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Biotechnology

October 18, 2016

Galapagos NV (GLPG) - BUY

GLPG: Cross Trial Comparisons With CELG - Filgotinib Appears to be the Better Drug

Price:	$63.51
Fair Value Estimate:	$64.00
52-Week Range:	$37.03 - $73.37
Market Cap (MM):	$2,932
Shr.O/S-Diluted (mm):	46.2
Average Daily Volume:	85,812
Cash/Share:	$26.00

FYE: Dec	2016E	2017E	2018E
EPS:	€(1.11)E	€4.25E	€(2.26)E
Prior EPS:	NC	NC	NC
P/E Ratio:	NA	11.4x	NA

Quarterly EPS:

Q1	€0.79A	€(0.56)E	--
Q2	€(0.08)A	€1.29E	--
Q3	€(0.73)E	€0.83E	--
Q4	€(1.06)E	€2.83E	--

Quarterly Revenue (M):

Q1	€15A	€73E	--
Q2	€39A	€145E	--
Q3	€25E	€113E	--
Q4	€28E	€181E	--
Year:	€107E	€512E	€278E

Flash Takeaways

Updated data from Celgene (CELG - No rating) on its competing Crohn's therapy highlights a modest 15% response rate (N= 52) based on the clinically relevant metric of a >50% reduction in SES-CD score (not sure if the data are derived from a central review or a single adjudicator). For reference, GLPG reported a 14% placebo response rate using a central review and a 23% placebo response rate based on a local reading. Bottom line CELG's GED-0301 treatment arm appears to be as good as the placebo cohort (N = 44) in the GLPG FITZROY study. Note, filgotinib delivered 25% and 39% response rates (N=128) based on central and local readings, respectively. Hence, we continue to be encouraged by filgotinib's clinical profile vs. available data from other competing oral therapies in IBD. For details on SES-CD scores, histopathology, and safety profile of filgotinib refer to Exhibits 5, 6, and 7, respectively, in the attachment. Flgotinib remains well-positioned to be the first, novel, oral therapy in IBD, in our view with a broad phase 3 program in Crohn's and phase 2/3 program in Ulcerative Colitis, all of which were recently initiated). For Galapagos, over the near to-intermediate term, focus shifts to the Cystic Fibrosis data readouts starting with small Saphira 2 study (S1251N mutation being presented at the NACFC next week) followed by the Saphira 1 study (G551D) by year end.

Analysts Notes

- Filgotinib is the first JAK inhibitor to show efficacy in Crohn's disease in a Crohn's population (TNF naïve and experienced, mild to moderate disease). Additionally, being JAK1-specific, filgotinib's hematologic profile suggests a compelling commercial opportunities in IBD. Efficacy was established in both TNF-naïve and TNF-failures in the FITZROY study (N=174, of which 44 were in the placebo cohort). ~58% of patients were TNF-refractory at baseline. Mean duration of disease was >8 years in the treatment cohort and the CDAI scores were ~291 at baseline. Recall, almost 50% of patients achieved disease remission at week-10 compared to 23% for the placebo cohort and the 25% delta between the two groups points to an active drug and validates selective JAK 1 inhibition in this setting. Remission rates were lower in TNF-failures (~39%), which is not a surprise and the 20-week update might provide a clearer picture in this population.
- Other key differences vs. GED-0301: 46% with prior TNF-therapy in CELG study vs. 58% in the filgotinib study; Filgotinib data derived from a placebo-controlled

RESEARCH ANALYST CERTIFICATIONS AND IMPORTANT DISCLOSURES ARE ON PAGES 9 - 10 OF THIS REPORT

study vs. all patients randomized to active treatment in the CELG study hence, uninterpretable, in our view; Statistically-significant reduction in histopathologic score in patients treated with filgotinib vs. no such data in the CELG abstract; Filgotinib data reported at week 10 vs. the 12-week readout for CELG; and 174 patients in the filgotinib study vs. 52 patients in the CELG study.

