

Q1 Report

2020



Contents

The Galapagos group

Letter from the management	4
COVID-19 impact	8
At a glance	9
Risk factors	11
The Galapagos share	11
Disclaimer and other information	12

Financial statements

Unaudited condensed consolidated interim financial statements	15
Notes	22

Auditor's report

Report on the limited review of the consolidated interim financial results	32
---	----

Other information

Glossary of terms	33
Financial calendar	47
Colophon	47
Contact	47

The Galapagos group

An overview of Galapagos, its strategy
and portfolio in Q1 2020



Letter from the management

Dear shareholders,

The first quarter of 2020 was marked by the global outbreak of COVID-19, and first and foremost, I hope that you and yours are staying safe and healthy as we continue to navigate this unprecedented crisis.

For us at Galapagos, the pandemic also brings unexpected challenges. We decided to postpone temporarily the start of early-stage clinical trials, and with our collaboration partner Gilead, we paused recruitment into the ongoing Phase 2 and 3 trials with filgotinib. We continuously monitor the situation, always putting patients' safety and needs front and center, and our teams work hand in hand with our CROs and clinical trial sites to define next steps.

Importantly, despite the challenging environment, we remain on track to report on a number of later stage clinical trials, and the remainder of the year promises to be particularly news flow rich.



The regulatory review process of our first product candidate, filgotinib in rheumatoid arthritis (RA), is progressing, and we still anticipate approval decisions in the U.S., Europe and Japan later this year.

Furthermore, in the first quarter, we made important progress in the build-out of our commercial organization. We are confident that we will hit the ground running upon potential approval of filgotinib in the EU5 and Benelux countries, hand in hand with our collaboration partner Gilead. We should be able to complete our transformation into a fully integrated biopharma company, bringing our first approved, novel mode of action product to patients later this year.

Moreover, we are on track to report the topline results from the SELECTION Phase 3 trial of filgotinib in ulcerative colitis (UC) in the second quarter. This is the first inflammatory bowel disease (IBD) Phase 3 data read-out for filgotinib. Pending positive results, we see an important potential role for filgotinib in this indication, given the high unmet need of patients suffering from UC.

Moving on to our other programs, we and collaboration partner Servier continue to advance the fully recruited ROCCELLA Phase 2b trial with our ADAMTS-5 inhibitor GLPG1972 in patients with knee osteoarthritis (OA). With current visibility in light of COVID-19, we still remain on track to report topline results for ROCCELLA in the second half of this year.

Our programs in fibrotic diseases are also making important progress. Patient recruitment continues in the global ISABELA Phase 3 program with ziritaxestat (GLPG1690) in idiopathic pulmonary fibrosis (IPF) that we conduct together with Gilead. While we see an impact on recruitment rates due to COVID-19, mitigations such as virtual visits and direct shipment of medication to patients keep the trial running relatively smoothly for the more than 1,000 patients randomized to date. We expect to report the outcome of the futility analysis for ISABELA in the first half of 2021.

Also for our NOVESA Phase 2a trial with ziritaxestat in systemic sclerosis (SSc), we remain on track to report topline results in the second half of this year, together with Gilead. We completed recruitment with GLPG1205 in the PINTA Phase 2 IPF trial in early 2020, and we expect to report topline results later this year.



With regard to Toledo, our novel mode of action program in inflammation, we completed Phase 1 studies in healthy volunteers with our Toledo drug candidates, GLPG3312 and GLPG3970. Given the superior profile of GLPG3970 observed in Phase 1, we decided to prioritize the further development of GLPG3970. We still anticipate the start of several proof-of-concept patient trials with GLPG3970 in the second half of the year, with topline results now expected in the first half of 2021.

In the labs, we continue to exploit our powerful target discovery engine to ensure long-term value creation, and to deliver on our ambition to maintain an active R&D portfolio in inflammation, fibrosis, and other severe diseases, including type 2 diabetes, hepatitis B and polycystic kidney disease.

From a financial perspective, we ended the first quarter of 2020 with a cash position of €5.7 billion which will allow us to grow our pipeline and attract new talent to support our ambitious growth plan. As a result of COVID-19, our cash burn guidance for FY2020 is expected to be in the range of €400 - €430 million, down versus the previously stated cash burn projection due to the pause in recruitment or postponed starts of some clinical trials.

Operational overview Q1 2020

In fibrosis

- Completed recruitment of the PINTA Phase 2 trial with GPR84 inhibitor GLPG1205 in IPF
- Obtained orphan drug designation for ziritaxestat (GLPG1690) in SSc from the FDA and the European Commission
- Expanded the Fibrocor R&D collaboration in fibrosis

Corporate & other

- Raised €5.4 million from warrant exercises

Recent events

- Announced a collaboration with Ryvu Therapeutics (WSE: RVU) focused on the discovery and development of novel small molecule drugs in inflammation, based on a novel drug target identified by Ryvu
- On 28 April 2020, Galapagos held its annual (ordinary) and extraordinary shareholders' meetings. Due to the COVID-19 pandemic, the meetings were held behind closed doors, with advance shareholders' participation only. All agenda items were approved, including the appointment of Dr. Elisabeth Svanberg as independent director, the remuneration policy and -report, the amendment of the company's object and the amendment of the articles of association in light of the new Belgian Code of Companies and Associations

Q1 2020 financial result

Revenues and other income

Our revenues and other income for the first three months of 2020 amounted to €106.9 million, compared to €40.9 million for the first three months of 2019. Revenues (€98.2 million for the first three months of 2020 compared to €33.0 million for the first three months of 2019) were higher due to the revenue recognition of the upfront payment received from Gilead in August 2019 related to (i) the exclusive access to our drug discovery platform during the collaboration period and exclusive option rights on our current and future clinical programs after Phase 2 outside Europe, and (ii) additional consideration received for the extended cost sharing for filgotinib.

Other income (€8.7 million vs €7.9 million for the same period last year) increased, mainly driven by higher incentives income from the government for our R&D activities.



Results

We realized a net loss of €50.6 million for the first three months of 2020, compared to a net loss of €48.7 million for the first three months of 2019.

We reported an operating loss amounting to €44.6 million for the first quarter of 2020, compared to an operating loss of €53.2 million for the first quarter of 2019.

Our R&D expenditure in the first three months of 2020 amounted to €116.8 million, compared to €83.2 million for the first quarter of 2019. This planned increase was mainly due to an increase of €19.4 million 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 of our R&D activities. This last factor, together with increased costs from the preparation of the commercial launch of filgotinib in Europe, contributed to the increase in our G&A and S&M expenses which were €34.7 million in the first three months of 2020, compared to €11.0 million in the first three months of 2019.

We reported a non-cash fair value loss from the re-measurement of initial warrant B issued to Gilead, amounting to €20.5 million, mainly due to the increased implied volatility of the Galapagos share price.

Net other financial income in the first three months of 2020 amounted to €14.8 million, compared to net other financial income of €4.7 million for the first three months of 2019, which was primarily attributable to €34.3 million of unrealized exchange gain on our cash position in U.S. dollars, partly compensated by a fair value loss on current financial investments of €14.5 million.

Cash and cash equivalents and current financial investments

Current financial investments and cash and cash equivalents totaled €5,722.4 million on 31 March 2020.

A net decrease of €58.4 million in cash and cash equivalents and current financial investments was recorded during the first three months of 2020, compared to a net decrease of €67.9 million during the first three months of 2019. This net decrease was composed of €83.4 million of operational cash burn¹, offset by (i) €5.4 million of cash proceeds from capital and share premium increase from exercise of warrants in the first three months of 2020, (ii) €19.6 million of unrealized positive exchange rate differences and fair value losses on current financial investments.

Finally, our balance sheet as at 31 March 2020 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 €115.2 million.

Outlook 2020

The remainder of the year promises to be eventful for Galapagos.

We and our collaboration partner Gilead expect to report Phase 3 SELECTION trial data of filgotinib in ulcerative colitis in the second quarter. We also expect approval of our first product candidate, filgotinib, in RA in the U.S., Europe, and Japan in the second half of 2020. Gilead and we plan to start later in 2020 the Phase 3 program with filgotinib in ankylosing spondylitis – a potential additional indication for our growing filgotinib franchise.

Within our fibrosis portfolio, in the second half of the year, we anticipate reporting topline results from the PINTA Phase 2 trial with GLPG1205 in IPF and, together with collaboration partner Gilead, from the NOVESA Phase 2a trial with ziritaxestat in SSc. In the meantime, we continue recruitment in our landmark Phase 3 ISABELA program with ziritaxestat in IPF, together with Gilead, and we expect to report the outcome of the futility analysis in the first half of 2021.

¹ We refer to the [note](#) on the liquid assets 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.



