Galapagos NV (GLPG.AS): P3 ISABELA 1/2 trials halted due to safety; lowering PT to €64/$77 as we remove ziritaxestat from our model

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What's new: Galapagos (GLPG) and partner Gilead (GILD, covered by Terence Flynn) have discontinued the development of ziritaxestat/GLPG1690 (a novel autotaxin inhibitor) following a joint decision by the companies to halt the replicate Phase 3 ISABELA 1 and ISABELA 2 trials for the asset in idiopathic pulmonary fibrosis (IPF). This follows recommendations of the independent data monitoring committee (IDMC), which during a regular review of unblinded data from the trials, found ziritaxestat to have an unfavorable risk/benefit profile. More specifically, the IDMC noted a dose-dependent increase in mortality, and as such, not only will the Phase 3 ISABELA program for ziritaxestat in IPF be discontinued, but so will an ongoing Phase 2 study for ziritaxestat in systemic sclerosis (SSc).

As a result of the news, we now remove all ziritaxestat-related revenue from our model, which had previously included not only sales of the candidate in IPF and SSc, but also other associated revenue from partner GILD (e.g., an opt-in payment, sales milestones, royalties). Given this, and other model changes — which also include (1) increasing our DCF discount rate to 11% vs our previous 10%, but (2) lower R&D and SG&A throughout our 2021E-2035E forecast period, to offset new, lower revenue projections — we now lower our 12-month price target (PT) on GLPG to €64/$77 (vs. our prior €74/$90), implying 13%/14.5% downside from current levels. Hence, we remain Sell-rated. More explicitly, the drivers of change to our PT can be summarized below.

Exhibit 1: PT Reconciliation (€)

PT Reconciliation	
Old PT	**74**
Remove GLPG1690	-38
Lower OpEx	28
Increase WACC	-0.7
New PT	**64**

Source: Goldman Sachs Global Investment Research

Our thoughts: Recall that we downgraded GLPG from Neutral to Sell in October 2020 (LINK) on the basis of (1) a lowered outlook for filgotinib, and (2) risk we saw with the rest of GLPG's pipeline, and in particular, ziritaxestat. The bad news with ziritaxestat, the most advanced and highest profile asset within GLPG's fibrosis

franchise, marks another disappointment for GLPG, which over the past nine months has witnessed a number of setbacks, including:

- Mixed Phase 2b/3 data for filgotinib in ulcerative colitis in May 2020 (LINK);
- Receipt of a US FDA complete response letter (CRL) for filgotinib in rheumatoid arthritis (RA) in August 2020 (LINK);
- Phase 2 failure of GLPG1972 in osteoarthritis in October 2020 (LINK);
- Phase 2 data for GLPG1205 in IPF that we also found to be mixed in nature (LINK) in December 2020; and
- A significant restructuring of its partnership with GILD in December 2020, following GILD's decision to no longer pursue approval for filgotinib in RA (LINK)

