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Biotechnology

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Galapagos NV (GLPG) - BUY

GLPG: Filgotinib Shaping Up To Be A "Blockbuster", But It's All CF Over The Near-Term; Initiate at Buy

Price:	$54.13
Fair Value Estimate:	$64.00
52-Week Range:	$37.03 - $65.70
Market Cap (MM):	$2,496
Shr.O/S-Diluted (mm):	46.1
Average Daily Volume:	64,323

FYE: Dec	2016E	2017E	2018E
EPS:	€(1.11)E	€4.25E	€(2.26)E
Prior EPS:	NC	NC	NC
P/E Ratio:	NA	9.8x	NA

Quarterly EPS:			
Q1	€0.79A	€(0.56)E	--
Q2	€(0.08)A	€1.29E	--
Q3	€(0.73)E	€0.83E	--
Q4	€(1.06)E	€2.83E	--

Quarterly Revenue (M):			
Q1	15A	73E	--
Q2	39A	145E	--
Q3	25E	113E	--
Q4	28E	181E	--
Year:	107E	512E	278E

1 Year Price History for GLPG

PORTFOLIO MANAGER BRIEF

Galapagos' discovery engine has generated differentiated, novel MOA drugs with two programs targeting RA and CF translating into significant licensing deals. Over the next six to nine months, the CF program will dominate headlines. Based on its high-risk nature, our $13 or $600M NPV for the program implies a 21% downside from current levels in case of a setback. For a well-capitalized, development-stage company with a maturing pipeline beyond RA/Crohn's/CF, the risk-reward is attractive, in our view. Initiating with a Buy and $64 FV estimate.

ANALYST NOTES

- Despite the availability of biosimilar's, oral JAK inhibitors have a significant role in the management of Rheumatoid Arthritis (RA): Conventional synthetic DMARDs do not prevent joint damage leading to suboptimal functional outcomes in RA patients. This necessitates the introduction of expensive biologics adding to the burden of a chronic condition. Hence, in the real-world setting and against the EULAR guidelines, the average duration of disease exceeds 8+ years prior to treatment with biologics. Since response to biologics is in many instances inversely proportional to the duration of disease, patients are routinely cycled from one drug to another in the hopes of delivering a remission. Hence, the emergence of oral-JAK inhibitors offers an interesting paradigm in the management of RA, and in filgotinib (partnered with Gilead, GILD – No rating) Galapagos has a "potential blockbuster".
- We are modeling peak sales of $1.9B for filgotinib in RA, and $658M in Crohn's with Ulcerative Colitis offers additional optionality (not in our FV): Yes, filgotinib is at least two years behind baricitinib (INCY/LLY); however, in case of RA being third in to launch, it may be a commercial positive, because: Xeljanz (PFE) experience suggests physicians are likely to get more comfortable with the safety profile of JAK inhibitors over the next two years; the anticipated launch of baricitinib increases share-of-voice; Filgotinib JAK1 specificity resulting in a superior hematologic safety profile over competitors could be an advantage (more so in IBD); oral dosing increases convenience over biologics; and although experience with GILD suggests otherwise, filgotinib could be priced attractively vs. other JAK's and biosimilars (we are modeling a $21K launch price in U.S.).
- Playing catch up in Cystic Fibrosis with partner Abbvie (ABBV - No rating): With Kalydeco and Orkambi, Vertex (VRTX - No rating) has established market leadership and has set sights on a triple-combo to improve upon Orkambi

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and potentially capture the under-served heterozygous population (up to 40% of the market). With ~70K patient commercial opportunity, Galapagos does not have the luxury of developing a potentiator and corrector sequentially, especially if Vertex's triple-combo succeeds in meaningfully improving upon Orkambi. Galapagos' higher-risk clinical strategy is not without pitfalls (drug-drug interactions could derail the program), the program appears well-positioned with robust preclinical and healthy volunteer data and is set up for important clinical readouts starting 2H16.