THE GALAPAGOS GROUP

Also in the second half of the year, we and Servier expect to report topline results from the ROCCELLA Phase 2b trial of GLPG1972 in knee osteoarthritis. Upon successful completion of this trial, Gilead has the option to license development and commercialization rights in the U.S. for GLPG1972.

We will continue to execute on our accelerated development plan for Toledo, our next generation inflammation program. Pending positive developments related to the COVID-19 pandemic, we expect to launch multiple proof-of-concept patient trials with GLPG3970 in the second half of the year, and we now expect to report topline data in the first half of 2021.

Due to the temporary pause in recruitment for a number of ongoing Phase 2 and 3 trials and delays in the start of a number of planned early-stage trials, our cash burn guidance has been revised down and is now expected to be in the range of €400 and €430 million compared to €420 and €450 million previously guided. The cash burn includes milestone income from Gilead for potential regulatory approvals of filgotinib in RA.

I would like to thank you all for your continued trust and support. We are in a strong position to navigate the sudden challenges caused by the COVID-19 pandemic, and we remain dedicated to breaking innovative ground to improve patients' lives. Please stay with us as we continue on this exciting innovation journey.

Onno van de Stolpe

CEO



COVID-19 impact

In light of the ongoing COVID-19 pandemic, we are committed to keeping our stakeholders informed as the situation evolves. We see the following impact at this point in time:

- *Staff*

Galapagos has strong measures in place to help prevent spread of the virus and protect the health of our staff. We rolled out our global and site business continuity plans and took appropriate recommended precautions and restrictions, including suspending all travel. In practice, this means that our employees are working from home, with the exception of lab personnel and skeleton IT and facility team to ensure safety and operational continuity essential to keep research going. For those, 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.

- *Clinical trials*

We have a business continuity plan for our non-clinical and clinical trials, including a pandemic response plan. We have decided to pause the start of early stage trials temporarily. We continuously monitor the situation, always putting patients' safety and needs front and center, and our teams are working hand in hand with our CROs and clinical trial sites to define next steps. Our collaboration partner Gilead and we have temporarily paused enrollment into the filgotinib trials in order to help protect patient safety. This includes the Phase 2 and Phase 3 trials of filgotinib in Crohn's disease (DIVERSITY), the Phase 3 in psoriatic arthritis (PENGUIN), the Phase 2 trial in uveitis, and the MANTA and MANTA-RAY trials. We anticipate the Phase 3 program in ankylosing spondylitis will now start later this year.

- *Filgotinib filing process in RA*

The FDA has confirmed priority review with a PDUFA goal date in the second half of this year. As with all applications, but particularly during these difficult circumstances, potential approval timings are subject to change. Gilead continues to work with the FDA and regulatory agencies in Europe and Japan as they review the application. Gilead also confirmed that all sites involved in the manufacturing of filgotinib are established sites that manufacture Gilead marketed products, are in good standing with the FDA, and are GMP certified.

- *Commercial organization*

Build-up of our commercial operations in the EU5 countries and the Benelux to prepare for the potential launch of filgotinib continues as planned.



At a glance

Consolidated Key figures

(thousands of €, if not stated otherwise)	Three months ended 31 March 2020	Three months ended 31 March 2019	Year ended 31 December 2019
Income statement			
Revenues	98,173	33,047	844,985
Other income	8,743	7,872	50,905
R&D expenditure	(116,763)	(83,195)	(427,320)
S, G&A expenses	(34,738)	(10,966)	(98,278)
Operating expenses	(151,501)	(94,161)	(525,597)
Operating profit/loss (-)	(44,585)	(53,242)	370,292
Net financial results	(5,681)	4,655	(220,233)
Taxes	(336)	(68)	(214)
Net profit/loss (-)	(50,601)	(48,656)	149,845
Balance sheet			
Cash and cash equivalents	2,743,573	1,222,901	1,861,616
Current financial investments	2,978,805	-	3,919,216
R&D incentives receivables	115,240	87,674	115,356
Assets	5,992,406	1,400,200	6,068,609
Shareholders' equity	2,840,041	1,175,755	2,875,658
Deferred income	2,913,398	123,822	3,000,646
Other liabilities	238,968	100,624	192,305
Cash flow			
Operational cash burn (-)/operational cash flow ^(*)	(83,398)	(76,344)	3,162,804
Cash flow used (-)/generated in operating activities	(68,874)	(71,698)	3,208,617
Cash flow generated/used (-) in investing activities	929,640	(3,398)	(3,764,660)
Cash flow generated in financing activities	3,930	2,233	1,335,751
Increase/decrease (-) in cash and cash equivalents	864,695	(72,863)	779,708
Transfer to current financial investments	-	-	(198,922)
Effect of currency exchange rate fluctuation on cash and cash equivalents	17,261	4,968	(9,966)
Cash and cash equivalents at the end of the period	2,743,573	1,222,901	1,861,616
Current financial investments at the end of the period	2,978,805	-	3,919,216
Total current financial investments and cash and cash equivalents at the end of the period	5,722,378	1,222,901	5,780,832

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

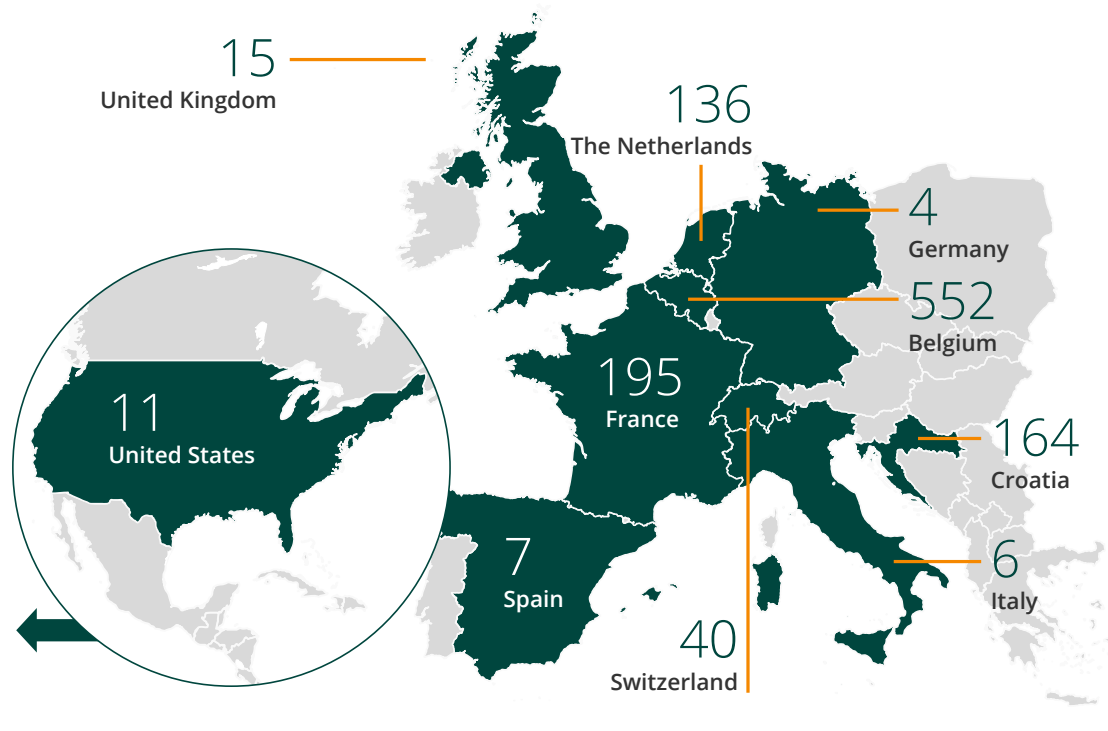


(thousands of €, if not stated otherwise)	Three months ended 31 March 2020	Three months ended 31 March 2019	Year ended 31 December 2019
Financial ratios			
Number of shares issued at the end of the period	64,819,022	54,614,791	64,666,802
Basic income/loss (-) per share (in €)	(0.78)	(0.89)	2.60
Diluted income/loss (-) per share (in €)	(0.78)	(0.89)	2.49
Share price at the end of the period (in €)	181.00	103.90	186.50
Total group employees at the end of the period (number)	1,130	779	1,003

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

Employees per site as of 31 March 2020

(total: 1,130 employees)





