

The Galapagos group

An overview of Galapagos, its strategy
and portfolio in H1 2020



Letter from the management

Dear shareholders,

We are very grateful that Galapagos remains well positioned to weather the storm, while facing challenges in view of the pandemic. In fact, just recently, we achieved, for the first time in the history of Galapagos, a positive opinion from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP¹) for our investigational rheumatoid arthritis (RA) drug filgotinib. The positive CHMP opinion is a crucial step toward European approval.



We are all very proud of this important milestone, which is a great reward after fifteen years of development of filgotinib. I want to thank and congratulate the Galapagos teams who have worked tirelessly to make this happen, and together with our collaboration partner Gilead, we look forward to bringing filgotinib to European patients suffering from moderate to severe RA, if approved by the European Commission.

We are encouraged by the positive CHMP opinion for filgotinib in RA, and await regulatory decisions in the EU, U.S. and Japan, expected in H2 2020.

In the second quarter, Gilead and we announced positive topline results from the SELECTION trial in patients suffering from ulcerative colitis (UC) – the first Phase 3 inflammatory bowel disease (IBD) read-out for filgotinib, and a second potential indication for commercialization. The SELECTION results demonstrate that patients receiving filgotinib 200 mg achieved clinical remission at Week 10, and both the filgotinib 100 mg and 200 mg dose maintained remission through Week 58 in a significantly higher proportion of patients compared to placebo. We are very pleased that filgotinib has the potential to help UC patients to achieve a meaningful and sustained improvement in treatment response, including those refractory to multiple treatment options, and look forward to presenting more detailed results at a future scientific conference.

After a pause in recruitment due to COVID-19 in DIVERSITY and PENGUIN – the ongoing filgotinib trials in Crohn's disease and psoriatic arthritis – Gilead recently restarted recruiting patients at select sites, and enrollment into the MANTA and MANTA-RAY studies has been concluded. We anticipate that Gilead will start the global Phase 3 program with filgotinib in ankylosing spondylitis (AS) in the second half of 2020.

Moving beyond filgotinib, we are making significant progress with our other clinical programs.

Our global Phase 3 ISABELA program in idiopathic pulmonary fibrosis (IPF) with ziritaxestat continues to recruit. While we see a slowdown in recruitment rates due to COVID-19, we remain on track for the futility analysis planned for the first half of 2021.

Furthermore, we are on track to report topline results from three patient trials in the second half of 2020. First, we anticipate the readout from the Phase 2a NOVESa trial with ziritaxestat in systemic sclerosis (SSc); secondly, the results from the PINTA Phase 2 trial with GLPG1205 in IPF; and finally, together with our collaboration partner Servier, we aim to release topline results of the ROCCELLA Phase 2b trial with GLPG1972 in patients with knee osteoarthritis (OA).

Our earlier-stage pipeline is also advancing well. In our growing fibrosis portfolio, we nominated an additional preclinical candidate, GLPG4586 – the first compound emerging from our collaboration with Fibrocor.

¹ Committee for Medicinal Products for Human Use



With regard to Toledo, our innovative program in inflammation, we recently nominated an additional preclinical candidate of the Toledo family, GLPG4605, a selective TOL2/TOL3 compound, and remain excited about the dual mechanism of action observed with the Toledo family of compounds.

Our balance sheet remains very strong with a cash position of €5.6 billion to support our R&D activities and the further ramp-up of our commercial organization. Receiving a positive CHMP opinion is a major step toward delivering on our promise to become a fully-integrated biopharma company, and we are ready. In the past two years, we built a strong team from the ground up to roll out the commercialization of filgotinib, and we are looking forward to bringing filgotinib to RA patients, hand in hand with our European co-commercialization partner Gilead.

Operational overview Q1 2020

We refer to our [Q1 2020 report](#).

