

H1

Report 2019

Think **big.**

Contents

The Galapagos group

Letter from the management	4
At a glance	8
Risk factors	9
The Galapagos share	10
Related party transactions	10
Statement of the board of directors	10
Disclaimer and other information	11

Financial statements

Unaudited condensed consolidated interim financial statements	14
Notes	19

Auditor's report

Report on the limited review of the consolidated interim financial results	29
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Other information

Glossary of terms	30
Financial calendar	42
Colophon	42
Contact	42

The Galapagos group

An overview of Galapagos, its strategy
and portfolio in H1 2019



Letter from the management

Dear shareholders,

It's our 20th anniversary year, and what a year so far! Just recently we signed a truly unique and landmark deal with our great collaboration partner Gilead. Galapagos has been highly effective at target identification and drug discovery, progressing novel molecules from research into the clinic. We will benefit greatly from Gilead's expertise and infrastructure and believe this collaboration will provide an accelerated path to advance our pipeline. This agreement is about maximizing innovation based on the identification and development of new mode of action medicines. With the capital provided by Gilead, we aim to progress innovation to patients.

The first half year in 2019 was already transformative, before we announced this remarkable deal. Together with Gilead, we announced positive 24 week data of the remaining and largest of the FINCH Phase 3 trials in rheumatoid arthritis (RA), FINCH 1 and FINCH 3. This brings our total patient exposure to beyond 3,000 patient-years. The FINCH trial efficacy and safety data were consistent with the long term data observed in the DARWIN 3 trial. This further strengthens our understanding of the impact of selective JAK1 inhibition on patients, and filgotinib's potentially differentiated safety profile. We are also proud that earlier this week, the FINCH 2 results were published in *JAMA*¹, which is recognition of the importance of the filgotinib program.



And this is only the beginning: we believe that the efficacy and safety results of filgotinib in RA have potential read-throughs to the overall filgotinib development program, currently ongoing in more than 10 different inflammatory conditions. In 2019, we anticipate readouts of proof-of-concept studies of filgotinib in Sjögren's syndrome and cutaneous lupus, and the initiation of a Phase 3 trial in psoriatic arthritis.

Early July, our collaboration partner Gilead announced the outcome of the pre-NDA meeting with the FDA. Gilead discussed with the agency the Phase 3 FINCH studies, as well as the ongoing Phase 2 MANTA safety study, and concluded that they intend to submit filgotinib for approval in RA in the US in 2019. In the meantime, European submission is on track for Q3 2019.

We also continue our extensive preparations to become a fully integrated biotechnology company: we are well underway with the hiring of our commercial team for Belgium, the Netherlands, and Luxembourg, and will begin hiring for commercial operations in the EU² as per our revised filgotinib agreement with Gilead.

We are excited about the regulatory and commercial progress made, as it will help us bring filgotinib to patients.

In the first half of 2019, we not only saw the very encouraging research results from FINCH, but also laid further foundation for future results with our late stage portfolio of drug candidates. Our research engine continues to be extremely productive, with additional late stage trial starts, including the GECKO Phase 2 trial with MOR106 in atopic dermatitis, and the completion of recruitment in ROCCELLA, a global Phase 2b trial with ADAMTS-5 inhibitor GLPG1972 in osteoarthritis. Recruitment was wrapped up months ahead of schedule, underlining the large unmet medical need for a disease-modifying drug for OA patients. We also initiated our first Phase 1 trial from the next-generation Toledo program for inflammation. We experience good recruitment of the ISABELA 1 & 2 Phase 3 trials with autotaxin inhibitor GLPG1690 in idiopathic pulmonary fibrosis and hope to give an update on timelines later this year. The enthusiasm for the ISABELA program amongst clinicians, centers, and patients is palpable, and we remain fully committed to moving ahead to potentially offer help for the large unmet medical

¹ Journal of the American Medical Association

² France, Germany, Italy, Spain and United Kingdom



need in IPF. We are running approximately 40 clinical trials at Galapagos this year and are gearing up for another big year of clinical trial execution in 2020, especially if the Toledo programs come through Phase 1 with green lights.

