

COMPANY NOTE

Estimate Change

Netherlands | Healthcare | Biotechnology

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Jefferies

Galapagos (GLPG NA) Plethora of CF Catalysts Ahead as Ambitious Plan for Triple Combo On-track

Key Takeaway

Catalysts this year hinge on the cystic fibrosis alliance and early-stage pipeline, notably GLPG1690 Phase IIa lung fibrosis (IPF) data in early-3Q. CF Phase I data in 1H are critical to achieve a triple combo in the clinic around 3Q17E and better assess the competitive profile. We still view the current share price to be a compelling entry point given filgotinib blockbuster potential and CF optionality; reiterate Buy with €80 PT.

Confident in filgotinib blockbuster potential: Impressive Phase IIb DARWIN rheumatoid arthritis (RA) data and positive Phase II FITZROY Crohn's data support our confidence in \$4bn WW peak sales with partner Gilead, including \$3bn in RA, \$600m in Crohn's, and now \$400m in ulcerative colitis. We now assume launch by 2H20E, from 2H19E, based on Phase III timelines. We estimate 20-30% tiered royalties but anticipate a 50:50 profit-share on co-promotion in EU5 and Benelux. Galapagos could receive up to \$1.35bn milestones and funds only 20% of R&D. AbbVie remains the most significant competitive threat, in our view, with its own once-daily JAK1 inhibitor ABT-494 in Phase III. Multiple POC studies in other indications are planned during 2017E.

Cystic fibrosis momentum: Management remains committed to the broad AbbVie CF alliance successfully moving the commercially important triple combination into the clinic around mid-17E for the most common class II ΔF508 cohort. Galapagos/AbbVie are likely lagging behind market incumbent Vertex, with two combos in Phase II at YE16, hence superior proof-of-concept in Phase I-II may be critical to expedite pivotal trial enrolment, and ultimately gain share. Starting a dual combo Phase I trial of C1 corrector '2222 and once daily potentiator '2451 is an important step, also likely suggesting '2451 itself was well-tolerated. C2 corrector '2737 safety data during 2Q17E are now a key focus to achieve a triple combo. Our sum-of-the-parts includes c.€13/share NPV for the CF alliance assuming a 20% likelihood of \$3bn peak sales.

Well funded to execute: Nearly €1bn Net Cash at YE16 is more than sufficient to fund pipeline plans and consider potential bolt-on acquisitions, in our view.

Valuation/Risks

Our €80 Price Target is based on a sum-of-the-parts valuation largely comprising a 65% probability-adjusted NPV for filgotinib plus Net Cash. Risks include: (1) efficacy, safety, or regulatory setbacks; (2) need to execute future out-licensing and alliances; and (3) clinical trial failures.

EUR	Prev.	2016A	Prev.	2017E	Prev.	2018E	Prev.	2019E
Rev. (MM)	155.4	151.6	186.0	175.2	214.2	136.8	297.7	155.0
EV/Rev		13.6x		11.8x		15.1x		13.3x
EBIT (MM)	(19.9)	(11.5)	(30.7)	(36.0)	8.2	(59.2)	88.8	(63.8)
EV/EBIT		NM		NM		NM		NM
Cash Position	96,758.9	973.2	824.4	841.0	761.5	729.8	824.0	649.2
EPS								
FY Dec	(0.43)	(0.08)	(0.51)	(0.62)	0.36	(1.09)	2.16	(1.15)
FY P/E		NM		NM		NM		NM

BUY

Price target €80.00
Price €65.70^

Financial Summary

Net Debt (MM):	(€973.2)
Long-Term Debt (MM):	€0.0
Cash & ST Invest. (MM):	€973.2

Market Data

52 Week Range:	€66.95 - €35.42
Total Entprs. Value (MM):	€2,068.7
Market Cap. (MM):	€3,041.9
Shares Out. (MM):	46.3
Float (MM):	42.7
Avg. Daily Vol.:	291,360

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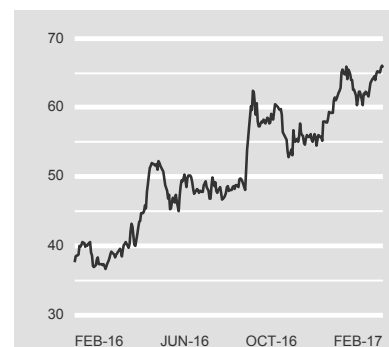
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Price Performance



^Prior trading day's closing price unless otherwise noted.

Reiterate Buy with €80 Price Target

Lead product filgotinib (GLPG0634) underpins the majority of our €80/share sum-of-the-parts valuation and remains the focus for investors. Gilead (GILD, \$69, Buy) licensed global rights in December 2015 providing a partner to maximise the drug's commercial potential, after AbbVie (ABBV, \$62, Buy) elected to opt-out in favour of prioritising its own JAK inhibitor ABT-494. We are encouraged by filgotinib's competitive profile based on the Phase IIb DARWIN rheumatoid arthritis (RA) clinical data, with results from the Phase II FITZROY trial also suggesting the drug is effective for inflammatory bowel disease (IBD). We forecast \$4bn global blockbuster potential largely comprising \$3bn in RA. The cystic fibrosis collaboration with AbbVie should provide an abundance of catalysts for the stock as the portfolio of potentiators and correctors complete Phase I-IIa trials. The alliance has the ambitious target of advancing a triple combo into the clinic around mid-2017E. Numerous other pipeline programmes could also crystallise value via possible milestones from existing alliances or new deals, and potentially drive positive share price momentum.

Filgotinib Phase IIIs underway

Selective JAK1 inhibitor filgotinib promises to be a safe and convenient oral treatment for rheumatoid arthritis. Encouraging Phase II data in Crohn's disease suggest the drug could also have potential in IBD, perhaps a greater unmet medical need albeit a smaller eligible patient population. Partner Gilead plans to initiate multiple proof-of-concept studies in other indications during 2017E.

- **Peak sales forecast:** \$4bn from \$3.5bn WW with \$3bn in RA, \$600m in CD, and now a \$400m contribution in ulcerative colitis (UC)
- **Valuation:** €45 per share with a 65% probability of success
- **Next news flow:** Proof-of-concept Phase II studies initiated in other diseases during 2017E. Futility analysis of the Phase IIb/III SELECTION study in UC around YE17E. Results from the Phase III FINCH programme in RA from YE18-1H20E and pivotal Phase III FITZROY data Crohn's around YE19E

Phase III programmes on-track with other indications to be investigated

The global filgotinib Phase III FINCH programme evaluates two doses of filgotinib, 100 mg/day and 200 mg/day, across three studies in a broad RA population comprising over 3,200 patients. FDA accepting inclusion of the highest 200 mg/day dose was an important positive, as this was excluded from US sites in the Phase IIb DARWIN trial on the basis of regulatory concerns on the male reproductive system based on rat/dog toxicology studies. We understand the DARWIN trials confirmed no clinically meaningful changes in male hormone levels, including at the 200 mg/day in ex-US patients. The FINCH programme also includes a dedicated male patient testicular safety study, which could finally lay safety concerns to rest, in our view.

The Phase III DIVERSITY study investigates 100 mg/day or 200 mg/day filgotinib in over 1,300 moderate-severe Crohn's disease patients. The Phase IIb/III SELECTION trial uses the same regimen in 1,300 moderate-severe ulcerative colitis patients. Both studies are recruiting patients who are naïve to and treatment experienced with biologics. US males enrolled in the trials are only eligible to receive the higher 200 mg/day dose if they have failed at least one prior biologic (an anti-TNF α and/or vedolizumab).

