

Ziritaxestat phase III stopped before fertility analysis

European Life Sciences

11 February 2021, 08:02

Galapagos and Gilead reported the discontinuation of the phase III ISABELA trial with ziritaxestat (autotaxin inhibitor) in IPF due to a recommendation of the Independent Data Monitoring Committee (IDMC). The IDMC concluded based on a regular review of unblinded data that ziritaxestat's risk/benefit profile did not support continuation. In addition, all clinical trials and further development (including in systemic sclerosis) will be stopped. Curiously, we noted Gilead already removed ziritaxestat in systemic sclerosis from its pipeline update at its earnings last week. For our valuation, we remove ziritaxestat arriving at a new PT of €80 (\$97 ADRs) with a NEUTRAL rating. Of note, our YE'21 cash position estimate is €73/share which could serve as a floor to the share price in the near-term.

Ziritaxestat stumbled with dose-dependent toxicity

Though a full analysis still needs to be performed, management disclosed that the IDMC saw dose-dependent toxicity in the trial. As previously noted, while we liked the MOA for ziritaxestat we were uncomfortable due to i) potential for tox issues due to the upstream activity of autotaxin (ATX) and ii) the small size of the POC FLORA trial. Drug development within the LPA-ATX has been plagued with failures due to tox issues (e.g. BMS, BI) so we look forward to learning more detailed information at a future medical conference that should help inform on the biology of IPF and other candidates in the development.

Two more shots on goal in the IPF pipeline

In the earlier pipeline, Galapagos is looking to enter a phase IIb trial with GLPG1205 in 2021, a GPR48 inhibitor based on encouraging POC results (note). Additionally, it has inlicensed GLPG4716 (CHIT1/AMCase inhibitor which similarly has to start phase IIb, most likely in H2'21. As GLPG1205 and GLPG4716 have different MOAs we don't see an immediate readthrough. To read more on the programs, see our note here.

We lower our PT to €80, seeing €73 as a potential floor

We remove ziritaxestat from our valuation arriving at a new PT of €80 (\$97 ADRs). Of note, our YE'21 cash position estimate is €73/share which could support the bottom in the near-term. The next (potentially) meaningful catalysts are the results from phase IIa with GLPG3970 (SIK2/3 inhibitor, also known as Toledo) in psoriasis, RA, and ulcerative colitis expected mid'21. We currently do not include this program in our valuation beyond near-term R&D expense and look for a strong set of results to do so.



Kempen

Kempen Life Sciences Team

Research Analyst

Alex Cogut alex.cogut@kempen.com	+31 20 348 8517
Suzanne van Voorthuizen suzanne.vanvoorthuizen@kempen.com	+31 20 348 8484
Ingrid Gafanhao ingrid.gafanhao@kempen.com	+31 20 348 9159
Rene Wouters rene.wouters@kempen.com	+31 20 348 8483
Sebastiaan van der Schoot sebastiaan.vanderschoot@kempen.com	+31 20 348 9161

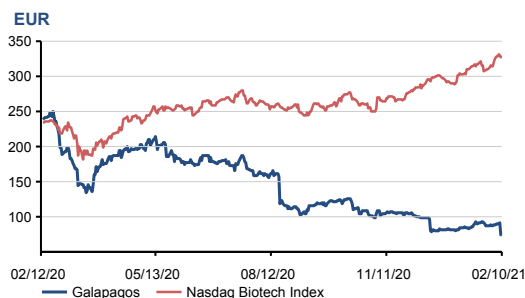
Rating	NEUTRAL
Price Target	€80.00
Closing price (10 Feb 2021)	€73.38

Previous rating and Price target

Change	Revision	Old
PT	06 Jan 2021	€91.00
Rating	11 Feb 2021	NEUTRAL

Company data

Market Cap	€4,799.9m
52-week range	€73.30 - €252.90
Number of shares	65.4m
Free float	41.4%
Avg. daily volume (20d)	354,616
Avg. daily turnover (20d)	€40,131,500
Daily turnover	€204,044,300
Next announcement date	18 February 2021
Reporting Period	FY'20 results



Source: Bloomberg

Galapagos - Company Profile

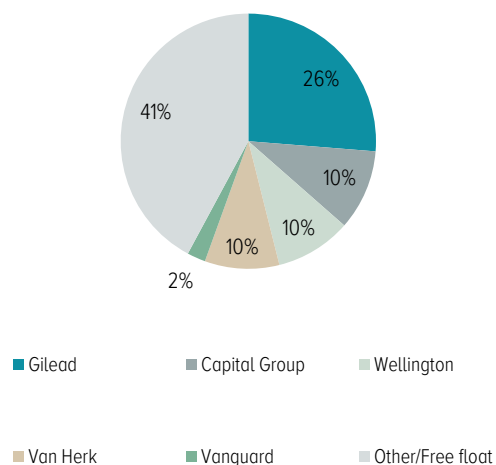
Galapagos is a Dutch-based biotech company that carries out small molecule drug discovery and development. The company's lead drug, Jyseleca (JAK inhibitor), is being commercialized for RA in Europe while in the US, partner Gilead discontinued development due to an unfavorable commercial prospect. In the rest of the pipeline, the next meaningful inflection point are phase II POC trial results with GLPG3970 in mid 2021.