- SES-CD backgrounder: SES-CD evaluates four endoscopic items (ulcer size, proportion of the surface area that is ulcerated, proportion of the surface area affected, and stenosis, Exhibit 1). Each item is scored by segment on a scale from zero to three. The maximum SES-CD score is 56, with higher scores indicating more severe disease. Numerical grading system generating a total score (0–56), all of which are recorded in five segments: terminal ileum; right colon; transverse colon; left colon and; rectum. The sum of the scores for each variable ranges from 0 to 15, except for stenosis, where it varies between 0 and 11, because 3 represents a stenosis through which an endoscope cannot be passed and therefore does not allow for further measurements.
- Definition of endoscopic response: A decrease from baseline in SES-CD score of at least 50% has become the more widely excepted measure of response. Recall, FITZROY study (filgotinib) is using this more stringent criteria in a randomized, placebo-controlled setting; however, in the Celgene-sponsored study, response was defined as 25% reduction from baseline and the study is not placebo-controlled.
- SAPHIRA 1 and 2 up next - Saphira 1 is fully enrolled with data during late 4Q16: Design - 32 CF patients with the G551D mutation are being treated for four weeks in an open label, multicenter study consisting of three consecutive treatment periods: two one-week periods followed by one two-week period, evaluating one dose of GLPG-1837, each followed by a seven to 10 days follow-up.
- While safety and tolerability are the primary endpoints, focus is on secondary endpoints, which include: Changes in sweat chloride concentration; Changes in pulmonary function (FEV1); Cmax, Tmax, and AUC.
- SAPHIRA 2 - Fully enrolled with data at the NACFC on 10/23/16: Design - Seven CF patients with the ultra-rare S1251N mutation are being treated for four weeks in an open label, multicenter study consisting of two consecutive treatment periods: two, two-week periods, evaluating one dose of GLPG-1837, each followed by a seven to 10 days follow-up.
- While safety and tolerability are the primary endpoints focus is likely to be on secondary endpoints, which include: Changes in sweat chloride concentration and; Changes in pulmonary function (FEV1).
- Lessons from VX-770 dose finding phase 2 study in patients with G551D mutation: Sweat chloride changes (biomarker for CFTR function) - In part 1 of the study (day 14), the mean change in the sweat chloride concentration from baseline to day 14 was: −32.9 mmol/liter, −40.4 mmol/liter, and −42.3 mmol/liter in the 25-mg, 75-mg, and 150-mg cohorts, respectively.
- The mean change from baseline in the placebo group was +4.4 mmol/liter (Exhibit 1). The changes were significant ($P<0.001$) in both within-subject and vs. placebo comparisons.
- Spirometric assessment: The mean relative change from baseline in the % of predicted FEV1 (day 14) was 4.9%, 10.0%; 10.5% in the patients treated with VX-770, 25-mg, 75-mg, and 150-mg cohorts, respectively. The mean change in the placebo group was 0.7%.

- Within subject improvements in the % of predicted FEV1 were significant in the VX-770 75-mg and 150-mg groups (P = 0.002 and P = 0.008, respectively), but not in the VX-770 25-mg.
- Differences in comparisons with the placebo group did not reach significance (P = 0.45, P = 0.09, and P = 0.10, respectively, for the VX-770 25-mg, 75-mg, and 150-mg groups).
    - We value GLPG based on a risk-adjusted, sum-of-parts analysis, and is driven by filgotinib (RA and Crohn's) and CF programs. Note, neither UC, nor the robust cash position (~$25/share) are reflected in our NPV, suggesting room for upside. We assign modest NPV to its OA and IFP clinical programs as we await clinical validation: We assign modest NPV to its OA and IFP clinical programs as we await clinical validation:
    - r-NPV for the Gilead-partnered RA program are $40/share based on a 65% probability of success (POS) in RA. RA represents 63% of our FV. Note the elaborate phase 3 program (three independent phase 3 studies were initiated on 8/22/16)
    - r-NPV for the Gilead-partnered Crohn's programs is $8/share based on $60% probability of success. Note, a phase 3 program in Crohn's is expected to begin enrollment during 4Q16. Crohn's represents 13% of our FV. Between RA and Crohn's we anticipate over $2.5B in peak sales and hence, blockbuster status. We are not currently including the Ulcerative Colitis opportunity as we await phase 2/3 study initiation/data
    - r-NPV for the Abbvie-partnered CF program is $11/share (or 17% of our FV). Our r-NPV assumes the following success rates: Triple-combo in homozygous patients at 20%; Triple-combo in heterozygous patients at 9%; Monotherapy in G551D, 2117H, etc. at 65%
    - r-NPV for the OA and IPF programs are $3 and $2/share, respectively with 9% probability of success.

