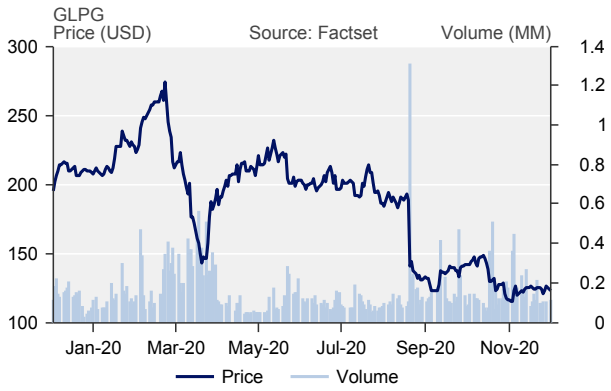
Biotechnology

GLPG - NSQ December 1, 2020

Closing Price 11/30/20	**$122.61**
Rating:	Buy
12-Month Target Price:	$170.00
52-Week Range:	$112.00 - $274.03
Market Cap (M):	8,011.4
Shares O/S (M):	65.3
Float:	99.0%
Avg. Daily Volume (000):	165.1
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	219,562	237,380
2Q	240,570A	226,829	247,701
3Q	208,119A	239,939	268,342
4Q	218,630	247,206	278,663
FY	846,090	933,536	1,032,086



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

Buy

Building-Out The IPF Franchise; Positive Phase 2 Data Reported for GLPG1205

Summary

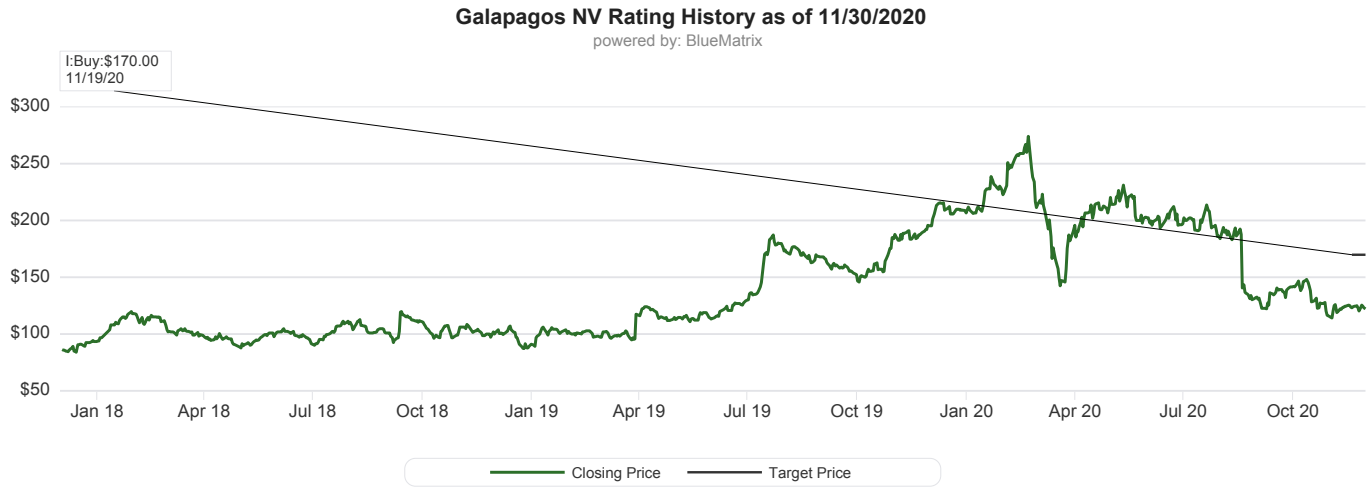
- **Galapagos reported yesterday post-close, positive data from the P2 PINTA proof-of-concept study for GLPG1205 in idiopathic pulmonary fibrosis (IPF).**
- **The study compared GLPG1205 or placebo + standard-of-care (pirfenidone, nintedanib, or neither) and found a reduction in forced vital capacity (FVC) decline across the GLPG1205 groups, which was correlated with change in pulmonary lobar volume.**
- **No relevant safety issues were found in the pirfenidone or monotherapy patients, however the combination with nintedanib did have a higher rate of discontinuations. Based on the different mechanisms, this is unlikely to translate to issues if combined with ziritaxestat, Galapagos' lead IPF asset.**
- **Next step is to move into a P2b dose finding study. We also note that an interim futility analysis for ziritaxestat is expected in 1H21.**
- **Conclusion. The PINTA data represents proof-of-concept for the second novel antifibrotic in Galapagos' IPF pipeline. Funded with $6.3B of cash, IPF represents a significant potential market, and having multiple assets with potential for combination is central to Galapagos' strategy.**

Details

Phase 2 PINTA study. The P2 PINTA trial is a randomized double-blind, placebo-controlled trial investigating the 100mg dose of GLPG1205. N=68 patients received GLPG1205 or placebo (randomized 2:1) on top of their existing regimen (pirfenidone, nintedanib, or neither) for 26 weeks. On the primary endpoint, change in 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. Additional secondary endpoints will include time to major disease events, changes in functional exercise capacity, QoL, PK/PD, and safety and tolerability. On the safety side, the most frequent adverse events for GLPG1205 monotherapy patients were GI-related (e.g. nausea). No relevant safety signal was observed for the monotherapy patients or in combination with pirfenidone. Nintedanib patients did experience a higher rate of discontinuation due to high-grade treatment-emergent adverse events. Full data from the study is expected to be published in a medical journal and presented at upcoming conferences.

Building-out the IPF franchise. IPF is a progressive fibrotic lung condition that impacts 200K individuals and has a median survival of 2-5 years. Current therapies, nintedanib and pirfenidone, generated $2.8B in 2019 (up from $2.1B in 2018), despite having an annual discontinuation rate of 25%. Galapagos has a pipeline of potentially synergistic assets including ziritaxestat in P3 and GLPG1205 in P2, as well as compounds in early development. Both ziritaxestat and GLPG1205 represent novel mechanisms within IPF. Ziritaxestat inhibits autotaxin, which stimulates fibrogenesis through the production of lysophospholipids. GLPG1205 inhibits GPR84, which is expressed in cells involved in the fibrotic pathway such as macrophages and fibroblasts, and is a key pro-inflammatory mediator. These mechanisms have the potential to be complementary to each other as well as the existing IPF therapies, pirfenidone (which is a pyridine) and nintedanib (which is a kinase inhibitor). Galapagos' strategy in IPF is to build-out a franchise of compounds that can then be combined for potential synergies (similar to Vertex's {VRTX - NR} strategy for cystic fibrosis). The company has demonstrated positive proof-of-concept for its first two novel compounds, and has earlier-stage drug candidates in its pipeline.

DISCLOSURES



Maxim Group LLC Ratings Distribution		As of: 11/30/20	
		% 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.	**81%**	**53%**
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.	**19%**	**50%**
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.

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, and in the US in 2022 with a 50% risk adjustment, in inflammatory bowel disease (IBD) in 2022 with a 30% risk adjustment, in psoriatic arthritis (PsA) and ankylosing spondylitis (AS) in 2023, and in uveitis in 2025 with a 70% risk adjustment. We also factor ziritaxestat in 2023 with a 30% risk adjustment. A 30% 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) the result of the upcoming Type A meeting will likely determine the path forward for filgotinib in the US, if the 200mg dose does not move forward, Gilead is unlikely to commercialize the product in the US outside of inflammatory bowel disease, which would limit the commercial opportunity; 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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