

Galapagos NV (GLPG.AS): 2Q21 First Take: OpEx higher, and Toledo and Tyk2 inhibitor plans expand; our initial thoughts and questions

What's new: Galapagos (GLPG) issued 2Q21 results via press release after market close yesterday (August 5) and will host a call later today (August 6) to discuss in further detail. In terms of the financials (see further details below), the company reported higher than anticipated revenue, but this was offset by higher than expected OpEx (on both R&D and SG&A), with net loss per share of €(0.98) comparing to GSe of €(0.73), and consensus of €(1.19). Of note, total liquidity as of the end of June 2021 stood at €5.0bn. On the product portfolio and pipeline front, key updates, from our perspective, included:

- Following the discontinuation of lead Toledo franchise compound GLPG3970 (an SIK2/3 inhibitor) last month ([LINK](#)), GLPG is now also advancing GLPG4399, a SIK3 inhibitor, into an initial trial in healthy volunteers this year. Further, GLPG plans to advance a follow-up SIK2/3 inhibitor into the clinic in 2022. (Recall that on the announcement of its 1Q21 results back in May ([LINK](#)), GLPG also introduced GLPG4876, yet another back up Toledo compound.)
- For GLPG3667 (GLPG's most advanced Tyk2 inhibitor), post-positive Phase 2a data in psoriasis, GLPG plans to initiate a dose finding Phase 2b trial in psoriasis. Newly disclosed, GLPG (1) is currently running an extended dose escalation study in healthy volunteers, and (2) plans to advance '3667 in a Phase 2 study in ulcerative colitis (UC) in 2022.
- GLPG expects completion of trial recruitment for (1) the pivotal Phase 3 DIVERSITY study of filgotinib in Crohn's disease (CD), and (2) the Phase 2a trial of GLPG2737 in polycystic kidney disease, both by YE21.
- GLPG and partner Gilead (GILD, covered by Terence Flynn) continue to execute on the commercial launch of Jyseleca across Europe, with operations established in 11 countries. As a reminder, as part of an amended agreement with GILD, Jyseleca sales will start flowing through GLPG's financial statements beginning in 2H21, as key EU countries are transitioned from GILD to GLPG. Further, Europe approval for filgotinib in UC is expected later this year.

Our take: Based on the 2Q21 print, we learned little that was meaningfully new; that said, we were most intrigued by the updates on the Toledo franchise and GLPG's Tyk2 candidate (programs we now come to view as GLPG's most high profile and of interest, for investors), and hence, we look forward to the company's conference call

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tomorrow to potentially learn of any incremental details and additional color.

Our thesis: While GLPG has experienced an unfortunate spate of serial pipeline setbacks, we nonetheless continue to see risk in the name, which in our view could come in the form of (1) potential negative headlines/news flow for filgotinib in its IBD indications in the US, for which we believe a meaningful contribution may still exist in consensus models, (2) execution on the European launch of filgotinib by GLPG (and without partner GILD), (3) the company's current considerable gap in pipeline (no late stage product after filgotinib/Jyseleca), (4) GLPG's uneven track record of clinical development and also efficient capital allocation, and (5) anticipated future cash burn. As such, still seeing a degree of implied downside (though modest) from a stock perspective, we maintain our Sell rating.

Exhibit 1: Upcoming catalysts

Timing	Product	Event Type	Details
2021			
2H21	filgotinib	Regulatory	EU approval in UC
2H21	filgotinib	Clinical	Complete enrolment in Phase 3 DIVERSITY study in CD
2H21	'555	Clinical	Announce Phase 1b data in OA
2H21	4399 (Toledo)	Clinical	Initiate healthy volunteer study
2022+			
1Q22	'4716	Clinical	Initiate Phase 2b study in IPF
1Q22	'3667	Clinical	Initiate Phase 2b study in psoriasis
1H22	'3667	Clinical	Initiate Phase 2 study in UC
1H22	filgotinib	Regulatory	Regulatory filing in US for UC
1H22	filgotinib	Regulatory	Japan approval in UC
2H22	filgotinib	Clinical	Announce Phase 3 DIVERSITY data in CD
4Q22	'2737	Clinical	Announce Phase 2a MANGROVE data in ADPKD
1Q23	filgotinib	Regulatory	Regulatory filing in US/EU/Japan for CD
2Q24	'4716	Clinical	Announce Phase 2b data in IPF

Source: Company data, Goldman Sachs Global Investment Research

Key questions for the call

GLPG will host an investor conference call at 8:00am ET/2pm CET, August 6, to discuss 2Q21 results. Some of our initial questions for the call will be:

- What do you hope to see in the extended dose escalation study for GLPG3667, and does completion of this study impact the timing of the initiations of the respective Phase 2 and Phase 2b studies in UC and psoriasis?
- What's the current status of GLPG4876, the Toledo compound introduced in May, and how does that candidate differ from GLPG4399?
- Has anything incrementally new been learned about differential SIK inhibition? In other words, should a SIK3 inhibitor have a better efficacy/safety profile vs. a SIK2/3 inhibitor?
- What's the status of the MANTA and MANTA-RAy studies for filgotinib, and also, what's the latest regulatory status of filgotinib in UC?
- What's management's view of FDA's decision to stay the potential approvals of pending NDA and sNDAs for various JAK inhibitors?
- With filgotinib/Jyseleca in Europe expected to hit GLPG's P&L in 2H21, what have the sales so far been like, and what do the current launch metrics look like?

- In light of the company's current cash balance of €5bn, how is GLPG thinking about business development (BD) opportunities and priorities?
- What's the current status of the company's search for a new Chief Scientific Officer (CSO)?
- Beyond the previously announced R&D organizational restructuring and pipeline rationalization, how is management and the board further addressing current R&D productivity (and share price) underperformance?