While making substantial progress in R&D, Galapagos ended the first half of 2019 with a very strong balance sheet. We continue to grow our organization to support this broad pipeline, while we continue to build a commercial organization for potential launch of filgotinib in Europe next year. Our late stage development is growing, leading to increased costs for our company. Our financial guidance for full year 2019 operational cash burn³ between €320 and €340 million is unchanged, excluding the proceeds from the recent deal announced with Gilead. Upon closing we will receive an upfront payment of \$3.95 billion and a \$1.1 billion equity investment, which are expected before the end of 2019.

Operational overview Q1 2019

We refer to our [Q1 2019 report](#).

Operational overview Q2 2019

Inflammation

- Completed recruitment of the ROCCELLA Phase 2b trial with GLPG1972 in osteoarthritis, with Servier, in 9 months
- Initiated GECKO Phase 2 trial in atopic dermatitis with MOR106 with collaboration partners MorphoSys and Novartis

Corporate & other

- Achieved a \$25 million milestone from AbbVie following the completion of the FALCON study
- Raised €4.3 million from warrant exercises in the second quarter
- Received a transparency notice from the Capital Group Companies that they hold 5.08% of outstanding shares

Recent events

- Gilead and Galapagos entered into a 10-year global R&D collaboration
- Gilead announced the outcome of the pre-NDA meeting with the FDA, concluding that a path has been established to file filgotinib in RA in the US in 2019
- Publication of the detailed FINCH 2 results in *JAMA*, a top-tier peer-reviewed journal
- We recently stopped a Phase 1 study with GLPG3121, a JAK1/TYK2 inhibitor targeting inflammation, due to an undesirable PK profile
- Received a transparency notice from Van Herk Group that they hold 10.57% of outstanding shares

H1 2019 financial result

Revenues and other income

Our revenues and other income for the first six months of 2019 amounted to €108.5 million, compared to €101.9 million for the first six months of 2018. Revenues (€91.8 million for the first six months of 2019 vs €87.6 million for the first six months of 2018) were higher due to a milestone achieved in June 2019 related to the CF program with AbbVie and higher reimbursement income mainly from Novartis in the scope of our collaboration for MOR106. This was partly compensated by a lower over time recognition in revenue of the upfront payments and milestone payments related to the filgotinib program with Gilead.

³ 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.



Other income increased (€16.7 million for the first six months of 2019 vs €14.3 million for the first six months of 2018), mainly driven by higher income from R&D incentives.

Results

We realized a net loss of €95.9 million for the first six months of 2019, compared to a net loss of €59.1 million for the first six months of 2018.

We reported an operating loss amounting to €97.6 million for the first six months of 2019, compared to an operating loss of €65.8 million for the first six months of 2018.

Our R&D expenditure in the first six months of 2019 amounted to €177.6 million, compared to €151.4 million for the first six months of 2018. This planned increase was mainly due to an increase of €10.2 million in subcontracting costs primarily related to our IPF program and other proprietary programs. Furthermore, personnel costs increased explained by a planned headcount increase and higher costs related to the warrant plans as a result of the increase in the number of beneficiaries and of the Galapagos share price. These also explained the increase in our G&A and S&M expenses which were €28.6 million in the first six months of 2019, compared to €16.2 million in the first six months of 2018.

Net financial income in the first six months of 2019 amounted to €1.8 million, compared to net financial income of €6.9 million for the first six months of 2018, which was primarily attributable to €1.9 million of unrealized exchange gain on our cash position in U.S. dollars (€5.3 million of unrealized exchange gain on our cash position in U.S. dollars in the first six months of 2018).

Liquid assets position

Cash and cash equivalents totaled €1,147.9 million on 30 June 2019.