- The CF corrector/potentiator commercial opportunity could exceed $7B globally, and we are assuming a 30% market share for GLPG/ABBV: The upcoming SAPHIRA 1 and 2 studies will provide first insights on GLPG1837 (potentiator) and is likely to set off comparisons with Kalydeco, especially because emerging data on chronic co-administration of Kalydeco with Orkambi points to reduction, rather than enhancement of functional rescue of F508del-CFTR. If -1837 or the follow-on correctors stabilize the CFTR protein during its transport to the surface, the potentiators alone could be commercially viable, in our view. The -1837 data is likely to be followed by multiple healthy volunteer studies from the other key components of the strategy (correctors and back up potentiators), setting the stage for a triple combo studies during late 2017. Whether GLPG/ABBV will choose a phase 3 program prior to a triple-combo phase 2 is not yet clear, but will likely be data dependent. Either way, progress on the CF program will be a key driver of sentiment on GLPG stock over the next 12 to 18 months, in our view.
    - Initiating coverage of Galapagos N.V. with a Buy rating and a $64 FV estimate: Our FV estimate is ~$64/share. We value GLPG based on a risk-adjusted sum-of-parts analysis and is driven by filgotinib (RA and Crohn's) and CF programs. We assign modest NPV to its OA and IFP clinical programs as we await clinical validation:
    - r-NPV for the Gilead-partnered RA program are $40/share based on a 65% probability of success (POS) in RA. RA represents 63% of our FV. Note the elaborate phase 3 program (three independent phase 3 studies were initiated on 8/22/16)
    - r-NPV for the Gilead-partnered Crohn's programs is $8/share based on $60% probability of success. Note, a phase 3 program in Crohn's is expected to begin enrollment during 4Q16. Crohn's represents 13% of our FV. Between RA and Crohn's we anticipate over $2.5B in peak sales and hence, blockbuster status. We are not currently including the Ulcerative Colitis opportunity as we await phase 2/3 study initiation/data
    - r-NPV for the Abbvie-partnered CF program is $11/share (or 17% of our FV). Our r-NPV assumes the following success rates: Triple-combo in homozygous patients at 20%; Triple-combo in heterozygous patients at 9%; Monotherapy in G551D, 2117H, etc. at 65%
    - r-NPV for the OA and IPF programs are $3 and $2/share, respectively with 9% probability of success.

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INVESTMENT THESIS

Galapagos has created a unique portfolio of novel, high-value, commercial targets through its robust discovery engine that has now been validated through two co-development agreements (valued at ~$2.5B in upfront and milestones) plus a mid-teens to mid-twenties royalty stream upon successful commercialization. Its current balance sheet (in excess of $1B in cash) is one of the healthiest amongst development-stage biotechnology peers. Company's balance sheet and anticipated milestones offers the opportunity and flexibility to invest heavily in pipeline and commercial organization development. While investor attention over the next 12 months is likely to be fixated its CF program and read-throughs to its RA program (commercial uptake of peer JAK-inhibitors), there will be key patient-level data both from the IPF and osteoarthritis programs, which could either cushion any short-term hiccups with the CF program or provide additional upside to our FV estimate.

ISSUES TO CONSIDER

Key Issue	Our Position	Timing	Impact
A lot rides on filgotinib - how will the RA and IBD commercial environment shape up?	RA patients responses to biologics decrease depending on the duration of disease and exposure to prior DMARDs. Hence, earlier intervention with a cost-effective, convenient (oral, OD), and safe (infection and malignancy) DMARD could alter treatment landscape. Being third to market (assuming successful phase 3 and regulatory filings) filgotinib is likely to benefit from the evolving physician comfort on the safety of JAK inhibitors compared to biologics. Additionally, being a JAK1 specific therapy, filgotinib's hematologic profile suggests compelling commercial opportunities in IBD.	12-24 Months	
Kalydeco maybe a phenomenal breakthrough but also could be efficacy limiting for ~85% of the market.	Efficacy of Vertex correctors may be self-limiting due to disruption of CFTR upon chronic Kalydeco administration. Hence, if Galapagos is right and its next generation potentiators helps rescue both homozygous and heterozygous patient cell in combination with a corrector, and does not negatively impact drug-induced F508del-CFTR correction, both functionally and structurally, then there is a shot at improving upon competitor Orkambi's efficacy. However, these have to be borne out in a clinically and triple-combo might be the only way to meaningfully tap into the heterozygous opportunity.	6-12 Months	
How should we think about its early-stage pipeline?	Early-stage pipeline opportunities should crystallize during 2017 and could act as a downside protection incase of a CF-related delay or show stopper, in our view. We anticipate exploratory phase 2 data from the ongoing wholly-owned IPF program during 2Q17, which if positive should be a key de-risking event for the program. Additionally, we expect clarity on the clinical path for the Servier partnered OA program (GLPG owns U.S. rights). Recall, GLPG has reported positive cartilage-degradation biomarker data from healthy volunteers.	6-12 Months	