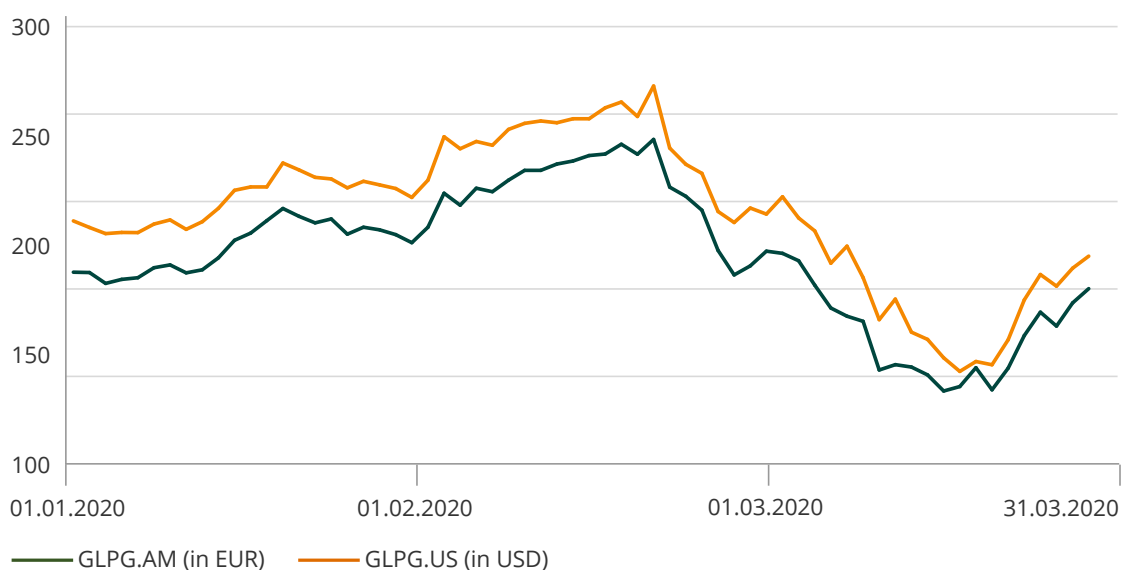
Risk factors

We refer to the [description of risk factors in the 2019 annual report](#), pp. 60-69, 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. 5-49. 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 2019 annual report](#), pp. 189-191, 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.

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:

Galapagos NV

Investor Relations

Generaal De Wittelaan L11 A3

2800 Mechelen, Belgium

Tel: +32 15 34 29 00

Email: ir@glpg.com

A digital version of this report is available on our website, www.glpg.com.

We will use reasonable efforts to ensure the accuracy of the digital version, but do not assume responsibility if inaccuracies or inconsistencies with the printed document arise as a result of any electronic transmission. Therefore, we consider only the printed version of this report to be legally valid. Other information on our website or on other websites does not form a part of this report.

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 2020”, guidance from management regarding the expected operational use of cash during financial year 2020, statements regarding the amount and timing of potential future milestone, opt-in and/or royalty payments by Gilead, statements regarding the expected timing, design and readouts of ongoing and planned clinical trials (i) with filgotinib in ulcerative colitis, Crohn’s disease, psoriatic arthritis, ankylosing spondylitis and other indications, (ii) with ziritaxestat (GLPG1690) and GLPG1205 in IPF and with ziritaxestat in SSc, (iii) with GLPG1972 in osteoarthritis, and (iv) with GLPG3312, GLPG3970, and GLPG4399 in inflammation, statements relating to interactions with regulatory authorities, the potential approval process for filgotinib and statements relating to the build-up of our commercial organization, the 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 2020 revenues and financial results and our 2020 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 in rheumatoid arthritis, Crohn's disease, ulcerative colitis, psoriatic arthritis, ankylosing spondylitis, idiopathic pulmonary fibrosis, systemic sclerosis, 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 for filgotinib and ziritaxestat, Gilead, and our collaboration partner for GLPG1972, Servier), 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 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.

Financial statements

Consolidated interim financial
statements for the first quarter 2020



Unaudited condensed consolidated interim financial statements for the first three months of 2020

Consolidated statements of income and comprehensive income

Consolidated income statement

(thousands of €, except per share data)	Three months ended 31 March	
	2020	2019
Revenues	98,173	33,047
Other income	8,743	7,872
Total revenues and other income	106,916	40,919
Research and development expenditure	(116,763)	(83,195)
Sales and marketing expenses	(9,836)	(1,746)
General and administrative expenses	(24,902)	(9,221)
Total operating expenses	(151,501)	(94,161)
Operating loss	(44,585)	(53,242)
Fair value re-measurement of warrants	(20,529)	-
Other financial income	39,722	6,999
Other financial expenses	(24,873)	(2,345)
Loss before tax	(50,266)	(48,588)
Income taxes	(336)	(68)
Net loss	(50,601)	(48,656)
Net loss attributable to:		
Owners of the parent	(50,601)	(48,656)
Basic and diluted loss per share	(0.78)	(0.89)

The accompanying notes form an integral part of these condensed consolidated financial statements.



FINANCIAL STATEMENTS

Consolidated statement of comprehensive income/loss (-)

(thousands of €)	Three months ended 31 March	
	2020	2019
Net loss	(50,601)	(48,656)
Items that may be reclassified subsequently to profit or loss:		
Translation differences, arisen from translating foreign activities	401	267
Other comprehensive income/loss (-), net of income tax	401	267
Total comprehensive loss attributable to:		
Owners of the parent	(50,200)	(48,389)

The accompanying notes form an integral part of these condensed consolidated financial statements.



Consolidated statements of financial position

	31 March	31 December
(thousands of €)	2020	2019
Assets		
Intangible assets	33,856	24,927
Property, plant and equipment	66,979	66,052
Deferred tax assets	4,206	4,205
Non-current R&D incentives receivables	93,156	93,407
Other non-current assets	13,945	14,091
Non-current assets	212,142	202,682
Trade and other receivables	27,096	54,009
Current R&D incentives receivables	22,084	21,949
Current financial investments	2,978,805	3,919,216
Cash and cash equivalents	2,743,573	1,861,616
Other current assets	8,705	9,138
Current assets	5,780,264	5,865,927
Total assets	5,992,406	6,068,609
Equity and liabilities		
Share capital	288,106	287,282
Share premium account	2,708,114	2,703,583
Other reserves	(4,919)	(4,842)
Translation differences	(663)	(1,142)
Accumulated losses	(150,597)	(109,223)
Total equity	2,840,041	2,875,658
Retirement benefit liabilities	8,444	8,263
Non-current lease liabilities	18,856	19,558
Other non-current liabilities	8,113	6,989
Non-current deferred income	2,494,327	2,586,348
Non-current liabilities	2,529,740	2,621,158



FINANCIAL STATEMENTS

	31 March	31 December
(thousands of €)	2020	2019
Current lease liabilities	6,210	5,826
Trade and other liabilities	169,477	143,434
Current tax payable	1,141	2,037
Current financial instruments	26,727	6,198
Current deferred income	419,071	414,298
Current liabilities	622,626	571,793
Total liabilities	3,152,366	3,192,951
Total equity and liabilities	5,992,406	6,068,609

The accompanying notes form an integral part of these condensed consolidated financial statements.



Consolidated cash flow statements

(thousands of €)	Three months ended 31 March	
	2020	2019
Net loss of the period	(50,601)	(48,656)
Adjustment for non-cash transactions	22,935	5,524
Adjustment for items to disclose separately under operating cash flow	(747)	(1,517)
Adjustment for items to disclose under investing and financing cash flows	(2,596)	(3)
Change in working capital other than deferred income	52,481	(2,294)
Decrease in deferred income	(91,677)	(25,979)
Cash used in operations	(70,205)	(72,925)
Interest paid	(171)	(327)
Interest received	2,745	1,565
Corporate taxes paid	(1,243)	(11)
Net cash flows used in operating activities	(68,874)	(71,698)
Purchase of property, plant and equipment	(2,866)	(2,103)
Purchase of and expenditure in intangible fixed assets	(10,159)	(1,201)
Proceeds from disposal of property, plant and equipment	-	1
Purchase of current financial investments	(2,187,948)	-
Interest received related to current financial investments	2,596	-
Sale of current financial investments	3,130,686	-
Acquisition of financial assets	(2,670)	(177)
Proceeds from sale of financial assets held at fair value through profit or loss	-	82
Net cash flows generated/used (-) in investing activities	929,640	(3,398)
Payment of lease liabilities	(1,425)	(1,248)
Proceeds from capital and share premium increases from exercise of warrants	5,355	3,481
Net cash flows generated in financing activities	3,930	2,233
Increase/decrease (-) in cash and cash equivalents	864,695	(72,863)



FINANCIAL STATEMENTS

(thousands of €)	Three months ended 31 March	
	2020	2019
Cash and cash equivalents at beginning of year	1,861,616	1,290,796
Increase/decrease (-) in cash and cash equivalents	864,695	(72,863)
Effect of exchange rate differences on cash and cash equivalents	17,261	4,968
Cash and cash equivalents at end of the period	2,743,573	1,222,901

The accompanying notes form an integral part of these condensed consolidated financial statements.

(thousands of €)	31 March	
	2020	2019
Current financial investments	2,978,805	-
Cash and cash equivalents	2,743,573	1,222,901
Current financial investments and cash and cash equivalents	5,722,378	1,222,901

The accompanying notes form an integral part of these condensed consolidated financial statements.



