Morgan Stanley

November 16, 2015

Galapagos NV

Risk/Reward Into December Crohn's Data

Industry View	Stock Rating	Price Target
In-Line	**Overweight**	**$75.00**

Our bull case moves to $107 (+~$10) as we now include positive Crohn's data. While Pfizer's JAK tofacitinib failed in Crohn's we see much better chances for filgotinib on better study design and drug properties. Positive Crohn's data would also offer mgt. add'l leverage in partnership discussions.

Phase II filgotinib Crohn's data expected in early December: Galapagos is running a ~180 patient PhII Crohn's disease study with its JAK inhibitor filgotinib. Mgt. is studying 200mg of filgotinib once-daily with a primary endpoint at 10 weeks. There is also an additional 10 weeks of maintenance dosing for a full study duration of 20 weeks. We expect to receive top-line data from the 10 week induction period, including the percentage of patients in remission, in early December. The full study design is **available here**.

Study design and drug properties suggest filgotinib can work in Crohn's Disease: Galapagos has included two key study design features which should limit the placebo response and allow filgotinib to separate: **(1)** All patients must have confirmed disease by endoscopy to enter the study which should limit the placebo response. Further, the week 10 endpoint also uses endoscopy, so in addition to remission by CDAI, remission will be confirmed by endoscopy; **(2)** The primary endpoint is at 10 weeks (unlike 4 weeks with Pfizer's tofacitinib) which should allow ample time for filgotinib to separate from placebo. Finally, **(3)** filgotinib's lack of impact on hemaglobin should not impede efficacy (baricitinib was not studied in this population for that reason and tofacitinib had a short duration study).

Risk/Reward skewed positively with limited investor expectations for Crohn's: With positive data we see potential upside of ~$10/share assuming ~$1B in peak Crohn's sales. We have now added explicit Crohn's forecasts to our bull case. Given that many investors have yet to focus on Crohn's, we believe there is little expectation of positive Crohn's data among investors. Further, we believe GLPG could rise above our theoretical potential upside on positive Crohn's data given that it would further differentiate filgotinib (it would be the only JAK with positive Crohn's data) and likely help cement a strong deal with a new commercial partner.

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Galapagos NV (GLPG.O, GLPG US)

Biotechnology / United States of America

Stock Rating	**Overweight**
Industry View	**In-Line**
Price target	**$75.00**
Shr price, close (Nov 13, 2015)	$49.37
Mkt cap, curr (mm)	$1,496
52-Week Range	$65.70-15.12

Fiscal Year Ending	12/14	12/15e	12/16e	12/17e
ModelWare EPS ($)	**(1.50)**	**0.96**	**(3.83)**	**(4.20)**
Prior ModelWare EPS ($)	**-**	**-**	**-**	**-**
P/E	**NM**	**51.5**	**NM**	**NM**
Consensus EPS ($)§	**-**	**1.92**	**(2.48)**	**(2.83)**
Div yld (%)	-	-	-	-

Unless otherwise noted, all metrics are based on Morgan Stanley ModelWare framework
§ = Consensus data is provided by Thomson Reuters Estimates
e = Morgan Stanley Research estimates