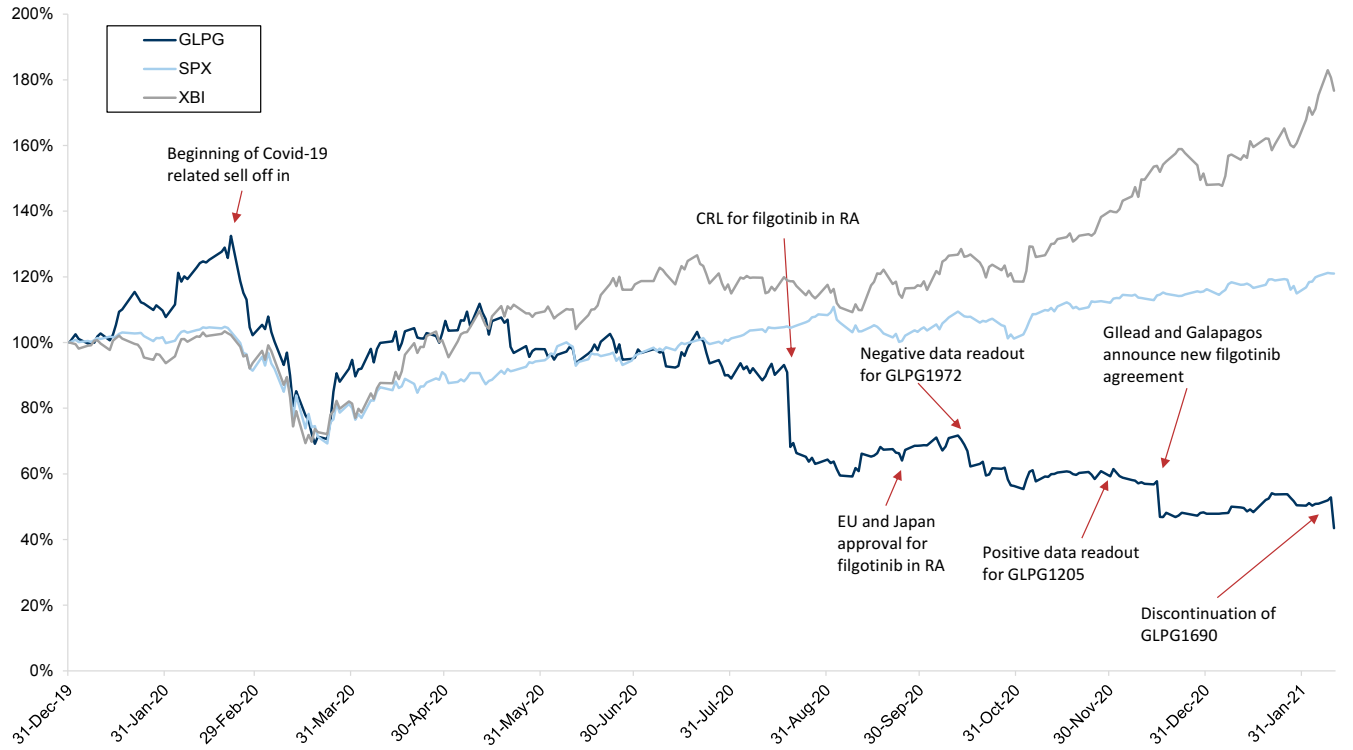
We remain cautious: Given the multiple mid- to late-stage pipeline disappointments just listed above, any remaining R&D enthusiasm, in our view, now rests primarily on the shoulders of a relatively early-stage and unproven inflammation franchise. We also continue to be cautious around execution risk by GLPG on the commercial launch of filgotinib in Europe (where GLPG is now solely responsible for its success) and ABBV's continued success with its JAK inhibitor, Rinvoq (2021 sales guidance of $1.7bn). Further, we remind that biosimilar versions of ABBV's Humira are expected to launch in the US in 2023, potentially complicating GLPG's plans and hopes to successfully commercialize Jyseleca in the US.

While acknowledging that our new PT sits below cash per share levels (recall that GLPG has c.$5bn in total liquidity on its balance sheet, thanks to the cash provided by the revised R&D collaboration with GILD in 2019, LINK), our current base case assumption is that GLPG will continue to meaningfully spend on both R&D (to support its inflammation and fibrosis R&D interests) and also SG&A (especially given GLPG's need to build out commercialization capabilities and infrastructure for Jyseleca/filgotinib on its own).

That said, we look forward to GLPG's 4Q/FY20 results, which will be announced via press release next week on February 18, and discussed live over a webcast/conference call the next day on February 19. Here, in particular, we will be looking out for (1) potentially revised financial guidance for 2021 (recall an initial view on 2021 was provided last month), and (2) any comments around a potential change in future corporate strategy, following recent high-profile pipeline disappointments.

With this in mind, however, should clinical trial results expected later this year (including MANTA/MANTA RAy safety results for filgotinib, multiple Phase 2 POC studies for the Toledo program, and data for an oral TYK2 inhibitor for inflammation) turn out better than expected, this could provide a shift in our current view.

Exhibit 2: Stock chart



Source: Goldman Sachs Global Investment Research, FactSet

Additional thoughts on ziritaxestat/GLPG1690

Based on our analysis, we had been cautious on the Phase 3 data readout for GLPG1690. Our low expectations were based on the limitations around the 12-week FLORA study data. Although, the efficacy and safety data of the FLORA study was encouraging, there were concerns around the imbalance in baseline characteristics of patients. There were fewer males (59% vs. 83%), more never smokers (65% vs. 50%) and then also higher baseline FVC (2.777 vs. 2.693) in the drug group vs. placebo group. Moreover, the decision to move directly to a pivotal trial with enrollment size of n=1500 based on the results from FLORA study which had enrollment size of only 23 patients and duration of 12 weeks made us cautious as based on data seen with other IPF studies of competitor drugs, FVC usually tends to decrease over time even when patients are receiving treatment.