Consolidated statements of changes in equity

(thousands of €)	Share capital	Share premium account	Translation differences	Other reserves	Accum. losses	Total
On 1 January 2019	236,540	1,277,780	(1,557)	(735)	(297,779)	1,214,249
Change in accounting policy (modified retrospective application IFRS 16)					416	416
Restated total equity at 1 January 2019	236,540	1,277,780	(1,557)	(735)	(297,363)	1,214,665
Net loss					(48,656)	(48,656)
Other comprehensive income/loss (-)			267			267
Total comprehensive income/loss (-)			267	-	(48,656)	(48,389)
Share-based compensation					6,000	6,000
Exercise of warrants	808	2,673				3,481
On 31 March 2019	237,348	1,280,452	(1,290)	(735)	(340,020)	1,175,755
On 1 January 2020	287,282	2,703,583	(1,142)	(4,842)	(109,223)	2,875,658
Net loss					(50,601)	(50,601)
Other comprehensive income/loss (-)			478	(77)		401
Total comprehensive income/loss (-)			478	(77)	(50,601)	(50,200)
Share-based compensation					9,227	9,227
Exercise of warrants	824	4,531				5,355
On 31 March 2020	288,106	2,708,114	(663)	(4,919)	(150,597)	2,840,041

The accompanying notes form an integral part of these condensed consolidated financial statements.



Notes to the unaudited condensed consolidated interim financial statements for the first three months of 2020

Basis of preparation

These condensed consolidated interim financial statements have been prepared in accordance with IAS 34 'Interim Financial Reporting' as adopted by the European Union and as issued by the IASB. The condensed consolidated interim financial statements do not contain all information required for an annual report and should therefore be read in conjunction with Galapagos' [Annual Report 2019](#).

The condensed consolidated interim financial statements were subject to a limited review by the statutory auditor, but have not been audited.

Significant accounting policies

There were no significant changes in accounting policies applied by us in these condensed consolidated interim financial statements compared to those used in the most recent annual consolidated financial statements of 31 December 2019.

New standards and interpretations applicable for the annual period beginning on 1 January 2020 did not have any impact on our condensed consolidated interim financial statements.

We have not early adopted any other standard, interpretation, or amendment that has been issued but is not yet effective.

New accounting policies as a result of recent transactions:

Financial assets at amortized cost

Current financial investments measured at amortized cost

Current financial investments measured at amortized cost include treasury bills that have a maturity equal or less than 12 months. We apply settlement date accounting for the recognition and de-recognition of current financial investments measured at amortized cost.



Details of the unaudited condensed consolidated interim results

Revenues and other income

Revenues

The following table summarizes our revenues for the three months ended 31 March 2020 and 2019.

(thousands of €)	Three months ended 31 March		
	Over time	2020	2019
Recognition of non-refundable upfront payments and license fees		88,287	20,232
Gilead collaboration agreement for filgotinib	✓	32,105	19,787
Gilead collaboration agreement for drug discovery platform	✓	56,182	-
AbbVie collaboration agreement for CF	✓	-	444
Milestone payments		3,272	5,302
Gilead collaboration agreement for filgotinib	✓	3,272	4,834
AbbVie collaboration agreement for CF	✓	-	468
Reimbursement income		3,193	5,135
Novartis collaboration agreement for MOR106	✓	3,193	4,680
AbbVie collaboration agreement for CF	✓	-	456
Other revenues		3,420	2,378
Fee-for-services revenues	✓	3,355	2,312
Other revenues		66	66
Total revenues		98,173	33,047

Revenues (€98.2 million for the first three months of 2020, compared to €33.0 million for the first three months of 2019) were higher due to the revenue recognition of the upfront payment received in August 2019 from Gilead related to (i) the access and option rights to our drug discovery platform, and (ii) additional consideration received for the extended cost sharing for filgotinib.



FINANCIAL STATEMENTS

The rollforward of the outstanding balance of the current and non-current deferred income between 1 January 2020 and 31 March 2020 can be summarized as follows:

(thousands of €)	Total	Gilead collaboration agreement for filgotinib	Gilead collaboration agreement for drug discovery platform ⁽¹⁾	Deferred income related to contracts in our fee-for-service segment	Other
On 1 January 2020	3,000,646	780,261	2,220,013	362	10
Significant financing component ⁽²⁾	4,435	4,435			
Revenue recognition of upfront	(88,287)	(32,105)	(56,182)		
Revenue recognition of milestones	(3,272)	(3,272)			
Other movements	(124)			(114)	(10)
On 31 March 2020	2,913,398	749,319	2,163,831	248	-

(1) The outstanding balance at 1 January 2020 and at 31 March 2020 comprise the issuance liability for subsequent warrant B and the upfront payment allocated to the drug discovery platform.

(2) With regard to the additional consideration received for the extended cost sharing for filgotinib, we assume the existence of a significant financing component reflecting the time value of money on the estimated recognition period.

Other income

Other income increased by €0.9 million, mainly driven by higher incentives income from the government for R&D activities.

Results

We realized a net loss of €50.6 million for the first three months of 2020, compared to a net loss of €48.7 million in the first three months of 2019.

We reported an operating loss amounting to €44.6 million for the first three months of 2020, compared to an operating loss of €53.2 million for the first three months of 2019.

Our R&D expenditure in the first three months of 2020 amounted to €116.8 million, compared to €83.2 million in the first three months of 2019. This planned increase was mainly due to an increase of €19.4 million 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.

The cost increase for filgotinib for the first three months of 2020 compared to the same period in 2019, was mainly due to the increased cost share from 20/80 to 50/50 on the global development activities effective as from the closing of our collaboration agreement with Gilead on 23 August 2019. As from this date, we also started to share the development costs equally with Gilead for ziritaxestat (GLPG1690), while those costs were carried fully by us before, which is the main driver of the decrease in our costs for this program.



FINANCIAL STATEMENTS

The table below summarizes our R&D expenditure for the three months ended 31 March 2020 and 2019, broken down by program.

(thousands of €)	Three months ended 31 March	
	2020	2019
Filgotinib program	(29,296)	(14,400)
IPF program on ziritaxestat (GLPG1690)	(13,783)	(20,013)
OA program on GLPG1972	(6,427)	(3,861)
Toledo program	(16,871)	(7,775)
AtD program on MOR106	(4,248)	(5,490)
CF program	-	(1,343)
Other programs	(46,138)	(30,313)
Total research and development expenditure	(116,763)	(83,195)

Our G&A and S&M expenses were €34.7 million in the first three months of 2020, compared to €11.0 million in the first three months of 2019. This increase mainly resulted from higher personnel costs due to a planned headcount increase and increased costs from the preparation of the commercial launch of filgotinib in Europe.

We reported a non-cash fair value loss from the re-measurement of initial warrant B issued to Gilead, amounting to €20.5 million, mainly due to the increased implied volatility of the Galapagos share price.

Net other financial income in the first three months of 2020 amounted to €14.8 million, compared to net other financial income of €4.7 million for the first three months of 2019, which was primarily attributable to €34.3 million of unrealized exchange gain on our cash position in U.S. dollars, partly compensated by a fair value loss on current financial investments of €14.5 million.

Segment information

We have two reportable segments: R&D and our fee-for-service business Fidelta, located in Croatia.

(thousands of €)	Segment information for the three months ended 31 March 2020			Group
	R&D	Fee-for-services	Inter-segment elimination	
External revenue	94,817	3,356		98,173
Internal revenue		2,092	(2,092)	-
Other income	8,743	-		8,743
Revenues & other income	103,560	5,448	(2,092)	106,916
Operating result	(46,170)	1,585		(44,585)
Financial (expenses)/income				(5,681)
Result before tax				(50,266)
Income taxes				(336)
Net loss				(50,601)



FINANCIAL STATEMENTS

Segment information for the three months ended 31 March 2019

(thousands of €)	R&D	Fee-for-services	Inter-segment elimination	Group
External revenue	30,735	2,312		33,047
Internal revenue		1,481	(1,481)	-
Other income	7,865	7		7,872
Revenues & other income	38,600	3,800	(1,481)	40,919
Segment result	(46,967)	(276)		(47,242)
Unallocated expenses ⁽¹⁾				(6,000)
Operating loss				(53,242)
Financial (expenses)/income				4,655
Result before tax				(48,588)
Income taxes				(68)
Net loss				(48,656)

(1) Unallocated expenses consist mainly of expenses for warrant plans under IFRS 2 Share based payments.

The basis of accounting for any transactions between reportable segments is consistent with the valuation rules and with transactions with third parties.

Liquid assets position

Cash and cash equivalents and current financial investments totaled €5,722.4 million on 31 March 2020.

