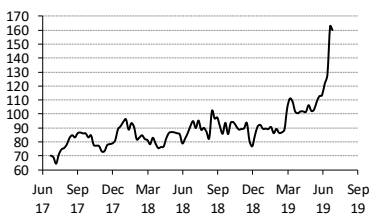
Belgium | Healthcare | www.glpg.com

BUY

Price (25/07/2019)	EUR 160.00
Target price	186.00
Risk	High
Reuters	GLPG AS
Bloomberg	GLPG NA
Shares number (m)	54.47
Market cap. (m)	8,714
Cash Position 12/19e (m)	5,654
1 year price perf.	69.5%
Diff. with Euro Stoxx	70.4%
Volume (sh./day)	442,914
H/L 1 year	168.85 - 75.60
Free Float	60.5%
Gilead	12.3%
Van Herk Investments	10.6%
Wellington Management Gro	6.3%
Sands Capital Management	5.3%
The Capital Group Companies	5.1%

Company description
Galapagos is a biotech company focused on small molecules in inflammatory and fibrotic indications. The company is supported by strong partnerships and has a broad and mature pipeline. Its lead product has completed Ph3.



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Galapagos

Strong cash position to accelerate pipeline development

No surprises in 1H19 results, guidance unchanged

- Galapagos reported its 1H19 financial results. Group revenues came in higher than expected at EUR 108.5m versus our anticipated EUR 86.03m (Css. EUR 86.7m). Revenues were higher YoY due to a milestone achieved in June 2019 related to the CF program with AbbVie and higher reimbursement income mainly from Novartis in the scope of the collaboration for MOR106.
- Operating expenses increased 23% YoY, landing at EUR 206.1m (DPe EUR 198m; Css EUR 198m), with R&D EUR 177.6m and SG&A EUR 28.5m. This increase in OpEx is mainly attributed to an increase in subcontracting costs primarily relating to the IPF and other programs, as expected. This leads to an operating loss of EUR 97.6m. The company realized a net loss of EUR 95.9m.
- Cash & cash equivalents came in at EUR 1,147.9m (DPe EUR 1,140.3m; Css EUR 1,136.4m)
- On the development pipeline, the company provides the following outlook for the remainder of 2019:
    - Following a meeting with the US FDA, the company's communicated that filing for filgotinib in RA is planned for 3Q19 in Europe and the US by YE19.
    - Further for filgotinib, readouts from Sjögren's syndrome and cutaneous lupus trials are expected in 2019 and the initiation of a Phase III in psoriatic arthritis has been planned.
    - The company expects to finish recruitment of the PINTA trial with GLPG1205.
    - The first Phase I readout from the Toledo program, GLPG3312, is expected in 2H19.
- The guidance for FY19 operational cash burn remains unchanged at EUR 320m-340m.
- Galapagos will host a conference call today at 2pm CEST (+32 2 404 0659, code 6080337).

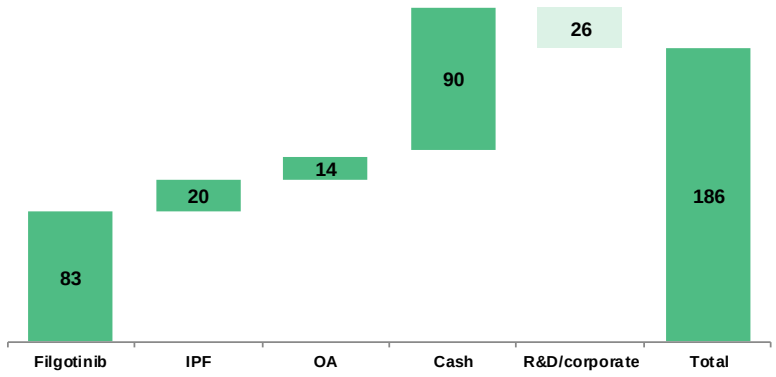
Multiple inflection points to drive value in coming years

- The deal with Gilead provides a substantial cash injection to accelerate pipeline development. Through the commercial rights in Europe, Galapagos will have the means to build out a European biopharma company.
- The companies are making strong progress in the filgotinib programs, nearing market approval and additional Phase II and Phase III readouts. The JAK inhibitors are making their mark in rheumatoid arthritis, already clearly taking market share from the anti-TNFs. In our view, the market is not fully recognizing the paradigm shift caused by JAK inhibitors in RA, as well as their potential beyond RA.
- In addition to filgotinib, the programs in idiopathic pulmonary fibrosis (IPF), osteoarthritis (OA) and Toledo are attracting more and more attention. GLPG1690 and GLPG1972 were two pillars in the collaboration with Gilead. Recent evolutions have positively impacted our valuation of these programs.

