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Galapagos NV GLPG.OQ GLPG US

EQUITY: AMERICAS BIOTECHNOLOGY

Initiating with Buy Rating, $87 TP

Triple or Bust: Near-Term Cystic Fibrosis Catalysts Upside to Evolving Filgotinib Opportunity

- **GLPG2222 Next-Gen Corrector in Combination with Kalydeco Sets Stage for Triple Combo in 1H17.** We anticipate Phase 2a ALBATROS, results in heterozygous F508del mutation with gating mutations to provide the first inpatient validation of GLPG's '2222 corrector. We look for improvement vs. Kalydeco in FEV and sweat chloride to indicate that '2222 does not interfere with Kalydeco's metabolic profile via CYP450 inhibition (as lumacaftor does), a factor potentially limiting of Orkambi's efficacy.
- **Triple-Combo Data and Significant CF Program Data Flow Offer Potential Upside in Next 12 Months.** GLPG's triple-combination trial, which starts in 2H17, with data in 1H18, looks to address unmet need in the Het/min population (20% of CF patients). We anticipate data for '2451 next-gen potentiator for CF, with a potential QD (vs. Kalydeco BID) dosing in 2Q17. We expect data for '2737 second-corrector in 1H17 and the triple combo in healthy volunteers in mid-2017 to set expectations for 1Q18 triple data in patients. We estimate US/EU peak triple-combo sales of $3bn.
- **Long-Term Upside from Filgotinib's First-Mover Advantage in Crohn's Underappreciated.** We view the first-in-class opportunity in Crohn's and best-in-class opportunity in UC as attractive opportunities for filgotinib, given limited JAK competition relative to RA. In the FITZROY Phase 2 study, filgotinib demonstrated a placebo-adjusted 24% remission rate and 18% response. These rates are comparable those achieved with anti-TNFs, which positions filgotinib as an oral alternative to the injectables and could drive a rapid launch. Phase 3 results in Crohn's are anticipated in 2H19.
- **Filgotinib, a Potentially Best-in-Class Contender in Large RA Market, First Phase 3 Data Mid-2018.** We anticipate that the long-term evolution of the RA market will support a place for multiple JAKs similar to the biologics market in RA today. Current Xeljanz trends point to a conservative new therapeutic uptake; however, we view the 2017-18 launch of baricitinib as a proxy for potential uptake of better-tolerated JAK inhibitors in this market.
- FLORA Phase 2a data from '1690, a wholly owned autotaxin inhibitor in IPF, could, if positive, represent 2H17 upside to our target price.

Summary of Financials (€ths except per share)	2016A	2017E	2018E
Total Revenues	€ 151,612	€ 166,055	€ 199,836
Operating Expense	€ 163,103	€ 385,451	€ 426,043
Operating Income	(€ 11,491)	(€ 219,396)	(€ 226,207)
Net Income, (GAAP)	**€ 54,012**	**(€ 211,373)**	**(€ 226,442)**
Diluted EPS, (GAAP)	**€ 1.14**	**(€ 4.35)**	**(€ 4.68)**
Cash (mn)	€ 973	€ 831	€ 637
Diluted Shares Outstanding (th)	47,308	48,624	48,434

Source: Company data, Instinet estimates

Key company data: See next page for company data and detailed price/index chart.

Instinet, LLC, Equity Research

1 March 2017

Rating Starts at	**Buy**
Target Price Starts at	USD 87.00
Closing price 28 February 2017	USD 70.55
Potential upside	+23.3%

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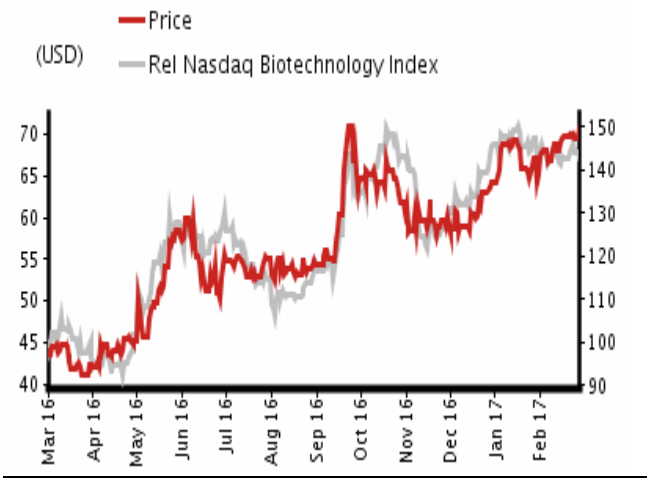
Key data on Galapagos NV

Rating

Stock	Buy
Sector	Not rated

Relative performance chart



Source: Thomson Reuters, Instinet research

Performance

(%)	1M	3M	12M
Absolute	8.4	19.3	71.9
Relative to Nasdaq Biotechnology Index	1.6	10.8	55.1

Stock price data

Current stock price ($)	70.55
Market cap ($ - mn)	3,257.3
52-week low ($)	40.91
52-week high ($)	73.37
Shares outstanding (mn)	46.17

Source: Thomson Reuters, Instinet research

Company Description

Galapagos NV is a clinical-stage biotechnology company focused on the discovery and development of small-molecule therapeutics in an area of disease with a considerable unmet need. The company's lead asset, filgotinib, is a JAK1-specific inhibitor for the treatment of inflammatory diseases. Filgotinib is being studied in three Phase 3 studies for the treatment of rheumatoid arthritis and two Phase 3 studies in inflammatory bowel disease. In addition, the company is developing a triple-combination therapy for the treatment of cystic fibrosis. One of the components of this combo demonstrated positive results in a Phase 2 study. The two additional compounds are in Phase 2 and 1 studies. Galapagos plans to initiate a triple-combo study in patients during 2H17.

Portfolio Manager's Summary

Cystic Fibrosis Upside Supported by a Validated JAK Base Franchise

Galapagos is a biotechnology company focused on the discovery and development of therapeutics for the treatment of autoimmune, orphan, and infectious diseases. The company's lead drug, filgotinib, partnered with Gilead, is a JAK1 inhibitor in three Phase 3 trials for rheumatoid arthritis (RA), Crohn's disease (CD), and ulcerative colitis (UC), the first of which reads out in 2H18. The company, in collaboration with AbbVie, is developing a pipeline of novel potentiators and correctors for the treatment of cystic fibrosis which will provide substantial data flow over the next 12 months.

We expect strong data flow from the company's next-generation correctors ('2222, '2851, '2737) and potentiators ('1837, '2451) for cystic fibrosis to drive appreciation of the shares in 2017. We anticipate incremental data updates to define a clinical path forward and breadth of opportunity in CF, as the company prepares to bring its triple combo to patients as early as 2H17, leading to potential 1Q18 data. Although competitor Vertex clearly has the clinical lead with the triple combo, we believe that, if Galapagos is successful in introducing a triple combo with superior tolerability, it could capture a considerable portion of the CF market. We anticipate that a successful triple combo could yield $4bn in peak sales, across the het/min, and F508del homozygous CF populations. In 2017, we expect Galapagos to exercise its option co-promote the CF program assets in the EU with AbbVie, netting a 50/50 profit split in this potentially $2bn market opportunity.

We believe that filgotinib may have the best-in-class profile among JAK inhibitors in development for RA, which should enable Galapagos to offset in part Lilly/Incyte's baricitinib three-year-plus lead time. Selective JAK1 inhibition and sparing JAK 2/3 by filgotinib could result in a better safety profile vs. baricitinib (JAK1/2 inhibitor) and Xeljanz (pan-JAK inhibitor). Filgotinib, like baricitinib, has avoided malignancies and GI perforation, which were observed with tofacitinib. We believe that lower incidences of anemia vs. baricitinib, due to selective-JAK1 inhibition, could also portend a better clinical experience for patients with RA. We await baricitinib's approval in 1H17, to assess the potential for label differentiation on safety vs. Xeljanz. In addition, we anticipate baricitinib's launch to yield insight into the potential for more rapid adoption of a new well-tolerated oral RA treatment, as our checks suggest Xeljanz's launch has been limited by poor tolerability.

In our view, the strength of filgotinib data in Crohn's and UC is underappreciated. Filgotinib, in our view, offers a first-in-class oral in Crohn's and best-in-class profile in UC. Crohn's and UC represent $8bn market opportunities that offer less direct JAK inhibitor competition than RA. Given the high unmet need in Crohn's and UC and the regular cycling of drugs, we believe that filgotinib could also penetrate this market more quickly than the uptake of unselective JAKs (Xeljanz) in RA.

Galapagos' wholly owned pipeline represents potential upside beyond 2018. In 2H17, the company will present disease-relevant biomarker data for '1690 in IPF patients, its wholly owned autotaxin inhibitor, which we view as potential upside to our target price and estimates.

Investment Summary

Investment Thesis

We are initiating coverage on Galapagos (GLPG) with a buy rating and $87 target price. We believe the company's rapidly advancing cystic fibrosis (CF) pipeline, partnered with AbbVie, will drive shares higher in the next 12 months. We also anticipate an increasing focus on filgotinib's opportunity in Crohn's disease, and ulcerative colitis (UC) in Phase 3 trials, may lead to upside in shares over the next 12-months. In our view, the current valuation is predominantly supported primarily by the blockbuster opportunity for the company's lead oral JAK1 inhibitor, filgotinib (partnered with Gilead), for the treatment of rheumatoid arthritis.

Valuation

- We arrive at our target price of $87 based on a DCF valuation of cash flows from 2018 to 2028, using a 15% discount rate and a 2% terminal growth rate.
- Our DCF is supported by commercialization of filgotinib in rheumatoid arthritis, Crohn's disease (CD), and ulcerative colitis (UC), and by commercialization of Galapagos' triple combo in cystic fibrosis.
- We forecast a US launch of filgotinib in RA in 2020, followed by an EU launch a year later, with sales estimates of $1.7bn in 2025, resulting in ~$400mn in royalties.
- For CD, we forecast a 2021 US launch, and a 2022 EU launch. We model ~$1.2bn in sales estimates in 2025 and ~$230mn in royalties in the same year.
- In UC, we forecast a 2022 US and a 2023 EU launch. We model ~$200mn in sales in 2025 and $52mn in royalties.

In CF, we forecast a 2021 US launch and a 2022 EU launch, and we model sales in the F508del and het/min populations alone. We apply a 70% probability of success to this program and arrive at $2.3bn in sales in 2025 and ~$340mn in royalties.