A net decrease of €142.9 million in cash and cash equivalents was recorded during the first six months of 2019, compared to a net decrease of €84.4 million during the first six months of 2018. This net decrease was composed of €152.5 million of operational cash burn, offset by (i) €7.8 million of cash proceeds from capital and share premium increase from exercise of warrants in the first six months of 2019 and (ii) €1.9 million of unrealized positive exchange rate differences.

Finally, our balance sheet as at 30 June 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 €94.3 million.

Outlook 2019

Following on the positive Phase 3 FINCH trial results, Gilead discussed submissions for approval of filgotinib in RA with regulatory authorities in 2019. Early July, Gilead announced that following a meeting with the U.S. FDA, a path forward for filing filgotinib in RA in 2019 has been established. Gilead intends to file filgotinib for approval in RA in Europe in Q3 2019. They also anticipate readouts from the proof-of-concept trials in Sjögren's syndrome and cutaneous lupus, and plan to launch a Phase 3 trial in psoriatic arthritis.

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. For MOR106, together with our collaboration partners MorphoSys and Novartis, we plan to continue executing the Phase 1 and 2 trials running.

With regard to our earlier and fully proprietary programs, we expect the Phase 1 readout of GLPG3312, our first Toledo compound, with a Phase 1 start for a second Toledo compound (GLPG3970) scheduled for the second half of the year.

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



THE GALAPAGOS GROUP

Our guidance for an operational cash burn between €320 - €340 million in 2019 is unchanged, excluding the proceeds from the recent deal announced with Gilead.

The Gilead transaction, which is expected to close late in the third quarter of 2019, is subject to certain closing conditions, including the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and receipt of merger control approval from the Austrian Federal Competition Authority.

Upon closing, we are entitled to an upfront payment of \$3.95 billion in addition to a \$1.1 billion equity investment.

We thank you again for your support of Galapagos, as we aim to discover and to develop more novel medications, bring successful therapies to the market, and improve patients' lives.

