

The Galapagos group

An overview of
Galapagos, its strategy
and portfolio in the first
three months of 2021

Letter from the management

Dear shareholders,

We present you with our report on the first quarter of 2021, one in which we both delivered progress with and faced adversity in our pipeline, while driving our commercial business in Europe through the launch of Jyseleca (filgotinib) in rheumatoid arthritis (RA). We move forward with confidence at Galapagos, applying lessons learned to our pipeline decisions, and re-fitting our organization to the new situation.

In February, we announced the end of the development program for ziritaxestat, a molecule in Phase 3 trials in idiopathic pulmonary fibrosis (IPF), due to the unfavorable risk/benefit profile observed by an Independent Data Monitoring Committee (IDMC). As disappointed as we were, and for patients in need of a new treatment option in this very complex, debilitating condition, we continue to work hard on our differentiated pipeline.

These last months, we embarked on a review of our plans. We listened to our shareholders and had constructive discussions with our R&D teams and management board members, as well as with our supervisory board. We all agree that our scientific foundations are solid, we have outstanding teams, and we have the financial resources to execute our own programs as well as to enrich our pipeline.



Onno van de Stolpe, CEO



Bart Filius, President & COO

We do not intend to deviate from our mission to build on novel targets to address unmet medical needs in inflammation, fibrosis, and kidney disease. Also, we remain fully committed to the launch of filgotinib in Europe. Our teams are working very hard to ensure our drug reaches the greatest number of patients and we've already hit some important milestones in RA. Furthermore, Gilead submitted the new drug application in Japan for filgotinib for the treatment of ulcerative colitis (UC) patients with an inadequate response to conventional therapies, and, in Europe, we anticipate a Committee for Medicinal Products for Human Use (CHMP) opinion on the submission for potential approval in UC later this year.

The key objective of our exercise was to refocus development plans for 2021, taking lessons learned on board and right-sizing our organization with the goal to select a more risk-balanced pipeline.

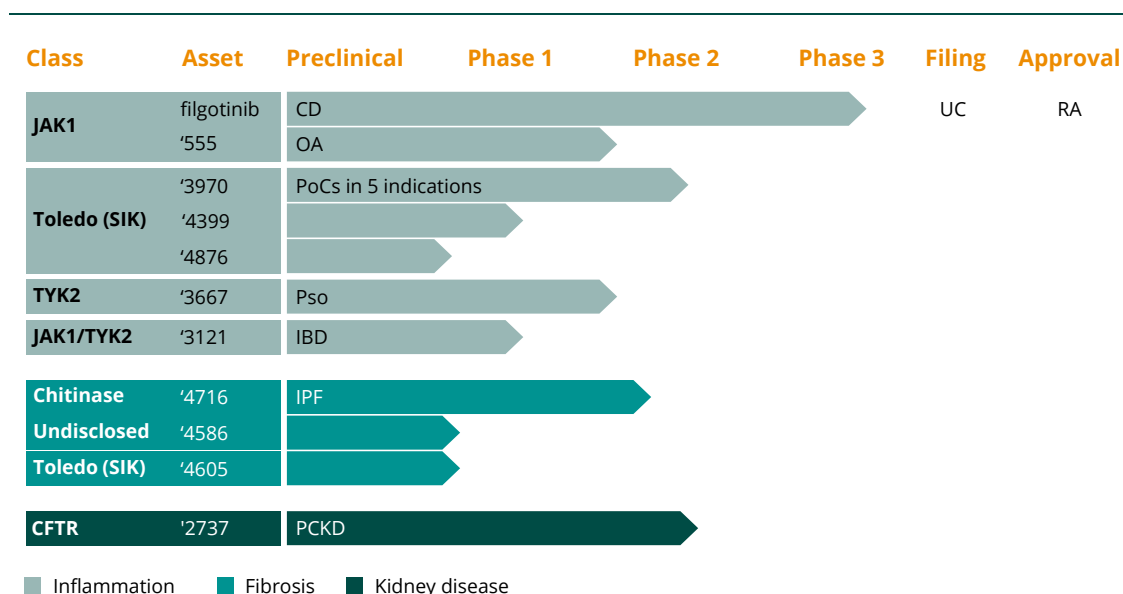
In the end we made three key decisions:

1. Refocus our clinical pipeline by critically examining its risk profile and breadth;
2. Cut significant cost in the organization to support this re-sized pipeline development; and
3. Task our business development team to identify and execute on a transformative opportunity.