Fig. 1: Target Price Breakdown per Asset/Indication

Asset	Indication	Price/Share
Filgotinib	RA	$33
Filgotinib	CD	$20
Filgotinib	UC	$4
Triple comb	CF	$30

Source: Instinet estimates

Fig. 2: Galapagos DCF Valuation

(in €*000*)	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Net FCFF (€000s)	(173,636)	(174,891)	(153,550)	(55,026)	222,310	457,375	596,940	833,630	975,750	982,214	1,043,376
Growth	nm	1%	-12%	-64%	nm	106%	31%	40%	17%	1%	6%
PV of Net FCFF	(150,988)	(132,243)	(100,962)	(31,461)	110,528	197,736	224,412	272,515	277,369	242,788	224,267
									Terminal value		***8,025,978***

Discounted Cash Flow (DCF) and Equity Valuation ($th, except per share amount):	
Assumed Discount Rate (%)	*15.0%*
Discounted Net Cash Flow (2018-25)	**$1,213,338**
Terminal Growth Rate (%)	*2.0%*
Implied Terminal Year FCF Multiple	7.8x
Present Value of Terminal Value	**$2,122,772**
Terminal Value as % of total	63.6%
Enterprise Value	**$3,336,110**
Add: Net Cash	889,558
Equity Value	**$4,225,667**
Shares Outstanding 2017E (million)	48,624
Equity Value per Share	**$87**

Value per Share

Terminal Value	Discount Rate	10.0%	12.0%	15.0%	17.0%	20.0%
	1.0%	$156	$118	$84	$69	$54
	1.5%	$162	$122	$85	$70	$55
	2.0%	$168	$125	$87	$71	$56
	2.5%	$176	$129	$89	$72	$56
	3.0%	$184	$133	$91	$73	$57

Source: Instinet estimates

Potential Catalysts

Fig. 3: Galapagos Upcoming Catalysts

Date	Program	Indication	Impact	Event Description
1Q17	Translarna	CF	+	Competitor: Phase 3 study results in CF patients with nonsense mutation
1H17	Filgotinib	RA	+++	Competitor: Baricitinib PDUFA date. Interested in whether baricitinib will receive the same label as tofaitinib
1H17	Mongersen	UC	++	Competitor: Potential Phase 2 study results in UC
1H17	Ozanimod	CD	++	Competitor: Potential Phase 2 study results in CD
1H17	Otezla	CD	++	Competitor: Potential Phase 2 study results in UC
1H17	filgotinib	RA	++	Interim analysis of the LTE study in RA will be presented at the EULAR,
1H17	Filgotinib	CD	+	Additional data presentation from the FITZROY studies at the DDW conference
1H17/ACR	GLPG1972	Osteoarthritis	+	Data from first in humans study will disclose cartilage breakdown and target
1H17	GLPG1972	Osteoarthritis	+	US IND and initiation of a Phase 1b study
1H17	ABT-494	CD	++	Competitor: Phase 2 readout from AbbVie's ABT-494 in CD
1H17	VX-661	CF	++	Competitor: Vertex results from a Phase 3 study with VX-661+ivacaftor
3Q17	Triple combo	CF	++	Initiation of a triple combo study in patients
2H17	2451+2222	CF	+++	Results of a combo study in healthy volunteers
2H17	Filgotinib	CD	+	Additional data presentation from the FITZROY studies at the UEGW conference
2H17	filgotinib	RA	+	Additional data presentation at the ACR conference
2H17	VX-440/VX-152	CF	++	Competitor: Vertex triple combo data from a Phase 2 study in CF patients
2H17	VX-659	CF	+	Competitor: Vertex triple combo data from a Phase 1 study in CF patients
2H17	2222	CF	+++	Results of Phase 2 in patients study in combination with Kalydeco
2H17	2451	CF	++	Results from a FIH study
3Q17	Triple combo	CF	+++	Results of the triple combo in healthy volunteers
1Q18	Triple combo	CF	+++	Results of the in patients study with the triple combo
Early2018	Filgotinib	UC	+++	Interim analysis of the Phase 2/3 study
2H18	Mongersen	CD	+++	Competitor: Phase 2 study results
2H18	Ozanimod	UC	+++	Competitor: Phase 2 study results

Source: Company data, Instinet research

Pipeline

Fig. 4: Galapagos Development Pipeline

Drug	Target	Indication	Partner	Pre clinical / Phase I / Phase II / Phase III	Next readout
Filgotinib	JAK1	RA	Gilead	Phase III	Topline results YE18
Filgotinib	JAK1	CD	Gilead	Phase III	Topline results YE19
Filgotinib	JAK1	UC	Gilead	Phase II	Early 2018 Phase 2/3 interim analysis
GLPG1837	CFTR - potentiator	Cystic fibrosis	Abbvie	Phase II	Mid-2018: potential part of the triple combo in patients
GLPG2451	CFTR - potentiator	Cystic fibrosis	Abbvie	Phase I	1H17: Phase I results informing on a QD dosing
GLPG3067	CFTR - potentiator	Cystic fibrosis	Abbvie	Pre clinical	1H17: Phase I initiation
GLPG2222	CFTR - C1 corrector	Cystic fibrosis	AbbVie	Phase II	2H17: Phase II results of combination with Kalydeco
GLPG2851	CFTR - C1 corrector	Cystic fibrosis	AbbVie	Pre clinical	2H17: Phase I initiation
GLPG2737	CFTR - C2 corrector	Cystic fibrosis	AbbVie	Phase I	1H17: Phase I results in healthy volunteers
GLPG3221	CFTR - C2 corrector	Cystic fibrosis	AbbVie	Pre clinical	2H17: Phase I initiation
MOR106	IL-17c	Atopic Dermititis	MorphoSys	Phase I	2H17: Phase I Topline results
GLPG1690	novel	IPF		Phase II	2H17: Phase 2a topline results, informing on biomarker data related to the level of autotaxin inhibition
GLPG1972	novel	Osteoarthritis	Servier	Phase I	1H17: IND and Phase 1b study in the US

Source: Company data, Instinet research

Cystic Fibrosis

- Cystic Fibrosis is a genetic disease caused by mutations in the Cystic Fibrosis Transmembrane Receptor (CFTR), resulting in impaired cellular chloride transport.
- The lack of chloride transport leads to high salt concentration within cells, which draws water from the airway surface liquids (ASL) that coat the lungs.
- The lack of sufficient ASL in the lungs increases the susceptibility of infections and increased mucus production, all of which leads to a high inflammatory activity in the lungs, resulting in lung damage.
- There more than 1,700 mutations linked to cystic fibrosis. These mutations are generally classified into six categories (Figure 5).

Fig. 5: Different Mutation Classes in CF

CF Class	Allele Frequency	CFTR Defect	Mutation Type	Specific mutations examples	Disease Severity	Drugs
I	**6%**	No functional CFTR protein	Nonsense, frameshift, canonical splice	G542X, W1282X, R553X, 621+1G→T	Severe	Ataluren
II	**87%**	CFTR trafficking defect	Missense, amino acid deletion	**F508del**, N1303K, I507del, R560T	Severe	Orkambi approved for homozygous F508del
III	**3%**	defective gating	Missense, amino acid change	G551D, G178R, G551S, S549N	Severe	Kalydeco
IV	**<2%**	Decreased channel conductance	Missense, amino acid change	R117H, R347P, R117C, R334W	Mild	
V	**<1%**	Reduced synthesis of CFTR	Splicing defect, missense	3849+10kbC→T, 2789+5G→A, 3120+1G→A, 5T	Mild	
VI	**<1%**	Decreased CFTR	Missense, amino acid change	4326delTC, Q1412X, 4279insA	Mild	

Source: Instinet research

Fig. 6: CF Mutation Industry Classification

Vertex Mutation Classification	Number of patients	Definition
Gating Mutations	4,000	Refers to the patients who have Class III mutations. Those patients express a mutated CFTR that does not open to allow ions flow. Those patients are indicated for Kalydeco.
Residual Function	5,000	Refers to patients who carry partial activity mutations. Mostly patients with Class IV and V mutations. These patients present with a mild form of the disease. In this group, Kalydeco is only approved for R117H patients
het/min	17,000	Refers to patients who carry one F508del allele and one allele with no minimal function. Patients with Class I, II and Class III mutations which are not indicated for Kalydeco
F508del Homozygous	35,000	refers to the patients who have Class II trafficking CFTR defect . Those patients are able to produce the full length CFTR. However, the protein can reach the membrane. These patients are indicated for Orkambi.

Source: Instinet research

Cystic Fibrosis – Standard of Care

- Palliative care was the mainstay of CF treatment until the introduction of Kalydeco in 2012. A daily regimen usually includes antibiotic for the treatment and prevention of lung infections, and anti-inflammatory treatment to reduce lung swelling and mucus mobilization.
- The approval of Kalydeco for the first-time offered a disease-modifying therapy for CF patients. However, this treatment only provides benefit to patients with gating mutations. These patients represent only 6% of the CF population (Figure 5).

Fig. 7: Kalydeco Efficacy in G551D Patients

		Phase 2	
Change in ppFEV1		**Trial 1**	**Trial 2**
n		161	52
Mean Absolute Change (percentage points)	Week 24	8.1	6.1
		p<0.0001	p=0.1092
	Week 48	8.6	5.1
		p<0.0001	p=0.1354

Source: Instinet research

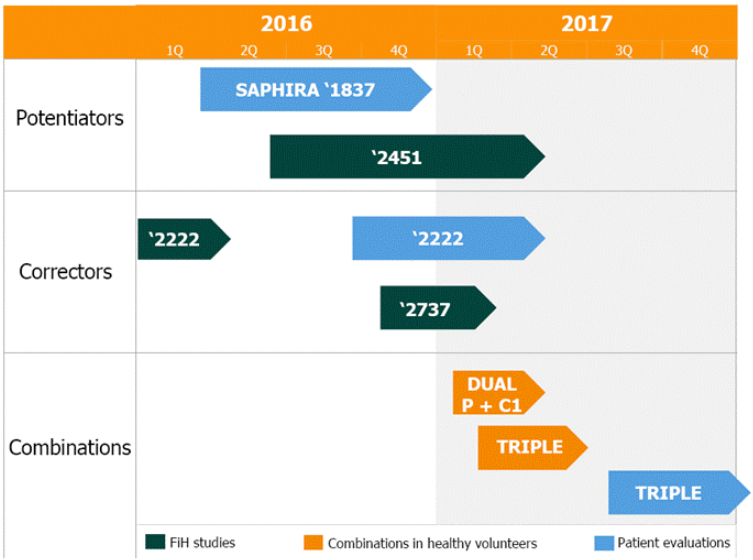
- Kalydeco is perceived as a truly transformative drug to those patients who carry the indicated mutations, to the point that some of the patients are debating whether to discontinue background treatment.
- Orkambi was approved in 2015 for the treatment of F508del homozygous patients. This patient segment represents about half of the CF population.
- The approval of Orkambi presented a new opportunity to a significant portion of the CF community. However, the small benefit that Orkambi provided to patients during the Phase 3 studies did not translate into a meaningful benefit in real life.
- While Kalydeco serves almost every eligible patient and benefits from high treatment adherence, Orkambi is prescribed to close to 40% of the eligible patients. In addition, a relatively high discontinuation rate is reported with Orkambi, which is mostly attributed to the adverse event of chest tightening during the first two months of treatment.
- Orkambi provides a suboptimal treatment to the largest portion of the CF patients, leaving the unmet need unchanged. Even in the presence of Orkambi, Galapagos's triple combo has a considerable market opportunity, if successfully developed, and provides the much-hoped-for benefit.