Key information

		Bloomberg, Kempen estimates	
Bloomberg ticker	GLPG NA	Cash YE'20 (€m)	5,340
Alternative listing	GLPG US	Cash YE'20/Mcap	90.4%
Market cap (€m)	5,904	Cash YE'21 (€m)	4,745
Shares outstanding (m)	65.4	Cash YE'21/Mcap	80.4%
Total FTE at YE'19	1,003	Runway guidance	N/A
Rating & PT	NEUTRAL, €80	WACC	12.5%
Upside/downside to PT	-11.4%	Tax rate	3.8%

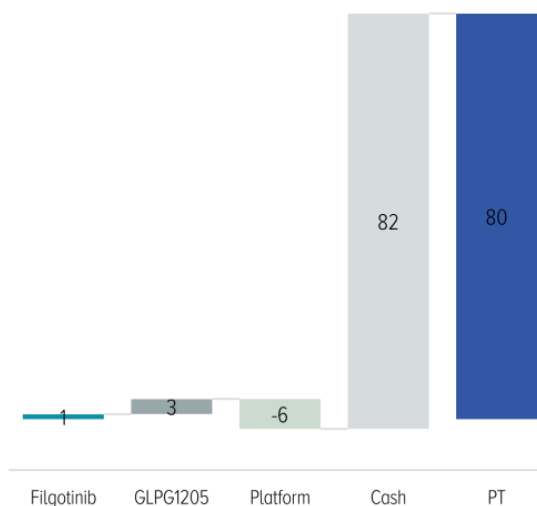
Major shareholders

Bloomberg



SOTP

Kempen estimates



News flow calendar

Company, Kempen estimates

Drug/product	Indication	Event	Timing	Up/Downside
Filgotinib	Ulcerative colitis	Filing for approval Japan	Q1'21	-
GLPG4059	Healthy volunteers	Data phase I (undisclosed type 2 diabetes target)	Q2'21	-
Filgotinib	Safety (male toxicity)	Data phase II MANTA/MANTA-Ray trials - 52 weeks	H2'21	+20% / -5%
GLPG3970	Psoriasis	Data phase I/II CALOSOMA	Mid'21	+/- 5%
GLPG3970	Rheumatoid arthritis	Data phase II LADYBUG	Mid'21	+/- 5%
GLPG3970	Ulcerative colitis	Data phase II SEA TURTLE	Mid'21	+/- 5%
GLPG4399	Healthy volunteers	Data phase I	Mid'21	-
Filgotinib	Ulcerative colitis	EMA review process conclusion	Q4'21	-
Filgotinib	Ulcerative colitis	Japan review process conclusion	Q1'22	-
GLPG3970	Systemic lupus erythem	Data phase II TAPINOMA	H1'22	+/- 5%
GLPG3970	Sjögren's syndrome	Data phase II GLIDER	H1'22	+/- 5%
Filgotinib	Crohn's disease	Data phase III DIVERSITY	H1'22	+/- 10%
GLPG3667	Psoriasis	Data phase II	H1'22	+/- 5%
GLPG2737	Autosomal Dominant Pc	Data phase II	H2'22	+/- 3%

Kempen analyst: Alex Cogut +31 20 348 8517 (alex.cogut@kempen.com)