Operational overview Q2 2020

In inflammation

- Collaboration partner Gilead resumed recruitment in the ongoing filgotinib trials, DIVERSITY and PENGUIN, at select trial sites
- Presented data from the 52 Week FINCH 1 and 3 Phase 3 trials at EULAR², together with Gilead, demonstrating sustained efficacy and a consistent safety profile of filgotinib across patient populations. Also presented an integrated safety analysis for over 4,500 patient years' exposure, highlighting the long-term safety profile of filgotinib in RA
- Completed recruitment into the MANTA and MANTA-RAY trials

In fibrosis

- Nominated a new preclinical candidate, GLPG4586, with undisclosed novel mode of action in fibrosis. This is the first candidate to emerge from the Fibrocor collaboration
- Nominated a new preclinical candidate of the Toledo-family, GLPG4605, a selective TOL2/TOL3 compound
- Continued recruitment in the ISABELA Phase 3 program in IPF with ziritaxestat; on track for futility analysis in H1 2021

Corporate & other

- On 28 April 2020, Galapagos held its annual (ordinary) and extraordinary shareholders' meetings. All agenda items were approved, including the appointment of Dr. Elisabeth Svanberg as independent director and the remuneration policy and -report. Furthermore, the extraordinary shareholders' meeting resolved to amend the articles of association in light of the new Belgian Code of Companies and Associations. A two-tier governance structure was introduced, with the supervisory board replacing the board of directors, and the management board replacing the executive committee
- Created new subscription right³ plans, offering all Galapagos employees the opportunity to participate
- Raised €17.9 million from subscription right exercises

Recent events

- Received positive CHMP opinion from the European Medicines Agency for filgotinib 100 mg and 200 mg in RA adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). Filgotinib may be used as monotherapy or in combination with methotrexate (MTX)

² European League Against Rheumatism (EULAR) E-Congress

³ "Subscription rights" is the new term for instruments formerly referred to as "warrants", under the new Belgian Code of Companies and Associations.

H1 2020 financial result

Revenues and other income

Our revenues and other income for the first six months of 2020 amounted to €224.6 million, compared to €108.5 million for the first six months of 2019. Revenues (€201.8 million for the first six months of 2020 compared to €91.8 million for the first six months of 2019) were higher mainly due to the revenue recognition of the upfront payment received from Gilead in August 2019 related to (i) the exclusive access to our drug discovery platform during the collaboration period and exclusive option rights on our current and future clinical programs after Phase 2 outside Europe, and (ii) additional consideration received for the extended cost sharing for filgotinib.

Other income (€22.8 million vs €16.7 million for the same period last year) increased, mainly driven by higher incentives income from the government for our R&D activities.

Results

We realized a net loss of €165.6 million for the first six months of 2020, compared to a net loss of €95.9 million for the first six months of 2019.

We reported an operating loss amounting to €130.8 million for the first half-year of 2020, compared to an operating loss of €97.6 million for the first half-year of 2019.

Our R&D expenditure in the first six months of 2020 amounted to €265.9 million, compared to €177.6 million for the first half-year of 2019. This planned increase was mainly due to an increase in subcontracting costs primarily related to our filgotinib program, our Toledo program and other clinical programs. Furthermore, personnel costs increased explained by a planned headcount increase following the growth of our R&D activities and increased cost of our subscription right plans. This last factor, together with increased costs from the preparation of the commercial launch of filgotinib in Europe, contributed to the increase in our G&A and S&M expenses which were €89.5 million in the first six months of 2020, compared to €28.6 million in the first six months of 2019.

We reported a non-cash fair value loss from the re-measurement of initial warrant B issued to Gilead, amounting to €21.1 million, mainly due to the increased implied volatility of the Galapagos share price.

Net other financial loss in the first six months of 2020 amounted to €13.0 million, compared to net other financial income of €1.8 million for the first six months of 2019, which was primarily attributable to negative changes in (fair) value of current financial investments of €12.5 million.

Cash position

Current financial investments and cash and cash equivalents totaled €5,566.5 million on 30 June 2020 (€5,780.8 million on 31 December 2019).

A net decrease of €214.3 million in cash and cash equivalents and current financial investments was recorded during the first six months of 2020, compared to a net decrease of €142.9 million during the first six months of 2019. This net decrease was composed of (i) €230.5 million of operational cash burn⁴, (ii) €23.3 million of cash proceeds from capital and share premium increase from exercise of subscription rights in the first six months of 2020, and (iii) €7.1 million of negative changes in (fair) value of current financial investments and unrealized positive exchange rate differences.

Finally, our balance sheet as at 30 June 2020 held a receivable from the French government (*Crédit d'Impôt Recherche*⁵) and a receivable from the Belgian Government for R&D incentives, for a total of €116.6 million.

⁴ We refer to the [note](#) on the cash position of our condensed consolidated interim financial statements for an explanation and reconciliation of this alternative performance measure.

⁵ *Crédit d'Impôt Recherche* refers to an innovation incentive system underwritten by the French government.