Investment conclusion

- Multiple inflection points can further provide upside in the short to mid-term, amongst which news flow from the Toledo program, filgotinib regulatory filing, Phase III readout in UC, futility analysis of GLPG1690 and a positive readout in OA.
- We have adjusted our TP to incorporate the cash payment, new deal terms and cost structure resulting from the Gilead collaboration. Gilead's option to license Galapagos' programs over the 10-year period reduces the upside for Galapagos for these programs and the deal has removed the take-out scenario. Nevertheless, this is offset by the large upfront payment and the room for substantial further value creation. We reiterate our Buy recommendation and raise our TP to EUR 186.

Exhibit 1 **Sum-of-the-parts valuation (EUR/share)**



Source: Degroof Petercam estimates; *per share figures calculated based on the average number of shares including Gilead's equity investment

The era of small molecules

We have adapted our model to include the collaboration, taking into account the enriched cash position and new cost structure. In our view, there is more upside to the story through filgotinib as well as the other pipeline products.

JAK inhibitors are taking over in RA

- We believe the market is still underestimating the impact of the JAK inhibitors (JAKi) in the treatment paradigm of inflammatory diseases. Following years of anti-TNFs dominating the biological disease-modifying anti-rheumatic drug (bDMARD) market, JAKi are making their way up the treatment ladder in RA. The two approved JAKi, Xeljanz and Olumiant, are rapidly taking market share from anti-TNFs. In Europe, over 14% of prescribed biologicals for RA are JAKi. Moreover, of the RA patients that have to move on to ≥3rd line therapy, already 26% are treated with a JAKi.
- Important news flow in the coming months will entail the regulatory filing for approval of filgotinib for the treatment of RA in Europe and the US. Given the FINCH data, we do not expect major surprises from the approval process and attribute a 95% probability of success.
- In terms of competitor news flow, the approval and launch of AbbVie's upadacitinib, expected in 2H19, may impact Galapagos in the short term. Like filgotinib, approval of upadacitinib is attributed a high probability of success. It was apparent at the EULAR conference this year that, in addition to safety, AbbVie seems to focus its efforts on promoting upadacitinib's strong remission data (see comparison below).

Exhibit 2 Long term safety data upadacitinib

	Upadacitinib	
E/100 PYE	15 mg QD PY=467.8	30 mg QD PY=1365.0
Serious infections	3.8	6.2
Herpes zoster	3.7	7
DVT / PE	0.6	0.3
Malignancy (excl. NMSC)	0.9	1.4