Given filgotinib's impressive Phase IIb RA data when compared across trials with both other oral JAK inhibitors and marketed biologics, we remain confident in blockbuster potential, forecasting \$3bn WW peak sales. The Phase II Crohn's FITZROY trial provided the first positive data for a JAK inhibitor in this indication, with Xeljanz discontinued after failing in Phase II, and the ABT-494 Phase II (Celest) study ongoing. Hence, filgotinib could

be the first to market in Crohn's disease. We believe there is a reasonable likelihood filgotinib may also be efficacious in ulcerative colitis, particularly given JAK inhibitor Xeljanz successfully improved remission rates in its Phase III OCTAVE trials, which are still ongoing to investigate maintenance of effect. A potential caveat from closer inspection of the FITZROY results is that filgotinib likely did not significantly improve remission rates until at least 6-weeks of treatment, whereas competing parenteral drugs have demonstrated an effect as early as weeks 4-6. On the other hand, a potential benefit of filgotinib for IBD is the lack of adverse effect on haemoglobin levels demonstrated in the DARWIN trial, with an actual increase in levels of up to 4%, and the FITZROY trial. This compares favourably to Xeljanz, which carries a warning requiring haemoglobin monitoring and dose-adjustment depending on levels. This is particularly important for IBD, with up to one-third of patients suffering from recurrent anaemia, and could potentially be a differentiating factor for filgotinib, in our view.

We now assume filgotinib filings during 2H19E for launch by 2H20E, slightly delayed versus our prior expectation based on the timelines of the pivotal trials.

Table 1: Comparison of the safety profiles for the oral JAK inhibitors

	Xeljanz (tofacitinib) Source: US FDA Label Target: JAK-3, -1 & -2	Olumiant (baricitinib) EU Label & Phase III JAK-1 & -2	filgotinib Phase IIb (DARWIN) JAK-1	ABT-494 Phase IIb (BALANCE) JAK-1
Serious infections	Boxed warning (1.7 events/100 pt-yrs)	Warning TB precautions Herpes/zoster risks	<1% (6 cases overall) No opportunistic	0 vs. 1 case placebo
Lymphoma & other malignancies	Boxed warning (0.3% solid cancers) (0.03% lymphomas)	3 non-melanoma skin cancers	None	1 skin cancer
GI perforations	Warning (Caution in patients at increased risk)	None	None	None
Lymphocytes	Warning (0.04% <500 cells/mm ³)	Minimal change	Minimal change	Minimal change
Neutrophils	Warning (0.07% <1000 cells/mm ³)	Dec with 2-10% Grade 2 & 1-2% Grade 3	Modest dec	Modest dec
Haemoglobin	Warning (Monitor & dose-adjust)	Min change wks 0-12 8-12% Grade 2 to wks 24	Increase up to 4%	Remained within normal range
Liver enzymes	Warning (>3x ULN observed but similar % to placebo)	Warning; checks Inc ALT in 2% (1 SAE inc ALT by wk 52)	Creatinine inc up to 13%; No ALT CTCAE Gr3-4	Inc ALT Grade 2+ in 6% vs. 7%
Lipids	Warning (Mean LDL +15%) (Mean HDL +10%)	Warning; checks (Mean LDL +8-16%) (Mean HDL +6-19%)	Inc LDL (up to 23%) & HDL (up to 24%) but lower atherogenic index	Inc LDL & HDL but ratio constant
Adverse Event Discontinuations	4% vs. 3% placebo	c.2%	3.9% vs. 3.6% placebo	5% vs. 4% placebo

Source: Jefferies research from: Xeljanz FDA approved package insert and FDA Briefing Documents for tofacitinib Advisory Committee meeting; Olumiant EU package insert, ACR 2012 Incyte presentation and EULAR 2015 abstracts; ACR 2012 presentation by F. Vanhoutte et al.; AbbVie press release 25 September 2015 and ACR 2015 poster

Filgotinib global sales and Gilead partnership model

Table 2: Filgotinib global sales and Gilead partnership model

(EUR millions Dec YE)	2016A	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
US DMARD-IR RA Patients on Biologics (000s)	434	447	461	474	489	503	518	534	550	567
% Moderate-Severe DMARD-IR Patients on Biologics	34%	34%	35%	35%	35%	35%	35%	36%	36%	36%
% Patients Unable/Ineligible to Receive a Biologic	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
US DMARD-IR RA Patients Not Receiving Biologics (000s)	77	79	81	84	86	89	91	94	97	100
Filgotinib Penetration of Patients on Biologics				0.0%	0.4%	1.0%	2.1%	3.4%	4.3%	4.8%
Filgotinib Penetration of Patients Not on Biologics				0.0%	1.5%	3.7%	7.4%	12.3%	15.4%	17.1%
Filgotinib Patients (000s)				0	3	8	17	30	38	44
Average Revenue per Patient p.a.				\$28,000	\$28,560	\$29,131	\$29,714	\$30,308	\$30,914	\$31,533
US Filgotinib RA Sales (\$mn)				0.0	93.7	246.0	516.9	905.2	1,188.7	1,387.6
Ex-US DMARD-IR RA Patients on Biologics (000s)	776	811	848	886	926	967	1,011	1,056	1,104	1,154
% Moderate-Severe DMARD-IR Patients on Biologics	32%	32%	33%	33%	34%	34%	35%	35%	36%	36%
% Patients Unable/Ineligible to Receive a Biologic	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Ex-US DMARD-IR RA Patients Not Receiving Biologics (000s)	194	203	212	221	231	242	253	264	276	288
Filgotinib Penetration of Patients on Biologics				0.0%	0.2%	0.9%	1.9%	2.9%	3.8%	4.5%
Filgotinib Penetration of Patients Not on Biologics				0.0%	0.7%	3.4%	6.7%	10.3%	13.8%	16.2%
Filgotinib Patients (000s)				0	3	17	36	58	80	99
Average Revenue per Patient p.a. (EUR)				12,500	12,500	12,500	12,500	12,500	12,500	12,500
Ex-US Filgotinib RA Sales (EURmn)				0.0	41.0	214.2	447.7	719.7	1,002.8	1,232.9
Ex-US Filgotinib RA Sales (\$mn)				0.0	38.7	202.1	422.3	679.0	946.1	1,163.1
WW Filgotinib RA Sales (\$mn)				0.0	132.3	448.1	939.3	1,584.2	2,134.8	2,550.7
US Moderate-Severe CD Patients (000s)	155.6	158.7	161.8	165.1	168.4	171.7	175.2	178.7	182.3	185.9
US Mod-Sev CD Patients Eligible for Biologics (000s)	124.1	126.6	129.1	131.7	134.3	137.0	139.8	142.6	145.4	148.3
% Moderate-Severe CD Patients on Biologics	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%
% Patients Unable/Ineligible to Receive a Biologic	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
US Mod-Sev CD Patients Not Receiving Biologics (000s)	21.9	22.3	22.8	23.2	23.7	24.2	24.7	25.2	25.7	26.2
Filgotinib Penetration of Patients on Biologics				0.0%	0.4%	0.9%	1.8%	3.0%	4.3%	5.4%
Filgotinib Penetration of Patients Not on Biologics				0.0%	0.6%	1.5%	3.0%	5.0%	7.2%	9.0%
Filgotinib Patients (000s)				0.0	0.6	1.6	3.3	5.6	8.1	10.4
Average Revenue per Patient p.a.				\$28,000	\$28,560	\$29,131	\$29,714	\$30,308	\$30,914	\$31,533
US Filgotinib CD Sales (\$mn)				0.0	18.0	46.9	97.5	169.1	251.3	326.9
Ex-US Moderate-Severe CD Patients (000s)	235.4	240.1	244.9	249.8	254.8	259.9	265.1	270.4	275.8	281.3
Ex-US Mod-Sev CD Patients Eligible for Biologics (000s)	169.5	174.6	179.8	185.2	190.8	196.5	202.4	208.5	214.7	221.2
% Moderate-Severe CD Patients on Biologics	72%	73%	73%	74%	75%	76%	76%	77%	78%	79%
% Patients Unable/Ineligible to Receive a Biologic	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Ex-US Mod-Sev CD Patients Not Receiving Biologics (000s)	42.4	43.6	45.0	46.3	47.7	49.1	50.6	52.1	53.7	55.3
Filgotinib Penetration of Patients on Biologics				0.0%	0.3%	0.9%	1.8%	3.0%	4.3%	5.4%
Filgotinib Penetration of Patients Not on Biologics				0.0%	0.5%	1.5%	3.0%	5.0%	7.2%	9.0%
Filgotinib Patients (000s)				0.0	0.7	2.5	5.2	8.9	13.1	16.9
Average Revenue per Patient p.a. (EUR)				12,500	12,500	12,500	12,500	12,500	12,500	12,500
Ex-US Filgotinib CD Sales (EURmn)				0.0	9.2	31.6	65.0	111.6	164.3	211.5
Ex-US Filgotinib CD Sales (\$mn)				0.0	8.7	29.8	61.4	105.3	155.0	199.5
WW Filgotinib CD Sales (\$mn)				0.0	26.7	76.6	158.9	274.4	406.3	526.4
US Moderate-Severe UC Patients (000s)	387.6	395.4	403.3	411.3	419.6	427.9	436.5	445.2	454.1	463.2
US Mod-Sev UC Patients on Biologics (000s)	52.0	54.1	56.2	58.5	60.8	63.3	65.8	68.4	71.2	74.0
% Moderate-Severe UC Patients on Biologics	13%	14%	14%	14%	14%	15%	15%	15%	16%	16%
Filgotinib Penetration of Patients on Biologics				0.0%	0.7%	1.8%	3.6%	6.0%	8.6%	10.8%
Filgotinib Penetration of Patients Not on Biologics				0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Filgotinib Patients (000s)				0.0	0.4	1.1	2.4	4.1	6.1	8.0
Average Revenue per Patient p.a.				\$28,000	\$28,560	\$29,131	\$29,714	\$30,308	\$30,914	\$31,533
US Filgotinib UC Sales (\$mn)				0.0	12.6	33.4	70.9	125.4	190.1	252.0
Ex-US Moderate-Severe UC Patients (000s)	586.5	598.2	610.2	622.4	634.8	647.5	660.5	673.7	687.2	700.9
Ex-US Mod-Sev UC Patients on Biologics (000s)	53.8	56.0	58.2	60.5	63.0	65.5	68.1	70.8	73.7	76.6
% Moderate-Severe UC Patients on Biologics	9%	9%	10%	10%	10%	10%	10%	11%	11%	11%
Filgotinib Penetration of Patients on Biologics				0.0%	0.5%	1.8%	3.6%	6.0%	8.6%	10.8%
Filgotinib Penetration of Patients Not on Biologics				0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Filgotinib Patients (000s)				0.0	0.3	1.2	2.5	4.3	6.4	8.3
Average Revenue per Patient p.a. (EUR)				12,500	12,500	12,500	12,500	12,500	12,500	12,500
Ex-US Filgotinib UC Sales (EURmn)				0.0	4.3	14.9	30.9	53.5	79.5	103.4
Ex-US Filgotinib UC Sales (\$mn)				0.0	4.0	14.0	29.1	50.5	75.0	97.6
WW Filgotinib UC Sales (\$mn)				0.0	16.7	47.4	100.1	175.9	265.1	349.6
Gilead Collaboration										
Galapagos Revenue for Profit Share in RA (EURmn)				0.0	(17.7)	(42.8)	4.3	54.5	97.8	164.6
% RA Sales in Other Territories Received as Royalties				0.0%	0.0%	20.0%	20.0%	20.0%	20.4%	21.2%
Galapagos Royalties in RA (EURmn)				0.0	0.0	18.4	54.0	121.4	226.2	309.1
Galapagos Revenue for Profit Share in CD (EURmn)				(7.1)	(23.6)	(25.0)	(20.5)	(13.9)	(5.9)	6.1
% CD Sales in Other Territories Received as Royalties				0.0%	0.0%	20.0%	20.0%	20.0%	22.5%	24.1%
Galapagos Royalties in CD (EURmn)				0.0	0.0	3.6	10.0	21.9	44.8	66.5
Galapagos Revenue for Profit Share in UC (EURmn)				(3.5)	(11.8)	(12.6)	(10.5)	(7.4)	(3.5)	2.4
% UC Sales in Other Territories Received as Royalties				0.0%	0.0%	20.0%	20.0%	20.0%	22.5%	25.0%
Galapagos Royalties in UC (EURmn)				0.0	0.0	2.5	6.8	15.0	30.9	49.1
Galapagos Revenue for Profit Share (EURmn)				(10.6)	(53.1)	(80.4)	(26.7)	33.3	88.4	173.1
Galapagos Royalties (EURmn)				0.0	0.0	24.4	70.8	158.4	302.0	424.7
Galapagos Total Revenue (EURmn)				(10.6)	(53.1)	(55.9)	44.2	191.6	390.3	597.8
Sales-related Milestones (\$mn)				0.0	0.0	0.0	150.0	150.0	0.0	150.0
Filgotinib Development Milestones (\$mn)	360.0	0.0	0.0	150.0	475.0	0.0	0.0	0.0	0.0	0.0
Galapagos Milestones (EURmn)	325.5	0.0	0.0	141.5	448.1	141.5	141.5	141.5	0.0	141.5