RESEARCH ANALYST CERTIFICATIONS AND IMPORTANT DISCLOSURES ARE ON PAGES 9 - 10 OF THIS REPORT

Exhibit 1: SES-CD scoring algorithm, Max score 56, each category score 15, expect category 4 (max score 11)

	SES CD score			
Variable	0	1	2	3
Presence of ulcers	None	Aphtous ulcers (∅ 0.1–0.5 cm)	Large ulcers (∅ 0.5–2 cm)	Very large ulcers (∅ > 2 cm)
Ulcerated surface	None	< 10%	10–30%	> 30%
Affected surface	Unaffected segment	< 50%	50–75%	> 75%
Presence of narrowings	None	Single, can be passed	Multiple, can be passed	Cannot be passed

	Ileum	Right colon	Transverse colon	Left colon	Rectum	SUM
Presence of ulcers						+
Ulcerated surface						+
Affected surface						+
Presence of narrowings						=
					Sum of all variables	TOTAL

Source: Inflammatory Bowel Disease, 2014; 20(10): 1850-1861

Exhibit 2: FITZROY eligibility and baseline characteristics

Phase 2 FITZROY – ELIGIBILITY CRITERIA

- Inclusion:
  - ileal, colonic, or ileocolonic Crohn's Disease (on colonoscopy and histology)
  - Crohn's Disease Activity Index (CDAI) ≥220 to ≤450
  - endoscopic confirmation of active disease, ulceration (SES-CD, central reading)
- Exclusion:
  - indeterminate colitis, ulcerative colitis
  - surgical bowel resection within past 6 months
- Concomitant medication:
  - discontinuation: anti-TNFs (8 wks <BL), immunomodulators (AZA, MTX, 6-MP; 25 days <first study dose)
  - allowed: stable doses of oral steroids, mesalazine, olsalazine, CD-related antibiotics, and probiotics

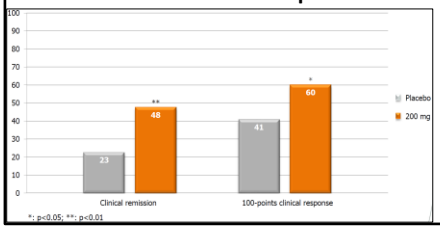
FITZROY – Baseline characteristics, 42% TNF-naïve and 58% TNF-failures

	Placebo (N=44)	200 mg (N=130)	Total (N=174)
Age, mean, years	35.1	37.4	36.9
Female	59%	55%	56%
Duration of CD, mean, years	6.8	8.8	8.3
CDAI, mean	298.6	291.3	293.1
Oral corticosteroids	52%	48%	49%
mean daily dose, mg/day	23.6	23.1	23.2

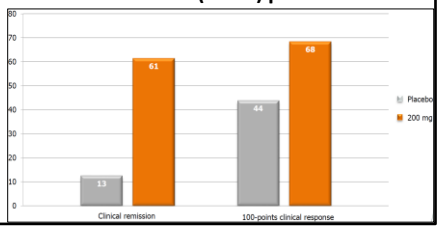
Source: GLPG presentation and Janney Montgomery Scott LLC

Exhibit 3: FITZROY CDAI-based clinical response and remission rates

FITZROY – week-10 primary endpoint – CDAI % clinical remission p=0.0067



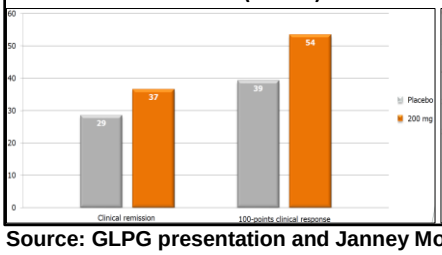
FITZROY – Compelling CDAI benefit in TNF-naïve (N=73) patients



