COWEN

Biotechnology

Galapagos NV (ADR)

Equity Research

Quick Take: Company Update

June 20, 2017

Price: $78.86 (06/20/2017)

Price Target: NA

OUTPERFORM (1)

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Key Data

Symbol	NASDAQ: GLPG
Market Cap (MM)	$4,007.3

R&D Update: CF Triple To Move Into Patients In Q4, Filgotinib Progressing

The Cowen Insight

GLPG provided a broad pipeline update at an R&D day. GLPG expects to move its first CF triple combo regimen into patients during Q4 vs. prior mid-2017 expectations, and to begin patient dosing of two other triple regimens during 2018. Interim data from filgotinib's DARWIN3 trial were released, and it continues to look effective, safe, and competitive with the other JAKs. We remain at Outperform.

Galapagos To Seek UK Scientific Advice On The Design Of Its CF Triple Trial In July, Anticipates Patient Dosing Will Begin During Q4.

Galapagos provided a comprehensive pipeline update at its annual R&D day in NYC this morning. Investors are keenly focused on Galapagos' progress towards assembling a triple combination regimen for the treatment of cystic fibrosis (CF). Management reports that it has completed Phase I single ascending dose (SAD) and multiple ascending dose (MAD) trials for all three components of its first internally developed triple combination of CFTR potentiator GLPG2451, 1st generation corrector GLPG2222, and 2nd generation corrector GLPG2737. Galapagos disclosed that all achieved high and consistent plasma levels in Phase I, with the exposures achieved 2-4x above the target levels established in preclinical testing.

Galapagos had previously guided to the initiation of patient dosing in a Phase II trial of the first triple combination around Mid-2017. However, this guidance had assumed that Galapagos would submit the proposed Phase II trial design to a number of EU countries simultaneously. Galapagos worries that there is too great a chance that it will receive contradictory feedback from the different countries under this strategy, and so now plans to first seek scientific advice from the UK first, in July. As the UK led the EMA reviews of the Vertex CF candidates, GLPG thinks the UK regulators are best positioned to provide feedback. During its scientific advice sessions with the UK, Galapagos plans to discuss the structure of doublet control arms that will be required and confirm the suitability of its preclinical toxicology package to support 3 month clinical trials. Galapagos will use the UK's advice to submit CTAs to the other EU countries. Galapagos anticipates the Phase II of '2451+'2222+'2737 will be conducted in both F508del homozygotes and F508del/minimal function heterozygotes. With the first CF patients dosed with '2451, '2222 and '2737 in Q4:17, Galapagos expects to be in position to release initial data around Mid-2018.

Galapagos disclosed today that '2451 has an active metabolite that has a one-month half life. This is seemingly not ideal, as it could lead to drug accumulation, or complicated drug-drug interactions. Management believes the related potentiator GLPG3067 (currently in Phase I) does not have this metabolite, and so Galapagos is advancing it rapidly through Phase I with the potential to test it in Phase II trials as part of triplet regimens during 2018. Galapagos anticipates a trial of the triplet of '3067+'2222+'2737 will begin in Q1:18 and a trial of the '3067+'2222+'3221 triplet will begin in mid-2018. U.S. INDs will be filed as these triplet studies are conducted and management expects to begin dosing of the triplet regimens in the U.S. during subsequent Phase IIb trials.

Please see pages 4 to 7 of this report for important disclosures.

Several Other Trials Of Galapagos' CF Candidates Also Either In Progress, Or Being Planned.

Galapagos is conducting the Phase II FLAMINGO trial of '2222 monotherapy in F508del homozygous patients. This trial will test 4 weeks of '2222 monotherapy at 4 dose levels vs. placebo in 50 F508del homozygous patients. Sweat chloride and FEV1 are secondary endpoints in this trial. Management expects to complete enrollment around YE:17 and report data in early 2018. Preclinical data indicates '2222 monotherapy generates ~80% of the benefit of Vertex' tezacaftor/ivacaftor combination in F508del homozygous patients. Therefore, Galapagos considers the FLAMINGO trial largely a safety study of '2222.

Galapagos' preclinical assays also indicate that '2222 provides additive benefit to Kalydeco monotherapy in F508del/gating mutation samples. Consequently, Galapagos is conducting the ALBATROSS trial of '2222+Kalydeco in F508del/gating mutation patients. This trial will enroll 35 stable Kalydeco patients (2:2:1) to receive '2222 at 150mg or 300mg QD, or placebo for 4 weeks. The primary endpoints are safety and tolerability, while sweat chloride and FEV1 are secondary endpoints. Management indicated that it believes '2222 could provide a 5% FEV1 benefit (above Kalydeco monotherapy) in ALBATROSS. Data from this trial is expected around YE:17.

Long-Term DARWIN3 Data Corroborates Filgotinib's Competitive Efficacy And Safety Profile

Galapagos reviewed data from the ongoing Phase II DARWIN3 extension study of filgotinib in rheumatoid arthritis (RA). The results demonstrate that filgotinib's efficacy is maintained through at least week 60 of the extension study as measured by ACR20, ACR50, ACR70, DAS28(CRP) low disease activity and DAS28(CRP) remission. Filgotinib's efficacy was similar whether it was dosed QD or BID, or whether given as a monotherapy or in combination with methotrexate. Galapagos anticipates that the week 84 analysis of the trial will be presented at ACR 2017 in November.

