888)	(357,923)	(108,409)	240,491
Fair value remeasurement	-	-	(214,340)	(24,224)	(695)	15,379		(9,540)	-	-	-	-	-	-
Other Financial Income	5,755	21,635	25,349	46,872	(30,013)	(238)		16,620	-	-	-	-	-	-
Other Financial expenses	(36,087)	(3,230)	(70,884)	(29,350)	(2,869)	(73,153)		(105,372)	-	-	-	-	-	-
	-	-	-					-	-	-	-	-	-	-
	-	-	-					-	-	-	-	-	-	-
	-	-	-					-	-	-	-	-	-	-
Total Other Income	**-**	**18,406**	**(259,875)**	**(6,702)**	**(33,577)**	**(58,012)**	**-**	**(98,292)**	**-**	**-**	**-**	**-**	**-**	**-**
Pretax Income	(136,299)	(34,467)	177,070	(59,313)	(135,309)	(96,191)	(211,015)	(501,829)	(722,260)	(367,876)	(586,888)	(357,923)	(108,409)	240,491
Taxes on income	234	59	253	396	440	457	-	1,293	-	-	-	-	-	-
Tax Rate														
GAAP Net Income (Loss)	(136,533)	(34,526)	176,817	(59,709)	(135,750)	(96,648)	(211,015)	(503,122)	(722,260)	(367,876)	(586,888)	(357,923)	(108,409)	240,491
Total comprehensive loss	(136,533)	(34,526)	176,817	(59,709)	(135,750)	(96,648)	(211,015)	(503,122)	(722,260)	(367,876)	(586,888)	(357,923)	(108,409)	240,491
GAAP-EPS	(2.76)	(0.66)	3.07	(0.92)	(2.09)	(1.49)	(3.25)	(7.75)	(11.08)	(5.62)	(8.93)	(5.43)	(1.64)	3.62
GAAP-EPS (Dil)	(2.76)	(0.66)	2.94	(0.92)	(2.09)	(1.49)	(3.25)	(7.75)	(11.08)	(5.62)	(8.93)	(5.43)	(1.64)	3.62
Wgtd Avg Shrs (Bas) - '000s	49,479	52,113	57,633	64,873	64,873	64,938	65,003	64,922	65,166	65,427	65,689	65,952	66,216	66,481
Wgtd Avg Shrs (Dil) - '000s	49,479	52,113	60,179	64,873	64,873	64,938	65,003	64,922	65,166	65,427	65,689	65,952	66,216	66,481

Source: Company reports and Maxim

DISCLOSURES



Maxim Group LLC Ratings Distribution		As of: 02/09/21	
		% of Coverage Universe with Rating	% of Rating for which Firm Provided Banking Services in the Last 12 months
Buy	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to outperform its relevant index over the next 12 months.	**83%**	**54%**
Hold	Fundamental metrics are currently at, or approaching, industry averages. Therefore, we expect this stock to neither outperform nor underperform its relevant index over the next 12 months.	**17%**	**45%**
Sell	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to underperform its relevant index over the next 12 months.	**0%**	**0%**
	**See valuation section for company specific relevant indices*		

I, Jason McCarthy, Ph.D., attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

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The research analyst(s) primarily responsible for the preparation of this research report have received compensation based upon various factors, including the firm's total revenues, a portion of which is generated by investment banking activities.

Maxim Group makes a market in Galapagos NV

Maxim Group expects to receive or intends to seek compensation for investment banking services from Galapagos NV in the next 3 months.

GLPG: For Galapagos, we use the BTK (NYSE Biotechnology Index) as the relevant index.

Valuation Methods

GLPG: We model commercialization of filgotinib rheumatoid arthritis (RA) in the EU and Japan in 4Q20 which is currently underway, and in inflammatory bowel disease (IBD) in 2022 with a 30% risk adjustment in the US, EU and Japan. We also factor IPF revenues (initially from

GLPG1205) in 2025 with a 50% risk adjustment. A 15% discount is applied to the free cash flow, discounted EPS, and sum-of-the-parts models, which are equally weighted to derive a 12-month price target.

Price Target and Investment Risks

GLPG: Aside from general market and other economic risks, risks particular to our price target and rating for Galapagos NV. include:(1) the regulatory and clinical risk associated with product development; (2); the rate and degree of progress of product development;(3) the rate of regulatory approval and timelines to potential commercialization of products; (4) the level of success achieved in clinical trials; (5) the requirements for marketing authorization from regulatory bodies in the United States and other countries; (6) the liquidity and market volatility of the company's equity securities; (7) regulatory and manufacturing requirements and uncertainties; (8) product and technology developments by competitors, potentially with more resources and commercial infrastructure; (9) inability, if product(s) is approved to gain adequate market share;(10) impact of comprehensive tax reform in the US and Ex-US tax policy; (11) delays related to COVID-19 could impact the company's ability operate and conduct clinical trials; (12) failure of third-parties to meet contractual obligations, potentially impacting drug development; (13) Gilead is responsible for commercialization in the US as well as other regions, which limits the influence which Galapagos has on commercialization in the largest pharmaceutical market; (14) Following the results of the Type A meeting for filgotinib in rheumatoid arthritis, Galapagos is now responsible for commercialization of filgotinib in the EU, as well as additional clinical trials, this will require a larger investment compared to the previous cost division between Galapagos and Gilead and carries higher risk if the product is not successful; (15) The MANTA and MANTA-RAy studies are required for filgotinib in the US in inflammatory bowel disease, there is significant risk that the trial will require a 52 week readout and delay filing in the US; (16) currency fluctuations as the company reports in Euros.

RISK RATINGS

Risk ratings take into account both fundamental criteria and price volatility.

Speculative – Fundamental Criteria: This is a risk rating assigned to early-stage companies with minimal to no revenues, lack of earnings, balance sheet concerns, and/or a short operating history. Accordingly, fundamental risk is expected to be significantly above the industry. Price Volatility: Because of the inherent fundamental criteria of the companies falling within this risk category, the price volatility is expected to be significant with the possibility that the investment could eventually be worthless. Speculative stocks may not be suitable for a significant class of individual investors.

High – Fundamental Criteria: This is a risk rating assigned to companies having below-average revenue and earnings visibility, negative cash flow, and low market cap or public float. Accordingly, fundamental risk is expected to be above the industry. Price Volatility: The price volatility of companies falling within this category is expected to be above the industry. High-risk stocks may not be suitable for a significant class of individual investors.

Medium – Fundamental Criteria: This is a risk rating assigned to companies that may have average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to approximate the industry average.

Low – Fundamental Criteria: This is a risk rating assigned to companies that may have above-average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to be below the industry.

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