Starting with our pipeline, we carefully evaluated the risk-balance and prioritized assets with what we believe have enhanced chances of clinical success in our core therapeutic areas:

- We are testing our lead Toledo program '3970, a SIK2/3 inhibitor, in five Proof of Concept studies in different indications, and pending on the outcome of the studies, we plan to roll out our further development plans in the second half of the year;
- We selected an additional molecule from our Toledo program, SIK2/3 inhibitor '4876, as a candidate to accelerate from preclinical phase into clinical development;
- We aim to progress our TYK2 inhibitor '3667 into Phase 2b;
- We selected chitinase inhibitor '4716 to progress to Phase 2 in IPF and decided to stop development of our other IPF molecule '1205;
- We stopped further work on '4059 for metabolic disease, given that this is not a core therapeutic area;
- We discontinued our early research efforts in metabolic diseases and osteoarthritis (OA); and
- We challenged and fine-tuned our stage-gating process to advance compounds.

Our reviewed pipeline offers significant newsflow and we look forward to sharing results this year and next.



In line with our review, we decided to discontinue or cancel certain studies, and we identified opportunities to reduce operational costs, for a total potential savings of €150 million on a full-year basis. Roughly half of these savings will be realized in 2021, resulting in a 2021 cash burn guidance of between €580 million and €620 million.

Meanwhile, we remain well on track in launching filgotinib in Europe. In the first quarter, we successfully completed the transitions of commercial and medical teams from Gilead in Germany, the UK, Spain, and Italy. Everything is in place to complete the final transitions from Gilead to us by year-end. Q1 also saw progress on access and reimbursement for filgotinib in RA. We are delighted with the recommendation by the National Institute for Health and Care Excellence (NICE) for filgotinib in the UK for the treatment of eligible adult patients

with moderate to severe active RA. Furthermore, we received an additional benefit in RA by the *Gemeinsamer Bundesausschuss* (G-BA) in Germany. We are encouraged by the primary endpoint outcome with the MANTA/RAy semen parameter studies as we await the CHMP opinion in UC.

We are pleased that our partner Gilead recently announced an extension of the lockup period for their current holding in Galapagos (16,707,477 shares) until 2024, which is testament to their continued support.

Altogether, these adjustments make for a right-sized, refocused version of Galapagos, on a path towards success with our first commercial product as well as with new R&D opportunities, substantial clinical news flow, and a lengthened cash runway for clinical validation of our early assets.

Operational overview Q1 2021

In inflammation

- We and Gilead announced interim data on the MANTA/RAy studies. 8.3% of patients on placebo and 6.7% of patients on filgotinib had a 50% or more decline in sperm concentration at week 13; these results are being shared with regulatory authorities
- We initiated two additional Proof of Concept trials with Toledo compound '3970, a SIK2/3 inhibitor. The first patients were dosed in both the TAPINOMA study in systemic lupus erythematosus and in the GLIDER study in Sjögren's syndrome
- Gilead announced that NICE recommended filgotinib for reimbursement for moderate to severe RA patients in the UK
- We published the FINCH 1 Phase 3 data (Combe *et al.* 2021) and FINCH 3 Phase 3 data (Westhovens *et al.* 2021) in the *Annals of the Rheumatic Diseases*

In fibrosis

- We discontinued development of ziritaxestat in the ISABELA Phase 3 program in IPF

Corporate & other

- Bart Filius was promoted to President and Chief Operating Officer
- We raised €2.3 million from subscription right exercises

