Goldman Sachs

Europe: Healthcare: Biotechnology

Equity Research

Looking ahead to 2017: Buy Galapagos; Innate Pharma to Neutral

2017 will be a catalyst-rich year for European biotech

2017 will be a year of key data readouts for our Europe Biotech coverage: Galapagos, Innate Pharma, Genmab and MorphoSys. Each of these companies is expecting significant news flow: Galapagos: development in cystic fibrosis; Innate Pharma: EffiKIR trial data for lirilumab; Genmab: Darzalex data in first-line multiple myeloma; and MorphoSys: incremental data for MOR-202 and MOR-208. In this note, we also roll forward our 12-month price targets to be based on the DCF value at year-end 2017.

Galapagos is our top pick

Galapagos (Buy) is our preferred name in European biotech, and we roll forward our 12-month price target to €81 (24% upside). We believe that the potential for cystic fibrosis at Galapagos is underappreciated by the market, and that 2017 will see more progress and news flow for its development, which could start to drive a reassessment.

We downgrade Innate Pharma to Neutral

Innate Pharma had a strong run at the end of 2016, and is now trading closer to our 12-month target price, which we roll forward to €18. We therefore revise our rating to Neutral (from Buy). The next catalyst that investors will be looking for is the EffiKIR study for lirilumab in acute myeloid leukemia. However, we believe that after this, focus will revert to the potential of Innate's drugs in combination therapies.

We continue to rate Genmab and MorphoSys Neutral

We raise our Genmab 12-month target price to Dkr1,370 from Dkr1,200, retaining our Neutral rating. Genmab has one of the most catalyst-rich stories for 2017, with the front-line multiple myeloma data for Darzalex key, but we believe that the shares price in success here. We roll forward our MorphoSys 12-month price target to €53. Key 2017 datapoints will be more mature data for unpartnered blood cancer assets MOR-202 and MOR-208, along with the potential approval of psoriasis drug guselkumab (partnered with JNJ).

What role could M&A play in 2017

We expect the prospect of M&A to remain a driver of valuations in 2017. However, we reduce Genmab's M&A ranking to 2 from 1 as we see fewer potential acquirers of the group given that JNJ (Genmab's partner for Darzalex) has entered into discussions with Actelion.

RATINGS AND PRICE TARGETS

	NEW Rating	NEW TP (LC)	*OLD TP (LC)*	Last close	Upside/ downside
Genmab	Neutral	1370	*1200*	1,286	7%
Innate Pharma SA	Neutral	18	*17*	15.4	17%
Galapagos NV	Buy	81	*75*	65.5	24%
MorphoSys AG	Neutral	53	*50*	48.9	8%

Source: Goldman Sachs Global Investment Research, FactSet.

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Overview: 2017 will be an important year for biotech catalysts

We assess the likely impact of the upcoming catalysts for our Biotech coverage. We expect 2017 to be a rich year for data readouts. The key data readouts investors are most focused on are EffiKIR (Innate Pharma), the progress of cystic fibrosis development (Galapagos), the data for daratumumab in front-line multiple myeloma (Genmab) and more mature data for MOR-208 and MOR-202 (MorphoSys).

Galapagos (Buy) remains the most attractive; raise 12M PT to €81

We continue to believe that Galapagos' cystic fibrosis program (partnered with AbbVie) is undervalued. This thesis has started to play out over the final quarter of 2016, but we believe that there remains valuation upside as Galapagos continues to prosecute its pipeline in 1H2017.

Galapagos has now shown efficacy data for its potentiator GLPG1837 in cystic fibrosis, which is encouraging because it effectively "solves" one part of three components needed for the triple combination therapy that Galapagos is planning to start testing in patients in mid-2017. In 2017, we await more data for individual components of Galapagos' targeted triple therapy, and in the second half of 2017, we expect Galapagos to begin dosing this in patients.

Based on rolling forward our DCF valuation to year-end 2017, we increase our 12-month price target for Galapagos to €81 (from €75).

Downgrading Innate to Neutral ahead of EffiKIR data readout

Our Buy thesis on Innate Pharma was based on our belief that the market capitalization fundamentally undervalues Innate's expertise in natural killer cell-driven immuno-oncology, and its three Big Pharma partnerships in this field. Innate Pharma has had a strong run recently, on the back of the positive efficacy data for lead drug lirilumab in combination with PD-1 drug Opdivo. We view this data as encouraging, and look forward to more readouts in other tumor types in 2017. However, given the extent of the rerating that has occurred at Innate Pharma (with the stock price increasing to €15.36 vs. our 12-month target price of €18), we see less valuation upside and therefore downgrade our rating to Neutral.

