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Biotechnology

October 27, 2016

Galapagos NV (GLPG) - BUY

GLPG: SAPHIRA-2 in S1251N patients - Signs of Activity At The Lower Limits of Dosing

Price:	$64.05
Fair Value Estimate:	$64.00
52-Week Range:	$37.03 - $73.37
Market Cap (MM):	$2,957
Shr.O/S-Diluted (mm):	46.2
Average Daily Volume:	92,884
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	11.5x	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

Galapagos' SAPHIRA 2 study at the NACFC highlights clinical activity GLPG-1837 in S1251N patients (not G551D). Data is from the lowest end of the dosing spectrum {not equivalent to the approved Kalydeco (Vertex, VRTX - No rating} dose. In patients with the same mutation (N=8), 150 mg BID Kalydeco dosed for two weeks resulted in an absolute change in ppFEV1 of 2 units (Exhibit 3), which is comparable with the data from the SAPHIRA 2 study where GLPG-1837 was being dosed at the lowest possible efficacious dose with an eye on advancing a triple-combo to the clinic in CF patients during the 2H17. SAPHIRA 1 study (N=32, will include a higher dose cohort and slightly longer follow up in G551D patients) is expected during December 2016.

Analysts Notes

- SAPHIRA 2 - Design - Six 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.
- Key take-away: Five S1251N patients were dosed with GLPG-1837 at 62.5 mg BID and 125 mg BID for two weeks each
- The doses/exposures evaluated the lower limits of the predicted efficacious range and showed dose-dependent increase in CFTR activity, with plasma levels predicted to show initial efficacy achieved at 125 mg BID.
- After 2 weeks treatment with 125 mg BID, three out of five subjects reached Ctrough plasma levels predicted to be active in lungs.
- In Kalydeco naïve patients (N=3) the mean change from baseline in the ppFEV1 was 2.66, which is similar to those reported for the 150 mg BID Kalydeco dose.
- After a one-week washout period, ppFEV1 remained relatively stable in Kaydeco experienced patients (N=3).
- After 29 days, four out of five patients had >15 mmol/L decrease in sweat chloride and one out five had a >50 mmol/L decrease.
- All TEAEs were mild or moderate, except for one case of severe abdominal pain. None of the TEAEs led to study drug discontinuation and no serious adverse events occurred during the study.
- SAPHIRA 1 - 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,

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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.
- 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% (Exhibit 2).
- 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).
- The CF corrector/potentiator commercial opportunity could exceed $7B globally, and we are assuming a 30% market share for GLPG/ABBV: The upcoming SAPHIRA 1 and 2 studies will provide first insights on GLPG1837. Recall, published literature suggests, VX-770 (VRTX – No rating), impairs the biochemical stability of F508-CFTR and other class II processing mutations (such as P67L and R170G). This potentially limits the efficacy of combination therapies like VX-809 and or VX-661. Hence, a new potentiator, without the limitations of VX-770 would be a meaningful addition as triple therapy (potentiation+ early corrector + late corrector) seems to be ultimate goal to improve efficacy in homozygous patients and provide first clinical benefit for heterozygous patients. Galapagos has two potentiators in the clinic, which include: GLPG-1837, and GLPG-2451. Importantly, Galapagos has two correctors in development, which include: early-corrector C1- 2222, its and backup (GLPG-2851); And late corrector C2 – 2737 and its backup (not yet disclosed). The -GLPG-1837 data is likely to be followed by multiple healthy volunteer studies from the other key components of the strategy (correctors and back up potentiators), setting the stage for a triple combo studies during late 2017. The CF program will be a key driver of sentiment on GLPG stock over the next 12 months, as Filgotinib phase 3 program is fully enrolled, in our view.
- 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.