Recent events

- All annual general meeting (AGM) proposals were approved by shareholders at the AGM on 28 April 2021
- We received a transparency notification from the Capital Group indicating they hold 4.65% of the current outstanding Galapagos shares
- Gilead submitted the new drug application in Japan for filgotinib for the treatment of UC with an inadequate response to conventional therapies
- We and Gilead ended the DIVERGENCE 2 trial with filgotinib in fistulizing CD
- We completed enrollment of the SEA TURTLE Phase 2 study with '3970 in UC
- We announced an extension of the lockup period for Gilead's current shares in Galapagos to 2024
- We received the second installment of €75 million from Gilead, following payment of an earlier installment of €35 million in January 2021, included under the revised filgotinib agreement as announced in December 2020

Q1 2021 financial result

Details of financial results

Due to the sale of our fee-for-service business (Fidelta) to Selvita on 4 January 2021 for a total consideration of €37.1 million (including customary adjustments for net cash and working capital), the results of Fidelta are presented as "Net profit from discontinued operations" in our consolidated income statements.

Revenues and other income from continuing operations

Our revenues and other income from continuing operations for the first three months of 2021 amounted to €124.2 million, compared to €103.6 million for the first three months of 2020.

Revenues amounted to €113.9 million for the first three months of 2021 compared to €94.8 million for the first three months of 2020, and were higher mainly driven by the increase in revenue recognition of upfront consideration and milestone payments received in the scope of the collaboration with Gilead for filgotinib amounting to €55.3 million for the first three months of 2021 (€35.4 million for the same period last year).

Other income (€10.3 million vs €8.7 million for the same period last year) increased, mainly driven by higher incentives income from the government for our R&D activities.

Results from continuing operations

We realized a net loss from continuing operations of €12.8 million for the first three months of 2021, compared to a net loss of €52.3 million for the first three months of 2020.

We reported an operating loss amounting to €50.8 million for the first three months of 2021, compared to an operating loss of €46.2 million for the same period last year.

Our R&D expenditure in the first three months of 2021 amounted to €130.0 million, compared to €115.5 million for the first three months of 2020. This increase was due to an increase in subcontracting costs primarily related to our filgotinib program, our Toledo program and other clinical programs, compensated by a decrease for ziritaxestat, the OA program with GLPG1972 and the program in atopic dermatitis (AtD) with MOR106. Furthermore, personnel costs increased explained by a planned headcount increase following the growth of our activities and increased cost of our subscription right plans. This last factor, together with increased costs of the commercial launch of filgotinib in Europe, contributed to the increase in our G&A and S&M expenses which were €45.0 million in the first three months of 2021, compared to €34.3 million in the first three months of 2020.

We reported a non-cash fair value gain from the re-measurement of initial warrant B issued to Gilead, amounting to €2.0 million, mainly due to the decreased implied volatility of the Galapagos share price as well as its evolution between 31 December 2020 and 31 March 2021.

Net other financial income in the first three months of 2021 amounted to €36.2 million, compared to net other financial income of €14.8 million for the first three months of 2020, which was primarily attributable to €45.5 million of currency exchange gain on our cash and cash equivalents and current financial investments in U.S. dollars and to €6.5 million of negative changes in (fair) value of current financial investments and financial assets.

Results from discontinued operations

The net profit from discontinued operations for the three months ended 31 March 2021 consisted of the gain on the sale of Fidelta, our fee-for-services business, for €22.2 million.

Group net results

The group realized a net profit for the first three months of 2021 amounting to €9.4 million, compared to a net loss of €50.6 million for the same period in 2020.

Cash position

Current financial investments and cash and cash equivalents totaled €5,114.7 million on 31 March 2021 (€5,169.3 million on 31 December 2020, including the cash and cash equivalents included in the assets classified as held for sale).

Total net decrease in current financial investments and cash and cash equivalents amounted to €54.6 million in the first three months of 2021, compared to a net decrease of €58.4 million during the first three months of 2020. This net decrease was composed of (i) €127.7 million of operational cash burn,¹ (ii) offset by €2.3 million of cash proceeds from capital and share premium increase from exercise of subscription rights in the first three months of 2021, (iii) €3.6 million of negative changes in (fair) value of current financial investments and €45.7 million of mainly positive exchange rate differences, (iv) €28.7 million cash in from the disposal of Fidelta, net of cash disposed.