Source: Jefferies estimates

Cystic Fibrosis: The Story for 2017

Beyond filgotinib, Galapagos has identified a series of compounds for cystic fibrosis (CF) and is exploring combinations with the goal of developing a “triple” of a potentiator plus two correctors. These products are partnered with AbbVie after a global alliance was signed in September 2013. Importantly, the first healthy volunteer has now been dosed with a combination of the lead C1 corrector GLPG2222 and potentiator GLPG2451, suggesting that GLPG2451 itself was well tolerated. As the first dual combo trial we view this to be a key step in the ambitious path to move a commercially important triple combination of a potentiator and two correctors into a safety study during 2Q17E for Phase II treating CF patients in 3Q17E. Phase I data for C2 corrector GLPG2737 in early-2Q are now the focus. We believe cystic fibrosis could be an incremental share price driver for Galapagos over the next 12 months.

- **Peak sales forecast:** \$3bn worldwide assuming launch in 2020E
- **Valuation:** €13 per share with a 20% probability of success
- **Next news flow:** Multiple clinical data read-outs in 1H17E for candidate correctors and potentiators before the start of the triple combination Phase II in Class II CF patients around mid-2017E

The goal is to develop a regimen that can improve the electrical current across the lung’s epithelial layer to at least 50% of the level observed in wild-type $\Delta F508/\Delta F508$ patients, the most common genetic mutation in CF. The c.20% of wild-type current levels achieved in this population with Vertex’s (VRTX, \$86, Buy) Orkambi (a combination of potentiator ivacaftor and corrector lumacaftor) are likely suboptimal, with Galapagos’ preclinical studies suggesting two of its corrector series in combination together could provide around 65%. We note Orkambi is approved to treat $\Delta F508$ mutation in the CFTR gene, accounting for c.70% of CF patients. We believe nearly all eligible CF patients in the US and Europe with at least one copy of the G551D or non-G551D CFTR gating mutation, are now receiving Kalydeco (ivacaftor), representing c.3% and <1% of the disease population.

Phase II dependent on upon multiple data readouts

Galapagos currently has three clinical trials ongoing with many more planned, the results of which will be used to determine the final triple combination that enters Phase II. Since all three drugs bind to the same target, the challenge in developing a combination is avoiding the individual drugs interfering with the binding of the others, which has led to the discontinuation of a number of C2 correctors in preclinical development, including GLPG2665. The key candidates in development are:

- **GLPG2222 (C1 corrector):** The lead C1 corrector is the cornerstone of the triple combination strategy. It was found to be safe and well tolerated in a Phase I trial in healthy volunteers announced June 2016, with PK data supporting once daily dosing. The Phase IIa ALBATROSS trial was recently initiated investigating GLPG2222 with Kalydeco in adult CF patients with a $\Delta F508$ and gating mutation. Results are anticipated by YE17E but we understand an undisclosed interim analysis is planned to provide a guide on GLPG2222’s PK and dose response to benefit the triple combo. Importantly, the first healthy volunteer has been dosed in a Phase I study of GLPG2222 in combination with the novel potentiator GLPG2451. The study will evaluate the safety, tolerability and PK of 14 days combination treatment in at least 40 healthy volunteers. The clinical trials record indicates initial data will be available in November 2017E, however we expect that, like the ALBATROSS trial, an undisclosed interim analysis will take place to guide on PK for the triple combination.
- **GLPG2451 (potentiator):** Phase I study initiated in healthy subjects during May 2016, initially evaluating multiple-ascending doses of GLPG2451 alone and subsequently multiple doses of GLPG2451 in combination with corrector

GLPG2222. We view the first dosing of a patient with the combination treatment as signifying that GLPG2451 itself was well tolerated. Given its once daily dosing this is the preferred lead potentiator to advance into the triple combo.