What's next for GLPG in IPF

GLPG now has two mid-stage assets in its IPF franchise — GLPG1205, which will enter a Phase2b in 2021, and GLPG4716, which is expected to enter a Phase2b in 4Q21/1Q22. Top-line data from these two assets is expected in 2023-2024. Based on our assumptions around launch timelines and patent expiration, we don't see a realistic path to commercial viability for GLPG1205 and thus, do not include it in our model. For GLPG4716, our model assumes US, EU and Japan launch in 2030/2031/2031 respectively. We assign a PoS of 25% and forecast peak risk unadjusted sales of

~€1.3bn in 2035.

Estimate changes

Following the discontinuation of ziritaxestat, we make following changes to our model:

- With the discontinuation of the clinical trials for GLPG1690 in IPF and systemic sclerosis, we now remove revenue contributions from these two indications from our model. For reference, we earlier projected peak unadjusted/risk-adjusted sales of $2.2bn/$1.4bn in IPF and $460mn/$230mn in systemic sclerosis.
- Further, we lower our OpEx estimates to incorporate the reduction in R&D and SG&A as GLPG will no longer be running trials or launching ziritaxestat. On an average, our R&D/SG&A estimates reduce by 42%/20%.
- Relative to our DCF, given recent pipeline setbacks — where examples include (1) failed Phase 2 data for GLPG1972 in knee osteoarthritis (OA), (2) mixed Phase 2 results for GLPG1205 in IPF, and (3) discontinuation of GLPG1690, we increase our WACC assumption to 11% vs. a prior 10%.