Outlook 2020

The remainder of the year will be a newsflow rich period for Galapagos.

Following the positive CHMP opinion for filgotinib in RA, we anticipate the potential approval of filgotinib by the European Commission in 2020. We also expect decisions from the U.S. and Japanese authorities before year-end, and continue full steam ahead with the preparations for commercial launch in the Benelux and EU5, hand in hand with our co-commercialization partner Gilead. We anticipate that Gilead will start the global Phase 3 program with filgotinib in ankylosing spondylitis (AS) in the second half of 2020.

We expect to report topline results from three patient trials later in 2020. Within our fibrosis portfolio, we anticipate reporting topline results from the PINTA Phase 2 trial with GLPG1205 in idiopathic pulmonary fibrosis (IPF) and, together with collaboration partner Gilead, from the NOVESA Phase 2a trial with ziritaxestat in systemic sclerosis (SSc). Also in the second half of 2020, we and Servier expect to report topline results from the ROCCELLA Phase 2b trial of GLPG1972 in knee osteoarthritis (OA), and upon successful completion of this trial, Gilead has the option to license development and commercialization rights in the U.S. for GLPG1972.

With regard to Toledo, our novel program in inflammation, we still expect to launch several proof-of-concept patient trials with GLPG3970 in the second half of this year, with topline data expected in the first half year of 2021. Pending the successful start of these trials, we intend to share more information on the Toledo program, including the target and more preclinical data, before year-end.

We retain our 2020 operational cash burn guidance of €400-€430 million, which includes \$205 million in potential milestone payments subject to regulatory approvals of filgotinib.

With respect,

Onno van de Stolpe

CEO

COVID-19 impact

In light of the ongoing COVID-19 pandemic, we are committed to keeping our stakeholders informed as the situation evolves. We see the following impact at this point in time:

- *Staff*

Galapagos has strong measures in place to help prevent spread of the virus and protect the health of our staff. We rolled out our global and site business continuity plans and took appropriate recommended precautions and restrictions, including suspending almost all travel. In practice, this means that most of our employees are working from home, with the exception of lab personnel and skeleton IT and facility team to ensure safety and operational continuity essential to keep research going. For those employees, we have stringent cleaning and sanitation protocols in place, and we strictly respect social distancing policies at all times, in order to minimize risk of exposure.

- *Clinical trials*

We have a business continuity plan for our non-clinical studies and clinical trials, including a pandemic response plan. Given the pandemic, we decided to pause the start of early stage trials temporarily, but are currently planning to initiate them in the second half of the year, including the Phase 2 Toledo trials with GLPG3970. We continuously monitor the situation, always putting patients' safety and needs front and center, and our teams are working hand in hand with our CROs and clinical trial sites to define next steps. Our collaboration partner Gilead is restarting enrollment into the filgotinib trials at select clinical trial sites, always keeping patients' safety in mind. This includes the Phase 2 and Phase 3 trials of filgotinib in Crohn's disease (DIVERSITY), the Phase 3 in psoriatic arthritis (PENGUIN), and the Phase 2 trial in uveitis. While the MANTA and MANTA-RAY trials are fully recruited, we cannot exclude potential delays in read-outs in light of COVID-19.

- *Filgotinib in RA – filing process*

Regulatory decisions in the U.S. and Japan are expected before year-end. As with all applications, but particularly during these difficult circumstances, potential approval timings are subject to change. Gilead also confirmed that all sites involved in the manufacturing of filgotinib are established sites that manufacture Gilead marketed products, are in good standing with the FDA, and are GMP certified.

- *Commercial organization*

Build-up of our commercial operations in the EU5 countries and the Benelux to prepare for the potential launch of filgotinib continues as planned.