Onno van de Stolpe

CEO



At a glance

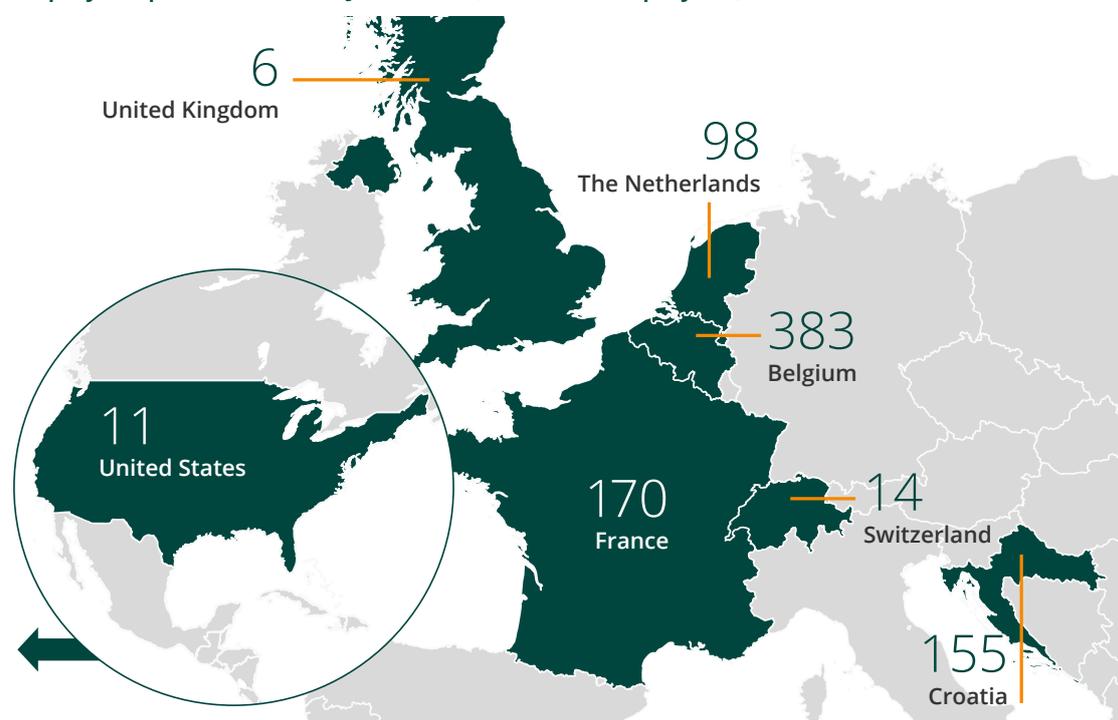
Consolidated key figures

(thousands of €, if not stated otherwise)	Second quarter of 2019	Second quarter of 2018	Six months ended 30 June 2019	Six months ended 30 June 2018	Full year 2018
Income statement					
Revenues	58,738	49,676	91,785	87,583	288,836
Other income	8,852	7,358	16,724	14,289	29,009
R&D expenditure	(94,372)	(81,680)	(177,567)	(151,444)	(322,875)
S, G&A expenses	(17,585)	(9,104)	(28,552)	(16,214)	(39,776)
Operating expenses	(111,958)	(90,784)	(206,119)	(167,658)	(362,652)
Operating loss	(44,367)	(33,750)	(97,610)	(65,786)	(44,807)
Net financial results	(2,820)	12,052	1,834	6,867	15,598
Taxes	(61)	(75)	(129)	(137)	(50)
Net loss	(47,249)	(21,773)	(95,905)	(59,056)	(29,259)
Balance sheet					
Cash and cash equivalents	1,147,923	1,066,766	1,147,923	1,066,766	1,290,796
R&D incentives receivables	94,288	86,221	94,288	86,221	84,646
Assets ⁽¹⁾	1,357,848	1,204,348	1,357,848	1,204,348	1,439,496
Shareholders' equity ⁽¹⁾	1,143,367	885,659	1,143,367	885,659	1,214,249
Deferred income	96,325	243,149	96,325	243,149	149,801
Other liabilities ⁽¹⁾	118,157	75,539	118,157	75,539	75,446
Cash flow					
Operational cash burn	(76,200)	(53,656)	(152,545)	(95,009)	(158,384)
Cash flow used in operating activities	(70,041)	(51,476)	(141,740)	(91,278)	(142,466)
Cash flow used in investing activities	(5,263)	(2,193)	(8,661)	(3,724)	(15,914)
Cash flow generated in financing activities	3,428	1,349	5,661	5,254	287,876
Increase / decrease (-) in cash and cash equivalents	(71,876)	(52,320)	(144,740)	(89,748)	129,497
Effect of currency exchange rate fluctuation on cash and cash equivalents	(3,102)	10,899	1,866	5,304	10,089
Cash and cash equivalents at the end of the period	1,147,923	1,066,766	1,147,923	1,066,766	1,290,796
Financial ratios					
Number of shares issued at the end of the period	54,823,101	51,337,763	54,823,101	51,337,763	54,465,421
Basic and diluted loss per share (in €)	(0.86)	(0.42)	(1.76)	(1.16)	(0.56)
Share price at the end of the period (in €)	113.45	78.94	113.45	78.94	80.56
Total group employees at the end of the period (number)	837	675	837	675	725

(1) We refer to the notes of the condensed consolidated interim financial report for additional information.



Employees per site as of 30 June 2019 (total: 837 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 and the additional risk identified below. 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 (including but not limited to certain risks related to our status as a U.S. publicly listed company following the public offering of shares (in the form of ADSs) and listing on Nasdaq in May 2015) and market risks relating to our shares and ADSs.