- **GLPG2737 (C2 corrector):** Now considered the lead C2 corrector having been identified as having superior lung penetration and more favourable interaction with other compounds in a potential triple combination than GLPG2665, which was discontinued. Phase I data in healthy subjects should be available around 2Q17E.
- **GLPG2851 (C1 corrector):** Potentially due to commence Phase I in 2H17E.
- **GLPG3067 (potentiator):** Could enter Phase I during 1H17E
- **GLPG3221 (C2 corrector):** Phase I could be initiated around 2H17E.
- **GLPG1837 (potentiator):** Found to be safe and well tolerated in a Phase I trial in healthy subjects. PK data suggest twice daily dosing. The Phase II SAPHIRA programme evaluated GLPG1837 in CF patients with G551D or S1251N mutations, demonstrating clinical activity possibly comparable to that of incumbent competitor Kalydeco. Importantly these data boosted our belief in the predictive platform pursued by Galapagos/AbbVie, but given the somewhat undifferentiated clinical profile and twice daily dosing, '1837 is not likely to be included in the triple combo provided there are no issues with '2451.

Timeline could be ambitious but management remains positive

Management has reiterated its timelines for the triple combination, with a trial in healthy patients to be initiated in 2Q17E before a Phase II in Δ F508 patients around mid-2017E, for data by end-2017E/early-2018E. We believe the key to achieving this goal is C2 corrector GLPG2737 successfully completing Phase I, as backup '3221 is likely 9-12 months behind.

There are risks to meeting the perhaps aggressive goal of advancing a triple combo into CF patients around mid-2017E, in our view, including potential unexpected safety findings, lower than anticipated potency, and the need to determine optimal dosing regimens for a combination based on relatively limited monotherapy Phase I-II data. Even if this timeline is adhered to, it is likely that Galapagos will still be behind market incumbent Vertex's triple combination which advanced into Phase II late-2016 with two next-generation correctors, '440 and '152. We note that the findings of teratogenic signals preclinically and CYP induction in Phase I with '440, and the potentially narrow therapeutic window of '152, suggest that there remains room for correctors with improved profiles, in our view. We believe Galapagos achieving superior proof-of-concept in Phase I-II may be critical to expedite pivotal trial enrolment, and ultimately gain share.

We see the start of the triple therapy Phase II as the key value inflection point for the AbbVie alliance. In recognition of the expanded CF programme, AbbVie and Galapagos revised the initial deal agreement in April 2016, with Galapagos eligible for potential milestones up to \$600m (from \$360m originally), inclusive of an additional \$250m for Phase I and II events, and tiered double-digit royalties on sales. These are attractive terms for such an early-stage programme and underscore the potential of these products, in our view.

Reiterate €80 Price Target

Our €80 per share Price Target is based on a sum-of-the-parts valuation comprising probability-adjusted NPVs for filgotinib and the cystic fibrosis collaboration, together with around €21 Net Cash per share.

Table 3: Galapagos sum-of-the-parts valuation

	Indication	Peak Sales (\$mn)	Value (EURmn)	Prob.	Adj. Value (EURmn)	EUR per share
filgotinib (GLPG0634)	RA, Crohn's & Ulcerative Colitis	4,000	3,212	65%	2,088	45.1
CF Collaboration	Cystic fibrosis	3,000	3,075	20%	615	13.3
GLPG1690	Idiopathic pulmonary fibrosis	600	644	0%	0	0.0
Net Cash/(Debt)			981	100%	981	21.2
Valuation			7,911		3,683	79.6
Potential Dilution for Funding	Min. Yrs of Cash	2.0		0%	0	0.0
Potential Diluted Valuation						79.6

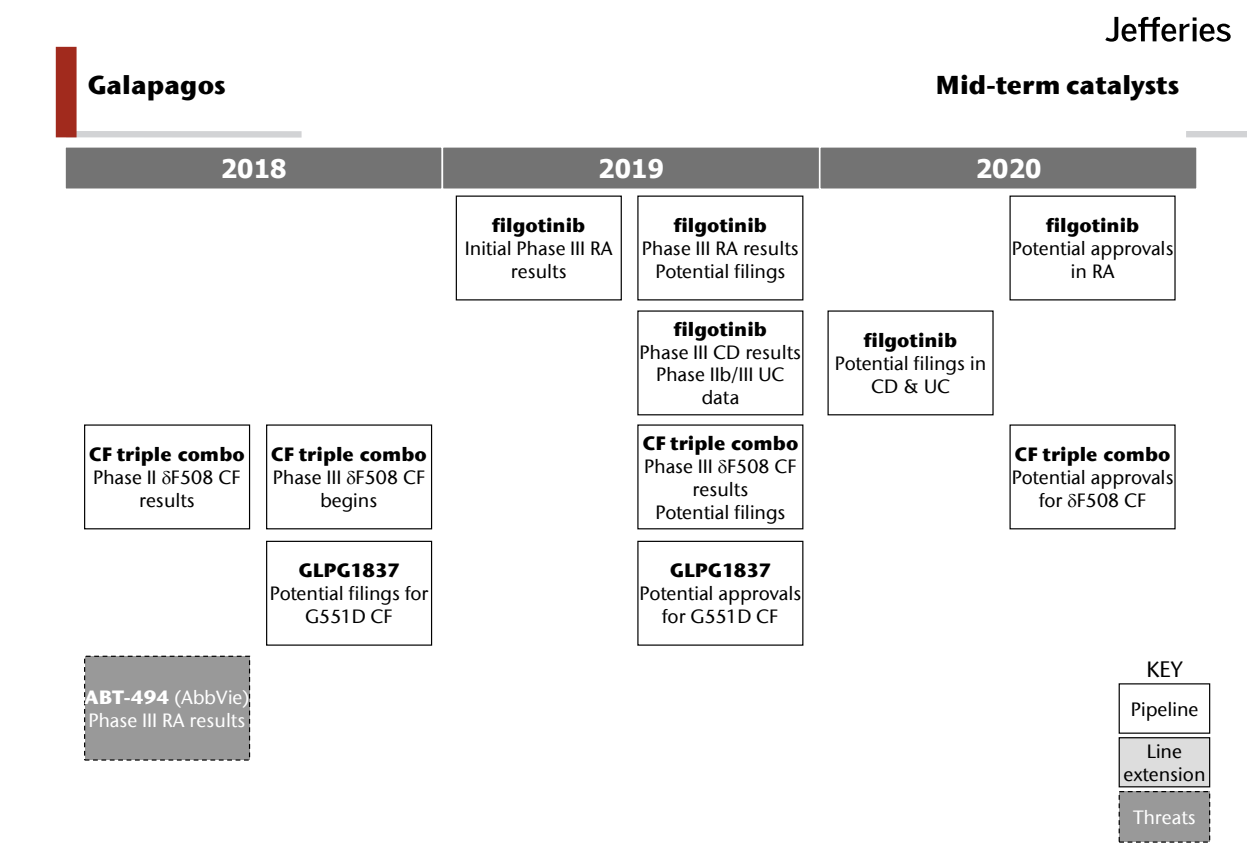
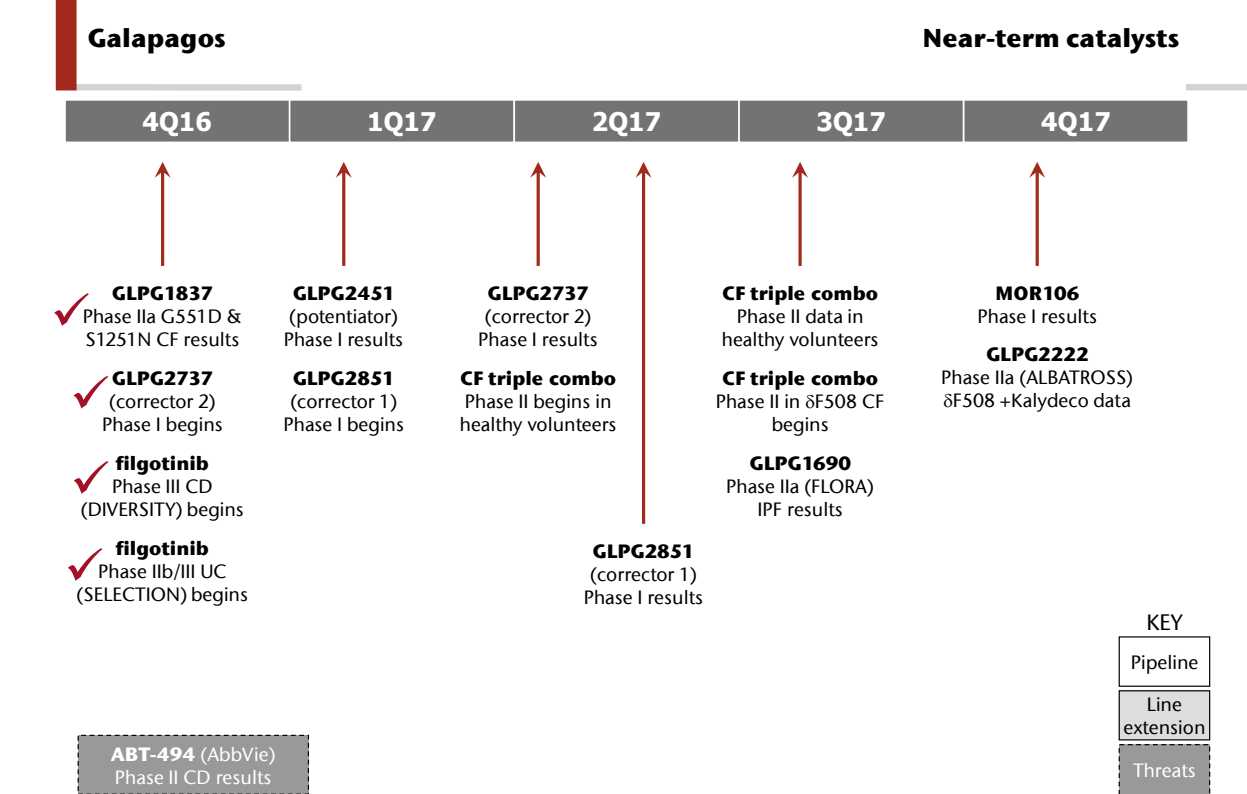
Source: Jefferies estimates