A net decrease of €58.4 million in cash and cash equivalents and current financial investments was recorded during the first three months of 2020, compared to a net decrease of €67.9 million during the first three months of 2019. This net decrease was composed of (i) €83.4 million of operational cash burn, (ii) €5.4 million of cash proceeds from capital and share premium increase from exercise of warrants in the first three months of 2020, (iii) €19.6 million of unrealized positive exchange rate differences and fair value losses on current financial investments.

The operational cash burn (or operational cash flow if this performance measure is positive) is a financial measure that is not calculated in accordance with IFRS. Operational cash burn/ cash flow is defined as 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.



FINANCIAL STATEMENTS

The following table represents a reconciliation of the operational cash burn:

(thousands of €)	Three months ended 31 March	
	2020	2019
Increase/decrease (-) in cash and cash equivalents (excluding effect of exchange differences)	864,695	(72,863)
Less:		
Net proceeds from capital and share premium increases	(5,355)	(3,481)
Net sale of current financial investments	(942,738)	-
Total operational cash burn	(83,398)	(76,344)

Cash and cash equivalents and current financial investments comprised cash at banks, short-term bank deposits, treasury bills, a short-term bond fund and money market funds. The short-term bank deposits and money market funds are readily convertible to cash and are subject to an insignificant risk of changes in value. Our cash management strategy may allow short-term deposits with an original maturity exceeding three months while monitoring all liquidity aspects. Cash and cash equivalents comprised €1,123.1 million of term deposits that are available upon maximum three month notice period. Cash at banks were mainly composed of savings accounts and current accounts. We maintain our bank deposits in highly rated financial institutions to reduce credit risk.

Cash invested in highly liquid money market funds represented €1,451.6 million and are presented as current financial investments on 31 March 2020 because we are not using them for meeting short-term cash commitments. The current financial investments also include a short-term bond fund and treasury bills. We also made additional purchases of treasury bills just before and on 31 March 2020 for a total amount of €379.7 million. These funds were still presented as cash and cash equivalents on 31 March 2020 because these transactions will only be settled at the beginning of April 2020.

(thousands of €)	31 March	31 December
	2020	2019
Cash at banks	1,620,488	907,939
Term deposits	1,123,085	953,677
Total cash and cash equivalents	2,743,573	1,861,616

On 31 March 2020, our cash and cash equivalents and current financial investments included \$1,496.8 million held in U.S. dollars which could generate foreign exchange gains or losses in our financial results in accordance with the fluctuation of the EUR/U.S. dollar exchange rate as our functional currency is EUR. The foreign exchange loss (-) / gain in case of a 10% change in the EUR/U.S. dollar exchange rate amounts to €136.6 million.

Finally, our balance sheet held R&D incentives receivables from the French government (*Crédit d'Impôt Recherche*), to be received in four yearly tranches, and R&D incentives receivables from the Belgian Government, for a total of €115.2 million as at 31 March 2020.



Capital increase

On 31 March 2020, Galapagos NV's share capital was represented by 64,819,022 shares. All shares were issued, fully paid up and of the same class. The below table summarizes our capital increases for the period ended 31 March 2020.

(thousands of €, except share data)	Number of shares	Share capital	Share premium	Share capital and share premium	Average exercise price warrants (in €/warrant)	Closing share price on date of capital increase (in €/share)
On 1 January 2020	64,666,802	287,282	2,703,583	2,911,912		
17 March 2020: exercise of warrants	152,220	824	4,531	5,355	35.18	141.40
On 31 March 2020	64,819,022	288,105	2,708,114	2,917,266		

**Note to the cash flow statement**

(thousands of €)	Three months ended 31 March	
	2020	2019
Adjustment for non-cash transactions		
Depreciation and amortization	4,189	2,758
Share-based compensation expenses	9,227	6,000
Increase in retirement benefit obligations and provisions	90	87
Unrealized exchange results and non-cash other financial expenses	(32,856)	(4,777)
Discounting effect of deferred income	4,435	-
Fair value re-measurement of warrants	20,529	-
Net fair value adjustment current financial investments	14,507	-
Fair value adjustment financial assets held at fair value through profit or loss	2,745	1,455
Other non-cash costs	70	-
Total adjustment for non-cash transactions	22,935	5,524
Adjustment for items to disclose separately under operating cash flow		
Interest expense	1,007	237
Interest income	(2,090)	(1,822)
Tax expense	336	68
Total adjustment for items to disclose separately under operating cash flow	(747)	(1,517)
Adjustment for items to disclose under investing and financing cash flows		
Gain on sale of assets	-	(3)
Interest income on current financial investments	(2,596)	-
Total adjustment for items to disclose separately under investing and financing cash flow	(2,596)	(3)
Change in working capital other than deferred income		
Increase (-)/decrease in inventories	(62)	2
Decrease/increase (-) in receivables	27,581	(1,239)
Increase/decrease (-) in liabilities	24,962	(1,057)
Total change in working capital other than deferred income	52,481	(2,294)



Fair value re-measurements

Gilead warrant B

The issuance of initial warrant B was approved on 22 October 2019 by the extraordinary general meeting of shareholders and is not yet exercised by Gilead at 31 March 2020. The fair value measurement of this financial liability is categorized as level 3 in the fair value hierarchy. Initial warrant B has been valued on the basis of a Longstaff-Schwartz Monte Carlo model. The input data used in the model were derived from market observations (volatility, discount rate and share price) and from management estimates (number of shares to be issued and applied discount for lack of marketability). The recognized fair value loss of €20.5 million was mainly the result of an increase in the implied volatility of our share price between 31 December 2019 and 31 March 2020. The fair value of the financial liability related to the initial warrant B amounted to €26.7 million on 31 March 2020 and was presented as a current financial instrument.

Subsequent warrant B is still subject to approval by an extraordinary general meeting of shareholders and is therefore still presented as warrant issuance liability in our deferred income.

Contingencies and commitments

Contractual obligations and commitments

We have certain purchase commitments principally with CRO subcontractors and certain collaboration partners.

On 31 March 2020, we had outstanding obligations for purchase commitments, which become due as follows:

(thousands of €)	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Purchase commitments	266,330	192,869	66,291	6,912	258

In addition we have engaged a property developer for the construction of a building in Leiden.

At 31 March 2020, we were committed to leases which have not yet started. The total future cash outflows for leases that had not yet commenced were as follows:

(thousands of €)	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Lease commitments not commenced	8,986	5,793	1,502	1,502	188

In addition to the table above, we have a contractual cost sharing obligation related to our collaboration agreement with Gilead for filgotinib. The contractual cost sharing commitment amounted to €602.8 million at 31 March 2020 for which we have direct purchase commitments of €25.8 million at 31 March 2020 reflected in the table above.

Contingent liabilities and assets

We refer to our [Annual Report 2019](#) for a description of our contingent liabilities and assets.



Events after the end of the reporting period

On 17 April 2020, the board of directors of Galapagos approved “Subscription Right Plan 2020 RMV”, a subscription right³ plan intended for the employees of its French subsidiary, Galapagos SASU, and “Subscription Right Plan 2020”, a subscription right plan intended for other members of the personnel of the company and its subsidiaries, within the framework of the authorized capital. Under these subscription right plans, 2,280,500 subscription rights were created, subject to acceptances, and offered to the beneficiaries of the plans. The subscription rights have an exercise term of eight years as of the date of the offer and have an exercise price of €168.42 (the average closing price of the share on Euronext Amsterdam and Brussels during the thirty days preceding the date of the offer). The subscription rights are not transferable and can in principle not be exercised prior to 1 January 2024. Each subscription right gives the right to subscribe to one new Galapagos share.

Approval of interim financial statements

The interim financial statements were approved by the management board on 5 May 2020.

³ “Subscription rights” is the new term for instruments formerly referred to as “warrants”, under the revised Belgian Code of Companies and Associations.



Report on the review of the consolidated interim financial information for the three-month period ended 31 March 2020

The original text of this report is in Dutch

In the context of our appointment as the company's statutory auditor, we report to you on the consolidated interim financial information. This consolidated interim financial information comprises the consolidated statement of financial position as at 31 March 2020, the consolidated statement of income and comprehensive income, the consolidated cash flow statements and the consolidated statements of changes in equity for the period of three months then ended, as well as selective notes.

Report on the consolidated interim financial information

We have reviewed the consolidated interim financial information of Galapagos NV ("the company") and its subsidiaries (jointly "the group"), prepared in accordance with International Accounting Standard (IAS) 34, "Interim Financial Reporting" as adopted by the European Union.

The consolidated statement of financial position shows total assets of 5 992 406 (000) EUR and the consolidated income statement shows a consolidated loss (group share) for the period then ended of 50 601 (000) EUR.

The management board of the company is responsible for the preparation and fair presentation of the consolidated interim financial information in accordance with IAS 34, "Interim Financial Reporting" as adopted by the European Union. Our responsibility is to express a conclusion on this consolidated interim financial information based on our review.