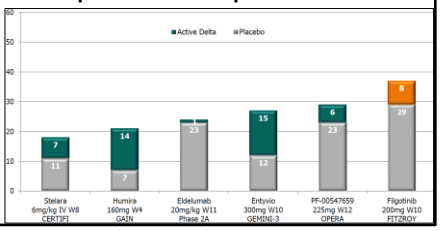
Source: GLPG presentation and Janney Montgomery Scott LLC

Exhibit 4: FITZROY CDAI-based clinical response in TNF-failures and competitive efficacy

FITZROY – week-10 CDAI responses in TNF-failures (N=101)

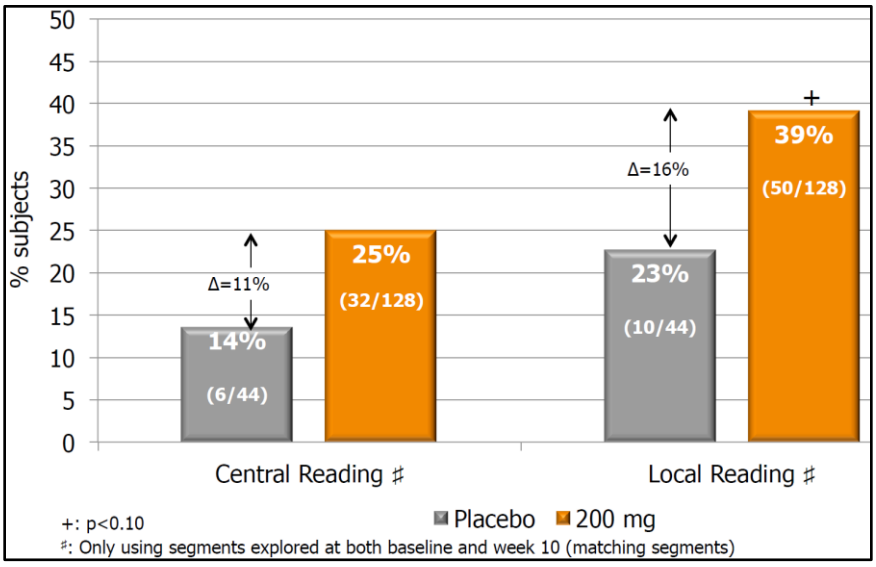


Competitive landscape in TNF-failures



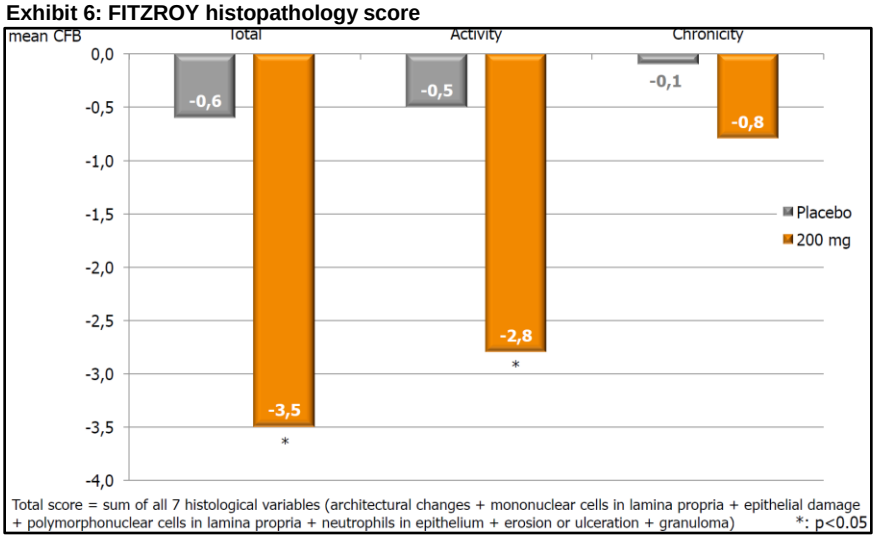
Source: GLPG presentation and Janney Montgomery Scott LLC