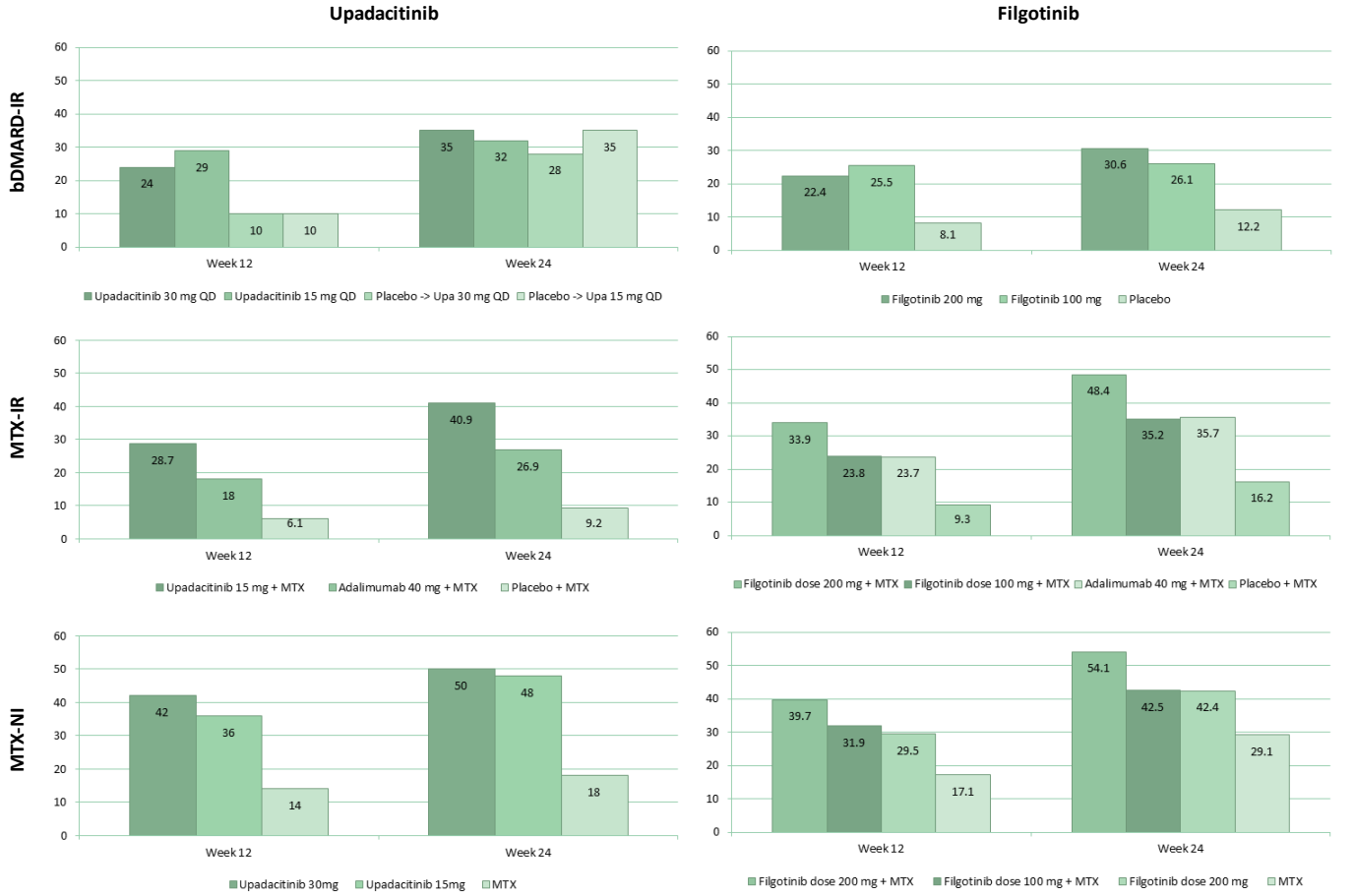
Source: Stanley B. Cohen et al. Ann Rheum Dis 2019;78:357

Exhibit 3 Long term safety data filgotinib

	Filgotinib
E/100 PYE	50 - 200 mg DARWIN 3 (week 156) PY=2,203
Serious infections	1.2
Herpes zoster	1.5
DVT / PE	0.1*
Deaths	0.2

Source: Galapagos;
*2/2,203 one patient experiencing both DVT and PE

Exhibit 4 Comparison DAS28CRP<2.6 clinical remission scores



Source: AbbVie press release April 9, 2018; AbbVie press release June 5, 2018; EULAR 12 June 2019, abstract LB0001; EULAR 15 June 2019, abstract LB0003

Beyond RA

- Next to arthritis, the JAKi are also making their mark in IBD. Xeljanz has proven to be a worthy competitor for Entyvio in the (second-line) treatment of ulcerative colitis (UC). Given the safety issues surrounding Xeljanz (infections, lymphopenia, venous thromboses), we expect filgotinib to be able to outperform this JAKi. Results from the ongoing filgotinib Phase II/III trial in UC and Phase III trial in Crohn's disease are expected in 1H20 and 2021, respectively. At this point, we estimate peak sales of EUR 745m and EUR 703m for CD and UC, with a probability of success of 73% and 68%, respectively.
- Filgotinib has shown very promising results in PsA and AS. These have been quoted by Gilead's management as very important programs next to RA and IBD. In our view, the market is still underestimating the value of these potential label extensions. The company expects to start Phase III trials with filgotinib in PsA by the end of 2019 and in AS early 2020. We estimate these indications could add EUR 1.8bn in peak sales to the filgotinib franchise.

Significant pipeline potential

In addition to filgotinib, the programs in idiopathic pulmonary fibrosis (IPF) and osteoarthritis (OA) are attracting attention. GLPG1690 and GLPG1972 were two pillars in the collaboration with Gilead.