Galapagos's Cystic Fibrosis Program

Triple or Bust. Galapagos is focused on introducing a triple combination to the market. This strategy carefully weighs the CF treatment landscape, defining where the true unmet need remains. Galapagos has adopted an aggressive timeline and plans to advance a triple combo to patients as early as 2H17.

- GLPG is developing four CF candidates in the clinic: GLPG1873, GLPG2451, GLPG2222, and GLPG2737.
- GLPG1837 is a CFTR potentiator. This molecule shares a similar MOA with Kalydeco, as it pops open the CFTR at the membrane.
- GLPG222 and GLPG2851 are CFTR correctors. These molecules have a similar MOA to lumacaftor, as they deliver more CFTR to the cell membrane.
- Galapagos is evaluating a second potentiator, GLPG2451, and GLPG2222, a corrector, for a potentially improved PK/PD that would allow a QD dosing.

Fig. 8: Moving Toward the Triple Combo

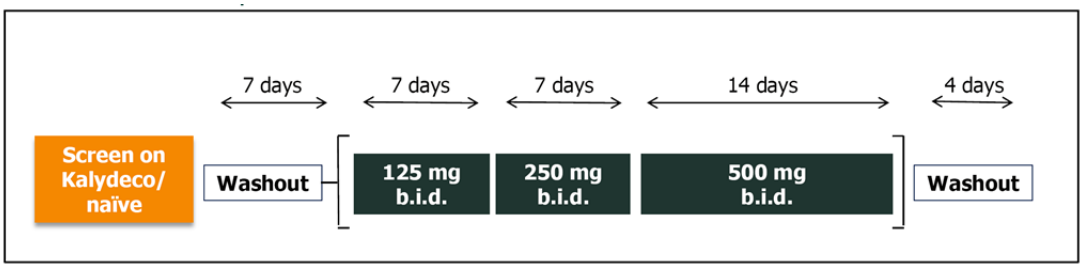


Source: Company data, Instinet research

Early Efficacy Findings

The Phase 2 SAPHIRA studies evaluated '1837 in G551D (SAPHIRA I) and S1251N (SAPHIRA II) patients. The studies suggested that '1837 has similar efficacy to ivacaftor. However, the nontraditional study design limits a direct comparison (Figure 9) with the approved drug.

Fig. 9: SAPHIRA II Study Design

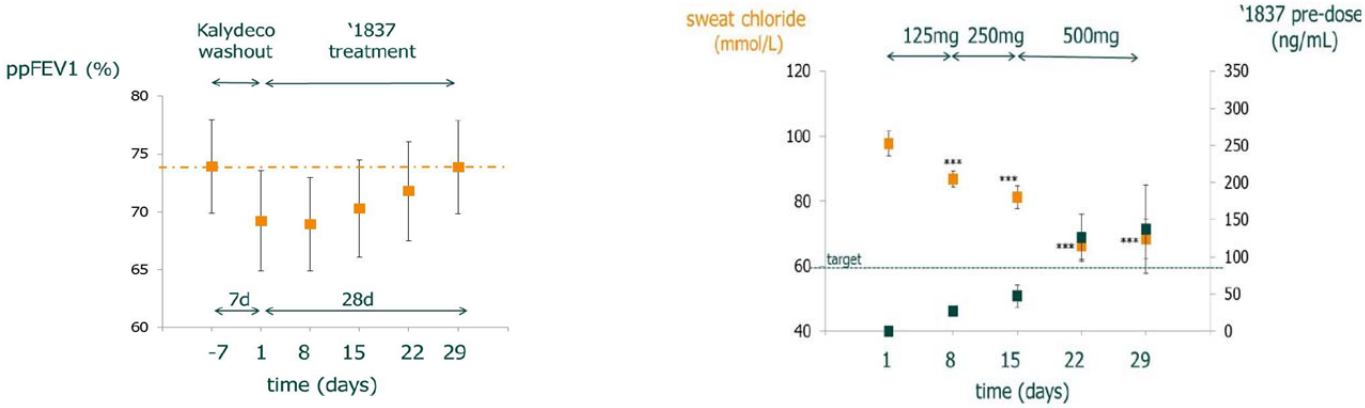


Source: Company data, Instinet research

SAPHIRA I Study Results

- Intra-patient dose escalation data showed that patients achieved a significant reduction in sweat chloride, during the first eight days on the lowest dose of '1837.
- Sweat chloride is a widely used biomarker to assess CFTR engagement. In this study, the reduction in sweat chloride followed a dose response curve and was further lowered in the 250 mg and 500 mg '1837 doses accordingly.
- In addition, the study showed that, after four weeks on '1837, patients achieved a ppFEV1 that was equivalent to the ppFEV1 achieved on Kalydeco.
- The company plans to incorporate the highest, 500 mg BID dose, into the triple combo (Figure 10).

Fig. 10: SAPHIRA I Study Shows That Patients with G551D Mutation Reached Their Kalydeco ppFEV1 Level



Source: Company data, Instinet research

SAPHIRA II Study Results

- This study tested '1837 in six patients with S1251N mutation. Three of the patients had received pretreatment with Kalydeco while the rest were Kalydeco-naïve. Due to the small size of the study, significance could not be evaluated.
- Treatment with '1837 maintained ppFEV1 in Kalydeco-pretreated patients, while increasing ppFEV1 in patients that were Kalydeco-naïve.
- In this study, 4/5 patients achieved more than 15 mmol/L reduction in sweat chloride by day 29, while one patient achieved more than 50 mmol/L reduction in sweat chloride.
- By comparison, in the Kalydeco Phase 3 study, patients achieved an average of 48.9 mmol/L reduction in sweat chloride at week 24.

Fig. 11: The SAPHIRA II Study Results Show That S1251N Patients Maintained Kalydeco ppFEV1 Levels

	Day 15 (2 wks on 62.5 mg b.i.d.)		Day 29 (2 wks on 125 mg b.i.d.)	
ΔSwCl	> 15 mmol/L	> 50 mmol/L	> 15 mmol/L	> 50 mmol/L
# Subjects	2/5	0/5	4/5	1/5

Source: Company data, Instinet research

GLPG1837 Matches Kalydeco's Activity – A First Step Toward a Triple Combo

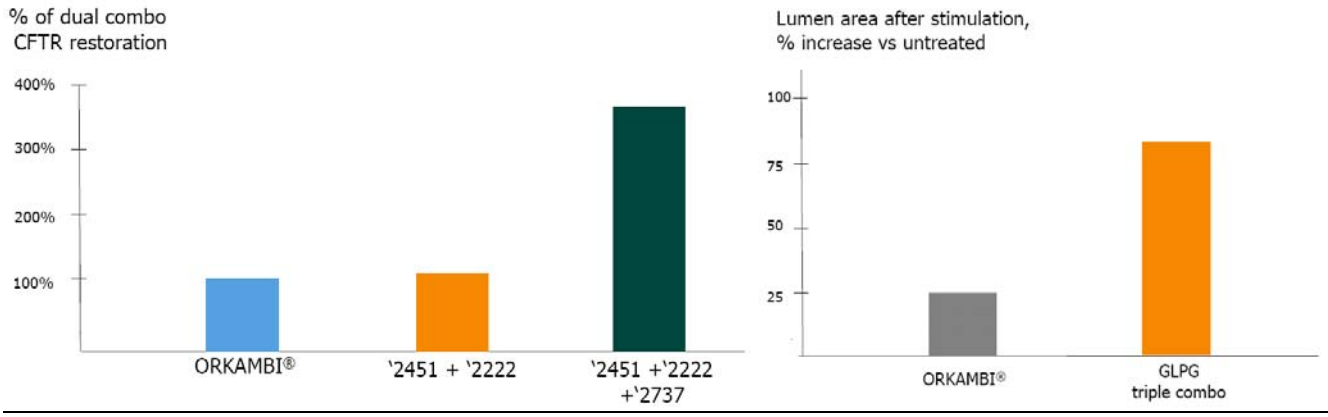
- SAPHIRA studies establish '1837 as a CFTR potentiator with activity that may match Kalydeco's. These findings represent the first piece of the triple combo.
- Galapagos is evaluating '2222, a corrector, in a Phase 2 study and is set to announce data from this study later in 2017.
- '2737, a corrector, is being evaluated in a Phase 1 study in healthy volunteers.
- The next step will be to combine the three molecules and introduce them to patents during the 2H17.

Key Safety Findings

- Two patients presented with three serious adverse events: the first patients had an elevated level of noncardiac creatinine phosphokinase, and the second patient had bowel obstruction and pulmonary exacerbation of CF, which resulted in hospitalization.
  - The most common adverse events were headaches and fatigue.
- Some patients reported respiratory adverse events during the first week, which are consistent with the symptoms of Kalydeco washout.
  - The rate of these events was lower between weeks two and four.

Fig. 12: Dual and Triple Combos Look Competitive in Vitro

Right, in F508del/F508del cells GLPG Triple achieves greater CFTR restoration vs. Orkambi / Left, Triple in het G542X/F508del organoids



Source: Company data, Instinet research

GLPG1837 Preclinical Data Show No Activation of CYP3A, Critical to the Triple Combo

- Preclinical in vitro studies with '1837 show a neutral effect on CYP enzymes inducement/ inhibition.
  - These data indicate that the drug can be safely combined with other drugs that are sensitive to CYP activity, such as ivacaftor or hormonal contraceptives.
- In contrast, lumacaftor is a strong inducer of CYP3A, leading to an 80% reduction of exposure to ivacaftor when both drugs are co-administered (i.e., Orkambi).