Exhibit 5: FITZROY SES-CD response rates based on a >50% improvement from baseline



Source: GLPG presentation and at the UEG week in Vienna 10/17/16

Exhibit 6: FITZROY histopathology score



Source: GLPG presentation and at the UEG week in Vienna 10/17/16

Exhibit 7: FITZROY filgotinib safety profile

	Placebo (N=44)	200 mg (N=130)
TE AE, n (%)	26 (59)	86 (66)
Infections and infestations, n (%)	9 (20)	32 (25)
Gastrointestinal disorders, n (%)	10 (23)	32 (25)
Nervous system disorders, n (%)	8 (18)	21 (15)
Serious TE AE, n (%)	3 (7)	6 (5)
Serious TE infections, n (%)	0 (0)	1 (1)♯
SAE leading to death, n (%)	0 (0)	0 (0)
TE AE leading to discontinuation, n (%)	5 (11)	15 (12)

Mean change from baseline	Placebo (N=44)	200 mg (N=130)
Hemoglobin (g/L)	+2.6	+2.5
Neutrophils (giga/L)	+0.09	-0.22
Lymphocytes (giga/L)	+0.09	+0.06
Creatinine (µmol/L)	+4.0	+6.1
ALT (U/L)	+0.6	+1.6
HDL (mmol/L)	+0.01	+0.24

♯ Community Acquired Pneumonia

Source: GLPG presentation and at the UEG week in Vienna 10/17/16

Exhibit 8: Upcoming milestones and significance

Upcoming Milestones							
Drug	Indication	Status	Program	Timing	Impact	Partner	Milestones and Royalty
Filgotinib	RA	Phase 3	FINCH 1, FINCH 2, FINCH 3	Underway	+	Gilead	$1.35B pending - $750 in clinical and the rest commercial. Royalty starts at 20% and heads higher
Filgotinib	Crohn's	Phase 3	DIVERSITY	Underway	+		
Filgotinib	Ulcerative Colitis	Phase 2/3	SELECTION	Underway	+		
Filgotinib	Crohn's	Phase 2	Endoscopy	Completed	++		
Filgotinib	Undisclosed	Phase 2		1H17	+		
GLPG1837	CF	Phase 2	SAPHIRA 1, SAPHIRA 2	2H16	+++	Abbvie	$600M of which $250M are due post-phase 2 completion. Royalty starts in the mid-teens and heads higher
GLPG2451	CF	Phase 2		2H16	++		
GLPG2222	CF	Phase 1		1H17	++		
GLPG2851	CF	Phase 1		Start 2H16	+		
GLPG1690	IPF	Phase 2		2Q17	++		Wholly owned
GLPG1972	OA	Phase 2		1H17 start	+	Servier	GLPG owns US rights