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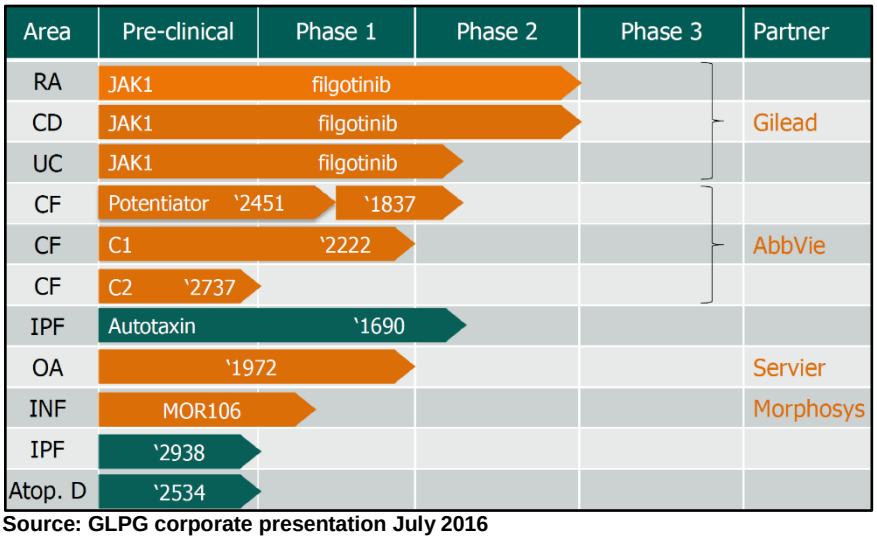
COMPANY OVERVIEW

Galapagos is a clinical-stage biotechnology company specialized in the discovery and development of novel mechanism of action, small molecule therapies for the treatment of chronic conditions associated with systemic or local inflammation. Galapagos' current clinical pipeline is focused on rheumatoid arthritis (RA), inflammatory bowel disease (both partnered with Gilead), cystic fibrosis (partnered with Abbvie), osteoarthritis (partnered with Servier); and one wholly-owned program targeting idiopathic pulmonary fibrosis. A comprehensive phase 3 program (four phase 3 studies targeting RA and Crohn's disease) are anticipated during 4Q16. The Galapagos group, including fee-for-service subsidiary Fidelta, has approximately 435 employees, operating from its Mechelen, Belgium headquarters and facilities in The Netherlands, France, and Croatia.

COMPANY PIPELINE



Source: GLPG corporate presentation July 2016

Upcoming Milestones

Upcoming Milestones							
Drug	Indication	Status	Program	Timing	Impact	Partner	Milestones and Royalty
Filgotinib	RA	Phase 3	FINCH 1, FINCH 2, FINCH 3	Underway, started on 8/22/16	+	Gilead	$1.35B pending - $750 in clinical and the rest commercial. Royalty starts at 20% and heads higher
Filgotinib	Crohn's	Phase 3		4Q16	+		
Filgotinib	Ulcerative Colitis	Phase 2/3		4Q16	+		
Filgotinib	Crohn's	Phase 2	Endoscopy	4Q16	++		
Filgotinib	Undisclosed	Phase 2		1H17	+		
GLPG1837	CF	Phase 2	SAPHIRA 1, SAPHIRA 2	2H16	+++	Abbvie	$600M of which $250M are due post-phase 2 completion. Royalty starts in the mid-teens and heads higher
GLPG2451	CF	Phase 2		2H16	++		
GLPG2222	CF	Phase 1		1H17	++		
GLPG2851	CF	Phase 1		Start 2H16	+		
GLPG1690	IPF	Phase 2		2Q17	++		Wholly owned
GLPG1972	OA	Phase 2		1H17 start	+	Servier	GLPG owns US rights

Source: Janney Montgomery Scott LLC estimates

FV ESTIMATE

Our FV estimate is ~$64/share (Exhibit 1). We value GLPG based on a risk-adjusted sum-of-parts analysis and is driven by filgotinib (RA and Crohn's) and CF programs. We assign modest NPV to its OA and IFP clinical programs as we await clinical validation:

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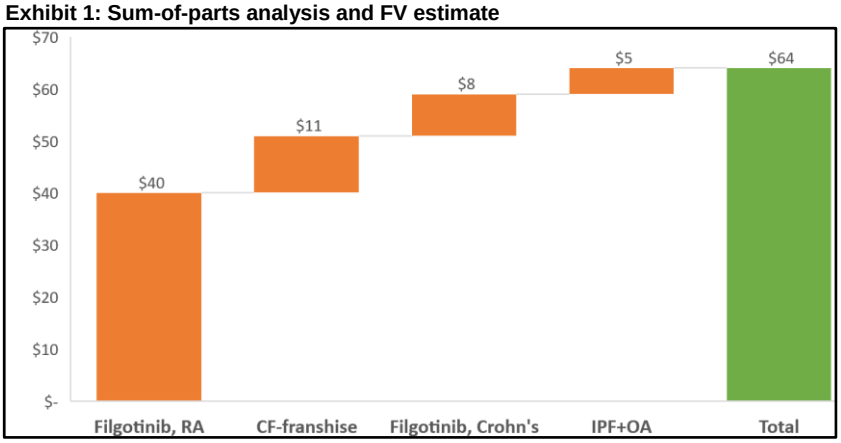
- r-NPV for the OA and IPF programs are $3 and $2/share, respectively with 9% probability of success.