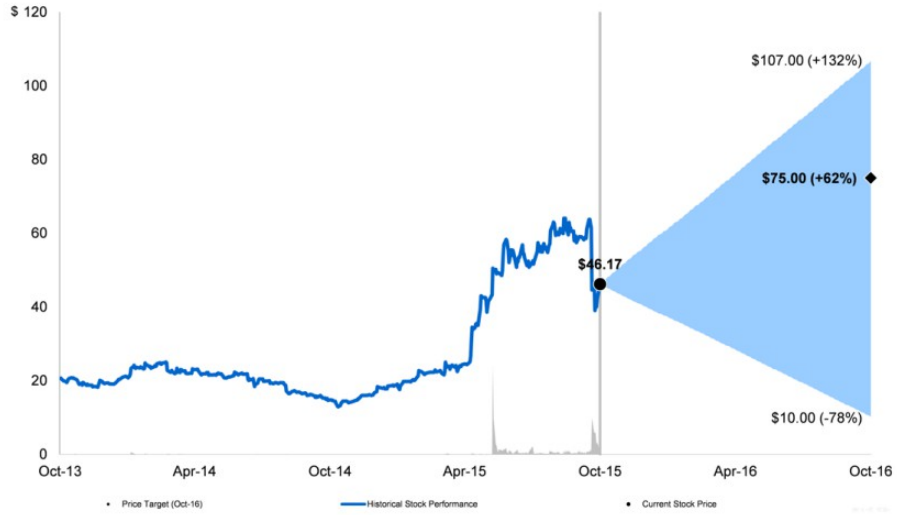
QUARTERLY MODELWARE EPS ($)

Quarter	2014	2015e Prior	2015e Current	2016e Prior	2016e Current
Q1	-	-	-	-	-
Q2	-	-	-	-	-
Q3	-	-	-	-	-
Q4	-	-	-	-	-

e = Morgan Stanley Research estimates

Risk Reward

Filgotinib in RA and Crohns; CF Pipeline Drive Risk-Reward



Source: Thomson Reuters, Morgan Stanley Research

Price Target	**$75**	We derive our PT from a discounted cash flow analysis that uses a WACC of 12.5% with cash flow forecasts through the 2030E expiration of the filgotinib patents. The main drivers are filgotinib royalties/milestones and CF program royalties/milestones.
Bull DCF	**$107**	**Filgotinib and CF assets are still the major driver, but we assume greater share in RA. We assume:** 1) ~$1B in 2030E from royalties from partner on sales of filgotinib in RA; 2) filgotinib milestones from partner of ~$1B; 3) CF program royalties from partner of ~$700M in 2030E; 4) Crohn's program royalties from partner of ~$200M in 2030E 5) CF program development/commercial milestones of $350M.
Base DCF	**$75**	**Filgotinib and CF assets drive our forecast. We assume:** 1) ~$750M in 2030E from royalties from partner on sales of filgotinib in RA; 2) filgotinib development/commercial milestones from partner of $1B; 3) CF program royalties from partner of ~$700M in 2030E; 4) CF program development/commercial milestones of $350M.
Bear Cash/ Share value	**$10**	**Filgotinib and the CF pipeline assets fail but management continues to invest in R&D.** We assume the cash/share value.

Investment Thesis

- We are OW Galapagos as we believe that the filgotinib and the CF pipeline are differentiated and can take share.
- **Filgotinib has a differentiated profile versus its oral competitors - both Xeljanz and baracitinib.** We believe it has best in class efficacy with a cleaner safety profile, especially on anemia. We believe that mgt. will find a suitable partner for filgotinib with commercial leverage and that filgotinib could position as a best in class oral agent. We model ~$3B in peak sales.
- We expect mgt. to find a partner for filgotinib with a deal similar or better to the one they had with AbbVie. AbbVie turned down the rights to filgotinib but have not been able to demonstrate their own internal compound is superior.
- The CF franchise has a competitive emerging profile with the second generation corrector entering the clinic in 2016 and preclincial data suggesting CFTR restoration rates above Kalydeco. We believe there is significant unmet need for new CFTR modulators/potentiators.

Key Value Drivers

- The main drivers are 1) Finding a partner to license Filgotinib in a deal similar or better to the prior one with AbbVie and 2) advancement of filgotinib and the CF pipeline.

Risks to Achieving Price Target

- Partnership Risk: Mgt. may not be able to find a partner for a deal similar to the one with AbbVie for filgotinib.
- Development Risk: Phase III RA studies take significant time and the Phase II profile does not assure unknown side-effects in the larger Phase III program. Further, the CF assets are just entering the clinic, so safety/efficacy are not well understood.
- Approval Risk: Regulatory approval is not assured and there is potential for failure to gain approval in one or more geographies.
- Commercial Risk: The RA and CF markets are competitive with a number of marketed agents along with agents in development.