In addition to the risk factors referred to above, we are subject to the following risk:

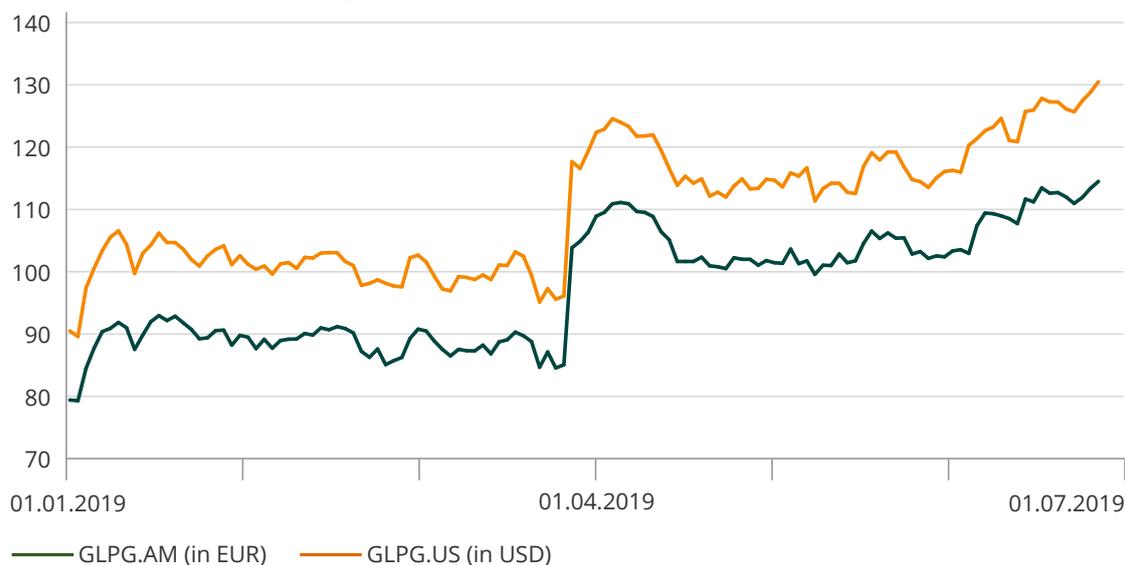
On 14 July 2019, we and Gilead announced the signing of a global research and development collaboration and option agreement (the "Transaction"). Under the terms of the Transaction, Galapagos will receive a \$3.95 billion upfront payment and a \$1.1 billion equity investment from Gilead. The completion of the Transaction is subject to certain conditions, including as to anti-trust clearances, and there can be no certainty that such conditions will be satisfied so as to allow the Transaction to be completed within the anticipated timeframe or at all. The potential uncertainty due to these or other factors may have a material adverse effect on our results of operations, and may cause increased volatility in our stock price.

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 six months of 2019”](#) part of this report.

Statement of the board of directors

The board of directors of Galapagos NV declares that, as far as it is aware, the financial statements in this H1 report are prepared according to the applicable standards for financial statements, and give a true and fair view of the equity, financial position and the results of Galapagos NV and its consolidated companies.

The board of directors of Galapagos NV further declares that this H1 report gives a true and fair view on the important developments and significant transactions with related parties in the period under review and their impact on the interim financial statements, as well as on the most important risks and uncertainties pertaining to the remainder of the current financial year.

Mechelen, 22 July 2019

On behalf of the board of directors,

Onno van de Stolpe
CEO

Raj Parekh
Chairman of the board of directors



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 to be addressed to:

Galapagos NV

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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 2019”](#), guidance from management regarding the expected operational use of cash during financial year 2019, statements regarding the expected timing of closing of the transaction with Gilead, filings and approvals relating to the transaction, 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 in inflammation, and statements regarding the regulatory pathway for filgotinib and the timing of regulatory filings. 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 uncertainty regarding the ability of the parties to complete the Gilead transaction considering the transaction is subject to closing conditions and any applicable antitrust clearance requirements, 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 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.