Scope of review

We conducted our review of the consolidated interim financial information in accordance with International Standard on Review Engagements (ISRE) 2410, "Review of interim financial information performed by the independent auditor of the entity". A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit performed in accordance with the International Standards on Auditing (ISA) and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion on the consolidated interim financial information.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the consolidated interim financial information of Galapagos NV has not been prepared, in all material respects, in accordance with IAS 34, "Interim Financial Reporting" as adopted by the European Union.

Zaventem, 7 May 2020

The statutory auditor

Deloitte Bedrijfsrevisoren/Réviseurs d'Entreprises CVBA/SCRL

Represented by Nico Houthaeve



Glossary of terms

100 points clinical response

Percentage of patients achieving a 100-point decrease in CDAI score during a clinical trial in CD patients

20-F

SEC filing submitted to the US Securities and Exchange

ACR

American College of Rheumatology

ACR20 (ACR 20/50/70)

American College of Rheumatology 20% response rate signifies a 20% or greater improvement in the number of swollen and tender joints as well as a 20% or greater improvement in three out of five other disease-activity measures. ACR50 and ACR70 reflect the same, for 50% and 70% response rates, respectively

ADAMTS-5

ADAMTS-5 is a key enzyme involved in cartilage breakdown (Larkin 2015)

ADS

American Depositary Share; Galapagos has a Level 3 ADS listed on Nasdaq with ticker symbol GLPG and CUSIP number 36315X101. One ADS is equivalent to one ordinary share in Galapagos NV

AFM

Dutch Authority for the Financial Markets

Anemia

Condition in which the patient has an inadequate number of red blood cells to carry oxygen to the body's tissues

Ankylosing spondylitis (AS)

AS is a systemic, chronic, and progressive spondyloarthropathy primarily affecting the spine and sacroiliac joints, and progressing into severe inflammation that fuses the spine, leading to permanent painful stiffness of the back

Anti-TNF

Tumor necrosis factor. An anti-TNF drug acts by modulation of TNF

ARGS neoepitope

Byproduct of the breakdown of cartilage by aggrecanase, can be used as a biomarker for cartilage breakdown

ASDAS

Ankylosing Spondylitis Disease Activity Score, a composite score of symptoms such as back pain, duration of morning stiffness, and peripheral pain and swelling. We measured ASDAS scores in the TORTUGA trial with filgotinib in AS



Assays

Laboratory tests to determine characteristics

Atherogenic index

Total cholesterol over HDL ratio. Improvement of the atherogenic index may be a forecast of cardiovascular health

Atopic dermatitis (AtD)

Also known as atopic eczema, atopic dermatitis is a common pruritic inflammatory condition affecting the skin, which most frequently starts in childhood

ATS

ATS, the American Thoracic Society improves global health by advancing research, patient care, and public health in pulmonary disease, critical illness, and sleep disorders

Attrition rate

The historical success rate for drug discovery and development, based on publicly known development paths. Statistically seen, investment in at least 12 target-based programs is required to ensure that at least one of these will reach a Phase 3 study. Most new drug R&D programs are discontinued before reaching Phase 3 because they are not successful enough to be approved

Autotaxin (ATX)

An enzyme important for generating the signaling molecule lypophosphatidic acid (LPA). GLPG1690 targets autotaxin for IPF and SSc

BID dosing

Twice-daily dosing (bis in die)

Bioavailability

Assessment of the amount of product candidate that reaches a body's systemic circulation after (oral) administration

Biomarker

Substance used as an indicator of a biological process, particularly to determine whether a product candidate has a biological effect

Black & Scholes model

A mathematical description of financial markets and derivative investment instruments that is widely used in the pricing of European options and warrants

Bleomycin model

A preclinical model involving use of bleomycin (a cancer medication) to induce IPF symptoms

Bridging trial

Clinical trial performed to "bridge" or extrapolate one dataset to that for another situation, i.e. to extrapolate data from one population to another for the same drug candidate, or to move from IV to subcutaneous dosing



Cash position

Current financial investments and cash and cash equivalents

CDAI

Crohn's Disease Activity Index, evaluating patients on eight different factors, each of which has a pre-defined weight as a way to quantify the impact of CD

CDAI remission

In the FITZROY trial, the percentage of patients with CD who showed a reduction of CDAI score to <150

CIR

Crédit d'Impôt Recherche, or research credit. Under the CIR, the French government refunds up to 30% of the annual investment in French R&D operations, over a period of three years. Galapagos benefits from the CIR through its operations in Romainville, just outside Paris

Clinical proof-of-concept (PoC)

Point in the drug development process where the product candidate first shows efficacy in a therapeutic setting

Compound

A chemical substance, often a small molecule with drug-like properties

Contract research organization

Organization which provides drug discovery and development services

Corticosteroids

Any of a group of steroid hormones produced in the adrenal cortex or made synthetically. They have various metabolic functions and some are used to treat inflammation

Crohns disease (CD)

An IBD involving inflammation of the small and large intestines, leading to pain, bleeding, and ultimately in some cases surgical removal of parts of the bowel

CRP

C-reactive protein is a protein found in the blood, the levels of which rise in response to inflammation

Cutaneous lupus

Cutaneous lupus is a heterogeneous autoimmune skin disease that can present itself as an organ-specific disease (e.g., in the skin only) or as a systemic disease involving multiple organs

Cutaneous lupus erythematosus

Lupus affecting the skin. In this autoimmune disease, the body's immune system attacks healthy skin

Cystic fibrosis (CF)

A life-threatening genetic disease that affects approximately 80,000 people worldwide. Although the disease affects the entire body, difficulty breathing is the most serious symptom as a result of clogging of the airways due to mucus build-up and frequent lung infections



Cytokine

A category of small proteins which play important roles in signaling in processes in the body

Dactylitis

Dactylitis is inflammation of a digit (either finger or toe) and is derived from the Greek word dactylos meaning finger. The affected fingers and/or toes swell up into a sausage shape and can become painful. Dactylitis was measured in the EQUATOR trial with filgotinib in psoriatic arthritis

DARWIN

Phase 2 program for filgotinib in RA. DARWIN 1 explored three doses, in twice-daily and once-daily administration, for up to 24 weeks in RA patients with insufficient response to methotrexate (MTX) and who remained on their stable background treatment with MTX. DARWIN 2 explored three once-daily doses for up to 24 weeks in RA patients with insufficient response to methotrexate (MTX) and who washed out of their treatment with MTX. DARWIN 1 and 2 were double-blind, placebo-controlled trials which recruited approximately 900 patients globally and for which results were reported in 2015. DARWIN 3 is a long term extension trial in which all patients are on 200 mg filgotinib, except for U.S. males who are on 100 mg. The week 156 results from DARWIN 3 were reported in 2019

DAS28 (CRP)

DAS28 is an RA Disease Activity Score based on a calculation that uses tender and swollen joint counts of 28 defined joints, the physician's global health assessment and a serum marker for inflammation, such as C-reactive protein. DAS28 (CRP) includes the C-reactive protein score calculation: scores range from 2.0 to 10.0, with scores below 2.6 being considered remission

Deep venous thrombosis (DVT)

The formation of one or more blood clots in one of the body's large veins, most commonly in the lower limbs. The blood clot can travel to the lung and cause a pulmonary embolism

Development

All activities required to bring a new drug to the market. This includes preclinical and clinical development research, chemical and pharmaceutical development and regulatory filings of product candidates

Discovery

Process by which new medicines are discovered and/or designed. At Galapagos, this is the department that oversees target and drug discovery research through to nomination of preclinical candidates

Disease-modifying

Addresses the disease itself, modifying the disease progression, not just the symptoms of the disease

DIVERSITY

Phase 3 program evaluating filgotinib in CD

DLCO

DLCO (diffusion capacity of the lung for carbon monoxide) is the extent to which oxygen passes from the air sacs of the lungs into the blood. This is measured in IPF patients



Dose-range finding study

Phase 2 clinical study exploring the balance between efficacy and safety among various doses of treatment in patients. Results are used to determine doses for later studies

Double-blind

Term to characterize a clinical trial in which neither the physician nor the patient knows if the patient is taking placebo or the treatment being evaluated

Efficacy

Effectiveness for intended use

EMA

European Medicines Agency, in charge of European market authorization of new medications

Endoscopy

A non-surgical procedure involving use of an endoscope to examine a person's digestive tract

Enthesitis

Inflammation of the tendons or ligaments; this is one of the key symptoms of psoriatic arthritis and was also measured in the EQUATOR trial with filgotinib

EQUATOR

A Phase 2 trial with filgotinib in psoriatic arthritis patients

Esbriet

An approved drug (pirfenidone) for IPF, marketed by Roche

FDA

The U.S. Food and Drug Administration is an agency responsible for protecting and promoting public health and in charge of American market approval of new medications

Fee-for-service

Payment system where the service provider is paid a specific amount for each procedure or service performed