Analysis

Filgotinib Crohns Study

Galapagos is studying filgotinib in a 20 week Crohn's Disease (CD) study enrolling ~180 patients. Data is expected in early December from this study. There are two doses of filgotinib being studied - 100mg and 200mg QD. Patients will receive 200mg QD during the 1st 10 weeks and then be re-randomized to two potential maintenance doses. The study (**details available here**) has three key features:

- **Endoscopic enrollment criteria** - This is one of the most important criteria in the study. Using endoscopy ensures that all patients in the study have active Crohn's disease. This should limit the placebo response and allow differentiation by the drug (assuming it is active). Further, given that endoscopies are taken at baseline and week 10, there should be sufficient information to make a clear dose determination.
- **10 week primary endpoint** - Unlike the Pfizer study of tofacitinib which used a 4 week primary endpoint, filgotinib has a 10 week primary endpoint in its study which should allow it to separate from placebo given the longer follow-up. Further, as described above, the 10 week endpoint will also use endoscopy to confirm response. Finally, there is another 10 weeks to measure maintenance response.
- **Lack of anemia** - Filgotinib's lack of anemia positions it well in this population where anemia would create worsening disease. Thus, anemia should not be a detriment to achieving efficacy.

Why Pfizer's failure with tofacitinib doesn't mean filgotinib will fail

For Crohn's disease (CD) Pfizer conducted a randomized, double-blind, placebo-controlled, multicenter Phase II study that evaluated 139 subjects with moderate to severe CD over four weeks. Patients were randomized to one of four groups given 1mg (n=36), 5mg (n=34), 15mg (n=35) or placebo (n=34) twice daily. The primary endpoint was clinical response defined as a reduction in CDAI score of at least 70 points. There was not a significant impact on CDAI70 by tofacitinib at any dose with a placebo responder rate (47.1%) similar to all the doses 1mg BID (36.1%), 5mg BID (57.6%) and 15mg BID (45.7%).

We believe there are at least three potential issues with the tofacitnib study in Crohn's disease which could have lead to its failure:

- **Baseline screening issues** - In the Phase II, patients were entered into the study based on radiographic or endoscopic evidence of disease within the last 24 months. There is a potential issues that some patients were misdiagnosed or did not have active disease when entering the study. This could in part explain the high placebo rate.

- **AEs, especially anemia** - Tofacitinib has a significant impact on Hb levels while patients with Crohn's disease already have anemia. Thus, this impact could have offset some of the positive impacts on the inflammatory cytokines. Remember that filgotinib does not have this same impact and actually improves Hb.

- **Short duration -** In the Pfizer study the induction period was only 4 weeks and only response rate was analyzed. In fact, Pfizer has recently completed a second Crohn's study with an 8 week induction period which could demonstrate an effect. Recall that filgotinib is being

studied for 10 weeks as an induction agent, likely allowing it plenty of time to have an impact. Further, there will be endoscopic data at both baseline and study end for filgotinib reducing the potential negative impact from a high placebo response.

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(as of October 31, 2015)

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STOCK RATING CATEGORY	COVERAGE UNIVERSE COUNT	COVERAGE UNIVERSE % OF TOTAL	INVESTMENT BANKING CLIENTS (IBC) COUNT	INVESTMENT BANKING CLIENTS (IBC) % OF TOTAL IBC	INVESTMENT BANKING CLIENTS (IBC) % OF RATING CATEGORY
Overweight/Buy	**1210**	**36%**	**340**	**43%**	**28%**
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Not-Rated/Hold	**91**	**3%**	**9**	**1%**	**10%**
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TOTAL	**3,397**		**790**		

