

The Galapagos group

An overview of Galapagos, its strategy
and portfolio in the first nine months
of 2019



Letter from the management

Dear shareholders,

There is no question that the third quarter of 2019 was defined by the unique and landmark deal with our long-time collaboration partner Gilead, announced mid-July. This 10-year research collaboration is about maximizing innovation based on the identification and development of new mode of action medicines. Thanks to the upfront payment of \$3.95 billion and a \$1.1 billion equity investment by Gilead, the deal gives us the financial strength – and the independence – to greatly expand our research engine and build a broader pipeline of new mode of action medicines. Gilead will have option rights on our programs outside of Europe, and as part of the agreement, they have already executed that right for our late-stage IPF compound, GLPG1690. We will also benefit greatly from Gilead's scientific expertise and infrastructure.

Gilead and we strongly believe that this collaboration will provide an accelerated path to advance our pipeline, and thus provide the opportunity to fast track our mission to bring innovation to patients worldwide.



In Q3, together with Gilead, we took important steps forward with our flagship program, filgotinib. Early July, Gilead announced the outcome of the pre-NDA meeting with the FDA. Gilead discussed with the agency the Phase 3 FINCH trials, as well as the ongoing Phase 2 MANTA safety trial, and concluded that they intend to submit filgotinib for approval in RA in the US in 2019. Together with Gilead, we also announced that the European Medicines Agency (EMA) validated the Marketing Authorization Application (MAA) for filgotinib in RA for the European market. In early October, Gilead announced submission of filgotinib to the Japanese Ministry of Health, Labor and Welfare, for approval in RA. Gilead remains on track to submit filgotinib for approval in RA to the FDA before year-end.

Thanks to the progress made, we are on track for potential new drug approvals as of the second half of 2020, and we are excited by the prospect of bringing filgotinib as a new treatment option to RA patients.

We are also proud that the FINCH 2 results for filgotinib in RA were published in *JAMA*¹, which is a further recognition of the importance of the program. Just recently, recruitment commenced for the PENGUIN Phase 3 program with filgotinib in psoriatic arthritis, an important next step to expand our filgotinib inflammation franchise to additional indications.

We also continue our plans to become a fully integrated biotechnology company. The core commercial team for Belgium, the Netherlands, and Luxembourg is firmly in place, and we hired key people for our commercial operations in France, Italy and Spain, following our revised filgotinib agreement with Gilead.

In the meantime, we work hard on progressing our late stage portfolio of other drug candidates. This includes our fully recruited Phase 2b trial with GLPG1972 in osteoarthritis, ROCCELLA, for which we expect data in the second half of next year. We experience good recruitment of the ISABELA 1 & 2 Phase 3 trials with autotaxin inhibitor GLPG1690 in idiopathic pulmonary fibrosis. The enthusiasm for the ISABELA program amongst clinicians, centers, and patients is palpable, as we noticed again at the recent *ERS* conference. Together with Gilead, we are fully committed to seeking new approaches to meet the large unmet medical need in IPF. Together with our collaboration partners Novartis and MorphoSys, we also continue the Phase 2 trials GECKO and IGUANA with MOR106 in atopic dermatitis, and we recently started a Japanese ethnobridging study.

¹ *Journal of the American Medical Association*



Furthermore, we are progressing our first Phase 1 trial from the next-generation Toledo program for inflammation, with GLPG3312, and we recently announced the start of a Phase 1 trial with Toledo compound GLPG3970.

Following the upfront payment of \$3.95 billion and a \$1.1 billion equity investment received in the Gilead transaction, we have an exceptionally strong balance sheet. As we continue to grow our organization to support our broad pipeline and build a commercial organization for the anticipated launch of filgotinib in Europe next year, our financial guidance for full year 2019 operational cash burn² between €320 and €340 million is unchanged, excluding the impact from the Gilead collaboration.

Operational overview H1 2019

We refer to our [H1 2019 report](#).