FEV

Forced expiratory volume measures how much air a person can exhale during a forced breath. The amount of air exhaled may be measured during the first (FEV1), second (FEV2), and/or third seconds (FEV3) of the forced breath

Fibrotic score

The Ashcroft fibrotic score involves measuring pulmonary fibrosis through examination of histopathology tissue

FIH

First-in-human clinical trial, usually conducted in healthy volunteers with the aim to assess the safety, tolerability and pharmacokinetics of the product candidate



Filgotinib

Formerly known as GLPG0634. Small molecule selective JAK1 inhibitor, currently under review for approval in RA in the U.S., Europa and Japan. Filgotinib is partnered with Gilead for the development and commercialization of filgotinib in a number of diseases. Filgotinib currently is in Phase 3 trials in UC, CD and PsA, and Phase 2 trials in additional indications

FINCH

Phase 3 program evaluating filgotinib in RA

Fistulizing CD

Fistulae are inflammatory tracts that most often occur between the distal colon and the perianal region. Fistulae are one of the most severe sequelae of luminal CD and the lifetime risk of occurrence is close to 50% of those with active CD

FITZROY

A double-blind, placebo controlled Phase 2 trial with filgotinib in 177 CD patients for up to 20 weeks. Full results were published in The Lancet in 2016

FLORA

A double-blind, placebo-controlled exploratory Phase 2a trial with GLPG1690 in up to 24 IPF patients; topline results were reported in August 2017

FRI

Functional respiratory imaging is a technology which enhances 3D visualization and quantification of a patient's airway and lung geometry

FSMA

The Belgian market authority: Financial Services and Markets Authority, or Autoriteit voor Financiële Diensten en Markten

FTE

Full-time equivalent; a way to measure an employee's involvement in a project. For example, an FTE of 1.0 means that the equivalent work of one full-time worker was used on the project

Futility analysis

Analysis of the likelihood of a trial to meet its primary endpoint, based on a subset of the total information to be gathered. The term 'futility' is used to refer to the low likelihood of a clinical trial to achieve its objectives. In particular, stopping a clinical trial when the interim results suggest that it is unlikely to achieve statistical significance can save resources that could be used on more promising research

FVC

Forced vital capacity is the amount of air which can be forcibly exhaled from the lungs after taking the deepest breath possible. FVC is used to help determine both the presence and severity of lung diseases such as IPF

G&A expenses

General & administrative expenses



OTHER INFORMATION

GLPG0555

A clinical candidate with undisclosed mode of action directed toward inflammation

GLPG0634

Molecule number currently known as filgotinib

GLPG1205

A GPR84 inhibitor fully proprietary to us. We initiated the PINTA patient trial with GLPG1205 in IPF

GLPG1690

Molecule currently known as ziritaxestat

GLPG1972/S201086

GLPG1972/S201086, also referred to as GLPG1972, is a novel mode-of-action product candidate that is part of the OA collaboration with Servier. Galapagos and Servier have completed recruitment of the ROCCELLA global Phase 2b trial with GLPG1972/S201086

GLPG2737

A clinical candidate with undisclosed novel mode of action. This compound is part of the CF collaboration with AbbVie but Galapagos regained rights outside of CF

GLPG3312

A compound part of the Toledo family with an undisclosed mode of action directed towards inflammation (IBD). GLPG3312 is the first Toledo compound which completed Phase 1

GLPG3667

A compound currently in Phase 1 with an undisclosed mode of action directed toward inflammation

GLPG3970

A compound with an undisclosed mode of action which completed Phase 1. GLPG3970 is part of the Toledo target family

GLPG4059

A compound with undisclosed mode of action currently in the preclinical phase directed toward metabolic diseases

GLPG4124

A compound with undisclosed mode of action currently in the preclinical phase directed toward fibrosis

GLPG4259

A compound with undisclosed mode of action currently in the preclinical phase directed toward inflammation

GLPG4399

A compound with undisclosed mode of action currently in the preclinical phase directed toward inflammation



GLPG4471

A compound with undisclosed mode of action currently in the preclinical phase directed toward inflammation

GPR84 inhibitor

Drug candidate aimed at inhibiting or blocking G-protein coupled receptor 84. GLPG1205 is a GPR84 inhibitor aimed at IPF

HDL

High-density lipoprotein. HDL scavenges and reduces low-density lipoprotein (LDL) which contributes to heart disease at high levels. High levels of HDL reduce the risk for heart disease, while low levels of HDL increase the risk of heart disease

Hemoglobin

A protein inside red blood cells that carries oxygen from the lungs to tissues and organs in the body and carries carbon dioxide back to the lungs

Histopathology

Microscopic examination of tissues for manifestations of a disease

IBD

Inflammatory Bowel Disease. This is a general term for an autoimmune disease affecting the bowel, including CD and UC. CD affects the small and large intestine, while UC affects the large intestine. Both diseases involve inflammation of the intestinal wall, leading to pain, bleeding, and ultimately, in some cases, surgical removal of part of the bowel

IL-17C

IL-17C has been shown to be distinct from other members of the IL-17 family of cytokines. IL-17C has been shown to be an important mediator in inflammatory skin diseases, and is the target of MOR106

In-/out-licensing

Receiving/granting permission from/to another company or institution to use a brand name, patent, or other proprietary right, in exchange for a fee and/or royalty

In vitro

Studies performed with cells outside their natural context, for example in a laboratory

Inflammatory diseases

A large, unrelated group of disorders associated with abnormalities in inflammation

Inspiratory capacity

Total lung capacity or the amount of gas contained in the lung at the end of a maximal inhalation

Intellectual property

Creations of the mind that have commercial value and are protected or protectable, including by patents, trademarks or copyrights



Intersegment

Occurring between the different operations of a company

Investigational New Drug (IND) Application

United States Federal law requires a pharmaceutical company to obtain an exemption to ship an experimental drug across state lines, usually to clinical investigators, before a marketing application for the drug has been approved. The IND is the means by which the sponsor obtains this exemption, allowing them to perform clinical studies

IPF

Idiopathic pulmonary fibrosis. A chronic and ultimately fatal disease characterized by a progressive decline in lung function. Pulmonary fibrosis involves scarring of lung tissue and is the cause of shortness of breath. Fibrosis is usually associated with a poor prognosis. The term "idiopathic" is used because the cause of pulmonary fibrosis is still unknown

ISABELA

Phase 3 clinical program investigating GLPG1690 in IPF patients. The ISABELA Phase 3 program consists of two identically designed trials, ISABELA 1 and ISABELA 2, and will enroll a total of 1,500 IPF patients combined

JAK

Janus kinases (JAK) are critical components of signaling mechanisms utilized by a number of cytokines and growth factors, including those that are elevated in RA. Filgotinib is a selective JAK1 inhibitor

LDL

Low-density lipoprotein. LDL contributes to heart disease at high levels

Lipoprotein

Lipoproteins are substances made of protein and fat that carry cholesterol through your bloodstream. There are two main types of cholesterol: High-density lipoprotein (HDL), or "good" cholesterol and Low-density lipoprotein (LDL), or "bad" cholesterol

Liver enzymes

Inflamed or injured liver cells secrete higher than normal amounts of certain chemicals, including liver enzymes, into the bloodstream

LPA

Lysophosphatidic acid (LPA) is a signaling molecule involved in fibrosis

Lymphocyte

Type of white blood cell that is part of the immune system

MACE

Major adverse cardiovascular events; a composite endpoint frequently used in cardiovascular research

MANTA

A Phase 2 semen analysis trial with filgotinib in male patients with CD or UC



MANTA-RAY

Phase 2 semen analysis trial with filgotinib in male patients with RA, PsA, or AS

Membranous lupus nephritis

Membranous lupus nephritis is an inflammation of the kidneys caused by systemic lupus erythematosus and is characterized by the presence of subepithelial immune complex deposits seen on kidney biopsy

MHLW

Japanese Ministry of Health, Labor and Welfare (MHLW), in charge of Japanese market authorization of new medications

Milestone

Major achievement in a project or program; in our alliances, this is usually associated with a payment

Molecule collections

Chemical libraries, usually consisting of drug-like small molecules that are designed to interact with specific target classes. These collections can be screened against a target to generate initial "hits" in a drug discovery program

MOR106

MOR106 acts on IL-17C, a novel antibody target discovered by Galapagos. In October 2019 Novartis, MorphoSys and Galapagos jointly announced the end of the clinical development program of MOR106 in patients with atopic dermatitis

MTX

Methotrexate; a first-line therapy for inflammatory diseases

NDA

New Drug Application

Neutrophil

Type of immune system cell which is one of the first cell types to travel to the site of an infection in the body. Neutrophils are another type of white blood cell which fight infection by ingesting and killing microorganisms

NK cells

Natural killer cells, type of white blood cell with granules of enzymes which can attack tumors or viruses

Nonalcoholic steatohepatitis (NASH)

