COWEN

Biotechnology

Galapagos NV (ADR)

Equity Research

Quick Take: Company Update

August 10, 2017

Price: $73.17 (08/9/2017)

Price Target: NA

OUTPERFORM (1)

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Key Data

Symbol	NASDAQ: GLPG
Market Cap (MM)	$3,722.0

GLPG1690 Shows Signals Of Activity In IPF

The Cowen Insight

GLPG released data from the FLORA trial of '1690 in IPF. '1690 showed target engagement, stat. sig. changes vs. placebo in FRI, and trends in FVC improvements vs. placebo. Admittedly, the patient numbers are small, follow up is short, and there are missing values, and so we consider the results early, though intriguing. We continue to expect GLPG to outperform as its broad pipeline progresses.

GLPG1690 Appears Active, And Will Advance Into A Potentially Pivotal Trial.

The News: Idiopathic pulmonary fibrosis (IPF) is a lung disease characterized by progressive fibrosis leading to declines in lung function and ultimately death. In recent years Ofev (nintedanib) and Esbriet (pirfenidone) have been approved. While both drugs slow the progression of disease, patients continue to die of IPF and so a significant medical need remains. Preclinical studies have shown that autotaxin generates lysophosphatidic acid A (LPA) which in turn signals through LPA1 to upregulate CTGF- and TGFb- mediated fibrosis, causing progression of IPF. Consequently, Galapagos developed the autotaxin inhibitor GLPG1690 and explored its efficacy in IPF in the Phase IIa FLORA trial. FLORA enrolled 23 patients who had IPF for an average of 1-2 years. At baseline the patients had an average age of 62-66 yrs, BMI of 29-32 kg/m2, average DLCO of 38%-41% of normal, and baseline FVC of 70%-75% of normal (approx. 2.7L - 2.8L). All enrolled patients were nintedanib/pirfenidone naive. Enrolled patients were randomized 3:1 to receive GLPG1690 at 600mg QD or placebo for 12 weeks. Forced vital capacity (FVC) was measured at weeks 0, 4, 8, and 12 as well as following a 2 week washout period. FVC measurements were excluded if the measurement was of poor quality or if the patient had taken a bronchodilator shortly before the FVC assay was performed.

GLPG1690 generated a statistically significant reduction in plasma LPA18:2 over the course of the trial, consistent with its mechanism and with the prior Phase I data. In the per protocol FVC analysis which included 17 patients at week 12, Galapagos reported that the GLPG1690 treated patients experienced a mean 8mL increase in FVC compared to an 87mL decline in the placebo group at 12 weeks. This difference was not statistically significant. FVC improvements were also seen at week 4 (n=19, +116mL for '1690 vs -87mL for placebo), week 8 (n=19, +15mL vs. -140mL), and during the post-treatment follow-up period (n=19, -55mL vs. -205mL), with the difference at week 8 achieving $p<0.05$. Functional respiratory imaging (FRI) also indicated that GLPG1690 patients experienced disease stabilization at week 12 while placebo patients experienced continued declines in lung function as measured by specific airway volume (+0mL/L for '1690 vs. +3 mL/L for placebo, p=0.0137) and specific airway resistance (+0.005 kPa/sec for '1690 vs. -0.035 kPa/sec for placebo, p=0.0255). Treatment emergent AEs were similar between the GLPG1690 and placebo groups and included headache and peripheral swelling of the shin. 1 placebo patient withdrew for an SAE, and 2 GLPG1690 patients withdrew, 1 for withdrawal of consent and the second for an SAE (cancer, ruled unrelated to '1690). Management reports no laboratory abnormalities were observed.

Please see pages 3 to 6 of this report for important disclosures.

Galapagos is now in discussions with regulators about next steps for GLPG1690. Management expects to pursue larger 52 week studies of GLPG1690 both as a monotherapy in nintedanib/pirfenadone naive or intolerant patients and as a combination with nintedanib or pirfenadone. Galapagos is hopeful that these trials will serve as pivotal trials that could support an FDA filing (either alone or in combination with other studies).

Our Take: We View The FLORA Data As Having Established Proof Of Concept, Though Much Remains To Be Learned About '1690's Efficacy and Safety.

In total we view FLORA as having (1) clearly demonstrated that GLPG1690 effectively engages the autotaxin/LPA pathway and (2) provided an intriguing efficacy signal in IPF that provides proof of concept, and is worthy of follow-up in longer and larger studies. The fact that there is concordance between GLPG1690's effects on LPA, FVC, and FRI suggest to us that '1690 is active, and provide proof-of-principle that '1690 can have an impact on IPF.

That being said, we think much remains to be learned about the efficacy and safety of GLPG1690. Taken at face value, the difference in FVC at week 12 appears striking, with '1690 patients having improved by 8mL while placebo patients declined by 87mL. This 96mL placebo-adjusted difference compares very favorably to a pooled analysis of pirfenidone's 2 global Phase III trials which showed a placebo adjusted treatment effect of just 36mL (n=1247; $p<0.001$) at 3 months. However, there are certain issues with FLORA's FVC data which prevent us from having full faith in the magnitude of the FVC benefit, and therefore we look forward to its corroboration by longer and larger studies. For example, the patient numbers are small, with only 3-4 placebo patients measured for FVC at each time point after baseline. The time of follow up is relatively short at 12 weeks, and the magnitude of '1690's benefit declined from week 4 to week 8, and from week 8 to week 12. While the 87mL decline in FVC at week 12 is consistent with the FVC decline seen in the placebo groups from the Phase III trials of pirfenadone and nintedanib, the drop in the FLORA placebo group appears to have been driven by an uncommonly large drop in FVC from baseline to week 4, while FVC remained stable after. The Phase III trials of pirfenadone and nintedanib showed a more consistent decline over time. Finally, there were a number of patients missing from the FVC analyses - there were 19 patients included in the FVC analysis at weeks 4 and 8, and 17 at week 12, despite the fact that 21 patients were evaluable for plasma LPA analysis at those time points. Management noted that FVC measurements were excluded if the measurement was of poor quality or if the patient had taken a bronchodilator shortly before the FVC assay was performed. Nonetheless, prior IPF trials reported ITT data, and the impact of the missing FVC readings on the magnitude of '1690's treatment effect is impossible to know.