Key Concerns – Addressing Unmet Need Given the Current Standard of Care

- Galapagos aims to develop the triple combo in the F508del heterozygous and homozygous populations, which together comprise about 80% of CF market.
- The F508del homozygous is currently served by Orkambi. It is well accepted that Orkambi is a sub-adequate drug in this population.
- However, its presence in the market makes it extremely difficult to avoid a riskier active comparator trial in this population, in our view.
- A potential alternative clinical strategy for GLPG may include studies in the het/min population, a harder-to-treat population to which neither Kalydeco nor Orkambi are indicated.

Targeting F508del Patients

- We expect Galapagos to continue to refine the triple combo in this population in countries where Orkambi has not been approved, as patient enrollment will be easier in these territories.
- Galapagos will have to conduct a pivotal study in the US to gain FDA approval. This requirement will be a challenge in terms of study design and execution. We expect the FDA to require an active comparator, Orkambi, for the F508del population, as it will be unethical to conduct a long-term placebo arm.
- We anticipate a challenging trial enrollment in the US, as patients will be required to discontinue Orkambi upon enrollment in the study. This concern could be partly mitigated, as many patients do not see the benefit of being on Orkambi. We expect positive results from a Phase 2 study with the triple combo to motivate additional patients to enroll in the Galapagos studies.

Targeting the Het/Min Patients

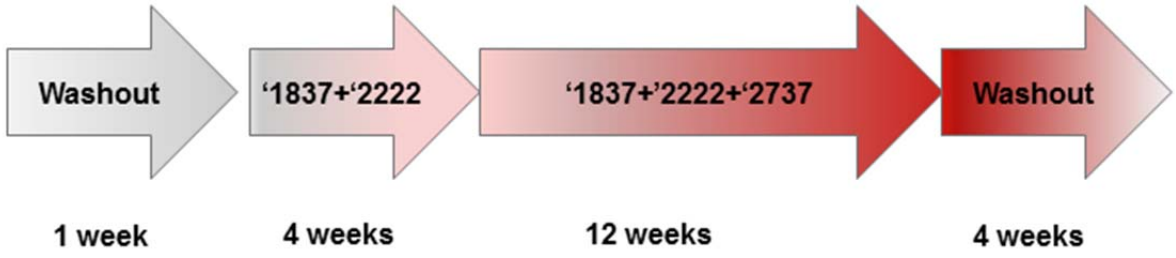
- The het/min population can provide a clear path forward for a conventional trial design, as neither Kalydeco nor Orkambi is approved for this genotype. However, this patient population is considered extremely difficult to treat, and we note the recent failure of VX-661+ivacaftor to achieve any clinical improvement in these patients.
- If Galapagos chooses to pursue development in the het/min population, we believe it can conduct its Phase 2 (and subsequent Phase 3) studies worldwide, as no treatment is approved for this population.

General Regulatory Considerations

- Galapagos plans to introduce the triple combo directly into patients without prior evaluation of the C2 corrector alone in patients or the evaluation of the dual combo in patients. We view this strategy as somewhat aggressive. We believe that in the initial Phase 2 study with the triple combo Galapagos will have to introduce each drug separately to evaluate drug-related adverse events and drug-drug interactions.
  - The combination can be evaluated in a tandem Phase 2 study design, in which each drug is added on top of the others over a pre-specified period. This design will allow for a smaller trial, albeit with a longer duration (Figure 13).
  - We believe that one of the biggest hurdles for the development of Galapagos' triple combo is the FDA requirement to test the efficacy of the individual triple combo components in the target population.

    "For combination programs, the Phase 3 program usually compares the combination to one or both of the monotherapies. . . ." (FDA briefing document, May 2015).
- Vertex was able to present data showing the lack of efficacy of Kalydeco in F508del patients; thus, the requirement to conduct an independent evaluation of each of the Orkambi components was waved.
- Given the unmet need in the het/min population and the previous dual-combo failures in this population, we believe that the FDA may demonstrate flexibility in its requirement to conduct trial with the individual combo components.

Fig. 13: Probable Phase 2 Study Design for the Evaluation of the Triple Combo in CF Patients



Source: Instinet research

The Threshold for Approval Is Set at ~3% FEV1 Improvement

- Vertex has already set the bar for approval in the F508del population, when it showed about a 3% improvement in absolute ppFEV1 across the TRAFFIC and TRANSPORT Phase 3 studies (Figure 14).
- We believe that the bar will be similar for drug approval in the het /min population, as this population presents a considerable unmet need, with no approved DMT to date.
  - However, the relatively low improvement in FEV1 with Orkambi in real-life experience makes it hard to argue for a significant treatment effect lower than 3%.

Fig. 14: The Bar for Approval Is Set at 2.8% Improvement in ppFEV1

		TRAFFIC		TRANSPORT		Pooled
Change in ppFEV1		**Placebo**	**Lum + Iva**	**Placebo**	**Lum + Iva**	**Lum + Iva**
n		184	182	187	187	369
Mean Absolute Change (percentage points)	Treatment Difference		**2.6** **p=0.0003**		**3.0** **p<0.0001**	**2.8** **p<0.0001**
	Within Group	-0.44 p=0.4002	**2.2** **p<0.0001**	-0.15 p=0.7744	**2.9** **p<0.0001**	**2.5** **p<0.0001**
Mean Relative Change (%)	Treatment Difference		**4.3** **p=0.0006**		**5.3** **p<0.0001**	**4.8** **p<0.0001**
	Within Group	-0.34 p=0.7113	**4.0** **p<0.0001**	0.0 p=0.9983	**5.3** **p<0.0001**	**4.6** **p<0.0001**

Source: Company data, Instinet research

The Evolving Competitive Landscape

- The discontinuation rate with Orkambi is ~15% during the first three months of treatment.
- We believe that any tolerability issues with the future triple combos will decrease treatment adherence, resulting in increased breakthroughs and the misinterpretation as an ineffective treatment.
- Vertex clearly has the clinical lead with the triple combo, in our view.
- However, if Galapagos is successful in introducing a triple combo with a superior tolerability, we believe that it could capture a considerable portion of the CF market.

Tezacaftor (VX-661) + Ivacaftor

A next-generation Orkambi a dual combo for F508del homozygous patients.

- Vertex is evaluating tezacaftor (VX-661) in combination with ivacaftor (Kalydeco) in a Phase 3 study in F508del homozygous patients.
- The study is set to report top-line results by 1Q17.
- If approved, the combination of tezacaftor (VX-661)+ivacaftor will provide an alternative to F508del homozygous patients who do not benefit from the treatment with Orkambi or cannot tolerate Orkambi (chest tightening side effects).

Early VX-661 + Ivacaftor Efficacy Findings

- In a Phase 2 in 34 patients, the combination of VX-661 and ivacaftor resulted in mean absolute change from baseline in ppFEV1 of 4.4% in week 4 and 3.0% in week 12. By comparison, the placebo group showed a mean change of -0.4% in week 4 and 1.0% in week 12 (Figure 15).

Fig. 15: Efficacy of VX-661 + ivacaftor

F508del homozygous patients

		Phase 2	
Change in ppFEV1		**VX-661 + Iva**	**Placebo**
n		15	18
Mean Absolute Change (percentage points)	Week 4	4.4	(0.4)
		p=0.009	p=0.827
	Week 12	3.0	1.0
		p=0.026	p=0.451

Source: Company data, Instinet research

Key Safety Findings

- Pulmonary exacerbations were the most common adverse event, which occurred in 38% of the patients who received the combo vs. 44% of the patients in the placebo group.
- Cough was reported in 33% of the patients in the treatment arm vs. 6*% of the patients in the placebo group.
- There was no mention of chest tightening. The leading adverse event for Orkambi discontinuation.

Triple Combo: Ivacaftor+VX661+VX-440/VX-152

Vertex has the most advanced triple combo in clinical development. However, notable safety issues may stand in the way of successful commercialization.

- Vertex recently announced that it is advancing two new correctors, VX-440 and VX-152, to Phase 2 studies in combination with VX-661(tezacaftor) and in patients who are F508del homozygous or who carry one F508del allele and one allele with a minimal CFTR function (het/min).

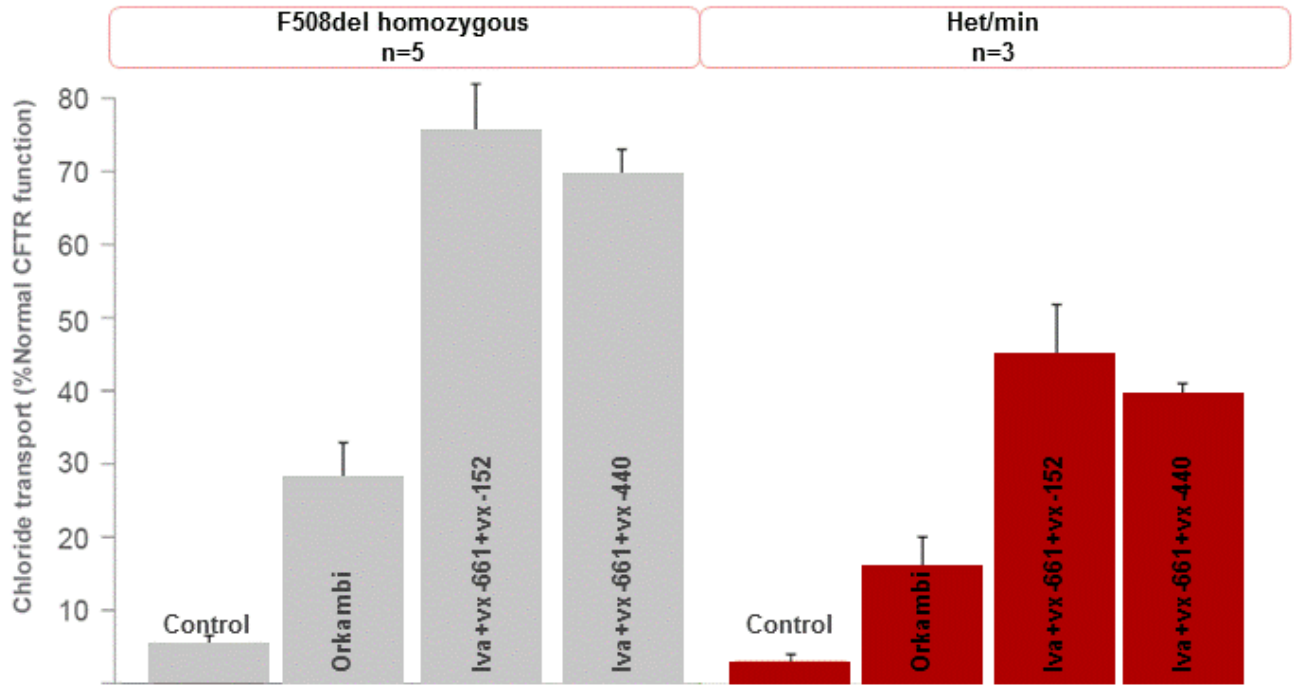
Early Ivacaftor+VX661+VX-440/VX-152 Efficacy Findings

- VX-152 and VX-440, next-gen correctors, were previously tested in Phase I studies in healthy volunteers; thus, efficacy data is not available.
- Data from in vivo studies in bronchial epithelial cell from CF patients evaluated the ability of the triple combo to increase chloride transport. The data suggest that the triple combination is superior to Orkambi in both the F508del homozygous patients and the het/min patients (Figure 16).

