# Galapagos refocuses pipeline and rightsizes operations

- **First three months 2021 financial results:**
  - **Group revenues and other income of €124.2 million**
  - **Operating loss of €50.8 million**
  - **Net profit of €9.4 million**
  - **Cash and current financial investments of €5.1 billion on 31 March 2021**
- **Refocused clinical pipeline by critically examining risk profile and breadth**
- **Filgotinib launch in Europe on track**
- **Initiated €150 million savings program**

***Webcast presentation tomorrow, 07 May 2021, at 14.00 CET / 8 AM ET, www.glpg.com, +32 2 793 38 47, code 5042688***

**Mechelen, Belgium; 06 May 2021, 22.01 CET; regulated information – Galapagos NV (Euronext & NASDAQ: GLPG) announces its unaudited Q1 results and operational highlights, which are further detailed in the Q1 2021 report available on the Galapagos website, www.glpg.com.**

"These last months, we completed a review of our portfolio and development plans with the goal to select a more risk-balanced pipeline. We decided to retain our focus on novel targets to address unmet medical needs in inflammation, fibrosis, and kidney diseases. We also remain fully committed to the launch of Jyseleca in Europe. Moving forward with confidence, we decided to:

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

We believe that our strong cash position, expert teams, and solid scientific foundation position us well for future growth," said Onno van de Stolpe, CEO of Galapagos.

**Refocused pipeline**

In the revision exercise, Galapagos set goals to focus and adjust the overall risk profile of its clinical pipeline. Consequently, we prioritized those assets with what we believe have enhanced chances of clinical success in our core therapeutic areas. As such, we announce:

- We are testing our lead Toledo program '3970, a SIK2/3 inhibitor, in five Proof of Concept studies in different indications, and pending 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 '4617 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; and
- We challenged and fine-tuned our stage-gating process to advance compounds.

**Commercial progress**
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. We believe 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 rheumatoid arthritis (RA). Gilead submitted the new drug application in Japan for the treatment of ulcerative colitis (UC). We are encouraged by the primary endpoint outcome with the MANTA/RAy semen parameter studies as we await the Committee for Medicinal Products for Human Use (CHMP) opinion in UC.

Bart Filius, President and COO, added, "In line with our review, we decided to discontinue or cancel certain studies and consequently identified opportunities to reduce operational costs, for a total potential savings of €150M on a full-year basis. Roughly half of these savings will be realized in 2021, resulting in a 2021 cash burn[i] guidance of between €580 million and €620 million. We are working towards a right-sized, refocused version of Galapagos, setting us on a path towards success with our first commercial product, new R&D opportunities, substantial clinical news flow, and a lengthened cash runway for validation of our early pipeline assets."

**Key figures first quarter report 2021 (unaudited)**
**(€ millions, except basic & diluted gain/loss (-) per share)**

| | 31 March 2021 group total | 31 March 2020 group total (*) |
|---|---|---|
| **Revenues and other income** | **124.2** | **103.6** |
| R&D expenditure | (130.0) | (115.5) |
| G&A[ii] and S&M[iii] expenses | (45.0) | (34.3) |
| **Operating loss** | **(50.8)** | **(46.2)** |
| Fair value re-measurement of financial instruments | 2.0 | (20.5) |
| Net other financial result | 36.2 | 14.8 |
| Income taxes | (0.2) | (0.3) |
| **Net loss from continuing operations** | **(12.8)** | **(52.3)** |
| Net profit from discontinued operations | 22.2 | 1.7 |
| **Net profit/loss (-) of the period** | **9.4** | **(50.6)** |
| Basic gain/loss (-) per share (€) | 0.14 | (0.78) |
| Diluted gain/loss (-) per share (€) | 0.14 | (0.78) |
| **Current financial investments and cash and cash equivalents** | **5,114.7** | **5,722.4** |

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

**Details of the 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 for the three months ended 31 March 2021 and 31 March 2020.

**Revenues and other income from continuing operations**
Our revenues and other income from continuing operations for the first three months of 2021 increased to €124.2 million compared to €103.6 million in the first three months of 2020. Our revenues from the Gilead collaboration in the first three months of 2021 (€113.7 million) related to (i) the exclusive access to our drug discovery platform (€57.8 million), (ii) the filgotinib revenue recognition (€55.3 million) and (iii) royalties (€0.7 million).

Our deferred income balance on 31 March 2021 includes €1.9 billion allocated to our drug discovery platform that is recognized linearly over 10 years, and €0.8 billion allocated for the filgotinib development (including considerations for the previous and the renegotiated collaboration combined) that is recognized over time until the end of the development period.

**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, the increase in personnel costs is explained by a planned headcount increase following the growth in our activities, and increased cost of the subscription right plans. This factor, and the increased cost of the commercial launch of filgotinib in Europe, contributed to the increase in our S&M and G&A expenses, which were respectively €14.6 million and €30.4 million in the first three months of 2021, compared to respectively €9.8 million and €24.5 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 and 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 31March 2021 consisted of the gain on the sale of Fidelta, our fee-for-services business, for €22.2 million.