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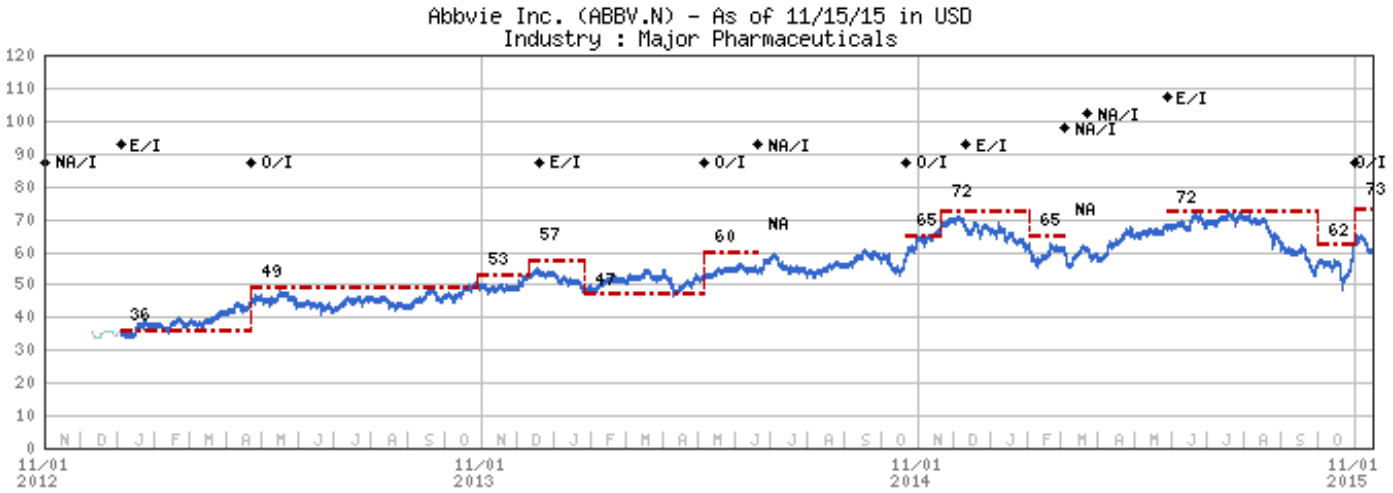
Stock Price, Price Target and Rating History (See Rating Definitions)



Stock Rating History: 11/1/12 : NA/I; 1/3/13 : E/I; 4/22/13 : O/I; 12/19/13 : E/I; 5/7/14 : O/I; 6/20/14 : NA/I; 10/22/14 : O/I; 12/11/14 : E/I; 3/4/15 : NA/I; 3/23/15 : NA/I; 5/28/15 : E/I; 11/2/15 : O/I

Price Target History: 1/3/13 : 36; 4/22/13 : 49; 10/29/13 : 53; 12/11/13 : 57; 1/27/14 : 47; 5/7/14 : 60; 6/20/14 : NA; 10/22/14 : 65; 11/21/14 : 72; 2/2/15 : 65; 3/4/15 : NA; 5/28/15 : 72; 10/1/15 : 62; 11/2/15 : 73