Table 4: Sources of upside potential and downside risk

	Upside	EUR per share	Downside	EUR per share
filgotinib Phase III in RA	Positive data confirm profile	10.4	Efficacy and/or safety concerns	(34.7)
filgotinib Phase III in Crohn's & Ulcerative colitis	Positive data confirm profile	6.9	Efficacy and/or safety concerns	(10.4)
Clinical progress with CF potentiators & correctors	Encouraging Phase I data	13.3	Discontinued or delayed	(13.3)
GLPG1690 Phase IIa in IPF	Positive results	2.8	Discontinued or delayed	0.0
Potential Upside/(Downside)		33.4		(58.4)
Potential Valuation		113.1		21.2

Source: Jefferies estimates

Exhibit 1: Galapagos catalysts



Jefferies

Source: Jefferies

Updated financial models

Table 5: Galapagos Revenue Model

(EUR millions Dec YE)	2017E								
	2016A	1H17E	2H17E	2017E	2018E	2019E	2020E	2021E	2022E
R&D Revenue	129.5	70.0	88.2	158.2	132.1	194.3	483.3	141.5	141.5
Other Income	22.1	9.0	8.0	17.0	15.3	13.8	12.4	11.2	10.0
filgotinib Royalties	0.0	0.0	0.0	0.0	0.0	0.0	24.4	70.8	158.4
filgotinib Revenues for EU5-Benelux Profit Share	0.0	0.0	0.0	0.0	(10.6)	(53.1)	(80.4)	(26.7)	33.3
Discontinued Operations	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Group Revenue (Prob. Adjusted)	151.6	79.0	96.2	175.2	136.8	155.0	439.8	196.8	343.2
% Change Year over Year									
R&D Revenue	227.4%	80.4%	(2.8%)	22.1%	(16.5%)	47.1%	148.7%	(70.7%)	0.0%
Other Income	5.1%	(9.6%)	(34.1%)	(23.1%)	(10.0%)	(10.0%)	(10.0%)	(10.0%)	(10.0%)
filgotinib Royalties	n/a	n/a	n/a	n/a	n/a	n/a	n/a	190.1%	123.5%
Total Group Revenue (Prob. Adjusted)	150.3%	62.0%	(6.5%)	15.6%	(21.9%)	13.3%	183.8%	(55.2%)	74.4%

Source: Jefferies estimates, company data

Table 6: Galapagos Margin Analysis

	2017E								
	2016A	1H17E	2H17E	2017E	2018E	2019E	2020E	2021E	2022E
Gross Margin	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Sales & Marketing Expenses	1.2%	1.2%	1.0%	1.1%	4.7%	14.3%	6.2%	16.4%	9.7%
General & Admin. Expenses	14.3%	13.9%	12.8%	13.3%	17.9%	16.6%	6.1%	14.4%	8.7%
R&D Expenses	92.1%	105.9%	106.3%	106.2%	120.6%	110.4%	40.1%	95.2%	58.4%
Operating Income	(7.6%)	(21.0%)	(20.2%)	(20.5%)	(43.3%)	(41.2%)	47.6%	(26.0%)	23.2%
Pretax Profit	35.8%	(15.9%)	(17.1%)	(16.6%)	(37.4%)	(35.4%)	50.3%	(18.9%)	27.9%
Net Income	35.6%	(15.9%)	(17.1%)	(16.6%)	(37.4%)	(35.4%)	50.3%	(18.9%)	27.9%