Exhibit 1: Sum-of-parts analysis and FV estimate



Source: Janney Montgomery Scott LLC estimates

FILGOTINIB: THE MAJOR DRIVER OF OUR NPV

Galapagos is developing filgotinib (JAK1 inhibitor) in collaboration with Gilead. We model peak sales of $2.5B in RA. Label expansion into other indications may support >$4B commercial opportunity:

- In January 2016, Gilead paid $725M to Galapagos for the rights to filgotinib of which $300M was an upfront payment and $425M was paid for an equity stake of ~15% at a stock price of €58
- Additionally, there are significant milestones:
    - $1.35B split out into development and sales-based milestones:
        - $755M in development and
        - $600M for sales
- On the commercial side, there is a co-marketing agreement in the big five EU countries as well as in the Benelux (Belgium, the Netherlands and Luxembourg):
    - In these countries Gilead and Galapagos will have a 50-50 profit split arrangement

- For markets outside those co-promotion territories, the royalties on net sales start at 20% and move higher

FILGOTINIB DEVELOPMENT PROGRAM IN RA AND IBD

Phase 3 program started on 8/22/16 and will be broadly known as the FINCH program. The FINCH program includes three studies with filgotinib:

- **FINCH 1** is a 52-week, randomized, placebo- and adalimumab-controlled study in combination with methotrexate (MTX)
  - Expected to enroll 1,650 patients who have had inadequate response to MTX. The primary endpoint is ACR20[1] at week 12
  - The study will also include radiographic assessment at weeks 24 and 52
- **FINCH 2** is a 24-week, randomized, placebo-controlled study (N=423) in patients who are on conventional disease-modifying anti-rheumatic drugs (cDMARD), and have had an inadequate response to biological treatment
  - The primary endpoint is ACR20 at week 12
- **FINCH 3** is a 52-week, randomized study (N=1,200) in MTX-naïve patients to study filgotinib in combination with MTX, as well as monotherapy
  - The primary endpoint is ACR20 at week 24
  - Radiographic progression will also be assessed

Recall the INCY/LLY baricitinib development program included the following:

- Are inadequate responders to MTX-based therapy
- Have limited or no treatment with DMARDs
- Are intolerant to at least one DMARD but were naïve to biologics
- Are inadequate responders to TNF inhibitors

Additionally, a phase 3 study targeting Crohn's disease is expected to begin during 4Q16 and a phase 2 study targeting ulcerative colitis is expected to initiate during 4Q16

THE GLOBAL RA MARKET LIKELY TO EVOLVE IN FAVOR OF JAKINIBS

Rheumatoid arthritis (RA) is a chronic condition and cannot be cured. The discomfort, disability, and joint damage that characterize RA are a result of autoimmune response driven by numerous inflammatory cell populations and cytokines. Methotrexate (MTX) continues to be the 'anchor' drug in RA therapy and in MTX-naive patients with early RA, MTX monotherapy delivers LDA (ACR70) status in up to 25% of patients, which can be further improved with glucocorticoids. Multiple targeted modalities directed at different implicated pathways provide good control. As of 2015, five biologic agents and one biosimilar targeting TNF are approved for the treatment of RA, as are other therapies that target the IL-6 receptor, IL-1, B cells and T-cell co-stimulation and JAK inhibition. However, adding an anti-TNF to the MTX regimen does not significantly increase LDA rates. Hence, both from a cost and safety perspective physicians hold off on introduction of biologics. Furthermore, when biologics (rituximab and abatacept, both IL-17 and IL-12/23) are introduced in anti-TNF experienced patients LDA rates are low presumably because these drugs are inhibiting similar pathways or TNF is hierarchically superior to cytokines.
While biologic agents enable good disease management primarily limited to ACR50 and ACR20 rates, the response to biologic therapy depends on treatment history and, especially, disease duration. Unfortunately, independent of the target, most therapies achieve similar effects in patients with RA, with none of them able to induce remission in a majority of patients. Additionally, many patients do not have a sufficient response to these biologic DMARDs or have unacceptable side effects, necessitating investments in alternative therapies.

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