Finally, our balance sheet on 31 March 2021 held a receivable from the French government (*Crédit d'Impôt Recherche*²) and a receivable from the Belgian Government for R&D incentives, for a total of €142.3 million.

Outlook 2021

We anticipate regulatory announcements with filgotinib as well as news on progress in our differentiated pipeline of novel target-based candidates this year.

We expect reimbursement decisions in most key European markets for filgotinib in RA this year, as we complete the transition to a full European commercial operation by year end. We anticipate a CHMP opinion and a European Commission decision for filgotinib in UC. We expect that our collaboration partner Gilead will complete recruitment for the global DIVERSITY Phase 3 trial in Crohn's disease this year.

Within our broader inflammation portfolio, we expect to report topline results from several trials this year, including a Phase 1b trial with TYK2 inhibitor '3667 in psoriasis and three Proof of Concept studies with lead Toledo candidate SIK2/3 inhibitor '3970 in psoriasis, UC, and RA.

Within our fibrosis portfolio, we expect to progress early clinical compounds with novel mechanisms of action, with the aim to develop novel treatments to help patients suffering from this debilitating condition.

Following the review of our plans for 2021, we give guidance for full year 2021 operational cash burn of €580 to €620 million, and potential savings of €150 million on a full-year basis.

We thank you for your continued support, as we move forward on our strategy to develop novel mechanism of action drugs aimed at addressing unmet need in inflammation, fibrosis, and kidney disease. We are confident that we have a strong cash position, expert teams, and excellent science to achieve this.

Onno van de Stolpe
CEO

Bart Filius
President & COO

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.

² *Crédit d'Impôt Recherche* refers to an innovation incentive system underwritten by the French government

COVID-19 impact

During the COVID-19 pandemic, we continue to innovate to accommodate for the current situation and minimize the impact to operations. We closely follow local governmental measures and apply these as appropriate within our organization, guided and supported by our dedicated COVID-19 task force teams. All local and global task force teams meet regularly and make recommendations directly to the COO.

We report the following impacts:

■ *Staff*

We implemented strict measures to help prevent the spread of the virus and protect the health of our staff. We rolled out our global and site-specific business continuity plans and took appropriate recommended precautions, including suspending almost all business travel. We continue to believe that during the pandemic most of the international travel can be replaced by virtual meetings, resulting in improved cost efficiency, a better work-life balance, and a reduced carbon footprint. The positive impact of this forced way-of-working will therefore be retained in our future habits and updated work place strategy, called “To the Next Normal.”

During lock-down periods, we arranged for essential tasks to be carried out within our facilities. Employees working on site need an authorization letter signed by the line leader and site head. Consequently, the majority of our Research staff continue working from the offices/labs, with periodic exceptions for local lockdowns during which no staff is allowed to come into the facilities. For those employees coming to the office, 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. Except for employees with laboratory operations and safety roles which require an on-site presence, over 95% of our staff systematically work from home.

As the global pandemic continues into 2021, we anticipate that we will maintain our measures and protocols to ensure the health of our employees.

■ *Research portfolio*

By prioritizing the most advanced projects very early on, increasing the flexibility of our staff in the labs within projects, and maintaining our hiring efforts and outsourcing as planned, we sustain our research delivery, keep the compound management facility running at all times, and continue our early drug research and the implementation of new modalities for target or drug discovery.

So far, the scorecard of the research department objectives shows a similar productivity compared to previous years, indicating that we continue to minimize the impact of the pandemic.

■ *Development portfolio*

We have a business continuity plan for our clinical development programs. We closely monitor each program in the context of the current global and local situation of the pandemic and the associated specific regulatory, institutional, and government guidance and policies related to COVID-19. Within the boundaries of these guidances and policies, and in consultation with our CROs and clinical trial sites, we applied various measures to minimize the impact of the COVID-19 pandemic on our clinical development programs, with the primary aim to ensure the safety of our trial participants and to preserve the data integrity and scientific validity of the trials. These measures continue to be implemented on a case-by-case basis, tailored to the specific study and country needs at any given time, with specific attention paid to vulnerable populations and the use of investigational medicines with immunosuppressive properties. The measures include, among others, increased, transparent communication to all stakeholders and the direct supply of investigational medicines to patients. For each clinical trial, we actively monitor and document the impact of COVID-19 on the study where necessary and to facilitate the interpretation and reporting of results.