At a glance

Consolidated key figures

(thousands of €, if not stated otherwise)	Second quarter of 2020	Second quarter of 2019	Six months ended 30 June 2020	Six months ended 30 June 2019	Full year 2019
Income statement					
Revenues	103,600	58,738	201,773	91,785	844,985
Other income	14,059	8,852	22,802	16,724	50,905
R&D expenditure	(149,114)	(94,372)	(265,877)	(177,567)	(427,320)
S, G&A expenses	(54,759)	(17,585)	(89,497)	(28,552)	(98,278)
Operating expenses	(203,873)	(111,958)	(355,374)	(206,119)	(525,597)
Operating profit/loss (-)	(86,214)	(44,367)	(130,799)	(97,610)	370,292
Net financial results	(28,454)	(2,820)	(34,135)	1,834	(220,233)
Taxes	(373)	(61)	(709)	(129)	(214)
Net profit / loss (-)	(115,042)	(47,249)	(165,643)	(95,905)	149,845
Balance sheet					
Cash and cash equivalents	2,384,220	1,147,923	2,384,220	1,147,923	1,861,616
Current financial investments	3,182,276	-	3,182,276	-	3,919,216
R&D incentives receivables	116,629	94,288	116,629	94,288	115,356
Assets	5,851,564	1,357,848	5,851,564	1,357,848	6,068,609
Shareholders' equity	2,773,263	1,143,367	2,773,263	1,143,367	2,875,658
Deferred income	2,823,833	96,325	2,823,833	96,325	3,000,646
Other liabilities	254,468	118,157	254,468	118,157	192,305
Cash flow					
Operational cash flow/operational cash burn (-) ⁽¹⁾	(147,088)	(76,200)	(230,486)	(152,545)	3,162,804
Cash flow used (-)/generated in operating activities	(140,955)	(70,041)	(209,829)	(141,740)	3,208,617
Cash flow generated/used (-) in investing activities	(216,836)	(5,263)	712,804	(8,661)	(3,764,660)
Cash flow generated in financing activities	16,316	3,428	20,246	5,661	1,335,751
Increase/decrease (-) in cash and cash equivalents	(341,473)	(71,876)	523,222	(144,740)	779,708
Transfer to current financial investments	-	-	-	-	(198,922)
Effect of exchange rate differences on cash and cash equivalents	(17,878)	(3,102)	(617)	1,866	(9,966)
Cash and cash equivalents at end of the period	2,384,220	1,147,923	2,384,220	1,147,923	1,861,616
Current financial investments at end of the period	3,182,276	-	3,182,276	-	3,919,216
Total current financial investments and cash and cash equivalents at end of the period	5,566,496	1,147,923	5,566,496	1,147,923	5,780,832

⁽¹⁾ We refer to the note on the cash position of our condensed consolidated interim financial statements for an explanation and reconciliation of this alternative performance measure.