	2018A	2019A	2020E	2021E	2022E	2023E
Income Statement (FY 31-Dec, EUR m)						
Total revenues	317.8	895.9	553.7	548.6	571.4	703.2
COGS	0.0	0.0	-0.4	-1.6	-8.5	-16.7
Gross profit	317.8	895.9	553.3	547.0	563.0	686.5
SG&A	-4.1	-24.6	-80.0	-140.0	-240.0	-222.0
R&D	-322.9	-427.3	-560.0	-555.0	-480.0	-306.9
Other operating expenses/income (net)	-34.9	-71.3	-105.9	-117.8	-115.9	-95.7
EBITDA	(44.0)	372.7	(192.6)	(265.8)	(272.9)	61.9
Depreciation and amortization	-4.3	-10.0	-5.5	-5.5	-8.6	-14.1
EBIT	-49.1	360.3	-199.2	-272.4	-282.6	46.5
Interest expense	15.6	-38.6	57.8	50.5	41.5	32.9
Taxes	-0.1	-0.2	0.0	0.0	0.0	0.0
Other financial items	0.0	-181.6	-181.6	-181.6	-181.6	-181.6
Net profit	-33.6	139.8	-323.0	-403.5	-422.8	-102.3
Balance Sheet (FY 31-Dec, EUR m)						
Cash and cash equivalents	1,290.8	5,780.8	5,053.6	4,147.3	3,289.5	2,806.5
Receivables	103.3	169.4	121.4	150.3	140.9	134.9
Inventories	--	--	--	--	--	--
Deferred tax assets	2.5	4.2	3.9	3.8	4.0	4.9
Financial assets and other current assets	16.2	23.2	23.2	23.2	23.2	23.2
Tangible fixed assets	23.1	66.1	93.7	115.7	130.0	136.4
Intangible fixed assets	3.6	24.9	24.9	24.9	24.9	24.9
Goodwill	--	--	--	--	--	--
Other non-current assets	--	--	--	--	--	--
Total assets	1,439.5	6,068.6	5,320.7	4,465.3	3,612.5	3,130.9
Payables	68.9	143.4	151.7	120.2	109.6	115.6
Deferred revenue (milestones / pre-payments)	149.8	3,000.6	2,580.4	2,160.1	1,739.9	1,349.6
Other current liabilities	1.2	33.6	20.8	20.6	21.4	26.4
Provisions	3.8	8.3	8.3	8.3	8.3	8.3
Long-term liabilities	1.6	7.0	7.0	7.0	7.0	7.0
Total liabilities	225.2	3,193.0	2,768.1	2,316.2	1,886.2	1,506.9
Total liabilities and shareholder's equity	1,439.5	6,068.6	5,320.7	4,465.3	3,612.5	3,130.9
Cash Flow Statement (FY 31-Dec, EUR m)						
EBITDA	-44.0	372.7	-192.6	-265.8	-272.9	61.9
Cash interest income/expenses	15.6	-220.2	-123.8	-131.1	-140.2	-148.7
Cash taxes	-0.1	-0.2	0.0	0.0	0.0	0.0
Changes in provisions	0.1	4.5	0.0	0.0	0.0	0.0
Changes in working capital	22.6	8.4	56.3	-60.4	-1.3	12.0
Changes in deferred revenue (milestones)	27.3	2,850.8	-420.3	-420.3	-420.3	-390.3
Other cash adjustments	-98.8	36.2	-12.5	-0.2	0.7	2.9
Cash flow from operating activities	-77.3	3,052.2	-692.9	-877.7	-833.9	-462.1
Cash flow from investments	-8.2	-30.8	-1.1	-1.1	-1.1	-1.4
Dividends paid	--	--	--	--	--	--
Proceeds from equity issues	235.8	1,521.6	0.0	0.0	0.0	0.0
Debt drawdowns/(repayments)	--	--	--	--	--	--
Cash flow from financing activities	235.8	1,521.6	-0.0	0.0	0.0	0.0
Ratios						
EV/revenues	23.4x	0.1x	1.5x	3.2x	4.6x	4.4x
EV/EBITDA	nm	0.3x	nm	nm	nm	50.0x
P/E	nm	53.4x	nm	nm	nm	nm
Net debt / EBITDA (x)	29.3x	-15.5x	26.2x	15.6x	12.1x	-45.3x
Metrics						
Total revenue growth	103.9%	181.9%	nm	-0.9%	4.2%	23.1%
COGS as % of revenue	0	0	0.1%	0.3%	1.5%	2.4%
SG&A as % of revenue	-1.3%	-2.7%	-14.4%	-25.5%	-42.0%	-31.6%
R&D as % of revenue	-101.6%	-47.7%	-101.1%	-101.2%	-84.0%	-43.6%
EBITDA margin (%)	-13.9%	41.6%	-34.8%	-48.5%	-47.8%	8.8%
EBIT margin (%)	-15.5%	40.2%	-36.0%	-49.7%	-49.5%	6.6%
Net profit margin (%)	-10.6%	15.6%	-58.3%	-73.6%	-74.0%	-14.5%
Cash as % of market cap	14.8%	97.9%	85.6%	70.2%	55.7%	47.5%
YE number of FTE	0.0	1,003.0	1,003.0	1,003.0	1,003.0	1,003.0

Source: Kempen estimates

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Price target	Expected share price in 12 months.

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Total	181 (100%)	100%

Rating distribution based on data of 11 February 2021.

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Galapagos 12 Months Rating and Price Target history as of 10 Feb 2021



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Netherlands

Kempen & Co N.V.
Beethovenstraat 300
P.O. Box 75666
1070 AR Amsterdam
Tel.: +31 (0) 20 348 8000

USA

Kempen & Co U.S.A., Inc
880 Third Avenue 17th Floor
New York, NY 10022
Tel.: +1 212 376 0130