Operational overview Q3 2019

Inflammation

- Gilead and Galapagos announced that the EMA validated the MAA for filgotinib in RA in Europe
- Gilead announced the outcome of the pre-NDA meeting with the FDA, concluding that a path has been established to submit an NDA for filgotinib in RA in the US in 2019
- Publication of the detailed FINCH 2 results in *JAMA*, a top-tier peer-reviewed journal
- Initiated the Japanese ethnobridging trial with MOR106, together with collaboration partners Novartis and MorphoSys, in Japanese patients with atopic dermatitis
- Initiated a Phase 1 trial with GLPG3970, a second generation Toledo compound against a novel and undisclosed inflammation target class discovered by Galapagos

Corporate & other

- Gilead and Galapagos entered into a 10-year global R&D collaboration; Gilead increased their shareholding in Galapagos to 22.04% of the then issued and outstanding shares of Galapagos NV
- We received transparency notices which can be consulted [on our website](#)
- Galapagos raised €6.7 million through warrant exercises in the third quarter of 2019

Recent events

- Together with collaboration partner Gilead, we announced that Week 52 data³ from the Phase 3 FINCH 1 and FINCH 3 trials of filgotinib for the treatment of RA are consistent with and support the profiles observed in the Week 12 and 24 analyses presented earlier this year
- Gilead commenced patient recruitment for PENGUIN, a Phase 3 trial with filgotinib in psoriatic arthritis
- Started Phase 1 trial with GLPG3667, a novel candidate with an undisclosed mode of action directed towards inflammation
- Gilead announced submission of filgotinib for approval in RA in Japan

² 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; and the movement in restricted cash, 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.

³ Data on file

Q3 2019 financial result

Revenues and other income

Our revenues and other income for the first nine months of 2019 amounted to €752.5 million, compared to €205.1 million for the first nine months of 2018. Revenues represented €725.7 million for the first nine months of 2019 compared to €182.5 million for the first nine months of 2018 and were higher due to the revenue recognition of the upfront payment received in August 2019 from Gilead related to (i) the GLPG1690 program and (ii) the access and option rights to our drug discovery platform, offset by (iii) a negative catch-up effect for revenues related to the previously received upfront and milestones due to the revised filgotinib collaboration agreement.

Other income increased by €4.1 million, mainly driven by higher incentives income from the government for our R&D activities.

Results

We realized a net profit of €265.3 million for the first nine months of 2019, compared to a net loss of €44.2 million for the first nine months of 2018.

We reported an operating profit amounting to €393.0 million for the first nine months of 2019, compared to an operating loss of €53.5 million for the first nine months of 2018.

Our R&D expenditure in the first nine months of 2019 amounted to €298.2 million, compared to €231.8 million for the first nine months of 2018. This planned increase was mainly due to an increase of €29.1 million in subcontracting costs primarily related to our IPF program, filgotinib and other programs. Furthermore, personnel costs increased explained by a planned headcount increase and higher costs related to bonuses and to warrant plans as a result of the increase of the Galapagos share price. These factors also contributed to the increase in our G&A and S&M expenses which were €61.2 million in the first nine months of 2019, compared to €26.8 million in the first nine months of 2018.

We reported a non-cash fair value loss from the re-measurement of a derivative financial instrument triggered by the share subscription agreement with Gilead between signing and closing of the agreement amounting to €142.3 million. Such amount reflects the increase in the Galapagos share price between signing and closing of the Gilead agreement.

Net other financial loss in the first nine months of 2019 amounted to €2.0 million, compared to net other financial income of €9.0 million for the first nine months of 2018, which was primarily attributable to €34.9 million realized exchange loss on the U.S. dollars upfront payment from Gilead, which was partly compensated by a €32.4 million of unrealized exchange gain on our cash position in U.S. dollars (compared to €6.6 million of unrealized exchange gain on our cash position in U.S. dollars in the first nine months of 2018).

We reported a tax income amounting to €16.7 million primarily from the recognition of deferred tax assets as a consequence of the deal with Gilead.

Liquid assets position

Cash and cash equivalents totaled €5,599.8 million on 30 September 2019.

