Galapagos NV (GLPG.AS): R&D Update: Toledo continues to intrigue as future R&D vision begins to emerge, but IPF P3 interim pushed to 1Q21

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What's new: We attended GLPG's annual R&D Update event last week, with topics discussed largely as we expected (see our previous note). We learned a number of things that were new to us, but the key headline coming out of the event, in our view, was a delay in the timing of the highly anticipated interim (and futility) analysis of the Phase 3 data for GLPG1690, an oral autotaxin inhibitor for the treatment of idiopathic pulmonary fibrosis (IPF) from early 2H20 to 1Q21. Beyond that, we were most interested in discussions (1) on GLPG's stealthy Toledo program (mechanism of action still unknown, but to be disclosed in 2020, along with first clinical data), (2) GLPG's interest in expanding beyond small molecules and into RNA-based approaches (which makes sense to us, given the companies interest in fibrosis and NASH), and (3) a key opinion leader-led discussion on IPF and the unmet need.

Bottom line and our take: We came away from the event generally positive with what we heard from GLPG, and admittedly, we continue to be impressed by the progress the company is making towards its ambition and goal of becoming a fully integrated, global biopharmaceutical company. At the current market capitalization of ~$12bn (the result of the stock returning +100% YTD), GLPG now stands as the second largest European biotechnology company. Further, given addition of GLPG to the MSCI Global Standard index on Nov. 26, we believe continued stock momentum upward heading into that event could be possible.

That said, post-Nov. 26, we believe the stock could begin to take a pause as investors begin to (1) debate the pro's and con's of GLPG's early vision of its future R&D strategy, and how it might deploy its $4-5bn in new dry powder that came from Gilead (covered by Terence Flynn) via the expansion of the R&D partnership, (2) debate the merits of holding the stock after the 26% bounce seen since the July 14 announcement of the Gilead deal (and again, the doubling in the stock since the beginning of the year) — especially now that the Phase 3 interim/futility analysis for '1690 in IPF has been pushed from summer 2020 to 1Q21, and (3) concentrate more deeply on the expected competitive dynamic between filgotinib and its rival JAK inhibitor, upadacitinib (AbbVie's Rinvoq, which was approved in August 2019, and is now in its early launch phase). Taken together, and with a view that current investor enthusiasm may temper after formal inclusion of GLPG in the MSCI index on Nov. 26, we maintain a Neutral rating.

Next clinical data catalysts: (1) Phase 3 data for filgotinib in ulcerative colitis (UC) in 1H20; (2) Phase 2b data for GLPG1972 in osteoarthritis in 2H20; (3) Phase 2 data in IPF for GLPG1205 (a second IPF asset) in 2H20; (4) Phase 2 data for GLPG1690 in systemic scleroderma (a second indication for '1690) in 2H20; and (5) Phase 2 data for GLPG3312 (a first-generation Toledo compound) in UC in 2020.

R&D Update key takeaways

Coming out of the R&D Update, the below captures what we found to be key takeaways:

On current progress: Since the last R&D Update last year, new targets have been identified in inflammation, metabolic disease, fibrosis, and OA (with several new lead candidates specifically called out, see below), while several new POC's have been initiated (PINTA for '1205 in IPF, and NOVESA for '1690 in systemic sclerosis), as well as a new Phase 3 program, PENGUIN 1 and 2 for filgotinib in psoriatic arthritis.

Exhibit 1: New preclinical candidates: GLPG's potential next wave of innovation

Candidate	Comment
GLPG4059	Novel MOA for Type 2 diabetes, will enter Phase 1 in 2020
GLPG4124	Novel MOA for fibrosis
GLPG4259	Backup for inflammation
GLPG4399	3rd Toledo compound
GLPG4471	Also a backup compound

Source: Company data

In terms of where GLPG spends on R&D, not surprisingly, the majority goes to inflammation and fibrosis (together, 57%), while we were surprised to hear that 18% goes to R&D on metabolic diseases (such as diabetes), 5% goes to polycystic kidney disease (new to us). We'll continue to monitor the situation closely. We note that GLPG discussed GLPG4059, noting that it featured a novel MOA that does not hit triglycerides, and preclinical data demonstrated lowering of blood glucose, with favorable effects also on hemoglobin HbA1c and body weight.

On Toledo: This represents GLPG's biggest program in terms of the discovery and early development efforts. The MOA is novel, and as stated earlier, GLPG did not reveal any specifics at the R&D Update, and instead plans to disclose further details in 2020. However, of particular interest, GLPG disclosed the following about its now three Toledo compounds:

- '3312 (first generation) is a pan-TOL compound, hitting what was referred to as TOL1, TOL2, and TOL3
- '3970 (second generation) hits TOL2 and TOL3 (i.e., is TOL2 and TOL3 selective); a Phase 1 started in 2019, and a broad Phase 2 development program (will include multiple Phase 2 POC studies) will begin in 2020; potential trials to begin in 2021 exploring utility beyond inflammation
- Newly disclosed '4399 (third Toledo candidate) is TOL3 selective

Future directions: In what we found to be an intriguing discussion, GLPG announced plans to expand its list of potential targets from the current 6,000+ that are druggable by small molecules to 20,000+ that are encoded by genes by 2025. It intends to do so by (1) expanding its scientific interests to pathways and more broadly networks, (2) layering in a greater reliance on patient data and new technology (such as single cell sequencing); and (3) using newer modalities. Here, in addition to its traditional small molecule approaches, GLPG will also now look to develop oligomernucleotide (i.e., RNA-based) candidates in order to knock down levels of aberrant protein expression and also a novel PROTACS (proteolysis-targeting chimeras) candidates which are small molecules that can induces rapid degradation.