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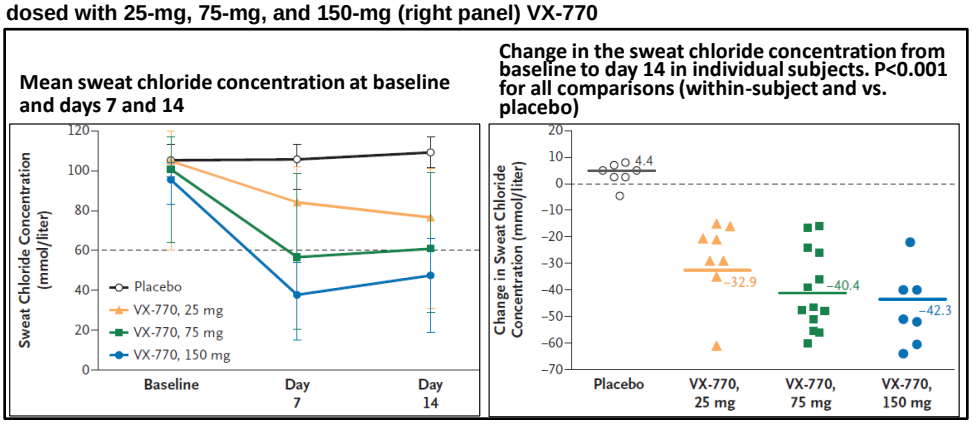
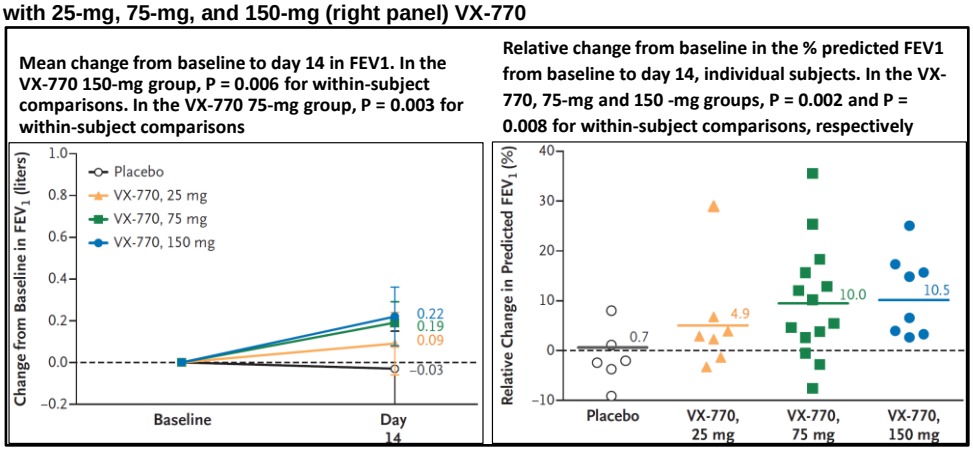
Exhibit 1: Mean changes sweat chloride in G551D patients (left panel) and sweat chloride changes in individual patients dosed with 25-mg, 75-mg, and 150-mg (right panel) VX-770



Source: Adapted from NEJM 2010, 363: 21; 1991, by Janney Montgomery Scott, LLC

Exhibit 2: Mean relative changes % predicted FEV1 in G551D patients (left panel) and changes in individual patients dosed with 25-mg, 75-mg, and 150-mg (right panel) VX-770