A net increase of €4,309.0 million in cash and cash equivalents was recorded during the first nine months of 2019, compared to a net increase of €192.5 million during the first nine months of 2018. This net increase was composed of (i) €3,302.0 million of operational cash flow, of which €3,535.0 million cash inflow from the Gilead collaboration and €233.0 million remaining cash outflow from operating activities, (ii) €960.1 million cash proceeds related to the share subscription by Gilead, (iii) €14.5 million of cash proceeds from capital and share premium increase from exercise of warrants in the first nine months of 2019 and (iii) €32.4 million of unrealized positive exchange rate differences.



Finally, our balance sheet as at 30 September 2019 held a receivable from the French government (*Crédit d'Impôt Recherche*⁴), payable in 4 yearly tranches, and a receivable from the Belgian Government for R&D incentives, for a total of €99.7 million.

Outlook 2019

Following on regulatory submissions in Europe and Japan, Gilead is on track to submit filgotinib for approval in RA in the US before year-end.

We will continue recruitment in our proprietary ISABELA, NOVESA and PINTA trials, and plan to provide an update on recruitment timelines for the ISABELA program in H2 2019. We and our collaboration partner Servier continue towards completion of the ROCCELLA trial in osteoarthritis, on track for topline results in the second half of next year. For MOR106, together with our collaboration partners MorphoSys and Novartis, we continue executing the Phase 1 and 2 trials currently ongoing.

We continue to execute on our Toledo program in order to deliver Phase 1 results and plan to start several Phase 2a trials start in 2020.

Our guidance for an operational cash burn between €320 - €340 million in 2019 is unchanged, excluding the impact from the Gilead collaboration.

Following the closing of our new collaboration with Gilead, we envision a significant scaling up of our R&D efforts, strengthening our target discovery platform capabilities and substantially growing our R&D team. In other words, stay tuned for Galapagos 2.0, powered for an exciting future. At this exceptional phase in our history, we want to express our sincere thanks for your support of Galapagos, as we focus on delivering innovation with the aim to improve patients' lives worldwide.

Onno van de Stolpe

CEO

⁴ *Crédit d'Impôt Recherche* refers to an innovation incentive system underwritten by the French government.



At a glance

Consolidated key figures

(thousands of €, if not stated otherwise)	Third quarter of 2019	Third quarter of 2018	Nine months ended 30 September 2019	Nine months ended 30 September 2018	Full year 2018
Income statement					
Revenues	633,934	94,874	725,719	182,457	288,836
Other income	10,020	8,334	26,744	22,623	29,009
R&D expenditure	(120,680)	(80,314)	(298,247)	(231,758)	(322,875)
S, G&A expenses	(32,643)	(10,623)	(61,195)	(26,837)	(39,776)
Operating expenses	(153,323)	(90,937)	(359,442)	(258,595)	(362,652)
Operating profit / loss (-)	490,631	12,271	393,021	(53,515)	(44,807)
Net financial results	(146,226)	2,091	(144,391)	8,958	15,598
Taxes	16,828	480	16,699	343	(50)
Net profit / net loss (-)	361,233	14,841	265,329	(44,215)	(29,259)
Balance sheet					
Cash and cash equivalents	5,599,787	1,343,668	5,599,787	1,343,668	1,290,796
R&D incentives receivables	99,711	80,447	99,711	80,447	84,646
Assets ⁽¹⁾	5,851,752	1,485,551	5,851,752	1,485,551	1,439,496
Shareholders' equity ⁽¹⁾	2,535,281	1,188,222	2,535,281	1,188,222	1,214,249
Deferred income	3,127,777	209,742	3,127,777	209,742	149,801
Other liabilities ⁽¹⁾	188,695	87,587	188,695	87,587	75,446
Cash flow					
Operational cash flow / burn (-) ⁽²⁾	3,454,585	(5,571)	3,302,041	(100,581)	(158,384)
Cash flow generated / used (-) in operating activities ⁽¹⁾	3,470,495	(3,640)	3,328,758	(94,918)	(142,466)
Cash flow used in investing activities	(14,221)	(1,933)	(22,881)	(5,657)	(15,914)
Cash flow generated in financing activities ⁽¹⁾	965,072	281,181	970,733	286,435	287,876
Increase in cash and cash equivalents	4,421,347	275,608	4,276,610	185,860	129,497
Effect of currency exchange rate fluctuation on cash and cash equivalents	30,514	1,292	32,380	6,596	10,089
Cash and cash equivalents at the end of the period	5,599,787	1,343,668	5,599,787	1,343,668	1,290,796