Galapagos also reported data from filgotinib's safety database that now includes 1314 patient years of exposure (PYE) with the majority of patients followed for at least 96 weeks. Galapagos believes filgotinib's per 100 PYE rates of death (0.2), malignancy (0.5), MACE (0.1), serious infection (1.9), and zoster (1.2) compare favorably to the rates produced by the approved doses of Actemra, Humira, and Xeljanz as well as the 2mg and 4mg doses of baricitinib that LLY/INCY used in Phase III development. Galapagos highlighted that patients' improved hemoglobin levels are sustained at ~6.5g/L through week 96, and management believes this is a sign of filgotinib's differentiated JAK1 vs. JAK2 specificity compared to baricitinib, Xeljanz, or ABBV's upadacitinib. Similarly, Galapagos believes filgotinib has a differentiated long-term impact on Natural Killer (NK) cell activity which may drive a lower infection rate. Finally, Galapagos highlighted baricitinib's AE of increased platelets vs. decreases on filgotinib or tofacitinib. Galapagos postulates this may be driving an imbalance in thrombotic events within baricitinib's trials.

Filgotinib's development outside of Phase III indications RA, UC, and Crohn's continues. Partner Gilead has begun Phase II proof-of-concept trial in small bowel CD, fistulizing CD, Sjogren's, Ankylosing Spondylitis, psoriatic arthritis, and cutaneous lupus, with more proof-of-concept trials planned.

Galapagos' Earlier Stage Pipeline Continues To Advance, With Results From 2 Proof-Of-Concept Trials Expected During H2:17

The Phase IIa FLORA study of **GLPG1690** in IPF has completed 12 weeks of dosing in all patients. Management anticipates releasing data in Q3:17. This trial enrolled 24 patients (3:1) to receive '1690 at 600mg QD or placebo for 12 weeks. The primary endpoints are safety, tolerability, and PK/PD. FVC is a secondary endpoint, although

management believes an impact on FVC is unlikely to occur without longer-term follow-up.

GLPG1972 (ADAMTS-5 inhibitor) is currently enrolling a 4 week Phase Ib dose escalation study for osteoarthritis. Management reports that the U.S. IND is now open and patient recruitment is expected to be completed by YE:17.

MOR106 (anti-IL-17c antibody) is partnered with Morphosys and is currently in a 4 week Phase Ib proof-of-concept trial for atopic dermatitis. Data is expected to be released in H2:17. The primary endpoint is safety/tolerability, and PK is the secondary endpoint. Exploratory objectives include measures of efficacy such as the EASI score, IGA score, and dermatology quality of life index. Management notes that participants in this trial are not allowed to utilize steroids concomitantly.

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.

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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 03/31/17

Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	441	58.57%	86	19.50%
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Sell (c)	9	1.20%	0	0.00%

(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's equity research rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's equity research ratings definitions. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's equity research ratings definitions. Cowen and Company Equity Research Rating Distribution Table does not include any company for which the equity research rating is currently suspended or any debt security followed by Cowen Credit Research and Trading.

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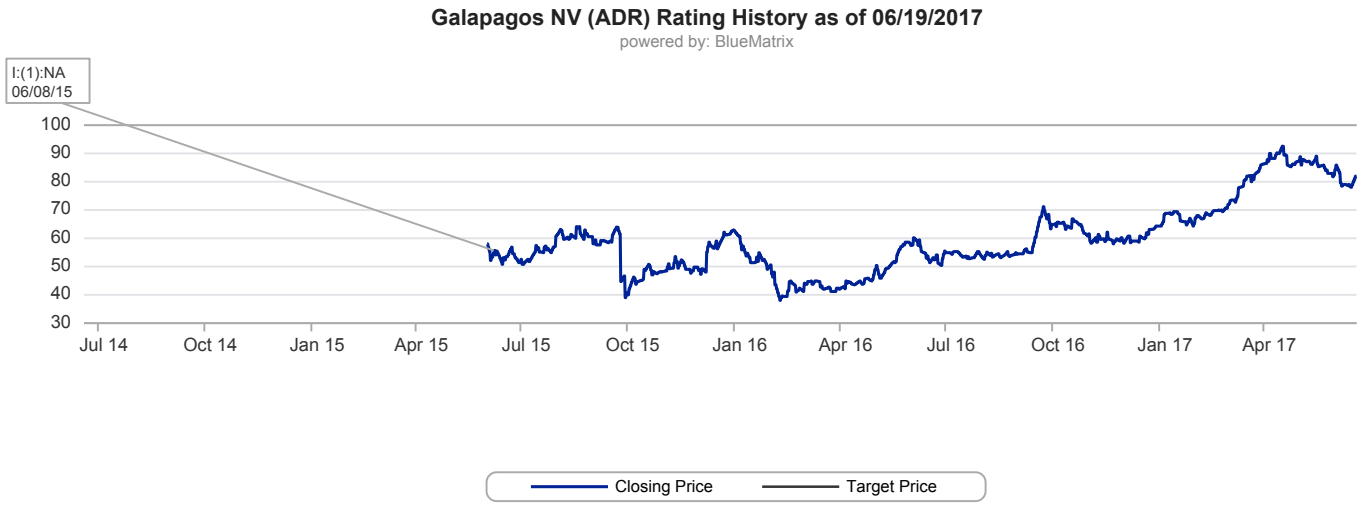

Legend for Price Chart:

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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