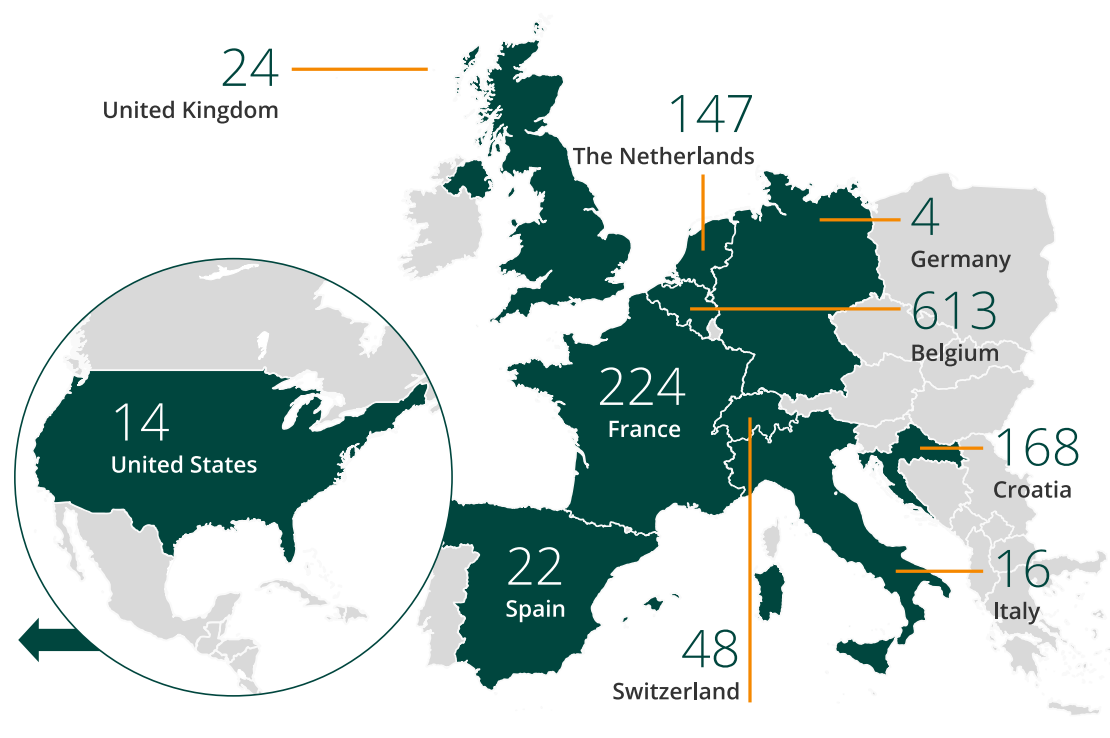


(thousands of €, if not stated otherwise)	Second quarter of 2020	Second quarter of 2019	Six months ended 30 June 2020	Six months ended 30 June 2019	Full year 2019
Financial ratios					
Number of shares issued at end of the period	65,254,562	54,823,101	65,254,562	54,823,101	64,666,802
Basic income / loss (-) per share (in €)	(1.77)	(0.86)	(2.55)	(1.76)	2.60
Diluted income / loss (-) per share (in €)	(1.77)	(0.86)	(2.55)	(1.76)	2.49
Share price at end of the period (in €)	175.05	113.45	175.05	113.45	186.50
Total group employees at end of the period (number)	1,280	837	1,280	837	1,003

⁽¹⁾ We refer to the note on the cash position of our condensed consolidated interim financial statements for an explanation and reconciliation of this alternative performance measure.

Employees per site as of 30 June 2020

(total: 1,280 employees)



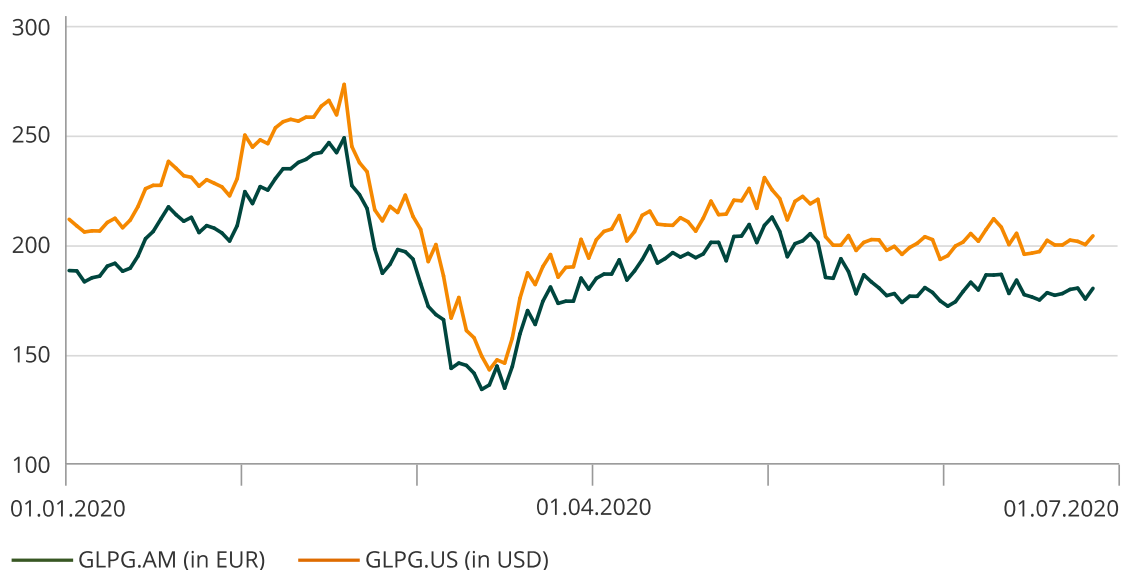
Risk factors

We refer to the [description of risk factors in the 2019 annual report](#), pp. 60-69, as supplemented by the description of risk factors in our annual report on Form 20-F filed with the U.S. Securities and Exchange Commission, pp. 5-49. In summary, the principal risks and uncertainties faced by us relate to: product development, regulatory approval and commercialization; our financial position and need for additional capital; our reliance on third parties; our competitive position; our intellectual property; our organization, structure and operation (including the emergence of epidemics such as COVID-19); and market risks relating to our shares and ADSs.

We also refer to the [description of the group's financial risk management given in the 2019 annual report](#), pp. 189-191, which remains valid.

The Galapagos share

Performance of the Galapagos share on Euronext and Nasdaq



Related party transactions

We refer to the statements included under the heading [Related party transactions](#) in the “Notes to the unaudited condensed consolidated interim financial statements for the first six months of 2020” part of this report.