Source: Jefferies estimates, company data

Table 7: Galapagos Profit and Loss Model

(EUR millions except EPS Dec YE)	2017E								
	2016A	1H17E	2H17E	2017E	2018E	2019E	2020E	2021E	2022E
Revenue	151.6	79.0	96.2	175.2	136.8	155.0	439.8	196.8	343.2
Cost of Sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Gross Profit	151.6	79.0	96.2	175.2	136.8	155.0	439.8	196.8	343.2
Total Operating Expenses	(163.1)	(95.6)	(115.6)	(211.2)	(196.0)	(218.8)	(230.6)	(248.0)	(263.5)
Sales & Marketing Expenses	(1.8)	(1.0)	(1.0)	(1.9)	(6.5)	(22.1)	(27.2)	(32.3)	(33.3)
General & Admin. Expenses	(21.7)	(11.0)	(12.3)	(23.3)	(24.5)	(25.7)	(27.0)	(28.3)	(29.7)
R&D Expenses	(139.6)	(83.7)	(102.3)	(186.0)	(165.0)	(171.0)	(176.4)	(187.4)	(200.4)
o/w Acquisition-related Amortisation/Write-down	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other Operating Income	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Operating Exceptionals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Operating Income	(11.5)	(16.6)	(19.4)	(36.0)	(59.2)	(63.8)	209.2	(51.2)	79.7
Adjusted Operating Income	(11.5)	(16.6)	(19.4)	(36.0)	(59.2)	(63.8)	209.2	(51.2)	79.7
EBITDA	(7.3)	(14.5)	(17.3)	(31.9)	(55.5)	(59.9)	213.7	(46.0)	85.4
Adjusted EBITDA	(7.3)	(14.5)	(17.3)	(31.9)	(55.5)	(59.9)	213.7	(46.0)	85.4
Net Financial Income	8.3	4.0	3.0	7.0	8.0	9.0	12.0	14.0	16.0
Exceptionals	57.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Income from Associates & JVs	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pretax Profit	54.2	(12.6)	(16.4)	(29.0)	(51.2)	(54.8)	221.2	(37.2)	95.7
Adjusted Pretax Profit	(3.2)	(12.6)	(16.4)	(29.0)	(51.2)	(54.8)	221.2	(37.2)	95.7
Taxation	(0.2)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Minority Interests	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income from Continuing Operations	54.0	(12.6)	(16.4)	(29.0)	(51.2)	(54.8)	221.2	(37.2)	95.7
Net Income from Discontinued Operations	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income	54.0	(12.6)	(16.4)	(29.0)	(51.2)	(54.8)	221.2	(37.2)	95.7
Adjusted Net Income	(3.5)	(12.6)	(16.4)	(29.0)	(51.2)	(54.8)	221.2	(37.2)	95.7
WA Basic Shares (mn)	45.7	46.7	46.7	46.7	47.2	47.7	48.2	48.7	49.2
WA Shares Diluted (mn)	47.3	46.7	46.7	46.7	47.2	47.7	49.8	48.7	50.8
EPS (EUR)	1.2	(0.3)	(0.4)	(0.6)	(1.1)	(1.2)	4.6	(0.8)	1.9
Adjusted EPS (EUR)	(0.1)	(0.3)	(0.4)	(0.6)	(1.1)	(1.2)	4.6	(0.8)	1.9
Diluted EPS (EUR)	1.1	(0.3)	(0.4)	(0.6)	(1.1)	(1.2)	4.4	(0.8)	1.9
Diluted Adjusted EPS (EUR)	(0.1)	(0.3)	(0.4)	(0.6)	(1.1)	(1.2)	4.4	(0.8)	1.9
% Change Year over Year									
Revenue	150.3%	62.0%	(6.5%)	15.6%	(21.9%)	13.3%	183.8%	(55.2%)	74.4%
Cost of Sales	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Gross Profit	150.3%	62.0%	(6.5%)	15.6%	(21.9%)	13.3%	183.8%	(55.2%)	74.4%
Total Operating Expenses	8.7%	30.8%	28.5%	29.5%	(7.2%)	11.6%	5.4%	7.6%	6.2%
Sales & Marketing Expenses	51.0%	8.4%	4.5%	6.4%	241.8%	240.2%	23.1%	18.8%	3.1%
General & Admin. Expenses	13.7%	11.4%	3.6%	7.2%	5.0%	5.0%	5.0%	5.0%	5.0%
R&D Expenses	7.6%	34.1%	32.6%	33.3%	(11.3%)	3.6%	3.2%	6.2%	7.0%
Operating Income	87.2%	31.9%	(250.9%)	(213.3%)	(64.4%)	(7.8%)	427.8%	(124.5%)	255.6%
Adjusted Operating Income	87.2%	31.9%	(250.9%)	(213.3%)	(64.4%)	(7.8%)	427.8%	(124.5%)	255.6%
Pretax Profit	145.3%	(139.1%)	(174.4%)	(153.5%)	(76.6%)	(7.1%)	503.5%	(116.8%)	357.2%
Adjusted Pretax Profit	96.4%	50.2%	(174.4%)	(797.2%)	(76.6%)	(7.1%)	503.5%	(116.8%)	357.2%
Net Income	145.6%	(139.1%)	(175.3%)	(153.7%)	(76.6%)	(7.1%)	503.5%	(116.8%)	357.2%
Adjusted Net Income	96.1%	50.1%	(175.3%)	(736.4%)	(76.6%)	(7.1%)	503.5%	(116.8%)	357.2%
EPS (EUR)	135.6%	(137.9%)	(173.8%)	(152.6%)	(74.7%)	(6.0%)	499.3%	(116.6%)	354.6%
Adjusted EPS (EUR)	96.9%	51.7%	(173.8%)	(719.1%)	(74.7%)	(6.0%)	499.3%	(116.6%)	354.6%

Source: Jefferies estimates, company data

Table 8: Galapagos Cash Flow Model

(EUR millions Dec YE)	2016A	2017E	2018E	2019E	2020E	2021E	2022E
Operating Income	(11.5)	(36.0)	(59.2)	(63.8)	209.2	(51.2)	79.7
Depreciation and Amortisation	4.2	4.1	3.7	3.9	4.5	5.2	5.7
EBITDA	(7.3)	(31.9)	(55.5)	(59.9)	213.7	(46.0)	85.4
Other Adjustments and Exceptionals	12.5	13.0	14.5	15.5	16.4	17.3	18.1
Decrease/(Increase) in Inventories	0.0	0.1	0.2	0.0	0.0	0.0	0.0
Decrease/(Increase) in Receivables	(13.0)	(1.8)	(6.4)	(1.5)	(23.4)	20.0	(12.0)
Increase/(Decrease) in Payables	2.1	0.8	0.8	4.0	5.7	(0.6)	4.5
Increase/(Decrease) in Deferred Income	245.8	(118.8)	(77.0)	(52.8)	(35.2)	0.0	0.0
Change in WC	235.0	(119.7)	(82.4)	(50.3)	(52.9)	19.4	(7.6)
Taxation Paid	(1.8)	(0.1)	0.0	0.0	0.0	0.0	0.0
Interest Paid	1.0	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)
Net Cash Flow from Operating Activities	239.4	(139.7)	(124.4)	(95.7)	176.3	(10.4)	95.0
Purchase of Tangible Fixed Assets	(4.5)	(6.5)	(4.8)	(5.4)	(15.4)	(6.9)	(12.0)
Proceeds from Sale of PP&E	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Purchase of Intangible Assets	(0.3)	0.0	0.0	0.0	0.0	0.0	0.0
(Purchase)/Sale of Investments	(2.8)	0.0	0.0	0.0	0.0	0.0	0.0
(Acquisitions)/Disposals of Subsidiaries	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Dividends Received from Associates	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Interest Received	0.0	8.0	9.0	10.0	13.0	15.0	17.0
Net Cash Flow from Investing Activities	(7.5)	(6.5)	(4.8)	(5.4)	(15.4)	(6.9)	(12.0)
Management of Liquid Resources	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Capital Changes	396.0	6.0	9.0	10.5	10.5	10.5	10.5
Debt Changes	(0.0)	(0.1)	(0.0)	0.0	0.0	0.0	0.0
Equity Dividends Paid	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other Financing Cash Flows	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Cash Flow from Financing Activities	396.0	13.9	18.0	20.5	23.5	25.5	27.5
Effect of FX on Cash and Cash Equivalents	4.8	0.0	0.0	0.0	0.0	0.0	0.0
Increase in Cash	632.7	(132.2)	(111.2)	(80.7)	184.4	8.3	110.4
Change in Net Debt	(627.9)	140.2	120.2	90.7	(171.4)	6.7	(93.4)
(Cash Burn)	231.9	(146.2)	(129.2)	(101.2)	160.9	(17.2)	82.9

Source: Jefferies estimates, company data

Table 9: Galapagos Balance Sheet Model

(EUR millions Dec YE)	2016A	2017E	2018E	2019E	2020E	2021E	2022E
Non-current Assets	76.1	78.5	79.6	81.1	92.0	93.7	100.0
Intangible Assets	1.0	0.1	0.0	0.0	0.0	0.0	0.0
Property, Plant and Equipment	15.0	18.2	19.4	21.0	31.9	33.6	39.9
Investments	2.9	2.9	2.9	2.9	2.9	2.9	2.9
Other Long-term Assets	57.2	57.2	57.2	57.2	57.2	57.2	57.2
Current Assets	1,007.2	876.7	771.8	692.6	900.4	888.7	1,011.1
Inventories	0.3	0.2	0.0	0.0	0.0	0.0	0.0
Trade Accounts Receivable	3.0	4.8	11.2	12.7	36.1	16.2	28.2
Other Current Assets	30.7	30.7	30.7	30.7	30.7	30.7	30.7
Cash and Cash Equivalents	973.2	841.0	729.8	649.2	833.5	841.8	952.2
Total Assets	1,083.3	955.2	851.3	773.7	992.4	982.4	1,111.2
Current Liabilities	103.8	110.6	87.2	73.6	44.1	43.6	48.0
Trade Accounts Payable	31.3	31.2	31.6	35.3	37.2	39.9	42.4
Other Current Liabilities	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Accrued Expenses	0.6	1.4	1.9	2.1	6.0	2.7	4.7
Deferred Income	70.8	77.0	52.8	35.2	0.0	0.0	0.0
Short-term Debt	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Leasing Obligations	0.1	0.0	0.0	0.0	0.0	0.0	0.0
Non-current Liabilities	220.8	95.9	43.1	7.9	7.9	7.9	7.9
Long-term Debt	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Leasing Obligations	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Deferred Tax Liabilities	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Deferred Income	214.8	89.8	37.0	1.8	1.8	1.8	1.8
Long-term Provisions	6.1	6.1	6.1	6.1	6.1	6.1	6.1
Total Shareholders' Equity	758.7	748.7	721.0	692.2	940.3	930.9	1,055.2
Share Capital	223.9	223.9	223.9	223.9	223.9	223.9	223.9
Share Premium Account	649.1	655.1	664.1	674.6	685.1	695.6	706.1
Other Reserves and Adjustments	(2.1)	(2.1)	(2.1)	(2.1)	(2.1)	(2.1)	(2.1)
Retained Earnings	(112.3)	(128.3)	(165.0)	(204.3)	33.4	13.4	127.2
Minority Interests	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Liabilities and Shareholders' Equity	1,083.3	955.2	851.3	773.7	992.4	982.4	1,111.2

