Galapagos NV (GLPG.AS): Path forward for filgotinib agreed with FDA; NDA submission confirmed by YE19

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What's new: Galapagos and partner Gilead (covered by Terence Flynn) have announced that a path forward has been established with the US FDA for the submission by year-end 2019 of the new drug application (NDA) for filgotinib, an oral, selective JAK1 inhibitor for the treatment of rheumatoid arthritis (RA) that is the company's main primary valuation driver. The news comes following a pre-NDA meeting that recently took place between the companies and the FDA, which will review filgotinib for approval on the basis of the Phase 3 FINCH trials in RA and also the ongoing MANTA safety study that was requested by FDA in order to further evaluate potential testicular toxicity that was originally observed in preclinical animal models.

Our take: While the news in itself is in line with both companies' public comments that a US regulatory submission for filgotinib would take place by YE19, we view the announcement as an incremental positive and an important de-risking event. This news comes amidst lingering concerns that the NDA for filgotinib might possibly be delayed (on the uncertainty of how much safety data from MANTA would be sufficient to support the US regulatory filing), thereby potentially placing Galapagos and Gilead at a further competitive disadvantage from a potential US launch timing perspective given that upadacitinib, another next-generation JAK inhibitor for RA being developed by AbbVie (also covered by Terence Flynn) is already expected to be approved in the US in 3Q19, at least 12 months ahead of filgotinib. As a result, we expect GLPG shares to move higher on this news.

Our current view on the stock: We maintain our Neutral rating on GLPG shares. We are optimistic on the prospects and potential of filgotinib (we model risk-adjusted peak year global sales of over $4bn, across eight indications) but that said, beyond potential proof-of-concept Phase 2 data for filgotinib in Sjogren's Syndrome and lupus (both expected in 2H19), we see little reason for the shares to outperform peers over the near term, and find current risk/reward balanced.

Valuation/Risks: We are Neutral rated on Galapagos with a DCF-derived 12-month price target of €108 (10% WACC and -10% terminal growth rate). Upside risks include: superior clinical data for filgotinib, relative to the other competing JAK inhibitors; better-than-expected launch and overall market uptake of filgotinib; and accelerated timelines for the IPF franchise. Downside risks include: any delays in

clinical development and/or regulatory timelines for filgotinib; and slower-than-expected market uptake and poor commercialization execution for filgotinib.

GLPG.AS	12m Price Target: **€108.00**	Price: **€114.60**	Downside: **5.8%**

Neutral

Market cap: €5.2bn / $5.9bn
Enterprise value: €4.2bn / $4.8bn
3m ADTV: €35.6mn / $40.0mn
Belgium
Europe Biotech
M&A Rank: 3
Leases incl. in net debt & EV?: No

GS Forecast

	12/18	12/19E	12/20E	12/21E
Revenue (€ mn)	317.8	215.0	232.4	272.2
EBIT (€ mn)	(44.8)	(276.6)	(276.0)	(236.9)
EPS (€)	(0.56)	(4.69)	(4.48)	(3.77)
P/E (X)	NM	NM	NM	NM
EV/EBITDA (ex lease,X)	NM	NM	NM	NM
Dividend yield (%)	0.0	0.0	0.0	0.0
FCF yield (%)	(3.4)	(5.3)	(4.8)	(3.3)
CROCI (%)	26.6	324.8	1,549.4	(531.6)
N debt/EBITDA (ex lease,X)	–	–	–	–

	12/18	3/19E	6/19E	9/19E
EPS (€)	0.30	(1.17)	(1.17)	(1.17)

Source: Company data, Goldman Sachs Research estimates, FactSet. Price as of 1 Jul 2019 close.

Disclosure Appendix

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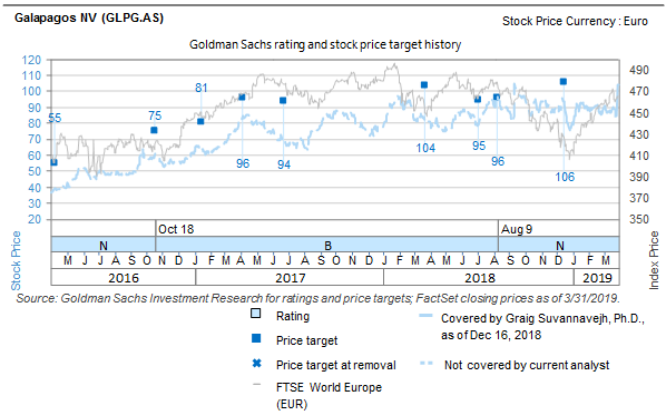

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