NASH is liver inflammation and damage caused by a buildup of fat in the liver. It is part of a group of conditions called nonalcoholic fatty liver disease

NOVESA

A Phase 2 trial to evaluate GLPG1690 in systemic sclerosis (SSc)

Ofev

An approved drug (nintedanib) for IPF, marketed by Boehringer Ingelheim



Oral dosing

Administration of medicine by the mouth, either as a solution or solid (capsule, pill) form

Organoids

Miniature organ produced from cells from a donor; organoids have all the phenotypic characteristics of the patient donor, making them useful tools for *in vitro* drug research

Osteoarthritis (OA)

The most common form of arthritis, usually occurring after middle age, marked by chronic breakdown of cartilage in the joints leading to pain, stiffness, and swelling

Outsourcing

Contracting work to a third party

PENGUIN

Phase 3 trials with filgotinib in psoriatic arthritis

Pharmacokinetics (PK)

Study of what a body does to a drug; the fate of a substance delivered to a body. This includes absorption, distribution to the tissues, metabolism and excretion. These processes determine the blood concentration of the drug and its metabolite(s) as a function of time from dosing

Phase 1

First stage of clinical testing of an investigational drug designed to assess the safety and tolerability, pharmacokinetics of a drug, usually performed in a small number of healthy human volunteers

Phase 2

Second stage of clinical testing, usually performed in no more than several hundred patients, in order to determine efficacy, tolerability and the dose to use

Phase 3

Large clinical trials, usually conducted in several hundred to several thousand patients to gain a definitive understanding of the efficacy and tolerability of the candidate treatment; serves as the principal basis for regulatory approval

Phenotypic screening

Phenotypic screening is a strategy used in drug discovery to identify molecules with the ability to alter a cell's disease characteristics. Animal models and cell-based assays are both strategies used to identify these molecules. In contrast to target-based drug discovery, phenotypic screening does not rely on knowing the identity of the specific drug target or its hypothetical role in the disease. A key benefit this approach has over target-based screening, is its capacity to capture complex biological mechanisms that are not otherwise achievable

PINTA

Phase 2 trial with GPR84 inhibitor GLPG1205 in IPF patients

Pivotal trials

Registrational clinical trials



Placebo-controlled

A substance having no pharmacological effect but administered as a control in testing a biologically active preparation

Preclinical

Stage of drug research development, undertaken prior to the administration of the drug to humans. Consists of *in vitro* and *in vivo* screening, pharmacokinetics, toxicology, and chemical upscaling

Preclinical candidate (PCC)

A new molecule and potential drug that meets chemical and biological criteria to begin the development process

Product candidate

Substance that has satisfied the requirements of early preclinical testing and has been selected for development, starting with formal preclinical safety evaluation followed by clinical testing for the treatment of a certain disorder in humans

Proof-of-concept (POC)

A clinical trial in which first evidence for efficacy of a candidate drug is gathered. A Proof-of-Concept trial is usually with a small number of patients and for short duration to get a first impression of drug activity

Proof-of-concept study

Phase 2 patient study in which activity as well as safety in patients is evaluated, usually for a new mechanism of action

Pruritis

Extreme itching, as observed in AtD patients

Psoriatic arthritis (PsA)

Psoriatic arthritis or PsA is an inflammatory form of arthritis, affecting up to 30% of psoriasis patients. Psoriatic arthritis can cause swelling, stiffness and pain in and around the joints, and cause nail changes and overall fatigue

Pulmonary embolisms

A blockage in one of the pulmonary arteries in the lungs

QD dosing

Once-daily dosing (qd from the Latin *quaque die*)

R&D operations

Research and development operations; unit responsible for discovery and developing new product candidates for internal pipeline or as part of risk/reward sharing alliances with partners

Rheumatoid arthritis (RA)

A chronic, systemic inflammatory disease that causes joint inflammation, and usually leads to cartilage destruction, bone erosion and disability



ROCCELLA

Global Phase 2b trial, together with our collaboration partner Servier, evaluating GLPG1972/S201086 (GLPG1972) in osteoarthritis (OA)

Screening

Method usually applied at the beginning of a drug discovery campaign, where a target is tested in a biochemical assay against a series of small molecules or antibodies to obtain an initial set of "hits" that show activity against the target. These hits are then further tested or optimized

SEC

Securities Exchange Commission in the US

SELECTION

Phase 3 program evaluating filgotinib in UC patients

Service operations

Business unit primarily focused on delivering products and conducting fee-for-service work for clients. Our service operations included the BioFocus and Argenta business units, which were both sold in April 2014 to Charles River Laboratories

SES-CD scores

Simple endoscopic score for CD, involving review of five pre-defined bowel segments, assigning values from 0 (unaffected) to 3 (highly affected)

Sjögrens syndrome

Sjögren's Syndrome is a systemic inflammatory disease which can be felt throughout the body, often resulting in chronic dryness of the eyes and mouth

S&M expenses

Sales and marketing expenses

Small bowel CD (SBCD)

CD causes chronic inflammation and erosion of the intestines. It can affect different regions of gastrointestinal tract including the stomach and small and large intestines. While isolated SBCD is an uncommon presentation of CD, involvement of some portion of the small bowel, particularly the ileum, is common

Spondylitis

About 20% of patients with psoriatic arthritis will develop spinal involvement, which is called psoriatic spondylitis. Inflammation of the spine can lead to complete fusion, as in AS, or affect only certain areas such as the lower back or neck. We measured spondylitis in the EQUATOR trial with filgotinib in psoriatic arthritis

Systemic sclerosis (SSc)

Systemic sclerosis (SSc) or scleroderma is an autoimmune disease. One of the most visible manifestations is hardening of the skin. In diffuse cutaneous SSc, which has one of the highest mortality rates among rheumatic diseases, fibrosis occurs in multiple organs, such as the lung



Target

Protein that has been shown to play a role in a disease process and that forms the basis of a therapeutic intervention or discovery of a medicine

Target discovery

Identification and validation of proteins that have been shown to play a role in a disease process

Technology access fee

License payment made in return for access to specific technology (e.g. compound or virus collections)

Tendinitis

Tendinitis is inflammation or irritation of a tendon, the thick fibrous cords that attach muscle to bone. The condition causes pain and tenderness just outside a joint. We measured tendinitis in the EQUATOR trial with filgotinib in psoriatic arthritis

Toledo

Toledo is a code name for a target family with a novel, undisclosed mode of action. GLPG3312 is the first of the Toledo compounds for which a Phase 1-trial has been initiated early 2019

Topical corticosteroids

Corticosteroids which are administered through the skin using an ointment

TORTUGA

Phase 2 trial with filgotinib in patients with ankylosing spondylitis. In 2018, we and Gilead reported that TORTUGA met its primary endpoint

Ulcerative colitis (UC)

UC is an IBD causing chronic inflammation of the lining of the colon and rectum (unlike CD with inflammation throughout the gastrointestinal tract)

Uveitis

Uveitis is the term that refers to inflammation inside the eye. This inflammation can be caused by infection, autoimmune reaction, or by conditions confined primarily to the eye

Venous thrombotic events

When a blood clot breaks loose and travels in the blood, this is called a venous thromboembolism (VTE). The abbreviation DVT/PE refers to a VTE where a deep vein thrombosis (DVT) has moved to the lungs (PE or pulmonary embolism)

Ziritaxestat

Formerly known as GLPG1690. Ziritaxestat is a novel drug candidate targeting autotaxin, with potential application in IPF & SSc. Topline results from the Phase 2a FLORA trial were reported in August 2017. The ISABELA Phase 3 program was initiated in 2018 and the NOVESA Phase 2 trial in SSc was initiated in early 2019. Gilead retained the rights on GLPG1690 in IPF outside of Europe in 2019



Financial calendar

06 August 2020

Half year 2020 results

05 November 2020

Third quarter 2020 results

18 February 2021

Full year 2020 results

Colophon

Concept, design and online programming

nexxar GmbH, Vienna – Online annual reports
and online sustainability reports

www.nexxar.com

Photography

Frank van Delft

Copy deadline: 7 May 2020

This report is also available in Dutch and
available for download in the [Downloads](#) section
of this report or at www.glp.com

Contact



Elizabeth Goodwin

Vice President Investor Relations
Galapagos NV

Generaal De Wittelaan L11 A3
2800 Mechelen, Belgium

Tel. +1 781 460 1784

Email: ir@glpg.com



Sofie Van Gijssel

Director Investor Relations
Galapagos NV

Generaal De Wittelaan L11 A3
2800 Mechelen, Belgium

Tel. +32 485 19 14 15

Email: ir@glpg.com



Carmen Vroonen

Senior Director Communications
& Public Affairs

Galapagos NV
Generaal De Wittelaan L11 A3

2800 Mechelen, Belgium

Tel. +32 473 82 48 74

Email:

communications@glpg.com