Source: Jefferies estimates, company data

Key changes to forecasts

Table 10: Summary estimates changes for Galapagos

Forecasts (EURm)	2017E New	2017E Old	% Chg	2018E New	2018E Old	% Chg
Sales	175.2	186.0	-6%	136.8	214.2	-36%
Adj. EBIT	(36.0)	(30.7)	+17%	(59.2)	8.2	-821%
Adj. EPS	(0.62)	(0.51)	+22%	(1.09)	0.35	-408%
Net Cash/(Debt)	841.0	824.4	+2%	729.8	761.5	-4%
Drivers of Change	Wider losses driven by lower milestone income, due to slightly delayed launch timelines for filgotinib, and revised assumptions for recognition of deferred revenues. OpEx estimates are little changed 2017-18E but increased in future years.					

Source: Jefferies estimates

Company Description

Galapagos is a Belgian biotech company focusing on drug discovery using cells taken from patients with diseases of interest; typically musculoskeletal, CNS and inflammatory disorders plus orphan indications. The company's most advanced product is filgotinib (GLPG0634 a JAK1 inhibitor) entering Phase III for rheumatoid arthritis and in Phase II for Crohn's disease partnered with Gilead. Galapagos also has a global alliance with AbbVie in cystic fibrosis. The company has active collaborations with GSK, Servier and MorphoSys.

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Investment Recommendation Record

(Article 3(1)e and Article 7 of MAR)

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Company Specific Disclosures

Jefferies Group LLC makes a market in the securities or ADRs of Galapagos.

Jefferies Group LLC makes a market in the securities or ADRs of Gilead Sciences, Inc..

Jefferies Group LLC makes a market in the securities or ADRs of Vertex Pharmaceuticals Incorporated.

Explanation of Jefferies Ratings

Buy - Describes securities that we expect to provide a total return (price appreciation plus yield) of 15% or more within a 12-month period.

Hold - Describes securities that we expect to provide a total return (price appreciation plus yield) of plus 15% or minus 10% within a 12-month period.

Underperform - Describes securities that we expect to provide a total return (price appreciation plus yield) of minus 10% or less within a 12-month period.

The expected total return (price appreciation plus yield) for Buy rated securities with an average security price consistently below \$10 is 20% or more within a 12-month period as these companies are typically more volatile than the overall stock market. For Hold rated securities with an average security price consistently below \$10, the expected total return (price appreciation plus yield) is plus or minus 20% within a 12-month period. For Underperform rated securities with an average security price consistently below \$10, the expected total return (price appreciation plus yield) is minus 20% or less within a 12-month period.

NR - The investment rating and price target have been temporarily suspended. Such suspensions are in compliance with applicable regulations and/or Jefferies policies.

CS - Coverage Suspended. Jefferies has suspended coverage of this company.

NC - Not covered. Jefferies does not cover this company.

Restricted - Describes issuers where, in conjunction with Jefferies engagement in certain transactions, company policy or applicable securities regulations prohibit certain types of communications, including investment recommendations.

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Jefferies Franchise Picks

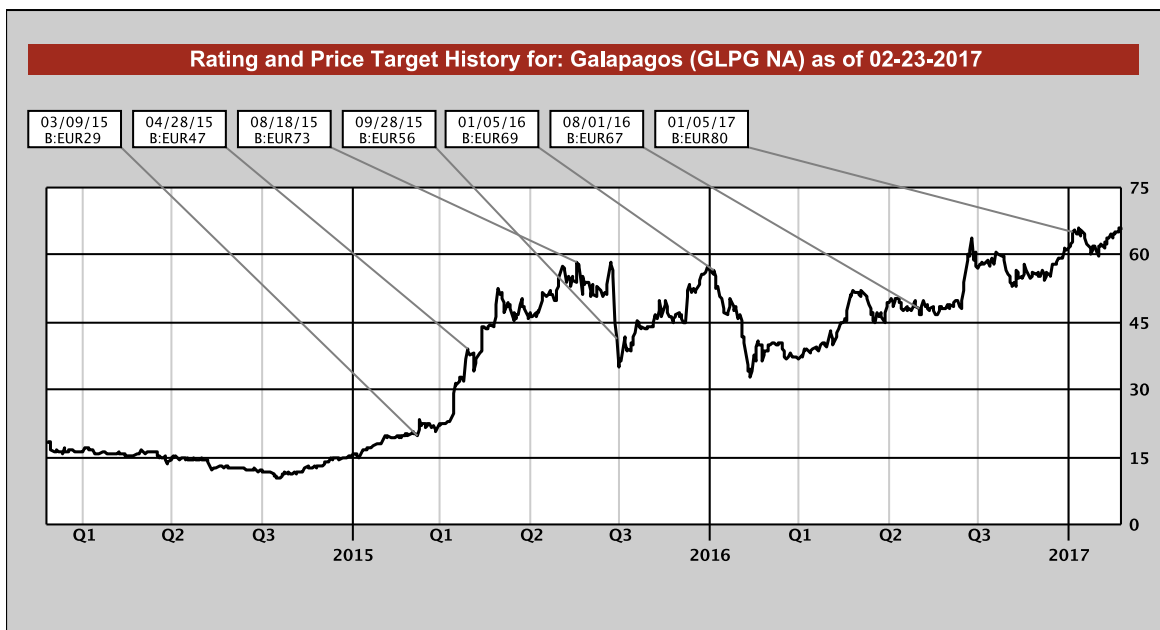
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Risks which may impede the achievement of our Price Target

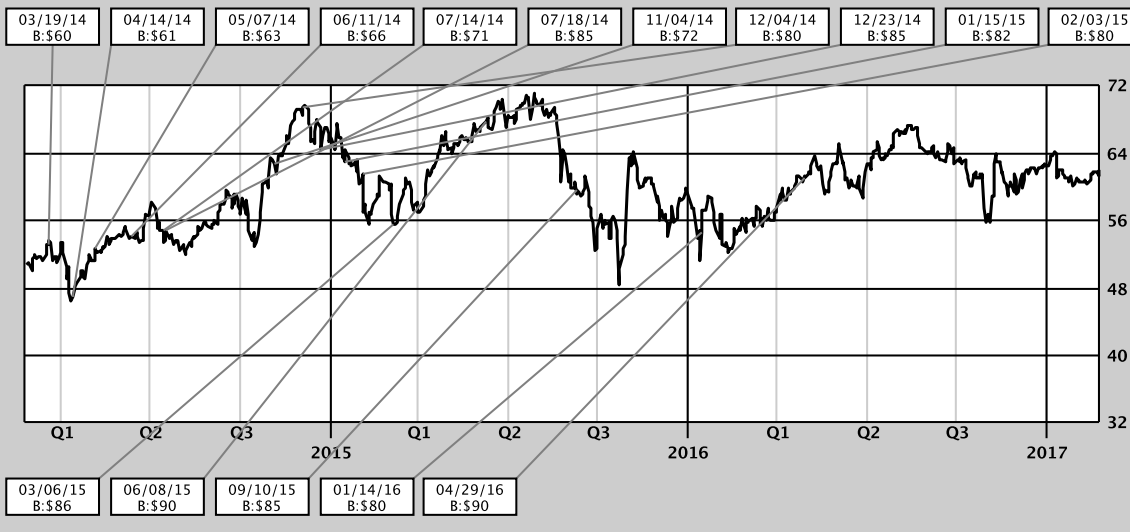
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Other Companies Mentioned in This Report