A promising mechanism of action in IPF

- GLPG1690 is an oral autotaxin inhibitor currently in Phase III clinical development. Autotaxin is an enzyme that converts lysophosphatidylcholine to the bioactive lipid lysophosphatidic acid (LPA).
- Autotaxin remains a promising target in IPF. The mechanism of action has been further validated through recent licensing deals and data by competitors. One of the largest players in IPF, Boehringer Ingelheim, recently announced a licensing deal with Bridge Biotherapeutics for up to USD 1.1bn (EUR 45m upfront) to get access to a Phase I autotaxin inhibitor, BBT-877. Further, Bristol-Myers Squibb obtained encouraging efficacy results with its LPA1 antagonist (BMS-986020) in IPF, demonstrating a significantly slower rate of decline in FVC vs. placebo. However, the program was discontinued due to compound-specific toxicity.
- GLPG1690 is currently in a pivotal trial, which should be completed in 2021 (data expected in 2022). Combination therapy will likely be the way forward in IPF. We appreciate the company's decision to include treatment-naïve patients as well as patients on Ofev or Esbriet, which could allow to obtain a broad label, potentially including monotherapy as well as add-on (combination) therapy.
- Although the data on GLPG1690 are still limited and do not allow straightforward extrapolation to the Phase III trial, the demonstration of stable disease up to 12 weeks is encouraging for the evolution of GLPG1690 in IPF. We have assigned a probability of success of 45% to the program at this stage. Adding Gilead to the equation, our rNPV points to a valuation of EUR 1.1bn (EUR 20/share).

Targeting the vast, but challenging osteoarthritis market

- Galapagos has been developing GLPG1972 for osteoarthritis (OA) in collaboration with Servier. The compound acts on ADAMTS-5, an aggrecanase involved in the breakdown of aggrecan in joint cartilage. In a placebo-controlled Phase Ib study including 30 OA patients, GLPG1972 demonstrated a dose-dependent reduction of ARGS neo-epitope vs. placebo.
- OA is the most common joint disorder, with an estimated global prevalence of 8.2%. To date, no disease-modifying treatment has been approved. Aiming to fill this gap, the FDA communicated last year on the inclusion of structural endpoints in clinical trials and not only the measurement of pain and function. However, more research is needed to effectively demonstrate the link between structural changes and symptoms. Additionally, OA is a very heterogeneous disease, which could impact the success rate of a trial. Likely, the company will have to focus on specific subpopulations.
- These points will make successful clinical development challenging, but worthwhile given the large addressable market. Galapagos has shown its strong interest in further developing new compounds in this space.
- As clinical proof-of-concept is currently based solely on biomarker data from a limited number of patients, we have attributed a probability of success of 35% to the Phase III OA program. This results in a rNPV of EUR 750m (EUR 14/share).

Toledo

- Galapagos is betting large on its so-called Toledo program that targets multiple inflammatory indications, but for which the identity remains unknown. The company aims to run eight parallel Phase II studies in 2020 in order to move as fast as possible and benefit from the time advantage.
- The Toledo program has at this stage not been included in our valuation model, it provides significant upside to our valuation going forward.

Investment conclusion

- Multiple inflection points can further provide upside in the short to mid-term, amongst which news flow from the Toledo program, filgotinib regulatory filing, Phase III readout in UC, futility analysis of GLPG1690 and a positive readout in OA.
- We have adjusted our TP to incorporate the cash payment, new deal terms and cost structure resulting from the Gilead collaboration. Gilead's option to license Galapagos' programs over the 10-year period reduces the upside for Galapagos for these programs and the deal has removed the take-out scenario. Nevertheless, this is offset by the large upfront payment and the room for substantial further value creation. We reiterate our Buy recommendation and raise our TP to EUR 186.

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	SELL	REDUCE	HOLD	ADD	BUY
High Beta >= 1.3	RP<-15%	-15%<=RP<-6%	-6%<=RP<+6%	+6%<=RP<+15%	RP>=15%
Medium 0.9 < Beta > 1.3	RP<-10%	-10%<=RP<-4%	-4%<=RP<+4%	+4%<=RP<+10%	RP>=10%
Low Beta <= 0.9	RP<-6%	-6%<=RP<-2%	-2%<=RP<+2%	+2%<=RP<+6%	RP>=6%

RP : Relative Performance against Degroof Petercam coverage universe

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