Following the global increase of COVID-19 testing and vaccinations, we issued an internal guidance on the impact of testing and vaccinations on clinical trials.

■ *Filgotinib filing process UC*

As of publication of this Q1 report, our collaboration partner Gilead has not been informed by the regulatory agencies in Europe of approval timeline delays related to the pandemic.

■ *Manufacturing and supply chain*

To date, there has been no COVID-19 impact to the commercial supply of filgotinib. Gilead also confirmed that all sites involved in the manufacturing of filgotinib are established sites that currently manufacture other Gilead marketed products and are in good standing with the FDA and are GMP certified. Under the revised agreement with Gilead for filgotinib in Europe, Galapagos plans to become the marketing authorization holder of filgotinib in Europe by year-end 2021, and then become responsible for manufacturing. We intend to work with the same manufacturing sites to ensure continuity.

■ *Commercial organization*

The form of outreach of our commercial teams to physicians and hospitals was impacted by the COVID-19 pandemic and consequent travel restrictions, becoming virtual instead. The teams invested in virtual channels as part of the overall commercial build strategy, and these channels are being utilized during our commercial launch today. We note as of now no material impact on our commercial operations due to travel restrictions, nor has there been an impact of COVID-19 on our ability to engage in market access discussions thus far. Nevertheless, healthcare systems are under pressure across Europe, increasing the risk of future volatility in reimbursement procedures and potentially reducing the number of new therapy initiations.

At a glance

Consolidated Key Figures

(thousands of €, if not stated otherwise)	Three months ended 31 March 2021	Three months ended 31 March 2020	Year ended 31 December 2020
Income Statement^(*)			
Revenues	113,892	94,817	478,053
Other income	10,266	8,743	52,207
R&D expenditure	(129,960)	(115,453)	(523,667)
S, G&A expenses	(44,996)	(34,325)	(185,225)
Operating expenses	(174,956)	(149,778)	(708,892)
Operating loss	(50,798)	(46,218)	(178,632)
Net financial results	38,125	(5,705)	(131,143)
Taxes	(157)	(336)	(1,226)
Net loss from continuing operations	(12,830)	(52,258)	(311,001)
Net profit from discontinued operations, net of tax	22,191	1,657	5,565
Net profit/loss (-)	9,361	(50,601)	(305,436)
Balance Sheet			
Cash and cash equivalents	2,553,950	2,743,573	2,135,187
Current financial investments	2,560,743	2,978,805	3,026,278
R&D incentives receivables	142,304	115,240	135,728
Assets	5,615,059	5,992,406	5,717,731
Shareholders' equity	2,701,462	2,840,041	2,670,355
Deferred income	2,698,417	2,913,398	2,809,133
Other liabilities	215,180	238,968	238,242
Cash Flow			
Operational cash burn ^(**)	(127,669)	(83,398)	(517,404)
Cash flow used in operating activities	(121,209)	(68,874)	(427,336)
Cash flow generated from investing activities	499,859	929,640	757,288
Cash flow generated from financing activities	478	3,930	22,040
Increase in cash and cash equivalents	379,129	864,695	351,994
Effect of currency exchange rate fluctuation on cash and cash equivalents	31,750	17,261	(70,539)
Cash and cash equivalents at end of the period	2,553,950	2,743,573	2,143,071

(*) The comparatives of 31 March 2020 have been restated to consider the impact of classifying the Fidelita business as discontinued operations in 2020.

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

(***) The number of employees on 31 December 2020 and on 31 March 2020 included respectively 185 and 164 employees of Fidelita, which has been sold to Selvita on 4 January 2021.