Key Safety Findings

- In a Phase 1 study with VX-152 in healthy volunteers, the drug was associated with increased nausea and vomiting.
- Preclinical animal studies with VX-440 suggest that this compound has teratogenic properties (can impact embryonic development). Therefore, the combination of VX-440 and VX-661, which induces cytochrome p450, can limit the use of hormonal contraceptives.

Fig. 16: In vivo Efficacy of Vertex Triple Combo



Source: Company data, Instinet research

CTP-656 – Deuterated Kalydeco

A deuterated Kalydeco with an improved PK/PD profile.

- Concert Pharma is evaluating CTP-656 in a Phase 2 study in CF patients with gating mutations who are stable on Kalydeco.
- The study is designed to enroll up to 40 patients who will be randomized to receive 20 mg, 100 mg, or 150 mg of CTP-656, or placebo. An open-label Kalydeco arm will run in parallel.
- Patients will be dosed for four weeks. The primary endpoint of the study is the change in sweat chloride. The secondary endpoints will evaluate the change from baseline in ppFVE1.
- The study is set to report top-line data by YE2017.

Early Efficacy Findings

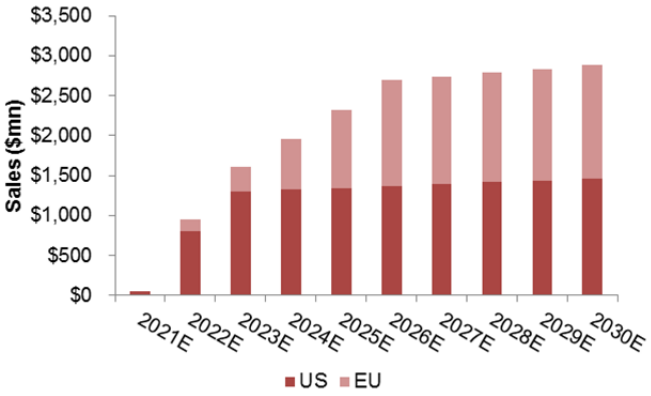
- CTP-656 was evaluated in a Phase I study in healthy adults.
- This study indicated that CTP-656 has a favorable PK/PD profile to ivacaftor. The AUC for CTP-656 was 22,452 ng*hr/mL compared with 7922 for Kalydeco.
- These data suggest that CTP-656 can provide a better exposure than ivacaftor. Given the identical structure of the two compounds, one can assume that increased exposure can result in increased efficacy.

Cystic Fibrosis Market Opportunity

- We model the sales of the triple combo in homozygous F508del patients and the het/min patients alone, which together comprise ~17,000 patients worldwide.
- Given the aggressive timelines adopted by Galapagos, we believe that the company can launch the triple combo as early as 2021.
- In the US, we model peak penetration of 40% at 2023, which is in line with the launch of Orkambi.
- In the EU, we forecast the launch or 2022 to account for the longer review times.
- We model 40% peak penetration in the EU in 2026 to account for the country-by-country reimbursement process.

Fig. 17: Cystic Fibrosis Market Opportunity

Cystic Fibrosis	US	EU
Prevalence of CF (000)	33,900	39,287
% available for treatment	60%	60%
Peak penetration	40%	40%
Average annual cost per patient	221,107	189,065
Patients treated in peak year	8,383	9,901
Valuation year sales est. ($mn)	$1,297	$1,323



Source: Instinet estimates

Filgotinib

A specific JAK1 inhibitor for the treatment of rheumatoid arthritis (RA), Crohn's disease (CD), ulcerative colitis (UC), and beyond.

- Early safety and efficacy data for filgotinib support its development across different inflammatory diseases, and JAK inhibition has been clinically validated by competitors across several indications.
- Galapagos and partner Gilead have initiated five studies in three indications: RA, CD, and UC (Figure 18).
- Specifically in RA, Galapagos and Gilead are conducting an extensive Phase 3 program to support NDA across all lines of treatment.

Fig. 18: Filgotinib Development Program

	Study	NCT#	Indication	n	Arms	Endpoint	Topline
RA	FINCH-1 monotherapy	NCT02889796	RA, MTX-IR	1,650	4	ACR20 @W12	YE19
RA	FINCH-2 monotherapy	NCT02873936	RA,TNF-IR	423	3	ACR20 @W12	YE18
RA	FINCH-3 Add-on to MTX/monotherapy	NCT02886728	RA, MTX naïve	1,200	4	ACR20 @ W24	1H20
CD	DIVERSITY-1/2	NCT02914561	CD - induction CD- maintenance	1,320	3	PRO2 @W10, Endoscopic response @W10 PRO2 @W58, Endoscopic response @W58	1H20
UC	SELECTION-1/2	NCT02914522	UC - induction UC maintenance	1,300	3	MCS @W10 % remission by MCS @W58	1H20

Source: Company data, Instinet research

JAK Market Opportunity in Inflammatory Disease

- Inflammatory disease is a highly competitive market with many existing treatment alternatives, and many more new treatments to come.
- In rheumatoid arthritis, we model filgotinib launch as early as 2020.
- We forecast a peak penetration rate of 4% in the moderate to severe RA population, an assumption that is in line with the Phase 3 trial population. The low penetration rate also accounts for the high competition in this market.
- In Crohn's disease and ulcerative colitis, we forecast the launch to 2022, with peak penetration of 20% in CD and 8% in UC in 2024.
- We attribute a higher penetration rate in this market to less direct competition in IBD.

Filgotinib in the RA Market – Safety First

- The RA market is expected to grow to $80bn by 2020.
- The RA market is currently dominated by anti-TNF injectable drugs, which offer a compelling risk/benefit profile.
- Xeljanz (tofacitinib) is the first JAK inhibitor approved for the treatment of RA. The drug has a black-box warning against the increased risk of infections and malignancies.
- Despite being the only orally available disease modifying therapies (DMT) besides methotrexate, tofacitinib (Xeljanz) was not widely adopted by physicians and patients (Figure 19). Both are unwilling to compromise safety for the convenience of an orally administered drug, often citing the increased risk of serious infections and malignancies as the main reasons.
- These concerns, coupled with the lack of clear efficacy advantage over anti-TNFs, position Xeljanz as the last line of treatment to many patients with RA.
- This market dynamics creates a considerable opportunity for an oral drug with a compelling risk/benefit profile.

Fig. 19: Safety Concerns Are Reflected in the Volatile Sales of Xeljanz

Source: Company data, Instinet research

Key Efficacy Findings

Filgotinib demonstrated compelling efficacy in the DARWIN studies.

- Filgotinib efficacy looks superior to tofacitinib, but comparable to both baricitinib and ABT494, positioning filgotinib in line with the competition (Figure 20).
- In the Phase 2 DARWIN studies, filgotinib demonstrated a 35% improvement over placebo on ACR20 in week 12 that remained consistent at week 24. These data indicate a rapid improvement in RA symptoms.
- Baricitinib demonstrated 28% improvement in RA symptoms within 12 weeks and 19% improvement within 24 weeks. We believe that, based on a trial-to-trial comparison, these outcomes are roughly similar.

Fig. 20: Filgotinib Efficacy Is in Line with the Competition

Drug/Study	Study Arm	n	ACR 20			ACR 50			ACR 70		
			4 wk	12 wk	24 wk	4 wk	12 wk	24 wk	4 wk	12 wk	24 wk
Filgotinib Phase 2b study DARWIN 1 (add-on to MTX)	Placebo	86		45%	42%		15%	17%		8%	9%
	50 mg QD	82		56%	55%		32%	35%		16%	22%
	25 mg BID	86		57%	56%		28%	35%		14%	21%
	100 mg QD	85		62%	60%		39%	46%		20%	33%
	50 mg BID	85		59%	60%		34%	35%		19%	24%
	200 mg QD	86		69%	73%		43%	50%		24%	29%
	100 mg BID	84		80%	80%		55%	55%		31%	39%
Filgotinib Phase 2b study DARWIN 2 (Monotherapy)	Placebo	72		31%			11%			4%	
	50 mg QD	72		67%	57%		36%	32%		8%	19%
	100 mg QD	70		66%	77%		34%	40%		19%	26%
	200 mg QD	69		73%	68%		44%	45%		13%	25%
Baricitinib Phase 3 study (RA-BEACON, TNF-IR)	Placebo	176	26%	27%	27%	6%	8%	13%	2%	2%	3%
	2 mg	174	39%	49%	45%	12%	20%	23%	3%	13%	13%
	4mg	177	51%	55%	46%	13%	28%	29%	3%	11%	17%
Baricitinib Phase 3 study (RA-BUILD, csDMARDS-IR)	Placebo	228	29	39%	42%	6%	13%	21%	3%	3%	8%
	2 mg baricitinib	229	52	66%	61%	9%	34%	41%	9%	18%	25%
	4mg baricitinib	227	54	62%	65%	14%	33%	44%	9%	18%	24%
ABT-494	Placebo			34%			16%			4%	
Phase 2 study	3 mg, BID			53%			24%			13%	
BALANCE-1	6 mg, BID			58%			36%			26%	
TNF-IR	12 mg, BID			71%			42%			22%	
	18 mg, BID			67%			38%			22%	
ABT-494	Placebo			43%			18%			6%	
Phase 2 study	3 mg, BID			62%			38%			22%	
BALANCE-2	6 mg, BID			68%			46%			28%	
MTX-IR	12 mg, BID			80%			50%			16%	
	18 mg, BID			64%			40%			26%	
	24 mg, QD			76%			39%			22%	
Tofacitinib Phase 3 study (SYNC)	Placebo	131			31%			13%			3%
	5mg tofacitinib +DMARD	132			53%			34%			13%
	10mg tofacitinib +DMARD	133			58%			37%			16%
Tofacitnib Phase 3 study (SOLO)	Placebo	120		27%	60%		13%	32%		6%	18%
	5mg tofacitinib +DMARD	241		60%	70%		31%	40%		15%	20%
	10mg tofacitinib +DMARD	242		66%			37%			20%	
Tofacitinib Phase 3 study (STEP)	Placebo	131		24%				8%		2%	
	5mg tofacitinib +DMARD	132		42%				27%		14%	
	10mg tofacitinib +DMARD	133		48%				28%		11%	

Source: Instinet research

Key Safety Findings

Filgotinib Phase 2 safety profile looks better than tofacitinib, but further validation is needed in a Phase 3 study.

