# Galapagos reports H1 financial results with refocused pipeline and operational progress

- **First half-year 2021 financial results:**
  - **Group revenues and other income of €277.2 million**
  - **Operating loss of €97.6 million**
  - **Net loss of €55.0 million**
  - **Cash and current financial investments of €5.0 billion on 30 June 2021**
- **Advancing refocused pipeline; encouraging clinical read-outs reported in earlier-stage inflammatory programs**
- **Commercial launch of filgotinib in Europe on track**
- **Executing on operational restructuring and savings program**

***Webcast presentation tomorrow, 6 August 2021, at 14.00 CET / 8 AM ET, www.glpg.com, +32 2 793 38 47, code 8245817***

**Mechelen, Belgium; 5 August 2021, 22.01 CET; regulated information – Galapagos NV (Euronext & NASDAQ: GLPG) is pleased to report progress on earlier-stage programs as well as its commercial launch of filgotinib in Europe. Following recent setbacks, the company is moving forward with its revised strategy and operational restructuring announced in May. The unaudited H1 financial and operational results are further detailed in the H1 2021 report available on the website, www.glpg.com.**

"Multiple assets are moving through clinical development, and we recently reported positive topline data on our TYK2 compound GLPG3667. In a Phase 1b trial in psoriasis (Pso), clinical activity was observed at 4 weeks, combined with an encouraging safety and tolerability profile. We currently are running an extended dose escalation study in healthy volunteers, and plan to progress GLPG3667 to a Phase 2b dose finding study in Pso as well as a Phase 2 study in ulcerative colitis (UC) in 2022.

We continue to develop our SIK portfolio of molecules, and recently reported encouraging early data from the first patient studies with SIK2/3 inhibitor GLPG3970. In a Phase 1b trial in Pso (CALOSOMA), clinical activity was observed at 6 weeks, and in a Phase 2a trial in UC (SEA TURTLE), biologically important effects were observed on a number of objective endpoints, both of which point to the potential of SIK inhibition as a novel mode of action in inflammation. No activity was observed in the LADYBUG study in rheumatoid arthritis (RA). GLPG3970 was generally safe and well tolerated. Based on these encouraging data, we work on optimizing the pharmacology of follow-up compounds from our SIK portfolio, and plan to bring an improved SIK2/3 molecule into the clinic in 2022.

On the commercial side, we report rapid progress in establishing our commercial operations for Jyseleca across Europe, with 11 countries launched to date. Reimbursement procedures are on track, and we are on target to achieve our commercial objectives.

We remain excited about the potential of our target discovery platform, our drug development capabilities, and the strength of our teams. We want to thank our shareholders for their continued

support and patience as we are working hard to build our pipeline and establish Galapagos as a fully integrated European biopharma," said Onno van de Stolpe, CEO of Galapagos.

Bart Filius, President and COO, added, "Following the strategic exercise announced at Q1, we are focused on advancing our pipeline, implementing our savings program, and diligently evaluating business development opportunities. At the same time, we have been delivering on the launch of Jyseleca, building out our organization in new European markets. In line with our review, we reiterate our 2021 operational cash burn[i] guidance of between €580 million and €620 million. We believe that the decisions and actions taken put us on the strongest footing for the future. We look forward to a busy second half of the year, not the least of which is the expected outcome of the regulatory review in Europe of Jyseleca in UC."

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

| | 30 June 2021 group total | 30 June 2020 group total (*) |
|---|---|---|
| **Revenues and other income** | **277.2** | **217.2** |
| R&D expenditure | (268.8) | (262.9) |
| G&A[ii] and S&M[iii] expenses | (106.0) | (88.7) |
| **Operating loss** | **(97.6)** | **(134.4)** |
| Fair value re-measurement of financial instruments | 2.8 | (21.1) |
| Net other financial result | 17.1 | (13.0) |
| Income taxes | 0.5 | (0.7) |
| **Net loss from continuing operations** | **(77.2)** | **(169.2)** |
| Net profit from discontinued operations | 22.2 | 3.6 |
| **Net loss of the period** | **(55.0)** | **(165.6)** |
| Basic and diluted loss per share (€) | (0.84) | (2.55) |
| | | |
| **Current financial investments and cash and cash equivalents** | **5,006.6** | **5,566.5** |

*(*) 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 unaudited condensed consolidated income statements for the six months ended 30 June 2021 and 30 June 2020.

**Revenues and other income from continuing operations**
Our revenues and other income from continuing operations for the first six months of 2021 increased to €277.2 million compared to €217.2 million in the first six months of 2020. Our revenues from the Gilead collaboration in the first six months of 2021 (€253.2 million) related to (i) the exclusive access to our drug discovery platform (€115.7 million), (ii) the filgotinib revenue recognition (€136.1 million) and (iii) royalties (€1.4 million).