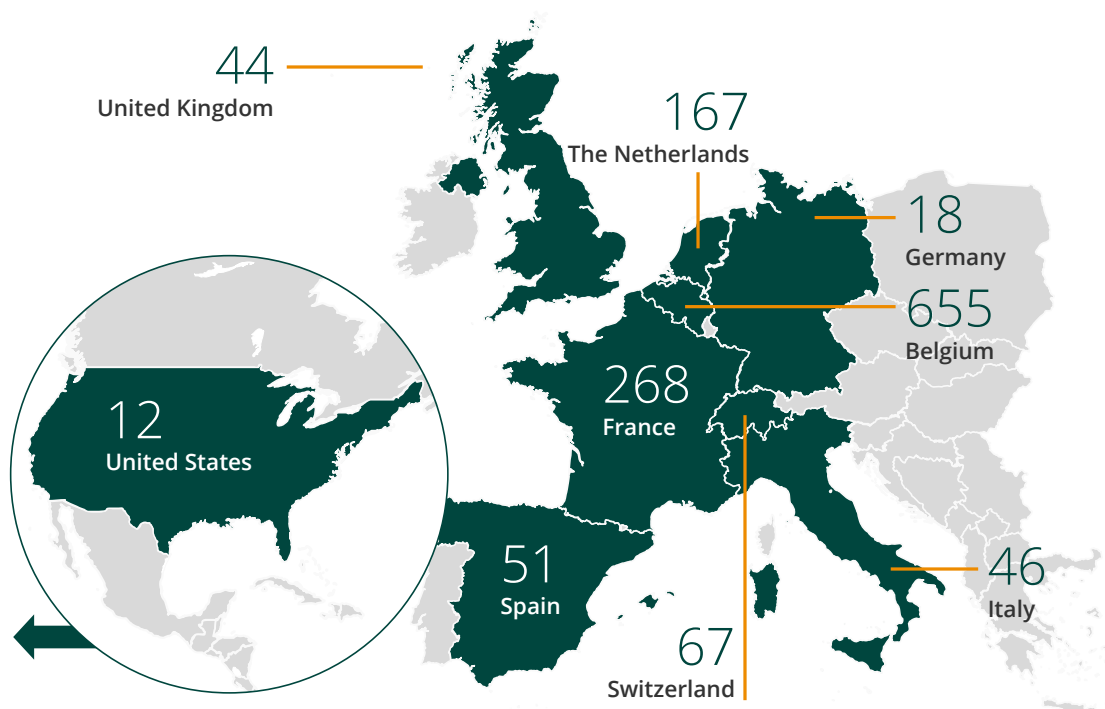
(thousands of €, if not stated otherwise)	Three months ended 31 March 2021	Three months ended 31 March 2020	Year ended 31 December 2020
Cash and cash equivalents from continuing operations	2,553,950	2,743,573	2,135,187
Cash and cash equivalents classified as assets held for sale	-	-	7,884
Current financial investments at the end of the period	2,560,743	2,978,805	3,026,278
Total current financial investments and cash and cash equivalents at the end of the period	5,114,693	5,722,378	5,169,349
Financial Ratios			
Number of shares issued at end of the period	65,511,581	64,819,022	65,411,767
Basic income/loss (-) per share (in €)	0.14	(0.78)	(4.69)
Diluted income/loss (-) per share (in €)	0.14	(0.78)	(4.69)
Share price at end of the period (in €)	66.12	181.00	80.48
Total group employees at end of the period (number) ^(***)	1,328	1,130	1,489

(*) The comparatives of 31 March 2020 have been restated to consider the impact of classifying the Fidelita business as discontinued operations in 2020.

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

(***) The number of employees on 31 December 2020 and on 31 March 2020 included respectively 185 and 164 employees of Fidelita, which has been sold to Selvita on 4 January 2021.

Employees per site as of 31 March 2021 (total: 1,328 employees)