Financial statements

Consolidated interim financial
statements for the first half-year
of 2019



Unaudited condensed consolidated interim financial statements for the first six months of 2019

Consolidated statements of income and comprehensive income (unaudited)

Consolidated income statement

(thousands of €, except share and per share data)	Second quarter of		Six months ended 30 June	
	2019	2018	2019	2018
Revenues	58,738	49,676	91,785	87,583
Other income	8,852	7,358	16,724	14,289
Total revenues and other income	67,590	57,034	108,509	101,872
Research and development expenditure	(94,372)	(81,680)	(177,567)	(151,444)
General and administrative expenses	(13,711)	(8,503)	(22,931)	(15,200)
Sales and marketing expenses	(3,875)	(602)	(5,620)	(1,014)
Total operating expenses	(111,958)	(90,784)	(206,119)	(167,658)
Operating loss	(44,367)	(33,750)	(97,610)	(65,786)
Financial income	(1,349)	6,499	5,651	8,109
Financial expenses	(1,472)	5,553	(3,816)	(1,241)
Loss before tax	(47,188)	(21,698)	(95,776)	(58,919)
Income taxes	(61)	(75)	(129)	(137)
Net loss	(47,249)	(21,773)	(95,905)	(59,056)
Net loss attributable to:				
Owners of the parent	(47,249)	(21,773)	(95,905)	(59,056)
Basic and diluted loss per share	(0.86)	(0.42)	(1.76)	(1.16)

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



Consolidated statement of comprehensive income / loss (-)

(thousands of €)	Second quarter of		Six months ended 30 June	
	2019	2018	2019	2018
Net loss	(47,249)	(21,773)	(95,905)	(59,056)
Items that may be reclassified subsequently to profit or loss:				
Translation differences, arisen from translating foreign activities	(215)	154	52	151
Other comprehensive income / loss (-), net of income tax	(215)	154	52	151
Total comprehensive income / loss (-) attributable to:				
Owners of the parent	(47,463)	(21,619)	(95,853)	(58,905)

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



Consolidated statements of financial position (unaudited)

	30 June	31 December
(thousands of €)	2019	2018
Assets		
Intangible assets	7,191	3,632
Property, plant and equipment	51,180	23,137
Deferred tax assets	2,516	2,514
Non-current R&D incentives receivables	82,644	73,443
Other non-current assets	5,712	7,919
Non-current assets	149,244	110,645
Trade and other receivables	42,067	18,609
Current R&D incentives receivables	11,644	11,203
Cash and cash equivalents	1,147,923	1,290,796
Other current assets	6,970	8,244
Current assets	1,208,604	1,328,851
Total assets	1,357,848	1,439,496
Equity and liabilities		
Share capital	238,475	236,540
Share premium account	1,283,650	1,277,780
Other reserves	(735)	(735)
Translation differences	(1,505)	(1,557)
Accumulated losses	(376,518)	(297,779)
Total equity	1,143,367	1,214,249
Retirement benefit liabilities	3,939	3,764
Non-current lease liabilities	20,457	-
Other non-current liabilities	1,373	1,578
Non-current liabilities	25,769	5,342
Current lease liabilities	5,141	-
Trade and other liabilities	86,216	68,928
Current tax payable	1,031	1,175
Current deferred income	96,325	149,801
Current liabilities	188,712	219,905
Total liabilities	214,481	225,247
Total equity and liabilities	1,357,848	1,439,496

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



Consolidated cash flow statements (unaudited)