Statement of the supervisory board

The supervisory board of Galapagos NV declares that, as far as it is aware, the financial statements in this H1 report are prepared according to the applicable standards for financial statements, and give a true and fair view of the equity, financial position and the results of Galapagos NV and its consolidated companies.

The supervisory board of Galapagos NV further declares that this H1 report gives a true and fair view on the important developments and significant transactions with related parties in the period under review and their impact on the interim financial statements, as well as on the most important risks and uncertainties pertaining to the remainder of the current financial year.

Mechelen, 3 August 2020

On behalf of the supervisory board,

Raj Parekh

Chairman of the supervisory board

Howard Rowe

Member of the supervisory board

Disclaimer and other information

Galapagos NV is a limited liability company organized under the laws of Belgium, having its registered office at Generaal De Wittelaan L11 A3, 2800 Mechelen, Belgium. Throughout this report, the term “Galapagos NV” refers solely to the non-consolidated Belgian company and references to “we,” “our,” “the group” or “Galapagos” include Galapagos NV together with its subsidiaries.

Filgotinib and all other drug candidates mentioned in this report are investigational; their efficacy and safety have not been fully evaluated by any regulatory authority.

This report is published in Dutch and in English. In case of inconsistency between the Dutch and the English versions, the Dutch version shall prevail. Galapagos is responsible for the translation and conformity between the Dutch and English version.

This report is available free of charge and upon request addressed to:

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Listings

Euronext Amsterdam and Brussels: GLPG

Nasdaq: GLPG

Forward-looking statements

This report contains forward-looking statements, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as “believe,” “anticipate,” “expect,” “intend,” “plan,” “seek,” “estimate,” “may,” “will,” “could,” “stand to,” “continue,” as well as similar expressions. Forward-looking statements contained in this report include, but are not limited to, statements made in the “[Letter from the management](#)”, the information provided in the section captioned “Outlook 2020”, guidance from management regarding the expected operational use of cash during financial year 2020, statements regarding the amount and timing of potential future milestones, opt-in and/or royalty payments by Gilead, statements regarding the expected timing, design and readouts of ongoing and planned clinical trials (i) with filgotinib in ulcerative colitis, Crohn’s disease, psoriatic arthritis, ankylosing spondylitis and other indications, (ii) with ziritaxestat (GLPG1690) and GLPG1205 in IPF and with ziritaxestat in SSC, (iii) with GLPG1972 in osteoarthritis, and (iv) with GLPG3970 and GLPG4605 in inflammation, and GLPG4586 in fibrosis, statements relating to interactions with regulatory authorities, the timing of the approval process for filgotinib or expectations regarding receipt of regulatory approval, statements relating to the build-up of our commercial organization for filgotinib, the expected impact of COVID-19, and our strategy, business plans and focus. We caution the reader that forward-looking statements are not guarantees of future performance. Forward-looking statements may involve known and unknown risks, uncertainties and other factors which might cause our actual results, financial condition and liquidity, performance or achievements, or the development of the industry in which we operate, to be materially different from any historic or future results, financial conditions, performance or achievements expressed or implied by such forward-looking statements. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. Among the factors that may result in differences are that our expectations regarding our 2020 revenues and financial results and our 2020 operating expenses may be incorrect (including because one or more of our assumptions underlying our revenue or expense expectations may not be realized), the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including that data from our clinical research programs in rheumatoid arthritis, Crohn’s disease, ulcerative colitis, psoriatic arthritis, ankylosing spondylitis, idiopathic pulmonary fibrosis, systemic sclerosis, osteoarthritis, and other inflammatory indications may not support registration or further development of our product candidates due to safety, efficacy, or other reasons), our reliance on collaborations with third parties (including our collaboration partner for filgotinib and ziritaxestat, Gilead, and our collaboration partner for GLPG1972, Servier), estimating the commercial potential of our product candidates and the uncertainties relating to the impact of the COVID-19 pandemic. A further list and description of these risks, uncertainties and other risks can be found in our Securities and Exchange Commission filing and reports, including in our most recent annual report on Form 20-F filed with the SEC and our subsequent filings and reports filed with the SEC. We also refer to the “[Risk Factors](#)” section of this report. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. We expressly disclaim any obligation to update any such forward-looking statements in this document to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements, unless specifically required by law or regulation.