Source: Adapted from NEJM 2010, 363: 21; 1991, by Janney Montgomery Scott, LLC

Exhibit 3: VX-770 efficacy in various mutation subgroups

Mutation (n)	Absolute change in percent predicted FEV_1			BMI (kg/m^2)	CFQ-R Respiratory Domain Score (Points)	Absolute Change in Sweat Chloride (mmol/L)
	At Week 2	At Week 4	At Week 8	At Week 8	At Week 8	At Week 8
All patients (n=39) Results shown as mean (95% CI) change from baseline KALYDECO vs. placebo-treated patients:						
	8.3 (4.5, 12.1)	10.0 (6.2, 13.8)	13.8 (9.9, 17.6)	0.66† (0.34, 0.99)	12.8 (6.7, 18.9)	-50 (-58, -41)*
Patients grouped under mutation types (n) Results shown as mean (minimum, maximum) for change from baseline for KALYDECO-treated patients**:						
G1244E (5)	11 (-5, 25)	6 (-5, 13)	8 (-1, 18)	0.63 (0.34, 1.32)	3.3 (-27.8, 22.2)	-55 (-75, -34)
G1349D (2)	19 (5, 33)	18 (2, 35)	20 (3, 36)	1.15 (1.07, 1.22)	16.7 (-11.1, 44.4)	-80 (-82, -79)
G178R (5)	7 (1, 17)	10 (-2, 21)	8 (-1, 18)	0.85 (0.33, 1.46)	20.0 (5.6, 50.0)	-53 (-65, -35)
G551S (2)	0 (-5, 5)	0.3 (-5, 6)	3††	0.16††	16.7††	-68††
G970R (4)	7 (1, 13)	7 (1, 14)	3 (-1, 5)	0.48 (-0.38, 1.75)	1.4 (-16.7, 16.7)	-6 (-16, -2)
S1251N (8)	2 (-23, 20)	8 (-13, 26)	9 (-20, 21)	0.73 (0.08, 1.83)	23.3 (5.6, 50.0)	-54 (-84, -7)
S1255P (2)	11 (8, 14)	9 (5, 13)	3 (-1, 8)	1.62 (1.39, 1.84)	8.3 (5.6, 11.1)	-78 (-82, -74)
S549N (6)	11 (5, 16)	8 (-9, 19)	11 (-2, 20)	0.79 (0.00, 1.91)	8.8 (-8.3, 27.8)	-74 (-93, -53)
S549R (4)	3 (-4, 8)	4 (-4, 10)	5 (-3, 13)	0.53 (0.33, 0.80)	6.9 (0.0, 11.1)	-61††† (-71, -54)

* n=36 for the analysis of absolute change in sweat chloride.
** Statistical testing was not performed due to small numbers for individual mutations.
† Result for weight gain as a component of body mass index was consistent with BMI.
†† Reflects results from the one patient with the *G551S* mutation with data at the 8-week time point.
††† n=3 for the analysis of absolute change in sweat chloride.

Source: Kalydeco label, red box added for emphasis by Janney Montgomery Scott LLC

Exhibit 4: 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	4Q16	+++	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**
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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**
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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**
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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**
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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.

Janney Montgomery Scott LLC ("Janney") Equity Research Disclosure Legend

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.

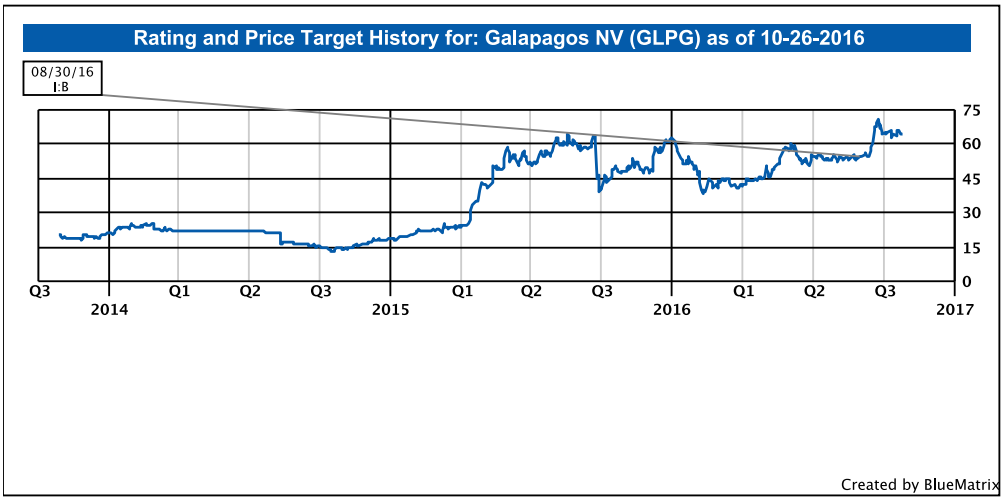
Definition of Ratings

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.

Other Disclosures

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