Source: Morgan Stanley Research Date Format : MM/DD/YY Price Target No Price Target Assigned (NA)
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Stock Ratings: Overweight (O) Equal-weight (E) Underweight (U) Not-Rated (NR) No Rating Available (NA)
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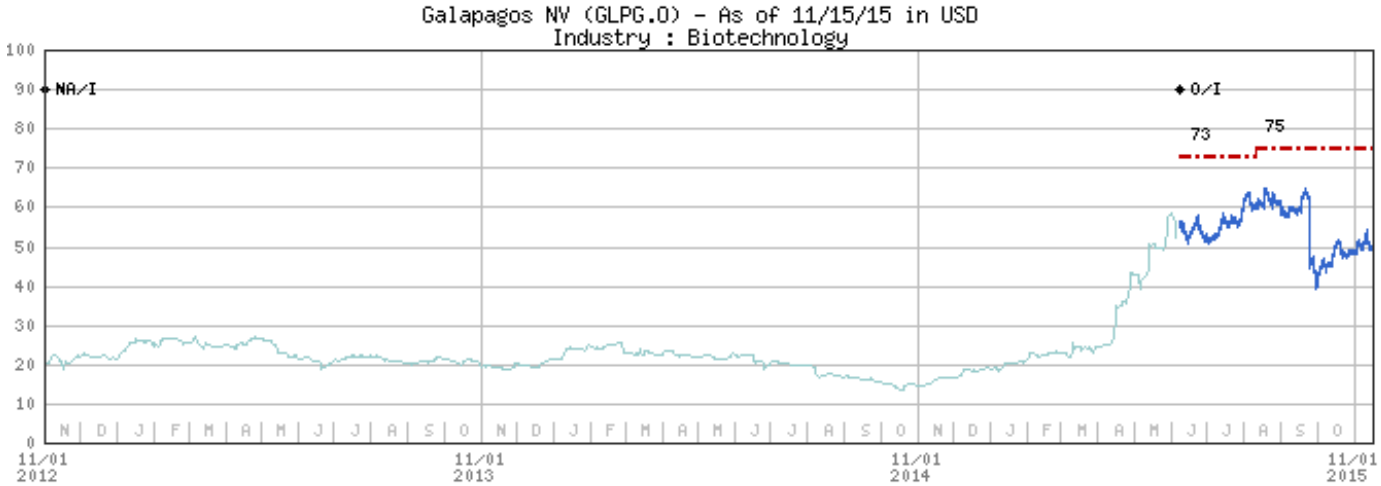

Stock Rating History: 11/1/12 : NA/I; 6/8/15 : O/I

Price Target History: 6/8/15 : 73; 8/10/15 : 75

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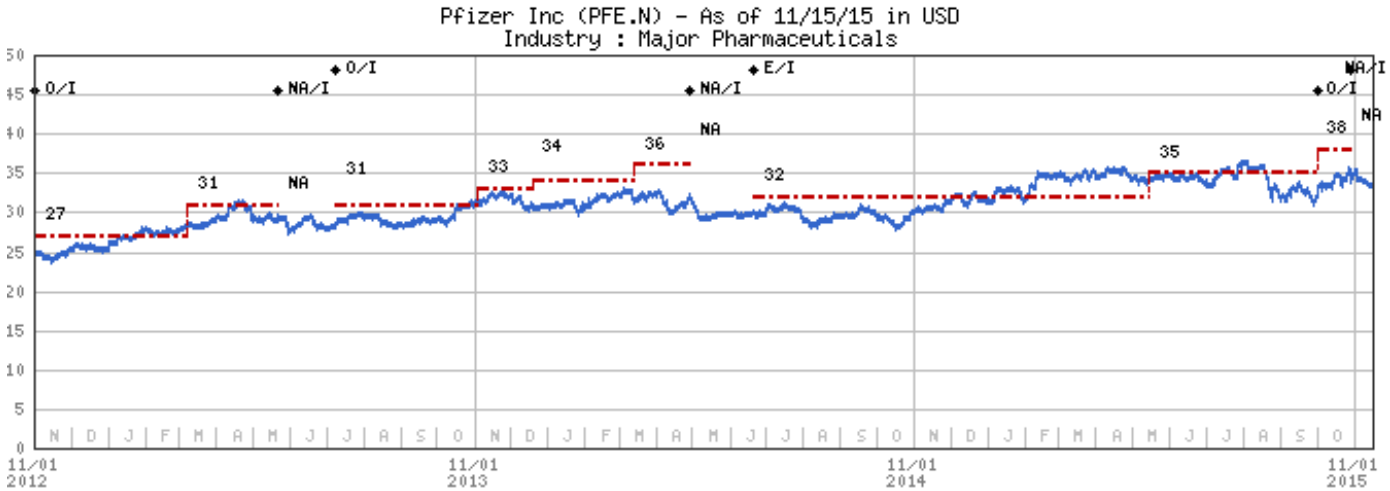