It remains unclear to us whether GLPG will be successful in its endeavor to develop RNA-based approaches, but we note that given the company's previous interest in hepatitis B and current interest in NASH (where the target organ for both is the liver, where RNA-based approaches appear to have some modicum of success), we're eager to see what emerges over the next several years, and we await next developments to be able to assess the feasibility and tractability of GLPG's efforts going down this road.

Filgotinib and operational update: GLPG reminded of its ambitions for filgotinib beyond the initial indication of rheumatoid arthritis (RA):

- Ulcerative colitis (UC): Top-line Phase 3 data in 2Q20
- Crohn's disease (CD): Phase 3 still recruiting (we believe this program is running at least one year behind that of the UC program)
- Psoriatic arthrits (PsA): the Phase 3 PENGUIN 1 (patients with inadequate response to methotrexate/MTX) and PENGUIN 2 (patients with inadequate response to biologic agents) studies are just beginning to enroll and will explore two doses (100/200mg)
- Ankylosing spondylitis (AS): preparations to initiate a Phase 3 pivotal program are underway
- Other indications also being explored

GLPG reminded us that the global inflammation market is large (expected to be $65bn by 2027, according to their estimates), with indication beyond RA expected to comprise c.60% of the market. Beyond that, however, we learned little new about filgotinib, and further when asked about the status of the ongoing MANTA and MANTA RAy studies and what would be submitted to support the expected new drug application (NDA) for filgotinib, GLPG (perhaps given that partner GILD controls official communications) added little, if anything, new. That said, we believe it is nonetheless key to remind that safety data from neither MANTA and MANTA-RAy are needed to support the NDA filing.

From an operational perspective, GLPG leadership provided a brief overview of the amended filgotinib terms and the overall plans to make GLPG a fully, integrated global biotechnology company, with the company expected to launch the drug for RA in France, Italy, Spain and the Benelux countries sometime in 2H20 and then in 2H21, GLPG plans to launch filgotinib in UC in the UK, Germany and again, the Benelux countries.

KOL discussion of IPF ... In a surprise to us, GLPG brought in an IPF KOL from the UK who oversees 5,000 pulmonary fibrosis patients, and also sees about 1500 new patients each year. With respect to severity and seriousness of IPF, he reminded us that:

- c.40-50,000 are diagnosed in the US each year; there are an estimated 250,000 patients with IPF now in the US (so technically not an orphan disease), with a doubling to 500,000 estimated by 2030.
- Median survival of a patient diagnosed with IPF is c.2-3 years, and while there now are two currently approved drugs (Roche's Esbriet and Boehringer Ingelheims' Ofev, which were both approved in the fall of 2014 and that on a combined basis, has generated over $2bn in 2018), there is still a significant need given the limitations of Ofev and Esbriet on both efficacy and tolerability (GLPG cited 25% discontinuations).
- Patients display three forms of disease progression, so there is some variability in the IPF disease phenotype.

And the potential of GLPG1690 in IPF: GLPG1690 is a small molecule inhibitor of autotaxin, which is the main source of LPA in the blood. Key takeaways on '1690 in our view, were: (1) the futility outcome is now expected in 1Q21 (vs. a prior summer 2020) due to a recalculation of the powering assumptions, representing a delay; (2) top-line Phase 3 data are expected in the early part of 2022; (3) the mechanism is believed to block LPA production and transport; (4) the autotaxin/LPA approach has been previously validated, via a Bristol-Myers Squibb (covered by Terence Flynn) candidate (BMS-986020), which ultimately lead to significant off-target toxicity, and therefore was discontinued.

Upcoming news flow

Exhibit 2: With the interim Phase 3 analysis for '1690 pushed to 2021, we next look to '1205 Phase 2 data in IPF and '1972 Phase 2b data in OA