In the near term, the data readout that investors are most focused on is the EffiKIR trial for lirilumab as a monotherapy in acute myeloid leukemia (AML). The readout of this trial has been delayed due to a slower-than-expected rate of events (clinical progression). In this note, we present a deep dive of the data reported so far in AML and what this could mean for EffiKIR.

Despite the uncertainty around the outcome of the EffiKIR trial, we believe that the data seen in 2016 has established combination therapy with lirilumab as the main market opportunity, with the progress of lirilumab as a single agent less important to the ultimate sales potential for the drug. During 2017, we could see partner BMY potentially start lirilumab in its first registrational trial, in combination with Opdivo in head and neck cancer.

We roll forward our DCF valuation date to year-end 2017, and as a result, increase our DCF based target price to €18 (from €17).

Other target price adjustments

For Genmab, we increase our Darzalex sales forecasts slightly. We also explicitly model the potential sales for ofatumumab (brand name Arzerra, partnered with Novartis) in multiple sclerosis, where the drug is currently in Phase 3 trials. As a result of this, and rolling forward our DCF based valuation to year-end 2017, we increase our 12-month price target to Dkr1,370 share (from Dkr1200), and retain our Neutral rating.

For MorphoSys, we roll forward our DCF based valuation to year-end 2017, and as a result, increase our 12-month target price to €53 (from €50). We retain our Neutral rating.

What role could M&A play?

As demonstrated recently with JNJ's approach for Actelion, M&A remains an important aspect of healthcare investing. We continue to view Genmab as the most likely potential takeout candidate among our coverage, but with partner JNJ (Genmab's partner for Darzalex) entering into discussions with Actelion, we see fewer potential acquirers of the group.

We therefore reduce our M&A ranking for Genmab to 2 from 1 and consequently lower the M&A weighting in our price target to 15% from 30%. 2017 will be a catalyst-rich year for Genmab, as we will see data in first-line multiple myeloma (the single largest market opportunity for Darzalex), as well as trials in multiple other indications and in combinations.

At MorphoSys, we view full M&A as less likely, but a partnership for MOR-202 or MOR-208 (potentially after incremental data for these assets in 2017) could also deliver upside to investors. We view M&A as less likely at Innate Pharma and Galapagos, as the main value drivers in both companies are already partnered.

Overview of key catalysts

Below we show the key data points to look out for during 2017, with the most important events for each company highlighted.

Exhibit 1: Overview of key catalysts for the year

Company	Price target (lc)	Rating	Key catalysts Q1	Q2	Q3	Q4
Galapagos	81	Buy	Phase 1 data readouts for cystic fibrosis	Phase 2a readout for IPF for GLPG1690	Start of Phase 2 cystic fibrosis trial	Continuation of filgotinib ulcerative colitis trial from Phase 2b to Phase 3
Innate Pharma	18	Neutral	EffiKIR readout	Potential start of Phase 3 trial for lirilumab with Opdivo in H&N cancer	Potential early stage read outs for lirilumab combinations	Potential early stage read outs for monalizumab trials
Genmab	1370	Neutral	FY 2016 Darzalex sales and FY 2017 guidance	Potential start of Phase 3 trial for subcutaneous daratumumab	ALCYONE readout in first line multiple myeloma	Clinical updates at the ASH conference; CENTAURUS data in smoldering MM
MorphoSys	53	Neutral	Early stage readouts	ASCO meeting: updates on MOR-202 and MOR-208	Early stage readouts	ASH meeting: updates on MOR-202 and MOR-208; Potential guselkumab approval

Key:

Minor positive

Potentially larger inflection

Target prices have 12-month timeframe

Source: Company data, Goldman Sachs Global Investment Research.

Galapagos: Readouts for cystic fibrosis, eyes on triple combination

Since we raised Galapagos to Buy last October, we have seen the group report first Phase 1 data for its potentiator in cystic fibrosis, receive US$50 mn of milestones on the beginning of the Crohn's Phase 3 study, receive US$10 mn of milestones for the ulcerative colitis Phase 2b/3 trial, and US$10 mn of milestones from beginning the Phase 2 trial for its C2 corrector in cystic fibrosis.

We rate Galapagos Buy because we believe that while the market broadly prices the group's cash and collaboration for filgotinib fairly, it undervalues the rest of Galapagos' pipeline. We expect more news on this pipeline in 2017, which we believe will lead to focus on the other opportunities Galapagos has. The key value driver will be cystic fibrosis.