THE GALAPAGOS GROUP

(thousands of €, if not stated otherwise)	Third quarter of 2019	Third quarter of 2018	Nine months ended 30 September 2019	Nine months ended 30 September 2018	Full year 2018
Financial ratios					
Number of shares issued at the end of the period	61,953,831	54,299,136	61,953,831	54,299,136	54,465,421
Basic gain / loss (-) per share (in €)	6.26	0.29	4.77	(0.86)	(0.56)
Diluted gain / loss (-) per share (in €)	6.03	0.28	4.59	(0.86)	(0.56)
Share price at the end of the period (in €)	139.80	97.42	139.80	97.42	80.56
Total group employees at the end of the period (number)	918	712	918	712	725

(1) Our assets, shareholders' equity, other liabilities, cash flow generated / used (-) in operating activities and cash flow generated in financing activities for the period ended 30 September 2019 were influenced by the adoption of the new standard IFRS 16 – Leases, on 1 January 2019. We refer to the notes of this condensed consolidated interim financial report for additional information.

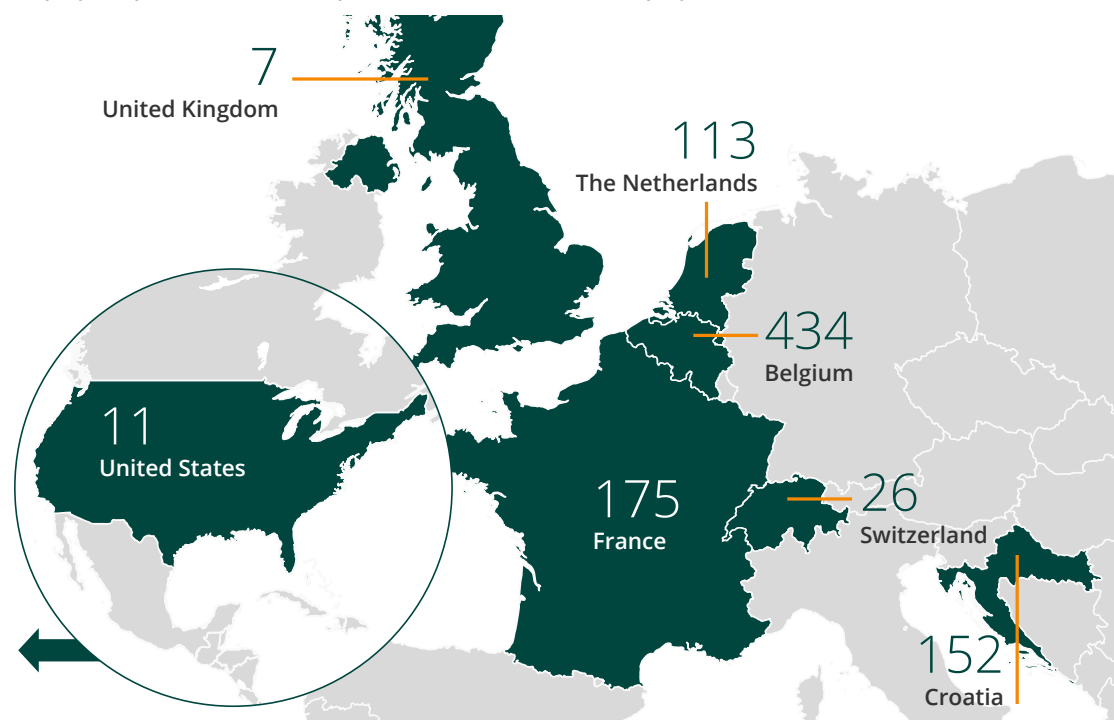
(2) The operational cash burn (or operational cash flow if this performance measure is positive) is equal to the increase or decrease in our cash and cash equivalents (excluding the effect of exchange rate differences on cash and cash equivalents), minus:

(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; and the movement in restricted cash, 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.