- The DARWIN Phase 2 studies indicated that the rate of serious infection with filgotinib is in line with the rate observed with other JAK inhibitors. No malignancies were reported in the Phase 2 studies, one of the key safety concerns expressed by the regulatory authorities in regard to tofacitinib (Figure 21).
- While the safety profile observed in the DARWIN studies is encouraging, the drug will have to be further validated in Phase 3 studies and long-term extension studies. We believe that maintaining a low rate of serious infections and malignancies is imperative to effectively compete in the RA market.
- The correlation between the duration of patients' exposure to tofacitinib and the increased risk of serious infections and malignancies was a key concern in the FDA review of the tofacitinib NDA. This concern resulted in a black-box warning and required Pfizer to conduct a long-term active comparator safety study.
- Baricitinib (LLY/INCY), a JAK 1/2 inhibitor, had three cases of cancer in the 4 mg arm of baricitinib across the two studies. Two of the cases emerged over the 24-week period.

- This signal was partly mitigated by a meta-analysis of baricitinib safety profile across all studies and the ongoing LTE study (presented at the EULAR 2016). This analysis indicated that no increase in the incidence of AE, including serious infections and malignancies, was observed in the baricitinib groups vs. placebo.
- Given that JAK inhibitors present a new class of molecules for the treatment of RA, the FDA may reflect its safety concerns across the whole class. These concerns can result in an identical black-box warning to all JAK inhibitors and similar requirements for a safety trial. We believe that the approval of baricitinib will be informative as to whether the FDA perceives safety as a class issue (PDUFA date 03/28/2017).

Fig. 21: Key Safety for Filgotinib and Competitive JAK Inhibitors

	Tofacitinib Phase 3			Baricitinib -Phase 3			Filgotinib Phase 2b				ABT-494 Phase 2b			
	Placebo	5 mg	10 mg	Placebo	2 mg	4 mg	Placebo	50 mg	100 mg	200 mg	Placebo	12 mg BID	18 mg BID	24 mg QD
Total AE	54.9%	51.0%	56.7%	56.5%	57.0%	63.5%	**48.0%**	**46.4%**	**38.2%**	**50.8%**	35.0%	62.0%	60.0%	35.0%
Serious AE	4.9%	0.4%	2.0%	4.0%	2.0%	4.0%	**4.3%**	**0.7%**	**2.4%**	**4.5%**	1.0%	6.0%	3.0%	4.0%
Dicontinuation rate due to AE	4.1%	0.8%	2.4%	3.0%	3.5%	4.5%	**4.6%**	**2.3%**	**3.0%**	**2.5%**	3.0%	3.0%	7.0%	2.0%
Malignancies (no. of cases)	1	2	3	0	0	3	**0**	**0**	**0**	**0**	0	0	0	0
Serious infection	0.0%	0.0%	0.4%	1.0%	1.0%	2.0%	**0.9%**	**0.7%**	**1.8%**	**1.3%**	1.0%	1.0%	0.0%	0.0%
Notes	Boxed warning contains serious infections, opportunistic infections, and malignancy. LDL levels were increased in the tofacitinib group.			Patients in the baracitinib group experienced reduction neutrophil count and an increase in creatinine levels and LDL.			Herpes zoster was more common in the filgotinib group.				Infections were the most common AE			

Source: Company data, Instinet research

Fig. 22: Key Laboratory Findings for Filgotinib and Competitive JAK Inhibitors

	Filgotinib				Baricitinib			ABT-494				
% patients with reduction in neutrophil count	Placebo	50 mg	100 mg	200 mg	Placebo	2 mg	4 mg	Placebo	3 mg BID	6 mg BID	12 mg BID	18 mg BID
Grade 1	1.4	0	0	2.9	<1	2%	5%					
Grade 2	0	0	0	0	<1	2%	3%	2	0	6	7	13
Grade 3	0	0	1.4	1.4	0	<1%	0	0	0	0	4	2
Grade 4	0	0	0	0				0	0	0	2	0
% patients with decreased Hb												
Grade 1	25	20.8	10	8.7	15	16	18					
Grade 2	1.4	4.2	2.9	1.4	3	8	5	0	6	9	13	20
Grade 3	0	0	0	0	0	<1	0	0	6	0	9	11
Grade 4	0	0	0	0	<1	0	0	0	0	7	4	4

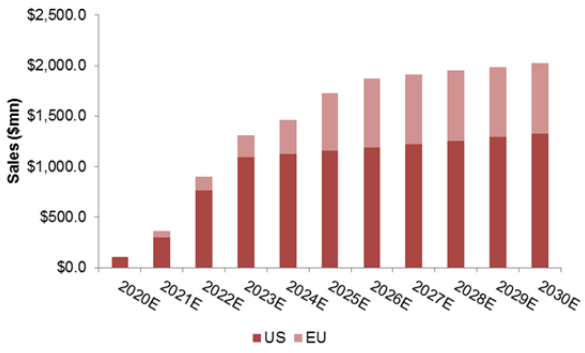
Source: Company data, Instinet research

Market Opportunity in Rheumatoid Arthritis

- We forecast a US launch of filgotinib in RA in 2020, followed by an EU launch a year later.
- We model a very low penetration rate at 4%, reflecting the high competition in this market.
- Under these assumptions, we arrive at a sales estimate of $1.7bn in 2025, resulting in ~$400mn in royalties.

Fig. 23: The RA Market Opportunity

Rheumatoid Arthritis	US	EU
Prevalence of RA (000)	2,506	3,641
% available for treatment	60%	60%
Peak penetration	4%	3%
Average annual cost per patient	18,427	10,014
Patients treated in peak year	61,957	68,349
Valuation year sales est. ($mn)	1,097	684



Source: Instinet estimates

Filgotinib in Inflammatory Bowel Disease

We view the IBD market as the larger opportunity for filgotinib. Limited development of JAK inhibitors in this space positions filgotinib as first in class.

- We estimate the IBD market at $3.2bn. However, current therapies underserve this patient population. We anticipate that the introduction of a new class of therapeutic will potentially expand this market. The leading treatment in IBD is Humira, which offers a modest improvement in disease symptoms compared to Remicade, which offers a greater improvement in CD symptoms. However, Remicade is seldom the first choice of treatment for many patients, due to the two-hour IV administration.
- This observation suggests that patients are willing to trade off lower efficacy for convenience, positioning a safe oral drug as an attractive alternative to injectable anti-TNFs.

Early Efficacy Findings in CD

- The FITZROY Phase 2 study demonstrated that treatment with filgotinib led to 24% placebo-adjusted remission rate and 18% placebo-adjusted response rate. These rates are comparable to the remission rates achieved with anti-TNFs, positioning filgotinib as an oral alternative to the injectable anti-TNFs, if safety profile is comparable.

Competitive landscape in CD

- There is a limited clinical development of JAK inhibitors in IBD. Filgotinib and ABT-494 (ABBV) are the only JAK inhibitors in development for the treatment of CD. Among the two, filgotinib is in Phase 3 and is expected to have a two-year advantage over ABT494, which will report Phase 2 study results by mid-2017.
- In CD, we expect the competition to arise from Celgene's mongersen, which demonstrated superior response and remission rates, coupled with a clean safety profile. Mongersen is in a Phase 3 study and is expected to report top-line results by mid-2018.

Fig. 24: Competitive landscape in CD

				Remission rate			Response rate			
Drug	**Target**	**Dose**	**Phase**	**Treated**	**Placebo**	**Placebo-adjusted**	**Drug**	**Placebo**	**Placebo-adjusted**	**Timepoint**
GED-0301	anti-SMAD7 antisensse RNA	10 mg	II	12.0%	10.0%	2.0%	37.0%	17.0%	20.0%	4 weeks
		40 mg		55.0%	10.0%	45.0%	58.0%	17.0%	41.0%	4 weeks
		160 mg		65.0%	10.0%	55.0%	72.0%	17.0%	55.0%	4 weeks
Tofacitinib	pan-JAK	1 mg	II	31.0%	21.0%	10.0%	36.0%	47.0%	-11.0%	4 weeks
		5 mg		24.0%	21.0%	3.0%	58.0%	47.0%	11.0%	
		15 mg		14.0%	21.0%	-7.0%	46.0%	47.0%	-1.0%	
filgotinib	**JAK1**	**200 mg**	**II**	**47.0%**	**23.0%**	**24.0%**	**59.0%**	**41.0%**	**18.0%**	**10 weeks**
Cimzia		400 mg	III	22.0%	17.0%	5.0%	35.0%	27.0%	8.0%	6 weeks
Entyvio		300mg	III	15%	7%	8%		Not significant		6 weeks
Humira		160/80mg	III	21-36%	7-12%	14-24%	52-58%	34.0%	18-24%	4 weeks
Tysabri		300mg	III	32%	21%	11%	56%	40%	16%	8 weeks
Remicade		5mg/kg	III	33%	4%	29%	81%	17%	64%	4 weeks

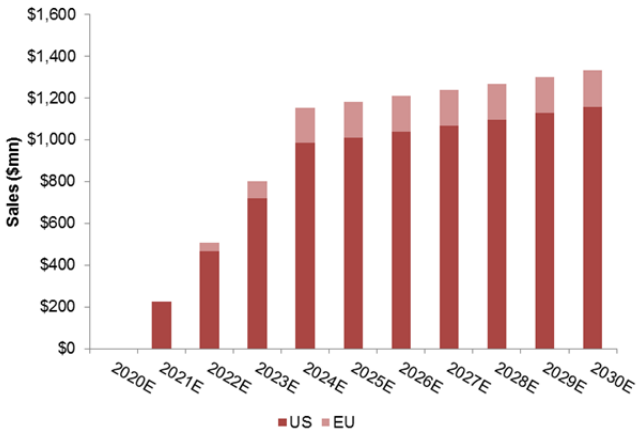
Source: Instinet research

Crohn's Disease Market Opportunity

- For CD, we forecast a 2021 US launch, with a 2022 EU launch, with a 20% peak penetration in 2024.
- We model ~$1.2bn in sales estimates in 2025 and ~$230mn in royalties (Figure 25).