The next event we look for is the Phase 1 data for potential in G551D mutated cystic fibrosis patients, which we expect by year-end. In 2017, the key events we look for are the ongoing cystic fibrosis data updates and idiopathic pulmonary fibrosis Phase 2a data (which we expect in mid-2017, and which we believe is close to a free option).

The table below shows the key expected updates for Galapagos in 2017. Also during 2017, we would expect Gilead and Galapagos to start more Phase 2 trials for filgotinib.

Exhibit 2: Upcoming Galapagos catalysts in 2017

Timing	Drug	Indication	Study	Partner	Phase	Event
24/02/2017						FY 2016 results
1Q17	GLPG2737	Cystic Fibrosis		ABBV	Phase I	Data readout
1H17	GLPG2451	Cystic Fibrosis		ABBV	Phase I	Data readout
2Q17	GLPG1690	IPF	FLORA	ABBV	Phase II	Topline results phase 2a
2Q17	GLPG2222	Cystic Fibrosis		ABBV	Phase II	Data readout
Mid 2017	CF Triple combination	Cystic Fibrosis		ABBV	Phase I	Phase 2 study initiation
2H17	MOR106	Atopic Dermatitis		Morphosys	Phase I	Data readout
YE 2017	Filgotinib	Ulcerative Colitis	SELECTION	Gilead	Phase IIb	Progression into Phase 3
2017	GLPG2534	Atopic dermatitis				Phase 1 study initiation

Source: Company data, Goldman Sachs Global Investment Research.

Cystic fibrosis readouts: We believe the key clinical datapoints for Galapagos that could drive a rerating of the stock will be progress of the cystic fibrosis trials. In the first half of 2017, we will look for data from Galapagos' tests of single agents in healthy volunteers and patients, as the group seeks to identify the three components for its triple combination. Galapagos continues to state that it is on track for beginning the Phase 2 trial of its triple combination therapy in cystic fibrosis patients in mid-2017.

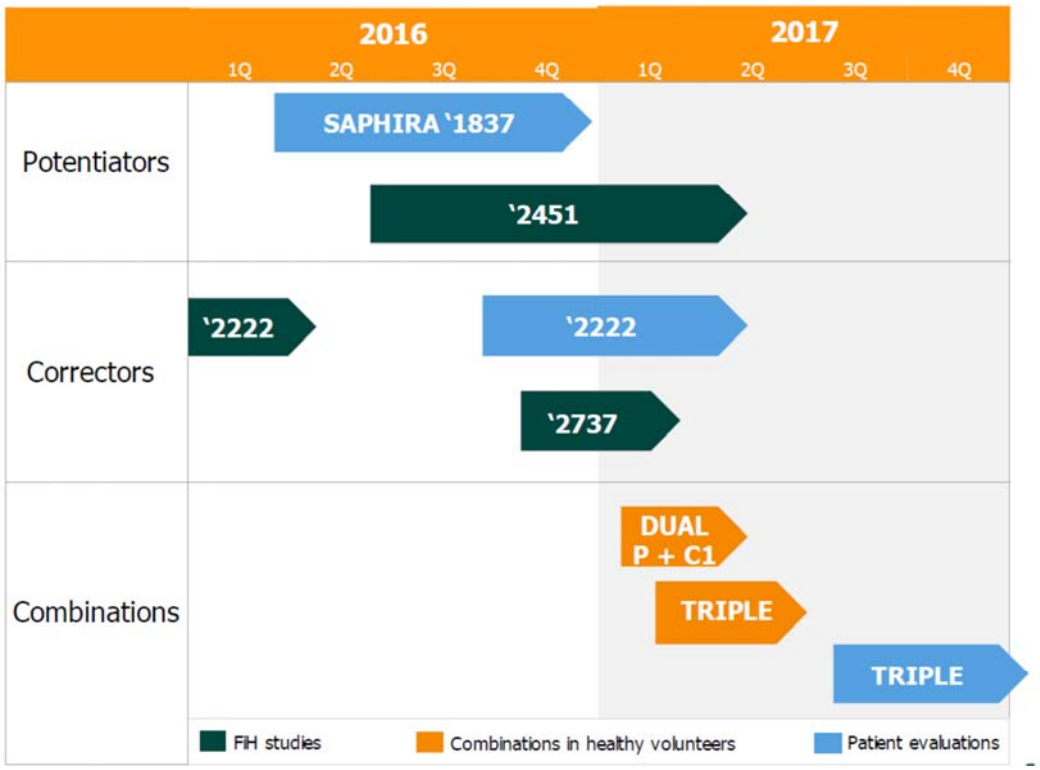
At the end of 2016, Galapagos reported efficacy data for potentiator GLPG 1837 in cystic fibrosis, from the SAPHIRA 1 study. Galapagos reported data in the relatively rare S1251N mutation earlier in 2016, in the SAPHIRA 2 study (seven patients).