Exhibit 3: Changes to estimates

	€mn, except EPS data	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
OLD	**Total Revenue**	**544.2**	**546.9**	**622.4**	**1,008.8**	**848.1**	**842.1**	**912.7**	**1,028.1**	**1,117.2**	**1,076.7**	**968.7**	**818.5**	**741.2**	**783.6**	**832.7**	**648.9**
	COGS	(0.2)	(2.0)	(6.0)	(7.4)	(12.8)	(17.4)	(20.8)	(24.5)	(26.5)	(28.6)	(29.7)	(22.0)	(17.1)	(17.3)	(18.5)	(14.6)
	R&D	(537.1)	(564.0)	(592.2)	(621.8)	(559.6)	(565.2)	(570.9)	(576.6)	(582.3)	(495.0)	(420.7)	(294.5)	(235.6)	(212.1)	(190.8)	(171.8)
	SG&A	(181.2)	(244.0)	(268.4)	(295.2)	(324.8)	(334.5)	(344.5)	(354.9)	(365.5)	(376.5)	(387.8)	(232.7)	(221.0)	(210.0)	(199.5)	(189.5)
	Opex	**(718.6)**	**(810.0)**	**(866.6)**	**(924.4)**	**(897.2)**	**(917.2)**	**(936.2)**	**(955.9)**	**(974.4)**	**(900.0)**	**(838.3)**	**(549.2)**	**(473.8)**	**(439.3)**	**(408.8)**	**(375.8)**
	EBIT	(174.4)	(263.0)	(244.2)	84.4	(49.1)	(75.1)	(23.5)	72.2	142.8	176.7	130.4	269.3	267.4	344.3	423.9	273.1
	Net Profit/Loss	(260.6)	(255.7)	(239.4)	87.3	(47.3)	(73.7)	(22.2)	73.9	145.4	180.6	136.5	277.8	278.6	358.1	440.3	272.4
	EPS	**(4.01)**	**(3.88)**	**(3.59)**	**1.29**	**(0.69)**	**(1.03)**	**(0.30)**	**0.97**	**1.89**	**2.33**	**1.74**	**3.49**	**3.46**	**4.40**	**5.34**	**3.26**
NEW	**Total revenue**	**544.2**	**546.9**	**619.1**	**786.5**	**708.8**	**624.8**	**625.4**	**682.3**	**725.1**	**654.7**	**534.7**	**377.4**	**289.9**	**320.3**	**356.7**	**409.7**
	COGS	(0.2)	(2.0)	(6.0)	(7.4)	(10.0)	(13.0)	(14.7)	(16.6)	(17.7)	(18.8)	(19.8)	(12.0)	(7.1)	(7.2)	(8.3)	(9.5)
	R&D	(537.1)	(483.4)	(483.4)	(483.4)	(386.7)	(309.4)	(318.7)	(328.2)	(338.1)	(287.4)	(244.3)	(171.0)	(136.8)	(123.1)	(110.8)	(99.7)
	SG&A	(181.2)	(232.0)	(239.0)	(246.1)	(253.5)	(261.1)	(269.0)	(277.0)	(290.9)	(305.4)	(336.0)	(201.6)	(151.2)	(155.7)	(160.4)	(165.2)
	Opex	**(718.6)**	**(717.4)**	**(728.4)**	**(736.9)**	**(650.2)**	**(583.5)**	**(602.3)**	**(621.9)**	**(646.7)**	**(611.6)**	**(600.0)**	**(384.6)**	**(295.0)**	**(286.0)**	**(279.5)**	**(274.4)**
	EBIT	(174.4)	(170.5)	(109.3)	49.5	58.5	41.3	23.1	60.5	78.5	43.0	(65.3)	(7.2)	(5.2)	34.3	77.2	135.3
	Net Profit /Loss	(260.6)	(163.1)	(104.5)	52.4	60.3	42.7	24.4	62.2	81.0	47.0	(59.2)	1.4	6.0	48.1	93.6	154.0
	EPS	**(4.01)**	**(2.48)**	**(1.57)**	**0.78**	**0.88**	**0.60**	**0.33**	**0.82**	**1.06**	**0.61**	**(0.75)**	**0.02**	**0.08**	**0.59**	**1.13**	**1.84**
% Change	**Total revenue**	**0%**	**0%**	**-1%**	**-22%**	**-16%**	**-26%**	**-31%**	**-34%**	**-35%**	**-39%**	**-45%**	**-54%**	**-61%**	**-59%**	**-57%**	**-37%**
	COGS	0%	0%	0%	0%	-22%	-26%	-30%	-32%	-33%	-34%	-33%	-45%	-59%	-58%	-55%	-35%
	R&D	0%	-14%	-18%	-22%	-31%	-45%	-44%	-43%	-42%	-42%	-42%	-42%	-42%	-42%	-42%	-42%
	SG&A	0%	-5%	-11%	-17%	-22%	-22%	-22%	-22%	-20%	-19%	-13%	-13%	-32%	-26%	-20%	-13%
	Opex	**0%**	**-11%**	**-16%**	**-20%**	**-28%**	**-36%**	**-36%**	**-35%**	**-34%**	**-32%**	**-28%**	**-30%**	**-38%**	**-35%**	**-32%**	**-27%**
	EBIT	0%	35%	55%	-41%	219%	155%	198%	-16%	-45%	-76%	-150%	-103%	-102%	-90%	-82%	-50%
	Net Profit/Loss	0%	36%	56%	-40%	228%	158%	210%	-16%	-44%	-74%	-143%	-100%	-98%	-87%	-79%	-43%
	EPS	**0%**	**36%**	**56%**	**-40%**	**228%**	**158%**	**210%**	**-16%**	**-44%**	**-74%**	**-143%**	**-100%**	**-98%**	**-87%**	**-79%**	**-43%**

Source: Company data, Goldman Sachs Global Investment Research

Upcoming catalysts

Exhibit 4: Upcoming newsflow

Timing	Product	Event Type	Details
2021			
1H21	'1205	Clinical	Initiate Phase 2b study in IPF
1H21	**Toledo**	**Clinical**	**Announce topline data from Phase 2 POC trials**
1H21	filgotinib	Regulatory	Regulatory filing in Japan for UC
1H21	**filgotinib**	**Clinical**	**Announce 26-week data from MANTA studies**
2H21	filgotinib	Regulatory	EU approval in UC
2H21	filgotinib	Clinical	Complete enrolment in Phase 3 DIVERSITY study in CD
mid-21	**'3667**	**Clinical**	**Announce Phase 1b data in psoriasis**
2021	**'555**	**Clinical**	**Announce Phase 1b data in OA**
4Q21/1Q22	'4716	Clinical	Initiate Phase 2b study in IPF
2022+			
1Q22	filgotinib	Regulatory	Regulatory filing in US for UC
1H22	filgotinib	Regulatory	Japan approval in UC
1H22	**filgotinib**	**Clinical**	**Announce Phase 3 DIVERSITY data in CD**
2H22	filgotinib	Regulatory	Regulatory filing in US/EU/Japan for CD
4Q22	'2737	Clinical	Announce Phase 2a MANGROVE data in ADPKD
2023	**'1205**	**Clinical**	**Announce Phase 2b data in IPF**
2024	**'4716**	**Clinical**	**Announce Phase 2b data in IPF**