Fig. 25: Crohn's Disease Market Opportunity

Crohn's Disease	US	EU
Prevalence of CD (000)	612,468	474,601
% available for treatment	45%	45%
Peak penetration	15%	8%
Average annual cost per patient	18,427	10,014
Patients treated in peak year	42,596	17,710
Valuation year sales est. ($mn)	$719	$169



Source: Instinet estimates

Filgotinib in UC

The UC market is a considerable opportunity with low competition from other oral drugs.

- Galapagos did not disclose data regarding the efficacy of filgotinib in ulcerative colitis.
- In UC, tofacitinib recently reported positive Phase 3 study results. Although the timeline for sNDA application was not provided by Pfizer, we expect the drug to be approved for this indication toward 2018. Given the safety concerns with tofacitinib, we expect a limited use of this drug in UC.
- Besides tofacitinib, we expect competition from Celgene's ozanimod, which reported a compelling risk/benefit profile in a Phase 2 study. Ozanimod is enrolling patients in a Phase 3 study, with data expected by YE18.
- Ozanimod drug class (e.g., Gilenya) is associated with bradycardia and elevated ALTs, which requires careful monitoring in the Phase 3 studies and are likely to draw the FDA's attention.

Fig. 26: Ulcerative Colitis – The Low-Hanging Fruit

				Response			Remission		
Drug	**Target**	**Dose**	**Phase**	**Treated**	**Placebo**	**Placebo-adjusted**	**Treated**	**Placebo**	**Placebo-adjusted**
Ozanimod	S1P-R	0.5 mg QD	II	14.0%	6.0%	8.0%	54.0%	37.0%	17.0%
		1.0 mg QD		16.0%	6.0%	10.0%	57.0%	37.0%	20.0%
Tofacitinib	pan-JAK	10 mg BID	III				18.5%	8.2%	10.3%
Humira	TNF-α	160/ 80 mg	III	17.5%	9.3%	8.2%	8.5%	4.1%	4.4%
Entyvio	α4β7 integrin	300mg	III	47.0%	26.0%	21.0%	42.0%	16.0%	26.0%
Remicade	TNF-α	10 mg/kg	III	69.0%	37.0%	32.0%	39.0%	15.0%	24.0%
Simponi	TNF-α	200 mg/ 100 mg	III	51.0%	30.0%	21.0%	42.0%	29.0%	13.0%

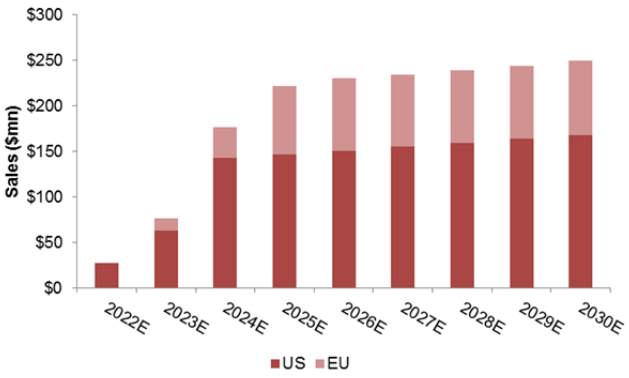
Source: Instinet research

Ulcerative Colitis Market Opportunity

• In UC, we forecast a 2022 US launch, followed by an EU launch in 2023. We model ~$200mn in sales in 2025 and $52mn in royalties.

Fig. 27: Ulcerative Colitis Market Opportunity

Ulcerative Colitis	US	EU
Prevalence of UC (000)	475,863	474,601
% available for treatment	21%	21%
Peak penetration	8%	8%
Average annual cost per patient	18,427	10,014
Patients treated in peak year	8,299	8,265
Valuation year sales est. ($mn)	$143	$75



Source: Instinet estimates

Partnerships and Collaborations

Fig. 28: GLPG'S Lead JAK and CF Programs Have Attracted Robust Partnering Interest

Partner	Indication	Drug(s)	Deal Economics	Year Signed
Gilead	Autoimmune	GLPG0634	$300mn upfront $425mn Equity investment 80% development costs funedd by Gilead $755 in development milestone payments $600 million in sales-based miledstone payments 20% and up in tiered royalties Profit split in co-promotion territories.	2015
AbbVie	Cystic Fibrosis	CFTR modulators	$45mn upfront up to $340mn in milestones double digit royalties Development co-funding	2013
Servier	Oncology		$328mn + US rights + royalties	2011
Servier	Osteoarthritis	GLPG1972	$378mn + US rights + royalties	2010
GSK	Inflammation	GSK2586184	$276mn + royalties	2006

Source: Company data, Instinet research

Fig. 29: Income Statement

(€1000s, except per share data) [FY - Dec]	2015	1Q16	2Q16	3Q16	4Q16A	2016A	1Q17	2Q17	3Q17	4Q17	2017E	2018E
US Filgotinib Sales (RA Only)	0	0	0	0	0	0	0	0	0	0	0	0
Intl Filgotinib Sales (RA Only)	0	0	0	0	0	0	0	0	0	0	0	0
US Filgotinib Sales (Crohn's)	0	0	0	0	0	0	0	0	0	0	0	0
Intl Filgotinib Sales (Crohn's)	0	0	0	0	0	0	0	0	0	0	0	0
	0											
US Filgotinib Sales (UC only)	0	0	0	0	0	0	0	0	0	0	0	0
Intl Filgotinib Sales (UC only)	0	0	0	0	0	0	0	0	0	0	0	0
Total Filgotinib Royalties	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
US GLPG- Triple Combo Royalties (CF)	0	0	0	0	0	0	0	0	0	0	0	0
Intl GLPG-Triple Combo Royalties (CF)	0	0	0	0	0	0	0	0	0	0	0	0
Total GLPG1837+Corrector Royalties	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
R&D revenue	39,563	10,121	28,674	11,214	79,510	129,519	22,274	28,956	37,643	48,935	137,807	151,588
Other Income	21,017	4,696	5,273	5,062	7,062	22,093	7,062	7,062	7,062	7,062	28,248	48,248
Total Revenues	**60,579**	**14,817**	**33,947**	**16,276**	**86,572**	**151,612**	**29,336**	**36,018**	**44,705**	**55,997**	**166,055**	**199,836**
Costs & Expenses:												
Cost of Goods Sold	0	0	0	0	0	0	0	0	0	0	0	0
R&D	129,714	27,818	34,594	34,327	42,834	139,573	55,684	72,389	94,106	122,338	344,518	378,970
SG&A	19,127	3,972	5,854	5,685	8,018	23,529	8,820	9,702	10,672	11,739	40,933	47,073
Restructuring and integration costs	1,182	422	454	396			0	0	0	0	0	0
Total Operating Expenses	**150,023**	**32,212**	**40,902**	**40,408**	**50,852**	**163,103**	**64,504**	**82,091**	**104,778**	**134,077**	**385,451**	**426,043**
Operating Income	**(89,444)**	**(17,395)**	**(6,955)**	**(24,132)**	**35,720**	**(11,491)**	**(35,168)**	**(46,073)**	**(60,074)**	**(78,080)**	**(219,396)**	**(226,207)**
Interest and Other Income (Expense), net	(30,632)	57,479	0	0	0	57,479	0	0	0	0	0	0
Interest Income	1,987	626	1,455	1,187	6,682	9,950	2,488	2,488	2,488	2,488	9,950	9,950
Interest Expense	(1,539)	(4,135)	1,129	(494)	1,808	(1,692)	(423)	(423)	(423)	(423)	(1,692)	(1,692)
Other Income (Expense)	0										0	0
Pretax Income (Loss)	**(119,627)**	**35,950**	**(4,371)**	**(23,439)**	**46,106**	**54,246**	**(33,104)**	**(44,009)**	**(58,009)**	**(76,016)**	**(211,138)**	**(226,207)**
Income tax expense (Benefit)	1,218	0	24	(95)	(164)	(235)	(59)	(59)	(59)	(59)	(235)	(235)
Net Income (Loss) as reported	**(118,410)**	**35,950**	**(3,721)**	**(24,091)**	**45,874**	**54,012**	**(33,163)**	**(44,068)**	**(58,068)**	**(76,074)**	**(211,373)**	**(226,442)**
Stock option expense	5,036	1,092	3,150	2,959	3,833	11,034	3,225	4,105	5,239	6,704	19,273	29,823
Other	0	0	0	0	0	(1,605)	0	0	0	0	0	0
Net Income (Loss) Non-GAAP	**(113,374)**	**37,042**	**(571)**	**(21,132)**	**49,707**	**63,441**	**(29,937)**	**(39,963)**	**(52,829)**	**(69,370)**	**(192,100)**	**(196,619)**
Diluted Earnings Per Share Non-GAAP	**(€ 2.90)**	**€ 0.83**	**(€ 0.01)**	**(€ 0.46)**	**€ 1.01**	**€ 1.34**	**(€ 0.62)**	**(€ 0.82)**	**(€ 1.07)**	**(€ 1.43)**	**(€ 3.95)**	**(€ 4.29)**
Basic Earnings Per Share Non-GAAP	(€ 2.81)	€ 0.81	(€ 0.01)	(€ 0.44)	€ 1.07	€ 1.39	(€ 0.64)	(€ 0.87)	(€ 1.14)	(€ 1.52)	(€ 4.16)	(€ 4.29)
Diluted Earnings Per Share	**(€ 3.03)**	**€ 0.81**	**(€ 0.10)**	**(€ 0.53)**	**€ 0.93**	**€ 1.14**	**(€ 0.69)**	**(€ 0.91)**	**(€ 1.18)**	**(€ 1.57)**	**(€ 4.35)**	**(€ 4.68)**
Basic Earnings Per Share as reported	(€ 2.94)	€ 0.79	(€ 0.10)	(€ 0.52)	€ 0.99	€ 1.18	(€ 0.71)	(€ 0.96)	(€ 1.25)	(€ 1.66)	(€ 4.58)	(€ 4.94)
Basic Shares Outstanding (th)	39,076	44,425	45,229	45,527	46,450	45,696	46,496	45,742	46,543	45,787	46,142	45,833
Diluted Shares Outstanding (th)	**40,308**	**45,492**	**46,756**	**48,328**	**49,251**	**47,308**	**48,023**	**48,542**	**49,344**	**48,588**	**48,624**	**48,434**