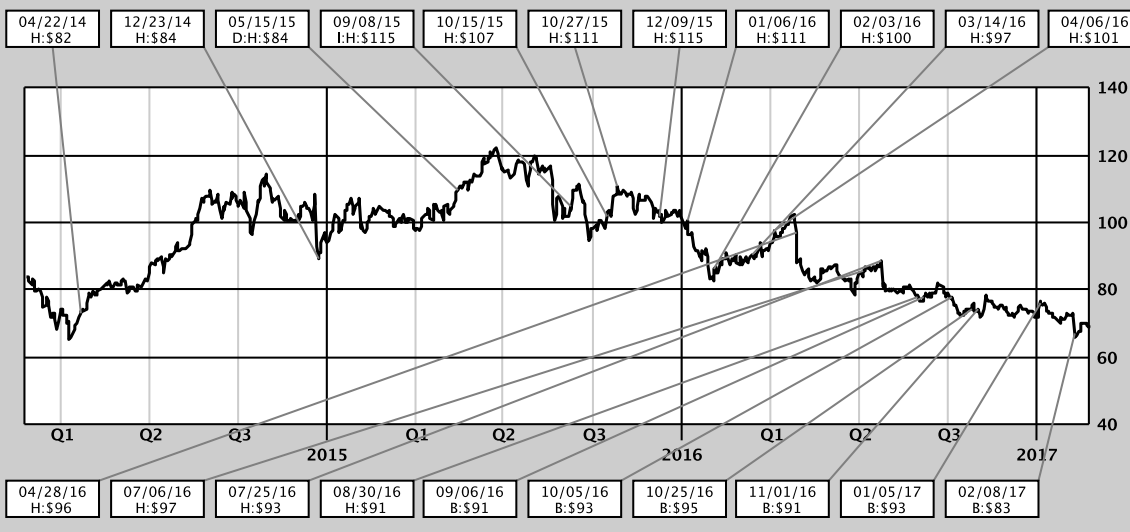
- AbbVie (ABBV: \$61.94, BUY)
- Gilead Sciences, Inc. (GILD: \$69.37, BUY)
- GlaxoSmithKline Plc (GSK LN: p1,632.50, BUY)
- Vertex Pharmaceuticals Incorporated (VRTX: \$85.73, BUY)

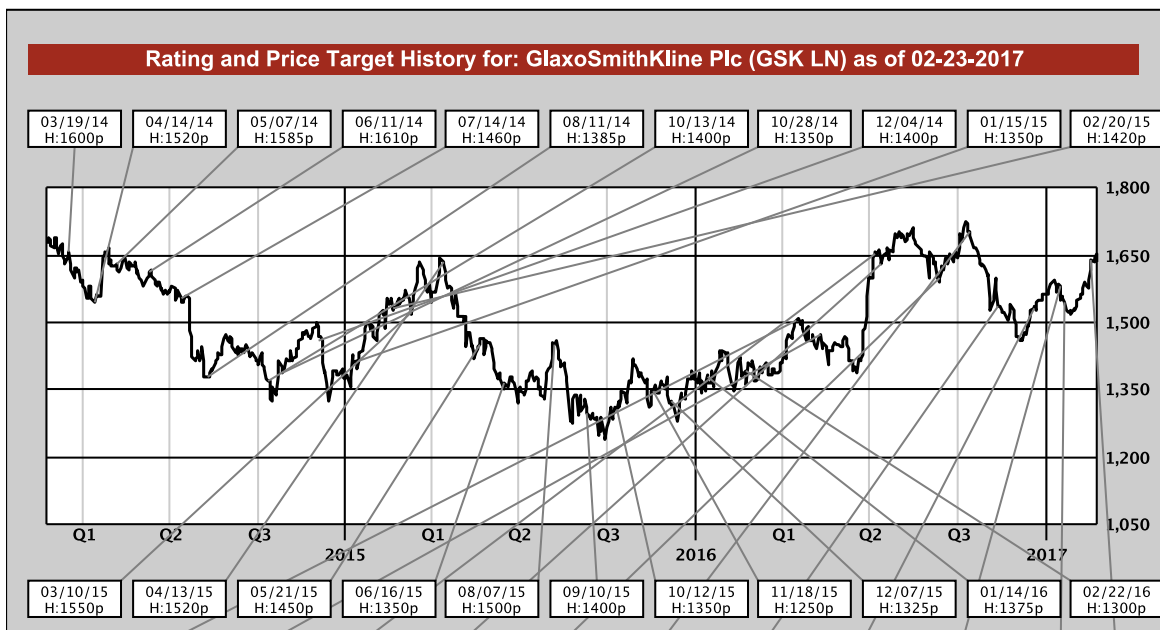
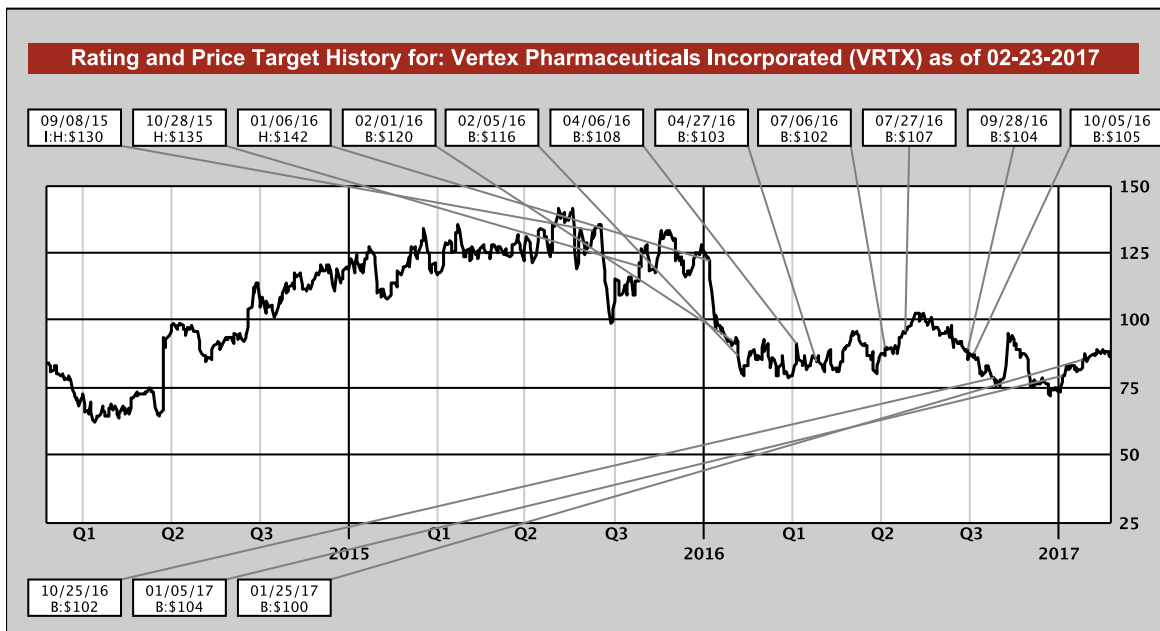


Rating and Price Target History for: AbbVie (ABBV) as of 02-23-2017



Rating and Price Target History for: Gilead Sciences, Inc. (GILD) as of 02-23-2017





Notes: Each box in the Rating and Price Target History chart above represents actions over the past three years in which an analyst initiated on a company, made a change to a rating or price target of a company or discontinued coverage of a company.

Legend:

- I: Initiating Coverage
- D: Dropped Coverage
- B: Buy
- H: Hold
- UP: Underperform

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Distribution of Ratings

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY	1101	50.41%	338	30.70%
HOLD	908	41.58%	175	19.27%
UNDERPERFORM	175	8.01%	15	8.57%

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