Source: Goldman Sachs Global Investment Research

Valuation/Risks

We are Sell-rated on GLPG, with a 12-month price target of €64/$77 vs. a prior €74/$90, which is derived from a DCF valuation that assumes 11% WACC and 0% terminal growth rate. Risks include: positive or better-than-expected pipeline clinical data; better market uptake and commercial launch for Jyseleca; and faster-than-expected clinical development and/or regulatory timelines for key pipeline products.

GLPG.AS	12m Price Target: **€64.00**	Price: **€73.38**	Downside: **12.8%**
GLPG	12m Price Target: **$77.00**	Price: **$89.90**	Downside: **14.3%**

Sell

Market cap: €4.9bn / $5.9bn
Enterprise value: €(336.2)mn / $(462.4)mn
3m ADTV: €43.9mn / $53.1mn
Belgium
Europe Biotech
M&A Rank: 3
Leases incl. in net debt & EV?: Yes

GS Forecast

	12/19	12/20E	12/21E	12/22E
Revenue (€ mn) New	**895.9**	**544.2**	**546.9**	**619.1**
Revenue (€ mn) Old	895.9	544.2	546.9	622.4
EBIT (€ mn)	370.3	(174.4)	(170.5)	(109.3)
EPS (€) New	**2.60**	**(4.01)**	**(2.48)**	**(1.57)**
EPS (€) Old	2.60	(4.01)	(3.88)	(3.59)
P/E (X)	49.1	NM	NM	NM
Dividend yield (%)	0.0	0.0	0.0	0.0
CROCI (%)	187.0	(9.1)	(16.0)	(10.9)
N debt/EBITDA (ex lease,X)	(15.3)	–	–	–

	9/20	12/20E	3/21E	6/21E
EPS (€)	(1.25)	(0.20)	(0.33)	(0.81)

Source: Company data, Goldman Sachs Research estimates, FactSet. Price as of 10 Feb 2021 close.

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Reg AC

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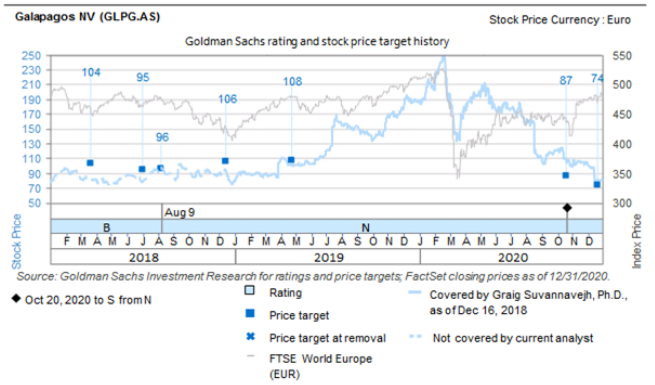

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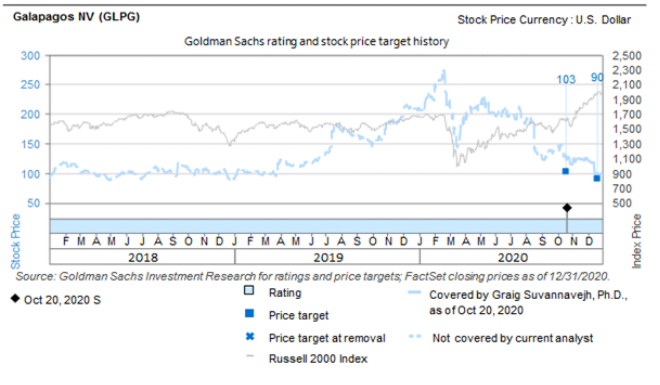

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