Source: GLPG presentation and Janney Montgomery Scott LLC., estimates

Balance Sheet									Estimates			
Assets	**Mar '16**	**Jun '16**	**Sep '16**	**Dec '16**	**Mar '17**	**Jun '17**	**Sep '17**	**Dec '17**	**FY '18**	**FY '19**	**FY '20**
Cash & Short-Term Investments	356	987	967	950	867	802	833	817	903	920	1,215	1,532
Cash Only	347	987	967	950	867							
Total Short Term Investments	8	0	0									
Short-Term Receivables	13	15	18	18	20	20						
Accounts Receivables, Net	1	6	7	9	9	10	12	35	59	120	145	220
Other Receivables	12	9	11	9	11	12						
Prepaid Expenses	0	--	--							35	45	25
Miscellaneous Current Assets	3	6	7	7	7	7	7	12	30		45	20
Total Current Assets	**372**	**1,008**	**992**	**1,001**	**921**	**860**	**864**	**899**	**1,032**	**1,155**	**1,589**	**1,897**
--	--	--	--									
Net Property, Plant & Equipment	14	14	15	16	17	18	18					
Long-Term Note Receivable	49	53	54	56	57	57	57					
Total Assets	**443**	**1,079**	**1,067**	**1,081**	**1,003**	**943**	**947**	**899**	**1,032**	**1,155**	**1,589**	**1,897**
--	--	--										
Liabilities & Shareholders' Equity	--	--										
ST Debt & Curr. Portion LT Debt	0	0	0	0								
Accounts Payable	29	24	23	20	23	25	18	10	9	53	227	375
Other Current Liabilities	40	78	87	95	95	80	80	95	120	210	135	165
Miscellaneous Current Liabilities	40	78	87	95	95							140
Total Current Liabilities	**72**	**105**	**112**	**115**	**118**	**107**	**100**	**107**	**131**	**249**	**361**	**515**
--	--	--	--									
Long-Term Debt	0	0	0	0								
Provision for Risks & Charges	3	3	3	3	3							
Deferred Tax Liabilities	--	--	--	2	3							
Other Liabilities	3	243	222	206	173	154	104	9	0	110	426	377
Deferred Tax Liability-Untaxed Reserves	--	--	--									
Other Liabilities (excl. Deferred Income)	3	243	222	205	173	200						
Deferred Income	--	--	--									
Total Liabilities	**78**	**351**	**337**	**326**	**297**	**261**	**204**	**116**	**131**	**359**	**787**	**892**
--	--	--	--									
Non-Equity Reserves	0	0	0	--								
--	--	--	--									
Preferred Stock (Carrying Value)	0	0	0	--								
Redeemable Preferred Stock	0	0	0	--								
Non-Redeemable Preferred Stock	0	0	0	--								
Preferred Stock issues for ESOP	--	--	--	--								
ESOP Guarantees - Preferred Stock	--	--	--	--								
Common Equity	365	729	730	728	729							
Common Stock Par/Carry Value	185	222	223	224	224	225	226	227	229	230	231	232
Additional Paid-In Capital/Capital Surplus	357	647	649	707	707	707	707	707	707	707	707	707
Retained Earnings	-177	-139	-141	-175	-224	-250	-190	-151	-19	-141	-135	66
Total Shareholders' Equity	**365**	**729**	**730**	**755**	**706**	**682**	**743**	**783**	**917**	**796**	**803**	**1,005**
Total Equity	**365**	**729**	**730**	**755**	**706**							
Total Liabilities & Shareholders' Equity	**443**	**1,079**	**1,067**	**1,081**	**1,003**	**943**	**947**	**899**	**1,032**	**1,155**	**1,589**	**1,897**

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Galapagos NV

Income Statement

All figures in millions of Euro, except per share items

				Estimates								
	Dec '15	**Mar '16**	**Jun '16**	**Sep '16**	**Dec '16**	**Mar '17**	**Jun '17**	**Sep '17**	**Dec '17**	**FY '18**	**FY '19**	**FY '20**
Sales+milestone	7.19	14.82	38.67	25.34	28.34	72.54	145.53	113.46	181.04	278.36	464.06	466.34
RA+crohn's+CF+etc											15.77	281.65
Gross Income	7.19	14.82	38.67	25.34	28.34	72.54	145.53	113.46	181.04	278.36	479.83	748.00
SG&A Expense	38.67	3.97	6.73	8.08	8.88	9.15	9.61	10.09	10.59	78.88	118.31	141.98
Depreciation & Amortization Expense	0.88	0.96	1.04	1.14	1.25	1.32	1.38	1.45	1.53	8.52	12.78	19.17
Research & Development	32.84	27.82	34.59	50.16	67.72	88.03	74.83	63.60	44.52	311.64	342.80	411.36
Net OPEX	78.22	33.18	42.36	59.38	77.86	98.50	85.82	75.14	56.64	399.03	473.89	572.50
EBIT (Operating Income)	**-32.36**	**-18.36**	**-3.69**	**-34.04**	-49.52	-25.96	59.71	38.32	124.40	-120.67	5.93	175.49
Pretax Income	**-56.81**	**35.95**	-3.69	-34.04	-49.52	-25.96	59.71	38.32	124.40	-120.67	5.93	175.49
Income Taxes	0.19	0.00	-0.02	-0.20	-0.30	-0.16	-0.36	-0.23	-7.46	-14.48	-0.71	-24.57
Net Income	**-57.00**	**35.95**	-3.67	-33.83	-49.22	-25.81	60.07	38.55	131.87	-106.19	6.65	200.06
Preferred Dividends	0.00	0.00	0.00	--								
Net Income available to Common	-57.00	35.95	-3.67	-33.83	-49.22	-25.81	60.07	38.55	131.87	-106.19	6.65	200.06
EPS (recurring)	-0.91	0.81	-0.08	-0.73	-1.06	-0.56	1.29	0.83	2.83	-2.26	0.14	4.17
EPS (diluted)	-1.46	0.79	-0.08	-0.73	-1.06	-0.56	1.29	0.83	2.83	-2.26	0.14	4.17
Basic Shares Outstanding	39.08	44.43	46.11	46.20	46.29	46.39	46.48	46.57	46.67	47.04	47.51	47.98
Diluted Shares Outstanding	39.08	45.84	46.11	46.20	46.29	46.39	46.48	46.57	46.67	47.04	47.51	47.98
EBITDA	**-31.48**	**34.99**	**-11.19**	-34.04	-49.52	-25.96	61.09	39.77	125.93	-112.15	18.71	194.66