Source: Company data, Instinet estimates

Fig. 30: Balance Sheet

($1000s, except per share data) [FY - Dec]	2015A	2016A	2017E	2018E
ASSETS				
Current assets:				
Cash and cash equivalents	340,314	973,241	831,362	637,430
Current restricted cash	6,857	6,570	6,570	6,570
Current R&D incentives receivables	9,161	10,154	10,154	10,154
Current financial assests from share subscription agreement	8,371	0		
Short term marketable securities	0		0	0
Trade & other receivables	3,931	9,728	2,918	2,918
Inventory	325	300	300	300
Prepaid expenses and other current assets	5,512	7,239	7,239	7,239
Total current assets	**374,470**	**1,007,232**	**858,544**	**664,612**
Property and equipment, net	13,782	14,961	17,908	23,461
Goodwill	0	0	0	0
Intangible assets	1,550	1,023	1,023	1,023
Deferred tax assets/receivables	1,726	1,957	1,957	1,957
Non-current R&D incentives receivables	49,384	54,188	54,188	54,188
Non-current restricted cash	1,046	1,098	1,098	1,098
Other non-current assets	557	2,880	2,879	2,879
Total assets	**442,514**	**1,083,338**	**937,596**	**749,218**
LIABILITIES AND STOCKHOLDER'S EQUITY				
Current liabilities:				
Trade and other payables	29,482	31,269	77,090	85,209
Current obligations under finance lease	52	54	54	54
Current tax payable	2,583	1,022	1,022	1,022
Accrued charges	490	619	1,156	1,278
Deferred income	39,806	70,827	70,827	70,827
Other current liabilities	0	0	0	0
Total current liabilities	**72,412**	**103,791**	**150,150**	**158,390**
Long term debt	0	0	0	0
Obligations under finance lease	63	9	9	9
Deferred Revenue	0	214,785	214,785	214,785
Provisions	55	63	63	63
Pension liabilties	2,693	3,520	3,520	3,520
Other liabilities	2,291	2,469	2,469	2,469
Total liabilities	**77,515**	**324,637**	**370,996**	**379,236**
Stockholders' equity:				
Common Stock	185,399	223,928	223,928	223,928
Additional paid in capital	357,402	649,135	649,135	649,135
Other reserves	(18)	(1,000)	(1,000)	(1,000)
Translation differences	(467)	(1,090)	(1,090)	(1,090)
Accumulated other comprehensive loss	0	0	0	0
Accumulated Deficit	(177,319)	(112,272)	(304,372)	(500,991)
Total stockholders' equity	**364,999**	**758,701**	**566,601**	**369,982**
Total liabilities and stockholders' equity	**442,514**	**1,083,338**	**937,596**	**749,218**

Source: Company data, Instinet estimates

Fig. 31: Cash Flow Statement

($1000s, except per share data) [FY - Dec]	2015A	2016A	2017E	2018E
CASH FLOWS FROM OPERATING ACTIVITIES				
Net Income (Loss)	(118,410)	54,012	(211,373)	(226,442)
Adjustments				
Tax income/expenses	(1,218)	235	0	0
Other net financial income	(448)	(8,258)	0	0
Fair value measurment of share subscription	30,632	(57,479)	0	0
Depreciation and amortization	3,402	4,182	3,740	4,477
Net realized loss for foreign exchange transaction	(398)	1,229	0	0
Stock based compensation	5,036	11,034	19,273	29,823
Other	0		0	0
Change in assets and liabilities:				
Increase/decrease in provisions	(125)	7	0	0
Increase pension liabilities	30	244	0	0
Gain on sale of fixed assests	(62)	(14)	0	0
Inventories	(44)	25	0	0
Account receivables	(7,220)	(12,978)	6,810	0
Prepaid expenses & other assets	0	0	0	0
Accounts payable and accrued expenses	(26,728)	2,102	46,359	8,240
Interest paid	(49)	(47)	0	0
Interest received	1,106	1,066	0	0
Income taxes paid/received	(94)	(1,763)	0	0
Current obligations under finance lease	0	2	0	0
Deferred revenues & other	0	245,806	0	0
Net cash provided by (used in) operating activities	**(114,590)**	**239,405**	**(135,192)**	**(183,902)**
CASH FLOWS FROM INVESTING ACTIVITIES				
Purchases of property and equipment	(6,100)	(4,458)	(6,687)	(10,031)
Purchase of and expenditure of intangible fixed assets	(565)	(332)	0	0
Proceeds from disposal of PPE	110	18	0	0
Increase/decrease in restricted cash	2,258	235	0	0
Investments, net	0	(2,750)	0	0
Other	0	0	0	0
Net cash used in investing activities	(4,297)	**(7,287)**	**(6,687)**	**(10,031)**
CASH FLOWS FROM FINANCING ACTIVITIES				
Proceeds from issuance of shares, net cost	271,413	391,784	0	0
Exercise of options	0	4,261	0	0
Repayment obligations under finance and other debt	(43)	(49)	0	0
Repurchase of common stock	**0**	0	0	0
Other	**0**		0	0
Net cash provided by financing activities	271,370	**395,996**	**0**	**0**
Effect of exchange rate on cash	118	4,816		
Net increase in cash and cash equivalents	152,483	632,927	(141,879)	(193,932)
Cash and cash equivalents at beginning of period	187,712	340,314	973,241	831,362
Cash and cash equivalents at end of period	**340,314**	**973,241**	**831,362**	**637,430**

Source: Company data, Instinet estimates

Appendix A-1

Analyst Certification

I, Christopher Marai, hereby certify (1) that the views expressed in this Research report accurately reflect my personal views about any or all of the subject securities or issuers referred to in this Research report, (2) no part of my compensation was, is or will be directly or indirectly related to the specific recommendations or views expressed in this Research report and (3) no part of my compensation is tied to any specific investment banking transactions performed by Nomura Securities International, Inc., Nomura International plc or any other Nomura Group company.

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Materially mentioned issuers

Issuer	Ticker	Price	Price date	Stock rating	Sector rating	Disclosures
Galapagos NV	GLPG US	USD 70.55	28-Feb-2017	Buy	Not rated	A6

A6 The Nomura Group expects to receive or intends to seek compensation for investment banking services from the subject company in the next three months.

Galapagos NV (GLPG US) **USD 70.55 (28-Feb-2017)** Buy (Sector rating: Not rated)

Rating and target price chart (three year history)

Date	Rating	Target price	Closing price
27-Oct-15	Not Rated		47.69
25-Sep-15		62.00	44.60
08-Jun-15	Buy		55.51
08-Jun-15		73.00	55.51

For explanation of ratings refer to the stock rating keys located after chart(s)

Valuation Methodology We arrive at our target price of $87 for Galapagos NV (GLPG) based on a DCF valuation of cash flows from 2018 to 2028, using a 15% discount rate and a 2% terminal growth rate. The benchmark for this stock is the Nasdaq Biotechnology index.

Risks that may impede the achievement of the target price Regulatory risk: The FDA may require Galapagos to present data on the efficacy of the individual triple combo drugs in the target patient population, which would require Galapagos to conduct a large Phase 2 study. Enrollment of patients in these studies might be challenging due to the low expectation of efficacy from a single compound. For filgotinib, the FDA may issue a class label concerning the risk for serious infections and malignancies. This action will not prevent filgotinib from reaching the market, but it could create a negative perception of the drug among patients and physicians, whih would affect commercial viability of the drug. Competitive risk: Baricitinib, a JAK 1/2 inhibitor, was expected to be approved by January 19, 2017. In clinical studies, the drug presented compelling efficacy, superior to adalimumab. If baricitinib is found to be safe and approved without a black-box warning, it has the potential to take the lion's share of the market. Celgene's mongersen, a SMAD7 anti-sense RNA, showed compelling safety and efficacy profile in a Phase 2 study in CD patients. The compound is in a Phase 3 study and is set to report top-line data by 2H18. If approved, mongersen would have first-mover advantage as the only orally available DMT for Crohn's. Clinical risk: The Phase 2 study with filgotinib in CD used the CDAI as the primary outcome measure. The Phase 3 study is using the more traditional PRO as the primary outcome measure. This difference in design may result in a smaller efficacy difference between the placebo and treatment arms in the Phase 3 study.

Important Disclosures

Online availability of research and conflict-of-interest disclosures

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As at 31 December 2016.
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STOCKS

A rating of **'Buy'**, indicates that the analyst expects the stock to outperform the Benchmark over the next 12 months. A rating of **'Neutral'**, indicates that the analyst expects the stock to perform in line with the Benchmark over the next 12 months. A rating of **'Reduce'**, indicates that the analyst expects the stock to underperform the Benchmark over the next 12 months. A rating of **'Suspended'**, indicates that the rating, target price and estimates have been suspended temporarily to comply with applicable regulations and/or firm policies. Securities and/or companies that are labelled as **'Not rated'** or shown as **'No rating'** are not in regular research coverage. Investors should not expect continuing or additional information from Nomura relating to such securities and/or companies. Benchmarks are as follows: **United States/Europe/Asia ex-Japan**: please see valuation methodologies for explanations of relevant benchmarks for stocks, which can be accessed at: http://go.nomuranow.com/research/globalresearchportal/pages/disclosures/disclosures.aspx; **Global Emerging Markets (ex-Asia)**: MSCI Emerging Markets ex-Asia, unless otherwise stated in the valuation methodology; **Japan:** Russell/Nomura Large Cap.

SECTORS

A **'Bullish'** stance, indicates that the analyst expects the sector to outperform the Benchmark during the next 12 months. A **'Neutral'** stance, indicates that the analyst expects the sector to perform in line with the Benchmark during the next 12 months. A **'Bearish'** stance, indicates that the analyst expects the sector to underperform the Benchmark during the next 12 months. Sectors that are labelled as **'Not rated'** or shown as **'N/A'** are not assigned ratings. Benchmarks are as follows: **United States:** S&P 500; **Europe:** Dow Jones STOXX 600; **Global Emerging Markets (ex-Asia):** MSCI Emerging Markets ex-Asia. **Japan/Asia ex-Japan:** Sector ratings are not assigned.

Target Price
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