**Group net results**
We reported a group net profit for the first three months of 2021 of €9.4 million, compared to a group net loss of €50.6 million for the first three months of 2020.

**Cash position**
Current financial investments and cash and cash equivalents totaled €5,114.7 million on 31 March 2021, as compared to €5,169.3 million on 31 December 2020.

Total net decrease in cash and cash equivalents and current financial investments amounted to €54.6 million during 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, (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 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 disposal of subsidiaries, net of cash disposed.

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

**Outlook 2021**
We anticipate several regulatory announcements on filgotinib as well as progress in our differentiated pipeline of novel target-based candidates.

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.

**First quarter report 2021**
Galapagos' financial report for the first three months ended 31 March 2021, including details of the unaudited consolidated results, is accessible via www.glpg.com/financial-reports.

**Results of annual ordinary shareholders' meeting**
On 28 April 2021, Galapagos held its annual ordinary shareholders' meeting. All agenda items were approved, including the re-appointments of Ms. Katrine Bosley and Dr. Raj Parekh as members of the supervisory board, and approval of the remuneration report. All documents relating to the shareholders' meeting are posted on our website at https://www.glpg.com/shareholders-meetings**.**

**Conference call and webcast presentation**
Galapagos will conduct a conference call open to the public tomorrow, 07 May 2021, at 14:00 CET / 8 AM ET, which will also be webcasted. To participate in the conference call, please call one of the following numbers ten minutes prior to commencement:

**CODE: 5042688**

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|---|---|
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A question and answer session will follow the presentation of the results. Go to www.glpg.com to access the live audio webcast. The archived webcast will also be available for replay shortly after the close of the call.

**Financial calendar**

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|---|---|---|
| 05 August 2021 | Half year 2021 results | (webcast 06 August 2021) |
| 04 November 2021 | Third quarter 2021 results | (webcast 05 November 2021) |
| 24 February 2022 | Full year 2021 results | (webcast 25 February 2022) |

**About Galapagos**

Galapagos NV discovers and develops small molecule medicines with novel modes of action, several of which show promising patient results and are currently in late-stage development in multiple diseases. Our pipeline comprises discovery through Phase 3 programs in inflammation, fibrosis and other indications. Our ambition is to become a leading global biopharmaceutical company focused on the discovery, development, and commercialization of innovative medicines. More information at www.glpg.com.

*Except for filgotinib's approval for the treatment of rheumatoid arthritis by the European Commission and Japanese Ministry of Health, Labour and Welfare, our drug candidates are investigational; their efficacy and safety have not been fully evaluated by any regulatory authority.*

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**Forward-looking statements**

*This release may contain forward-looking statements, including, among other things, statements regarding the global R&D collaboration with Gilead, 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,*

*the guidance from management (including guidance regarding the expected operational use of cash during financial year 2021), financial results, statements regarding the expected timing, design and readouts of ongoing and planned clinical trials, including recruitment for trials and topline results for our trials and studies in our inflammation portfolio, statements regarding the strategic re-evaluation, 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 UC and IBD indication 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. Galapagos cautions the reader that forward-looking statements are not guarantees of future performance. Forward-looking statements involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial condition and liquidity, performance or achievements of Galapagos, or industry results, to be materially different from any historic or future results, financial conditions and liquidity, performance or achievements expressed or implied by such forward-looking statements. In addition, even if Galapagos' results, performance, financial condition and liquidity, and the development of the industry in which it operates 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 its assumptions underlying its expense expectations may not be realized), Galapagos' expectations regarding its development programs may be incorrect, the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including the risk that data from Galapagos' 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 its product candidates due to safety, efficacy or other reasons), Galapagos' 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 Galapagos' Securities and Exchange Commission (SEC) filings and reports, including in Galapagos' most recent annual report on Form 20-F filed with the SEC and other filings and reports filed by Galapagos with the SEC. 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. Galapagos expressly disclaims any obligation to update any such forward-looking statements in this document to reflect any change in its 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.*

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[i] The operational cash burn (or operational cash flow if this performance measure is positive) is equal to the increase or decrease in our cash and cash equivalents (excluding the effect of exchange rate differences on cash and cash equivalents), minus:

i. the net proceeds, if any, from share capital and share premium increases included in the net cash flows generated from/used in (-) financing activities
ii. the net proceeds or cash used, if any, in acquisitions or disposals of businesses; the movement in restricted cash and movement in current financial investments, if any, included in the net cash flows generated from/used in (-) investing activities.

This alternative performance measure is in our view an important metric for a biotech company in the development stage.

The operational cash burn for the three months ended 31 March 2021 amounted to €127.7 million and can be reconciled to our cash flow statement by considering the increase in cash and cash equivalents of €379.1 million, adjusted by (i) the cash proceeds from capital and share premium increase from the exercise of subscription rights by employees for €2.3 million, (ii) the net sale of current financial investments amounting to €475.8 million, and (iii) the cash in from sale of subsidiaries, net of cash disposed of, of €28.7 million.

[ii] General and administrative

[iii] Sales and marketing

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