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IMPORTANT DISCLOSURES

Research Analyst Certification

I, Debjit Chattopadhyay, the Primarily Responsible Analyst for this research report, hereby certify that all of the views expressed in this research report accurately reflect my personal views about any and all of the subject securities or issuers. No part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views I expressed in this research report.

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Janney Montgomery Scott LLC intends to seek or expects to receive compensation for investment banking services from Galapagos NV in the next three months.

The research analyst is compensated based on, in part, Janney Montgomery Scott's profitability, which includes its investment banking revenues.

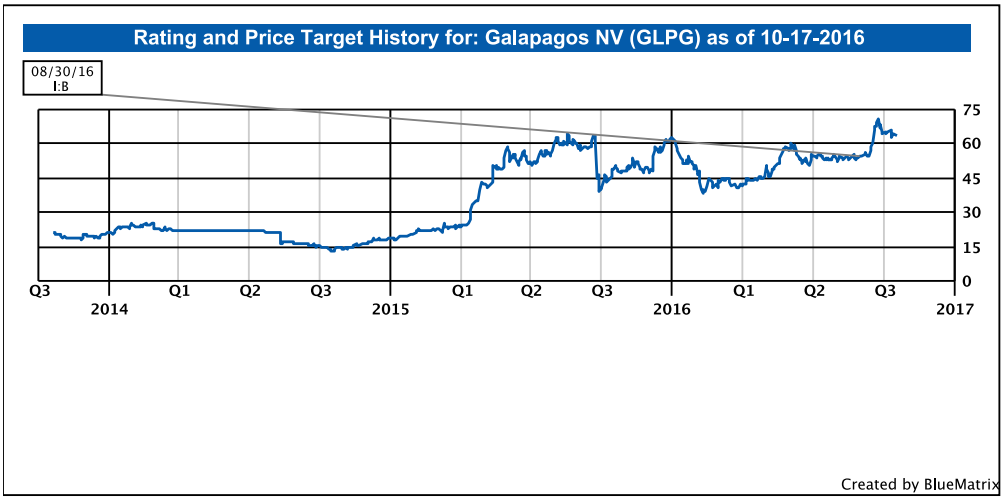
Definition of Ratings

BUY: Janney expects that the subject company will appreciate in value. Additionally, we expect that the subject company will outperform comparable companies within its sector.

NEUTRAL: Janney believes that the subject company is fairly valued and will perform in line with comparable companies within its sector. Investors may add to current positions on short-term weakness and sell on strength as the valuations or fundamentals become more or less attractive.

SELL: Janney expects that the subject company will likely decline in value and will underperform comparable companies within its sector.

Price Charts



Janney Montgomery Scott Ratings Distribution as of 09/30/16

			IB Serv./Past 12 Mos.*	
Rating	**Count**	**Percent**	**Count**	**Percent**
BUY [B]	124	52.54	28	22.58
NEUTRAL [N]	109	46.19	11	10.09
SELL [S]	3	1.27	0	0.00

*Percentages of each rating category where Janney has performed Investment Banking services over the past 12 months.

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