Employees per site as of 30 September 2019 (total: 918 employees)



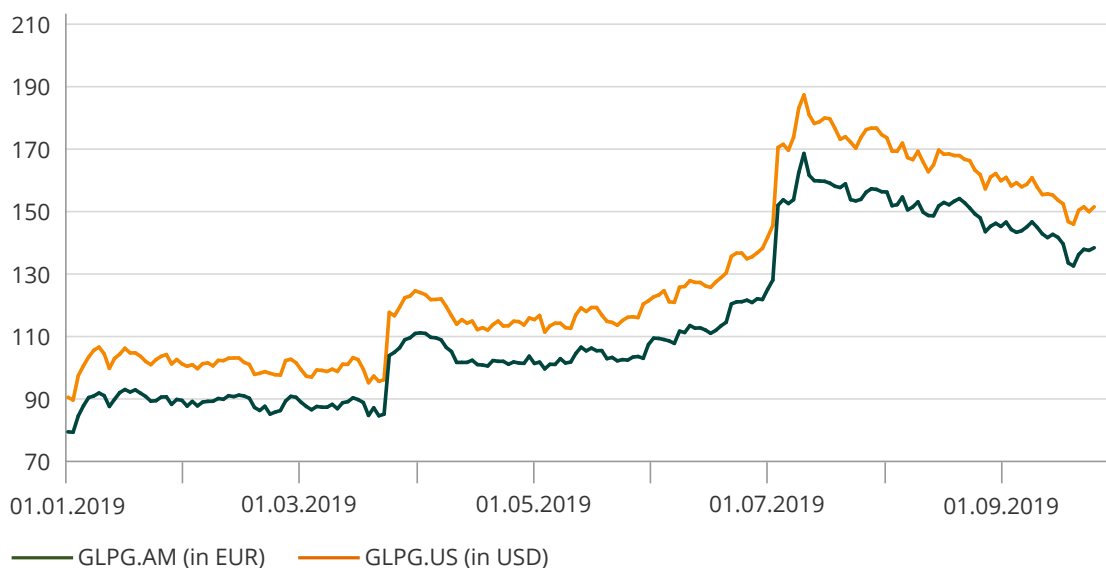
Risk factors

We refer to the [description of risk factors in the 2018 annual report](#), pp. 57-66, 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. 4-45. 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 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 2018 annual report](#), pp. 161-163, 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 nine months of 2019” part of this report.

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 2019”; guidance from management regarding the expected operational use of cash during financial year 2019, statements regarding the amount and timing of potential future milestone, opt-in and/or royalty payments by Gilead; regarding the expected timing, design and readouts of ongoing and planned clinical trials (i) with filgotinib in rheumatoid arthritis, Crohn’s disease, ulcerative colitis and other indications, (ii) with GLPG1690 in IPF and SSc and GLPG1205 in IPF, (iii) with GLPG1972 in osteoarthritis, (iv) with MOR106 in atopic dermatitis, and (v) with GLPG3312, GLPG3970 and GLPG3667 in inflammation, and statements regarding the regulatory pathway for filgotinib and the timing of regulatory filings and potential approval thereof. 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 2019 revenues and financial results and our 2019 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 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, Gilead, our collaboration partner for GLPG1972, Servier and our collaboration partners for MOR106, Novartis and MorphoSys), and estimating the commercial potential of our product candidates. A further list and description of these risks, uncertainties and other risks can be found in our U.S. Securities and Exchange Commission filings and reports, including in our most recent Annual Report on Form 20-F filed with the SEC and our other filings and reports. 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.