2021 Financials

2Q21 revenue of €153mn came in above GSe (€131.5mn) and consensus (€97.6mn). OpEx of €199.8mn was higher than our €174.8mn estimate and consensus of €172.3mn. Total liquidity (current financial investments + cash + cash equivalents) as of June 30, 2021 stood at €5bn (vs. €5.1bn as of March 31, 2021). Importantly, the company reiterated operational cash burn guidance of €580mn-€620mn.

Exhibit 2: 2Q21 variance

€mn, except EPS data	2Q20		2Q21		Estimated 2Q21				
	Reported	Reported	% Growth	Gse	% Growth	% Var	Cons	% Growth	% Var
Revenue	117.7	153.0	30%	131.5	12%	16%	97.6	-17%	57%
R&D	(149.1)	(138.8)	-7%	(126.7)	-15%	-10%	(126.0)	-16%	-10%
SG&A	(54.8)	(61.0)	11%	(48.0)	-12%	-27%	(46.3)	-15%	-32%
OpEx	(203.9)	(199.8)	-2%	(174.8)	-14%	-14%	(172.3)	-15%	-16%
EBIT	(86.2)	(46.8)	-46%	(43.2)	-50%	-8%	(74.2)	-14%	37%
Net profit	(115.0)	(64.4)	-44%	(48.0)	-58%	-34%	(87.4)	-24%	26%
EPS	(1.77)	(0.98)	-45%	(0.73)	-59%	-34%	(1.19)	-33%	18%

Source: Company data, Goldman Sachs Global Investment Research, FactSet

Valuation/Risks

We are Sell-rated on GLPG, with a 12-month price target of €49 (\$58 for the US ADR) that is based on a DCF valuation that assumes a 13% WACC/discount rate and 0% terminal growth rate. Risks include: positive or better-than-expected pipeline clinical data; better market uptake and commercial launch for Jyseleca (in the EU and Japan, where it is approved); and faster-than-expected clinical development and/or regulatory timelines for key pipeline products.

GLPG.AS	12m Price Target: €49.00	Price: €51.05	Downside: 4.0%
GLPG	12m Price Target: \$58.00	Price: \$60.06	Downside: 3.4%

Sell	GS Forecast				
	12/20	12/21E	12/22E	12/23E	
Market cap: €3.4bn / \$4.0bn	Revenue (€ mn)	530.3	538.5	641.7	744.0
Enterprise value: €(1.4)bn / \$(1.6)bn	EBIT (€ mn)	(178.6)	(139.5)	(13.0)	64.5
3m ADTV: €28.1mn / \$33.8mn	EPS (€)	(4.78)	(1.77)	(0.50)	0.82
Belgium	P/E (X)	NM	NM	NM	62.3
Europe Biotech	EV/EBITDA (ex lease,X)	NM	12.8	NM	NM
M&A Rank: 3	Dividend yield (%)	0.0	0.0	0.0	0.0
Leases incl. in net debt & EV?: Yes	FCF yield (%)	(5.1)	(14.2)	(11.2)	(11.5)
	CROCI (%)	(4.4)	(18.7)	(11.9)	(12.5)
	N debt/EBITDA (ex lease,X)	-	-	(492.6)	(45.1)
		3/21	6/21E	9/21E	12/21E
	EPS (€)	(0.20)	(0.73)	(0.45)	(0.39)

Source: Company data, Goldman Sachs Research estimates, FactSet. Price as of 5 Aug 2021 close.

Disclosure Appendix

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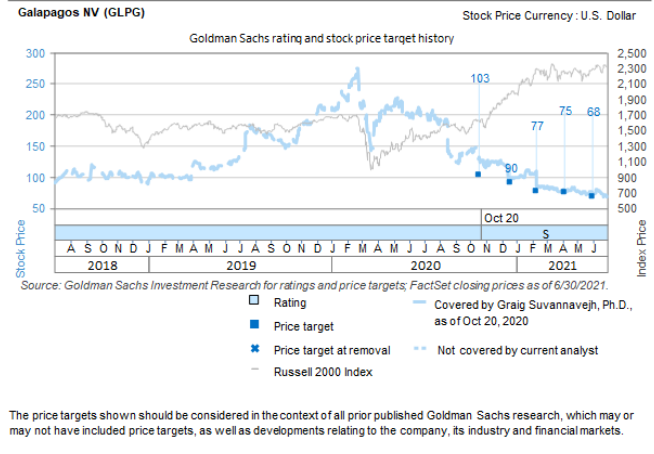
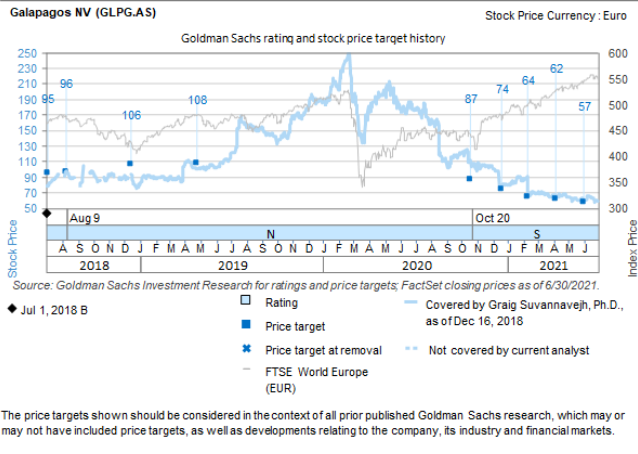
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