Our deferred income balance on 30 June 2021 includes €1.9 billion allocated to our drug discovery platform that is recognized linearly over 10 years, and €0.7 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 €77.2 million for the first six months of 2021, compared to a net loss of €169.2 million for the first six months of 2020.

We reported an operating loss amounting to €97.6 million for the first six months of 2021, compared to an operating loss of €134.4 million for the same period last year.

Our R&D expenditure in the first six months of 2021 amounted to €268.8 million, compared to €262.9 million for the first six months of 2020. This increase, primarily related to our filgotinib program and our Toledo program, was compensated by a decrease for ziritaxestat, the osteoarthritis (OA) program with GLPG1972, and the program in atopic dermatitis (AtD) with MOR106. Personnel costs increased due to an increase in headcount compared to the same period last year and increased costs of our 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 €29.1 million and €76.9 million in the first six months of 2021, compared to respectively €26.9 million and €61.8 million in the first six months of 2020.

We reported a non-cash fair value gain from the re-measurement of initial warrant B issued to Gilead, amounting to €2.8 million, mainly due to the decreased implied volatility of the Galapagos share price and its evolution between 31 December 2020 and 30 June 2021.

Net other financial income in the first six months of 2021 amounted to €17.1 million, compared to net other financial loss of €13.0 million for the first six months of 2020, which was primarily attributable to €33.4 million of currency exchange gain on our cash and cash equivalents and current financial investments in U.S. dollars, to €8.7 million of negative changes in (fair) value of current financial investments and financial assets and to €4.4 million of interest expenses. The other financial expenses also contained the effect of discounting our long term deferred income of €4.8 million.

**Results from discontinued operations**
The net profit from discontinued operations for the six months ended 30 June 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 loss for the first six months of 2021 of €55.0 million, compared to a group net loss of €165.6 million for the first six months of 2020.

**Cash position**
Current financial investments and cash and cash equivalents totaled €5,006.6 million on 30 June 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 €162.7 million during the first six months of 2021, compared to a net decrease of €214.3 million during the first six months of 2020. This net decrease was composed of (i) €223.2 million of operational cash burn, (ii) offset by €2.6 million of cash proceeds from capital and share premium increase from exercise of subscription rights in the first six months of 2021, (iii) €5.8 million negative changes in (fair) value of current financial investments and €35.0 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 30 June 2021 held a receivable from the French government (Crédit d'Impôt Rechercheiv) and a receivable from the Belgian Government for R&D incentives, for a total of both receivables of €142.7 million.

**Outlook 2021**
In 2021, we expect the European regulatory assessment of filgotinib for the treatment of UC and anticipate both an opinion from the Committee for Medicinal Products for Human Use (CHMP) and a decision from the European Commission later this year. We also expect additional reimbursement decisions for filgotinib in RA across a number of European countries. We are on track to complete the transition from our collaboration partner Gilead to us of the full European commercial operations for filgotinib by year-end, and we anticipate reporting on our own European sales of filgotinib starting in the second half of the year.

Completion of the recruitment in the global DIVERSITY Phase 3 trial with filgotinib in Crohn's disease by our collaboration partner Gilead is also expected later this year.

With regard to our SIK portfolio, we are advancing our SIK3 inhibitor GLPG4399 in healthy volunteers this year, and we aim to advance a follow-up SIK2/3 preclinical candidate into the clinic in 2022.

Following the positive topline data from our TYK2 inhibitor, GLPG3667, we currently are running an extended dose escalation study in healthy volunteers, and we are preparing for a Phase 2b trial in Pso and a Phase 2 trial in UC next year.

In our other programs, by year-end we intend to finalize recruitment into the GLPG2737 Phase 2a trial in polycystic kidney disease.

Following the previously announced review of our plans for 2021, we reiterate our guidance for full year 2021 operational cash burn of €580 to €620 million.

**First half-year report 2021**
Galapagos' financial report for the first half-year ended 30 June 2021, including details of the unaudited consolidated results, is accessible via www.glpg.com/financial-reports.

**Conference call and webcast presentation**
Galapagos will conduct a conference call open to the public tomorrow, 6 August 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: 8245817**

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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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|---|---|---|
| 4 November 2021 | Third quarter 2021 results | (webcast 5 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 clinical 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, Great Britain's Medicines and Healthcare products Regulatory Agency 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 Toledo platform, 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, Great-Britain, 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, statements and expectations regarding commercial sales for filgotinib, 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, other inflammatory indications and kidney disease 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 the implementation of the transition of the European commercialization responsibility of filgotinib from Gilead to us, 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 six months ended 30 June 2021 amounted to €223.2 million and can be reconciled to our cash flow statement by considering the increase in cash and cash equivalents of €477.4 million, adjusted by (i) the cash proceeds from capital and share premium increase from the exercise of subscription rights by employees for €2.6 million, (ii) the net sale of current financial investments amounting to €669.4 million, and (iii) the cash in from sale of subsidiaries, net of cash disposed, 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