

Biotechnology

Price:	\$71.00
Fair Value Estimate:	\$64.00
52-Week Range:	\$37.03 - \$73.37
Market Cap (MM):	\$3,278
Shr.O/S-Diluted (mm):	46.2
Average Daily Volume:	74,411
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	12.8x	NA

Quarterly EPS:

Quarter	2016E	2017E	2018E
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):

Quarter	2016E	2017E	2018E
Q1	€15A	€73E	--
Q2	€39A	€145E	--
Q3	€25E	€113E	--
Q4	€28E	€181E	--
Year:	€107E	€512E	€278E

September 26, 2016

Galapagos NV

(GLPG) - BUY

GLPG: Anticipating Volatility Surrounding UEG Abstracts, Buyers on Meaningful Pullbacks

Flash Takeaways

The FITZROY endoscopy abstract is expected on 9/26/16 and immediate comparisons with competitive data from Celgene (CELG - No rating, GED-0301 program) may lead to some volatile trading. Important to note some key differences, including: Definition of responses (50% reduction in SES-CD scored from baseline for filgotinib vs. 25% reduction for GED-0301), suggesting a higher hurdle for GLPG; FITZROY data being derived from a placebo-controlled study; and Patient population included ~58% TNF-refractory patients. The higher clinical hurdle and inclusion of TNF-refractory patients may translate into a lower overall clinical response rate compared to GED-0301, hence, a flawed comparison, in our view. Also, note the filgotinib Crohn's phase 3 program, and the ulcerative colitis phase 2/3 program are expected to commence during 4Q16, and the ulcerative colitis commercial opportunity is not currently reflected in our risk-adjusted NPV.

Analysts Notes

- Crohn's disease and endoscopy: Endoscopic outcome measures are gaining in significance as they are potentially more objective than symptom-based indices, and there is relatively poor correlation between symptoms, as measured by activity scores like Crohn's Disease Activity Index (CDAI), and endoscopic measures. The two most commonly used objective measures are the Crohn's Disease Endoscopic Index of Severity (CDEIS) and the more recently developed Simple Endoscopic Score for Crohn's Disease (SES-CD). Since, the SES-CD requires fewer calculations it may therefore be easier to use than the CDEIS.
- SES-CD background: 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 expected 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. Also, note the FITZROY study reflects a real-world population with only 42% of patients who are TNF-naïve. Hence, the topline data is not comparable, in our view. Similarly, the two accepted post-treatment definitions of remission based on SES-CD are: SES-CD score of 0 or SES-CD score between 0-2. Note, we do not expect any remission data in the abstract, although that does not imply no remissions were observed. Recall, Celgene in its interim data readout reported responses (using the lower 25% cutoff) and remissions across all the three dose groups at week 12.

- Filgotinib is the first JAK inhibitor to show efficacy in Crohn's disease in a Crohn's population (both TNF naïve and treatment failures) with mild to moderate disease. Additionally, being a JAK1-specific therapy, 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.
 - 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 IFP programs are \$3 and \$2/share, respectively with 9% probability of success.

Exhibit 5: 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, started on 8/22/16	+	Gilead	\$1.35B pending - \$750 in clinical and the rest commercial. Royalty starts at 20% and heads higher
Filgotinib	Crohn's	Phase 3		4Q16	+		
Filgotinib	Ulcerative Colitis	Phase 2/3		4Q16	+		
Filgotinib	Crohn's	Phase 2	Endoscopy	4Q16	++		
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	++		
GLPG1972	OA	Phase 2		1H17 start	+	Servier	GLPG owns US rights

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

Balance Sheet	Estimates											
	Mar '16	Jun '16	Sep '16	Dec '16	Mar '17	Jun '17	Sep '17	Dec '17	FY '18	FY '19	FY '20	
Assets												
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	--	--	--									
Long-Term Note Receivable	14	14	15	16	17	18	18					
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	--	--	--									
Accounts Payable	0	0	0	0								
Other Current Liabilities	29	24	23	20	23	25	18	10	9	53	227	375
Miscellaneous Current Liabilities	40	78	87	95	95	80	80	95	120	210	135	165
Total Current Liabilities	72	105	112	115	118	107	100	107	131	249	361	515
Long-Term Debt	--	--	--									
Provision for Risks & Charges	0	0	0	0								
Deferred Tax Liabilities	3	3	3	3	3							
Other Liabilities	--	--	--	2	3							
Deferred Tax Liability-Untaxed Reserves	3	243	222	206	173	154	104	9	0	110	426	377
Other Liabilities (excl. Deferred Income)	--	--	--									
Deferred Income	3	243	222	205	173	200						
Total Liabilities	78	351	337	326	297	261	204	116	131	359	787	892
Non-Equity Reserves	--	--	--									
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

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

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.

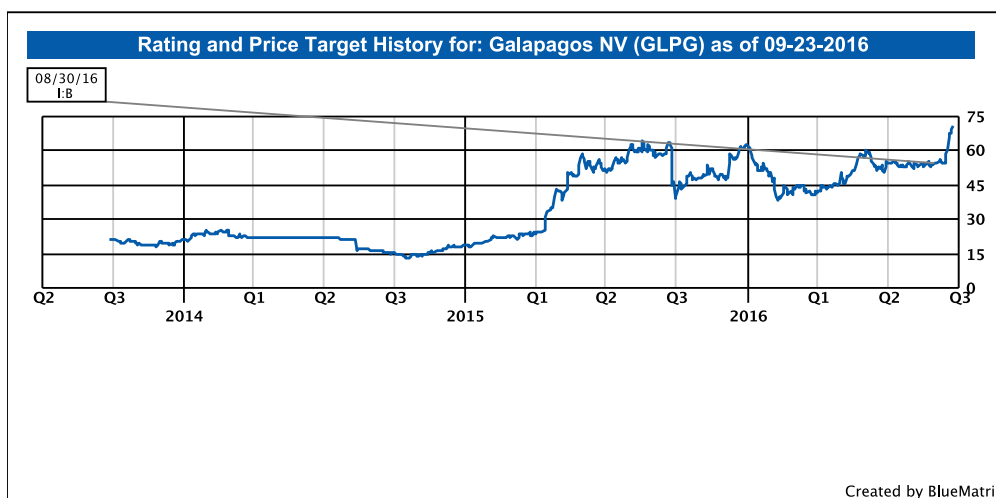
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BUY: Janney expects that the subject company will appreciate in value. Additionally, we expect that the subject company will outperform comparable companies within its sector.

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 06/30/16

Rating	Count	Percent	IB Serv./Past 12 Mos.*	
			Count	Percent
BUY [B]	109	52.15	26	23.85
NEUTRAL [N]	98	46.89	11	11.22
SELL [S]	2	0.95	0	0.00

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

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