Despite the questions that remain, FLORA establishes '1690 as another viable candidate in Galapagos' pipeline. We think prior to the FLORA data few investors ascribed much value to '1690. With the data establishing proof-of-concept, we think the results are clearly positive for GLPG and make GLPG's broadening pipeline even more interesting.

Upcoming Events/Milestones: During Q3:17 management expects to conduct scientific advice sessions for its CF triplet regimens enabling trials to begin in Q4:17. Top-line data from a Phase IIa study of MOR106 (anti-IL17C antibody) in atopic dermatitis is expected in Q3:17. Full 84 week extension data from the DARWIN3 trial of filgotinib in RA will be presented at ACR in November 2017. Finally, data from the ALBATROSS trial of GLPG2222+Kalydeco in gating mutation patients is expected around YE:17.

Valuation Methodology And Risks

Valuation Methodology

Biotechnology:

In calculating our 12-month target price, we employ one or more valuation methodologies, which include a discounted earnings analysis, discounted cash flow analysis, net present value analysis and/or a comparable company analysis. These analyses may or may not require the use of objective measures such as price-to-earnings or price-to-sales multiples as well as subjective measures such as discount rates.

We make investment recommendations on early stage (pre-commercial) biotechnology companies based upon an assessment of their technology, the probability of pipeline success, and the potential market opportunity in the event of success. However, because these companies lack traditional financial metrics, we do not believe there are any good methodologies for assigning a specific target price to such stocks.

Investment Risks

Biotechnology:

There are multiple risks that are inherent with an investment in the biotechnology sector. Beyond systemic risk, there is also clinical, regulatory, and commercial risk. Additionally, biotechnology companies require significant amounts of capital in order to develop their clinical programs. The capital-raising environment is always changing and there is risk that necessary capital to complete development may not be readily available.

Risks To The Price Target

Galapagos has no approved products and limited revenue. The company may need to raise additional capital from the public markets prior to turning profitable. Each of Galapagos's candidates faces a number of clinical, regulatory, and commercial hurdles prior to becoming successful. The value of Galapagos' developmental candidates can be influenced by investors' appetite for clinical, regulatory, and commercial risk.

We make investment recommendations on early stage (pre-commercial) biotechnology companies based upon an assessment of their technology, the probability of pipeline success, and the potential market opportunity in the event of success. However, because these companies lack traditional financial metrics, we do not believe there are any good methodologies for assigning a specific target price to such stocks.

Addendum

Stocks Mentioned In Important Disclosures

Ticker	Company Name
GLPG	Galapagos NV (ADR)

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Assumption: The expected total return calculation includes anticipated dividend yield

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Distribution of Ratings/Investment Banking Services (IB) as of 06/30/17

Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	461	60.03%	102	22.13%
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Sell (c)	9	1.17%	0	0.00%

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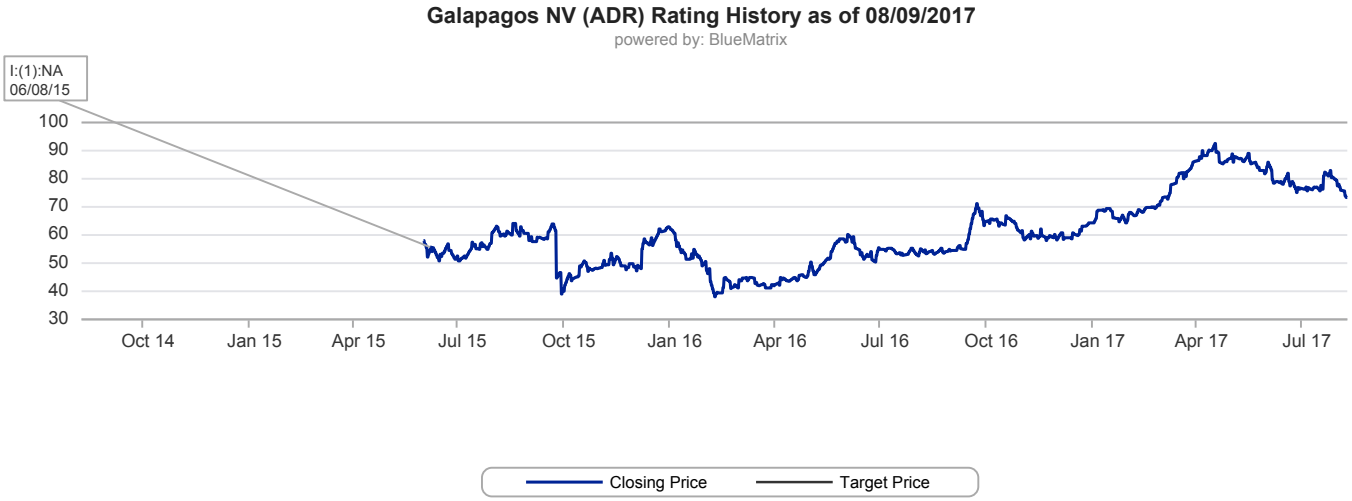

Legend for Price Chart:

I = Initiation | 1 = Outperform | 2 = Market Perform | 3 = Underperform | UR = Price Target Under Review | T = Terminated Coverage | $xx = Price Target | NA = Not Available | S=Suspended

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