Timing	Product	Event Type	Details
2019			
4Q19	filgotinib	Regulatory	Submit NDA in RA (by partner Gilead)
2H19	'2534	Clinical	Initiate Phase 1 study
2020			
1Q20	filgotinib	Clinical	Initiate Phase 3 trial in ankylosing spondylitis (AS)
2Q20	filgotinib	Clinical	Fully enroll Phase 3 DIVERSITY trial in Crohn's disease (CD)
1H20	**filgotinib**	**Clinical**	**Announce Phase 3 SELECTION data in UC**
1H20	filgotinib	Clinical	Announce Phase 2 data in lupus membranous nephropathy
1H20	'2534	Clinical	Announce Phase 1 data
1H20	'3312 (1st gen Toledo)	Clinical	Initiate Phase 2 trial in UC
2H20	**'1205**	**Clinical**	**Announce Phase 2 PINTA data in IPF**
2H20	**'1690**	**Clinical**	**Announce Phase 2 NOVESA data in systemic sclerosis**
2H20	**'1972**	**Clinical**	**Announce Phase 2b ROCCELLA data in OA**
2H20	filgotinib	Clinical	Announce Phase 2 MANTA data in UC
2H20	filgotinib	Regulatory	Potentially submit sNDA in UC
2H20	filgotinib	Clinical	Announce Phase 2 data in small bowel CD
3Q20	filgotinib	Regulatory	Potential EU approval in RA
2H20	filgotinib	Commercial	Launch in France, Italy, Spain and Benelux countries for RA
4Q20	filgotinib	Regulatory	Potential US approval in RA
4Q20	filgotinib	Commercial	Potential US launch in RA
2020	**'3312 (1st gen Toledo)**	**Clinical**	**Announce topline Phase 1 data**
2020	**'3312 (1st gen Toledo)**	**Clinical**	**Announce topline Phase 2 data in UC**
2020	'3970 (2nd gen Toledo)	Clinical	Initiate multiple short Phase 2 POC trials
2020	'4059	Clinical	Initiate Phase 1 trial in healthy volunteers
2020	'4399 (3rd gen Toledo)	Clinical	Initiate Phase 1 trial in healthy volunteers
2021+			
1Q21	**'1690**	**Clinical**	**Announce futility analysis for Phase 3 ISABELA1 data in IPF**
1H21	filgotinib	Clinical	Announce Phase 2 data in fistulizing CD
2H21	filgotinib	Commercial	Launch in UK, Germany, Benelux countries for UC
2021	**filgotinib**	**Clinical**	**Announce Phase 3 DIVERSITY data in CD**
2021	filgotinib	Clinical	Announce Phase 2 OLE data in psoriatic arthritis
2021	filgotinib	Clinical	Announce Phase 2 data in uveitis
2021	filgotinib	Regulatory	Potential FDA approval in UC
2021	'3970 (2nd gen Toledo)	Clinical	Initiate dose-finding studies, larger POC trials, trials beyond inflammation

Bolded items reflect those that we believe have potential to be impactful from a stock perspective

Source: Company data, Goldman Sachs Global Investment Research

A word on our model

We note that there are several sensitivities that result in risks to our estimates mainly to account for the newly expanded relationship with Gilead and the various pushes and pulls arising from the deal. Positives include $5bn in new cash on the balance sheet, new potential up-front and milestone payments associated with GILD opt-ins for GLPG pipeline candidates, and GLPG's recording of filgotinib-related revenue in Spain, Italy and France (represents an expansion beyond GLPG's original commercial rights in the Benelux countries); offsets include the capping of the potential upside from the IPF franchise (i.e., GLPG now stands to receive a sales royalty vs. prior recording of 100% of the revenue), and added cost-sharing for filgotinib.

In addition, other pushes and pulls for our GLPG model are revenue-related and potentially include: (1) addition of other GLPG candidates (e.g., GLPG1972 for osteoarthritis/OA, and Toledo franchise, though both have yet to demonstrate clinical proof-of-concept); (2) potential removal of filgotinib revenue from Sjogren's syndorme

and lupus, given recent negative Phase 2 proof-of-concept readouts; and (3) potential adjustment of overall filgotinib revenue given what we believe could now be an increased likelihood of a class label (and hence, black-box warning) for filgotinib that may ultimately result in lack of competitive differentiation.

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: better than expected clinical data for pipeline products (such as filgotinib); better-than-expected market uptake of key products; contributions from earlier stage products not currently modeled. Downside risks include: negative clinical data for pipeline products; delays in development and/or regulatory timelines for key products (such as filgotinib; slower-than-expected market uptake for key products (such as filgotinib).

GLPG.AS	12m Price Target: **€108.00**	Price: **€166.25**	Downside: **35.0%**

Neutral

Market cap: €7.6bn / $8.4bn
Enterprise value: €6.6bn / $7.3bn
3m ADTV: €62.0mn / $68.5mn
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)	(3.6)	(3.3)	(2.3)
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 15 Nov 2019 close.

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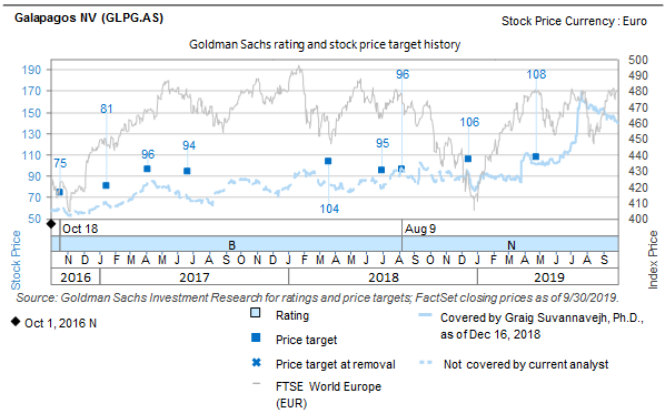

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