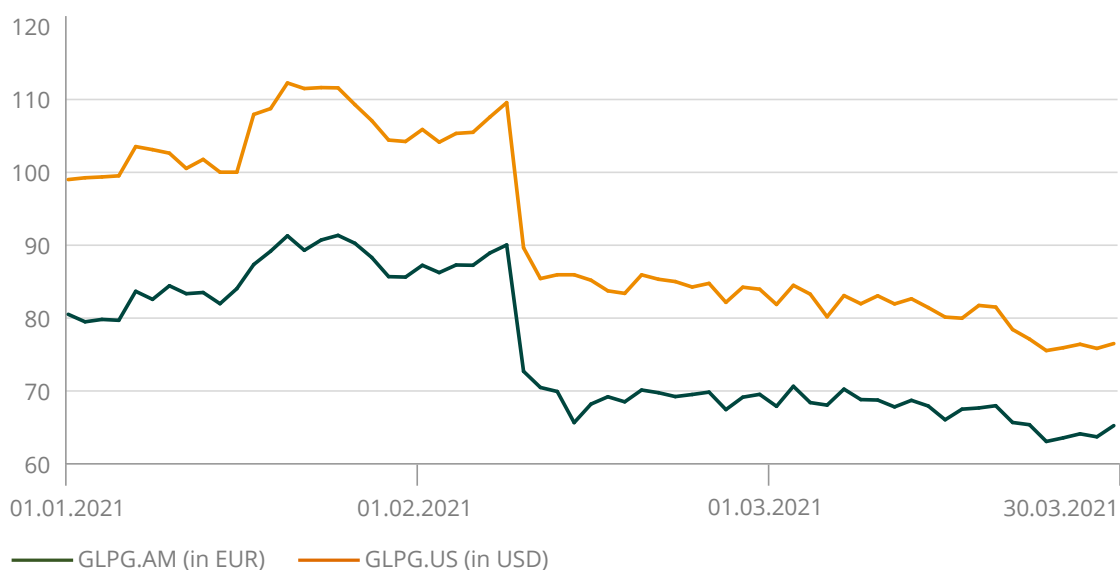
Risk factors

We refer to the [description of risk factors in the 2020 annual report](#), pp. 51-61, 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. 8-48. In summary, the principal risks and uncertainties faced by us relate to: commercialization, product development and regulatory approval; 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 2020 annual report](#), pp. 193-196, which remains valid.

The Galapagos share

Performance of the Galapagos share on Euronext and Nasdaq



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.

With the exception of filgotinib's approval for the treatment of rheumatoid arthritis by the European Commission and Japanese Ministry of Health, Labour and Welfare, our 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 2021”, guidance from management regarding the expected operational use of cash during financial year 2021, statements regarding the amount and timing of potential future milestones, opt-in and/or royalty payments by Gilead, Galapagos' strategic R&D ambitions, including progress on our fibrosis portfolio, and potential changes of such ambitions, statements regarding the strategic re-evaluation, our statements and expectations regarding commercial sales of filgotinib, statements regarding the global R&D collaboration with Gilead and regarding the amendment of our arrangement with Gilead for the commercialization and development of filgotinib.

statements regarding the expected timing, design and readouts of ongoing and planned clinical trials (i) with filgotinib in ulcerative colitis and Crohn's disease, (ii) with GLPG4716 in IPF, (iii) with GLPG3970 in inflammation, ulcerative colitis, rheumatoid arthritis and psoriatic arthritis, (iv) with GLPG0555, GLPG4399 and GLPG3121 in inflammation, (v) with GLPG3667 in psoriasis, (vi) with GLPG2737 in PCKD, (vii) with GLPG4876 in inflammation, and (viii) with GLPG4586 in fibrosis, statements relating to interactions with regulatory authorities, the timing or likelihood of additional regulatory authorities' approval of marketing authorization for filgotinib for RA, UC or any other indication, including the UC and IBD indications for filgotinib in Europe, the UK, Japan, and the U.S., such additional regulatory authorities requiring additional studies, the timing or likelihood of pricing and reimbursement interactions for filgotinib, statements relating to the build-up of our commercial organization and commercial sales for filgotinib, including in Europe, 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 2021 revenues and financial results and our 2021 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 the risk that data from our ongoing and planned clinical research programs in rheumatoid arthritis, Crohn's disease, ulcerative colitis, idiopathic pulmonary fibrosis, 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, Gilead), the timing of and the risks related to implementing the amendment of our arrangement with Gilead for the commercialization and development of filgotinib, estimating the commercial potential of our product candidates and Galapagos' expectations regarding the costs and revenues associated with the transfer of European commercialization rights to filgotinib may be incorrect, 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.