Stock Rating History: 11/1/12 : O/I; 5/22/13 : NA/I; 7/9/13 : O/I; 4/28/14 : NA/I; 6/20/14 : E/I; 10/1/15 : O/I; 10/29/15 : NA/I

Price Target History: 10/4/12 : 27; 3/7/13 : 31; 5/22/13 : NA; 7/9/13 : 31; 11/4/13 : 33; 12/19/13 : 34; 3/14/14 : 36; 4/28/14 : NA; 6/20/14 : 32; 5/15/15 : 35; 10/1/15 : 38; 10/29/15 : NA

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INDUSTRY COVERAGE: Biotechnology

COMPANY (TICKER)	RATING (AS OF)	PRICE* (11/13/2015)
Andrew S Berens		
Acceleron Pharma Inc (XLRN.O)	O (08/13/2015)	$35.47
Akebia Therapeutics Inc (AKBA.O)	O (09/09/2015)	$8.30
Cempra Inc (CEMP.O)	E (08/13/2015)	$27.63
GW Pharmaceuticals PLC (GWPH.O)	O (08/13/2015)	$82.71
Intercept Pharmaceuticals Inc (ICPT.O)	U (08/13/2015)	$181.01
Keryx Biopharmaceuticals Inc (KERX.O)	E (10/05/2015)	$5.07
Ocular Therapeutix Inc (OCUL.O)	E (10/23/2015)	$8.48
Relypsa, Inc. (RLYP.O)	U (08/13/2015)	$18.96
Rockwell Medical Inc (RMTI.O)	U (08/13/2015)	$10.01
Versartis, Inc. (VSAR.O)	E (08/13/2015)	$10.25
ZS Pharma Inc (ZSPH.O)	E (11/09/2015)	$89.56
Matthew Harrison		
Alexion Pharmaceuticals (ALXN.O)	O (10/01/2015)	$166.44
Amgen Inc. (AMGN.O)	E (01/05/2015)	$151.55
Biogen Inc (BIIB.O)	O (03/26/2014)	$284.84
Bluebird Bio Inc (BLUE.O)	O (10/05/2015)	$71.39
Celgene Corp (CELG.O)	E (03/26/2014)	$107.49
Chimerix Inc (CMRX.O)	E (10/05/2015)	$38.78
DBV Technologies SA (DBVT.O)	O (09/15/2015)	$34.82
Galapagos NV (GLPG.O)	O (06/08/2015)	$49.37
Gilead Sciences Inc. (GILD.O)	E (10/01/2015)	$102.57
Global Blood Therapeutics Inc (GBT.O)	O (09/08/2015)	$45.35
ImmunoGen Inc. (IMGN.O)	U (09/21/2015)	$12.49
Infinity Pharmaceuticals Inc (INFI.O)	O (09/21/2015)	$7.78
Ironwood Pharmaceuticals, Inc. (IRWD.O)	E (08/14/2014)	$11.87
Juno Therapeutics Inc (JUNO.O)	E (01/13/2015)	$50.00
Ophthotech Corp (OPHT.O)	O (08/14/2014)	$54.38
Portola Pharmaceuticals Inc (PTLA.O)	O (08/14/2014)	$48.96
Regeneron Pharmaceuticals Inc. (REGN.O)	E (10/01/2015)	$548.90
Regenxbio Inc (RGNX.O)	O (10/12/2015)	$23.20
Theravance Inc (THRX.O)	U (08/14/2014)	$8.86
Ultragenyx Pharmaceutical Inc (RARE.O)	E (07/27/2015)	$95.70
Vertex Pharmaceuticals (VRTX.O)	O (10/01/2015)	$123.05

Stock Ratings are subject to change. Please see latest research for each company.
* Historical prices are not split adjusted.