Galapagos reports solid H1 2020 progress

- **First half-year 2020 financial results:**
  - **Group revenues and other income of €224.6 million**
  - **Operating loss of €130.8 million**
  - **Net loss of €165.6 million**
  - **Cash and current financial investments on 30 June 2020 of €5.6 billion**
- **Positive CHMP opinion for filgotinib in rheumatoid arthritis (RA)**
- **Positive SELECTION Phase 3 results for filgotinib in ulcerative colitis (UC)**
- **Commercial readiness for potential European approval of filgotinib in RA in Q3**
- **On track to report topline results from three patient trials later this year**

Webcast presentation tomorrow, 7 August 2020, at 14.00 CET / 8 AM ET, www.glpg.com, +32 2 404 0659, code 8997710

Mechelen, Belgium; 6 August 2020, 22.01 CET; regulated information – Galapagos NV (Euronext & NASDAQ: GLPG) announces its unaudited H1 results and key events, which are further detailed in its H1 2020 report available on the Galapagos website, www.glpg.com.

"During the past six months, we made substantial progress despite the global pandemic. We ended the period with important achievements, including a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP[i]) for our investigational rheumatoid arthritis (RA) drug filgotinib and positive topline data for the SELECTION Phase 3 program in ulcerative colitis (UC). We added two preclinical candidates to our early stage pipeline and completed preparation for a number of new clinical trials, building further on our innovative pipeline for future growth," said Onno van de Stolpe, CEO of Galapagos.

Bart Filius, COO and CFO added, "We ended the first half of 2020 with a strong cash balance, positioning us well to further grow our pipeline and deliver on operational excellence for the anticipated commercial launch of filgotinib. We maintain our 2020 operational cash burn guidance of €400-€430 million."

Key figures first half-year report 2020 (unaudited)
(€ millions, except basic & diluted loss per share)

	30 June 2020 group total	30 June 2019 group total
Revenues and other income	**224.6**	**108.5**
R&D expenditure	(265.9)	(177.6)
S&M[ii] expenses	(26.9)	(5.6)
G&A[iii] expenses	(62.6)	(22.9)
Operating loss	**(130.8)**	**(97.6)**
Fair value re-measurement of warrants	(21.1)	-
Net other financial result	(13.0)	1.8
Taxes	(0.7)	(0.1)
Net result for the period	**(165.6)**	**(95.9)**
Basic and diluted loss per share (€)	(2.55)	(1.76)
Current financial investments and cash and cash equivalents	**5,566.5**	**1,147.9**

Revenues and other income

Revenues and other income for the first half-year of 2020 increased to €224.6 million compared to €108.5 million in the first half-year of 2019. The impact of the Gilead collaboration on our revenues is €187.7 million and consists of (i) the access and option rights to our drug discovery platform (€112.7 million), and (ii) the filgotinib revenue recognition (€75.0 million).

As a result of the upfront payment received from Gilead in the third quarter of 2019, our deferred income on 30 June 2020 includes €2.1 billion allocated to our drug discovery platform that will be recognized linearly over 10 years, and €0.7 billion allocated to filgotinib (2015 filgotinib contract and recent revised collaboration combined) that will be recognized over a period of 4 to 5 years.

Results

We realized a net loss of €165.6 million for the first half-year of 2020, compared to a net loss of €95.9 million for the first half-year 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 half-year 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 in our R&D investments, 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 €26.9 million and €62.6 million in the first half-year of 2020, compared to respectively €5.6 million and €22.9 million in the first half-year 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, as result of the increased implied volatility of the Galapagos share price.

Net other financial loss in the first half-year of 2020 amounted to €13.0 million, compared to net other financial income of €1.8 million for the first half-year of 2019, which was primarily attributable to a negative change 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.

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

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

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 with 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.

First half-year report 2020
Galapagos' financial report for the first half-year ended 30 June 2020, 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, 7 August 2020, 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: 8997710

USA:	+1 323 794 2093
UK:	+44 330 336 9105
Netherlands:	+31 20 721 9251
France:	+33 1 76 77 2274
Belgium:	+32 2 404 0659

Or, select the click-to-join link and you'll get connected automatically.

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

5 November 2020	Third quarter 2020 results (webcast 6 November 2020)
18 February 2021	Full year 2020 results (webcast 19 February 2021)

About Galapagos
Galapagos (Euronext & NASDAQ: GLPG) discovers and develops small molecule medicines with novel modes of action, three 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, osteoarthritis 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.

Filgotinib and all other drug candidates mentioned in this press release 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, the guidance from management (including guidance regarding the expected operational cash burn during financial year 2020), financial results, timing and/or results of clinical trials, mechanisms of action and potential commercialization of our product candidates, interaction with regulators, 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. 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 Galapagos' expectations regarding its 2020 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 that data from Galapagos' ongoing clinical research programs 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 for filgotinib and ziritaxestat, Gilead, and our collaboration partner for GLPG1972, Servier), and 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 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.

[i] Committee for Medicinal Products for Human Use

[ii] Sales and marketing

[iii] General and administrative

[iv] 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 / 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 / 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 2020 amounted to €230.5 million and can be reconciled to our cash flow statement by considering the increase in cash and cash equivalents of €523.2 million, adjusted by (i) the cash proceeds from capital and share premium increase from the exercise of subscription rights by employees for €23.3 million and (ii) the net sale of current financial investments amounting to €730.4 million.

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