In SAPHIRA 1, Galapagos tested 26 patients with the G551D mutation (25 of whom were being treated with Kalydeco pre study). '1837 was generally well tolerated when dosed up to 500 mg twice daily for 14 days. Statistically significant and dose dependent decreases in sweat chloride were observed. At the 500 mg bid dose, sweat chloride decreased from a mean value of 98 mmol/L at baseline to 66 mmol/L ($p < 0.0001$). Patients also saw their FEV1 levels return to where they were on Kalydeco treatment. One patient dropped out due to an increase in non-cardiac creatine phosphokinase (CK). Another patient, who had distal intestinal obstruction at screening, had pulmonary exacerbation on the final day of the study. Galapagos is continuing to investigate the increase in CK, but states that it was a one-off, with no signal being seen in any of the other patients.

One positive from the SAPHIRA 1 data is that it validates the in vitro data Galapagos is seeing against the in vivo response, which gives us more confidence in the subsequent clinical development (recognizing that the correctors could be more challenging to optimize than the potentiators).

The below chart shows the cadence of clinical fibrosis data we expect in 2017 (as per Galapagos' disclosure):

Exhibit 3: Expected news flow on cystic fibrosis



Source: Company data.

During 1H2017 we expect to see Phase 2 readout for the C1 corrector GLPG2222. This is the one remaining "efficacy" readout we look for before Galapagos starts trials with the triple combination. Also in 1H, we expect Phase 1 readout for the C2 corrector GLPG2737 in 2Q of 2017. This C2 corrector is especially important for the "critical path" of Galapagos' cystic fibrosis development, because unlike for the potentiator and C1 corrector, Galapagos' backups for the C2 corrector are just starting in the clinic. So if GLPG2737 turns out to be unsafe or otherwise unsuitable, we believe this could delay the start of the triple combination in patients by a few months.

During 2017, we also expect Phase 1 results for Galapagos' second potentiator, GLPG2451. Compared to GLPG1837, this potentiator has the advantage of being dosed once daily. Galapagos states that while it has decided on the identity of the two correctors for the triple combination (C1: GLPG2222, C2: GLPG2737), it has yet to decide on the potentiator. It could be GLPG1837 if it is prepared to have twice daily dosing, but it is also happy to incorporate GLPG2451 in the triple combination with the Phase 1 results, with safety but not in vivo efficacy data, if it is looking for once daily dosing for the triple combination.

IPF data is a free option: In mid-2017, we expect Galapagos to publish Phase 2a data for its idiopathic pulmonary fibrosis (IPF) asset GLPG1690. The Phase 2a Flora trial tests GLPG1690 at a dose of 600mg once daily for 12 weeks (18 patients) vs placebo (six patients) for safety tolerability and PK/PD. Secondary endpoints include forced vital capacity (FVC), spirometry, quality of life, FRI, serum and BALF biomarkers. The trial is set up as dosing with GLPG1690 (600 mg once daily) for 12 weeks, followed by a 2-week follow-up, and will be placebo-controlled. 18 patients will be on the active arm and six on placebo. We see IPF as a significant market opportunity. It is a fatal disorder, and the only two approved drugs, Esbriet and Ofev, demonstrate modest efficacy without survival benefit. A positive trend of FVC at Phase 2a could lead to this asset being increasingly included in consensus valuations.

Ongoing updates on filgotinib: During 2017, we expect new Phase 2 trials to be initiated for Galapagos' lead agent filgotinib, the JAK-1 inhibitor partnered with Gilead. Galapagos has indicated that we could potentially see a "double digit" number of trials. Gilead has publicly discussed its commitment to this R&D program, and we expect to see new trials initiated for filgotinib in new indications, both as a standalone therapy and in combinations. The next clinical data point we expect is the readout for the Phase 2b component of the ulcerative colitis trial, which we expect towards the end of 2017.

We rate Galapagos as Buy, with a DCF-based 12-month price target of €81 (increased from €75 as we roll forward our valuation date to year-end 2017). Key risks are the outcomes of the clinical trials, ability to recruit patients into later-stage cystic fibrosis trials, and potential value-destructive M&A.