(thousands of €)	Six months ended 30 June	
	2019	2018
Net loss of the period	(95,905)	(59,056)
Adjustment for non-cash transactions	23,278	8,978
Adjustment for items to disclose separately under operating cash flow	(2,864)	(1,340)
Adjustment for items to disclose under investing and financing cash flows	(3)	-
Change in working capital other than deferred income	(15,918)	18,165
Decrease in deferred income	(53,478)	(59,967)
Cash used in operations	(144,890)	(93,219)
Interest paid	(628)	(848)
Interest received	3,866	2,789
Corporate taxes paid	(88)	-
Net cash flows used in operating activities	(141,740)	(91,278)
Purchase of property, plant and equipment	(5,033)	(3,003)
Purchase of intangible fixed assets	(3,535)	(722)
Proceeds from disposal of property, plant and equipment	2	1
Acquisition of financial assets held at fair value through profit or loss	(177)	-
Proceeds from sale of financial assets held at fair value through profit or loss	82	-
Net cash flows used in investing activities	(8,661)	(3,724)
Payment of lease liabilities	(2,144)	(7)
Proceeds from capital and share premium increases from exercise of warrants	7,805	5,261
Net cash flows generated in financing activities	5,661	5,254
Decrease in cash and cash equivalents	(144,740)	(89,748)
Cash and cash equivalents at beginning of the period	1,290,796	1,151,211
Decrease in cash and cash equivalents	(144,740)	(89,748)
Effect of exchange rate differences on cash and cash equivalents	1,866	5,304
Cash and cash equivalents at end of the period	1,147,923	1,066,766

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



Consolidated statements of changes in equity (unaudited)

(thousands of €)	Share capital	Share premium account	Translation differences	Other reserves	Accumul. losses	Total
On 1 January 2018	233,414	993,025	(1,754)	(1,260)	(211,441)	1,011,983
Change in accounting policy (modified retrospective application IFRS 15)					(83,220)	(83,220)
Change in accounting policy (modified retrospective application IFRS 9)				619	(619)	-
Restated total equity at 1 January 2018	233,414	993,025	(1,754)	(641)	(295,279)	928,766
Net loss					(59,056)	(59,056)
Other comprehensive income			151			151
Total comprehensive income / loss (-)	-	-	151	-	(59,056)	(58,905)
Share-based compensation					10,540	10,540
Exercise of warrants	2,169	3,092				5,261
On 30 June 2018	235,583	996,117	(1,604)	(641)	(343,796)	885,659
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					(95,905)	(95,905)
Other comprehensive income			52			52
Total comprehensive income / loss (-)	-	-	52	-	(95,905)	(95,853)
Share-based compensation					16,751	16,751
Exercise of warrants	1,935	5,870				7,805
On 30 June 2019	238,475	1,283,650	(1,505)	(735)	(376,518)	1,143,367

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



Notes to the unaudited consolidated interim financial statements for the first six months of 2019

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 2018](#).

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 2018, except for the adoption of new standards and interpretations described below.

- IFRS 16 Leases (applicable for annual periods beginning on or after 1 January 2019)

The nature and the effect of these changes were taken into consideration, and the above amendments affected the condensed consolidated interim financial statements as follows:

We adopted IFRS 16 on 1 January 2019, in accordance with the transitional provisions of IFRS 16, using the modified retrospective approach. Consequently, the cumulative effect of adopting IFRS 16 was recognized as an adjustment to the opening balance of retained earnings as at 1 January 2019, with no restatement of the comparative figures.

On adoption of IFRS 16, we recognized lease liabilities in relation to leases which had previously been classified as 'operating leases' under IAS 17. These liabilities were measured at the present value of the remaining lease payments and discounted using our incremental borrowing rate as of 1 January 2019. Our weighted average incremental borrowing rate applied to the lease liabilities on 1 January 2019 was 1.55%.

The differences between our total operating lease commitments as reported in note 25 of our consolidated financial statements of 31 December 2018 and the total lease liabilities recognized in our statement of financial position as at 1 January 2019 are summarized below.

(thousands of €)	
Operating lease commitments disclosed as at 31 December 2018	27,704
Less: discounting effect using the lessee's incremental borrowing rate at the date of initial application	(1,223)
Less: other	(569)
Lease liability recognized as at 1 January 2019	25,912
Of which are:	
current lease liabilities	4,516
non-current lease liabilities	21,396



FINANCIAL STATEMENTS

The change in accounting policy affected the statement of financial position as at 1 January 2019 as follows:

(thousands of €)	1 January 2019
Property, plant and equipment (right-of-use assets)	26,406
Other current assets (prepaid expenses)	(494)
Effect on total assets	25,912
Accumulated losses	416
Lease liabilities (current and non-current)	25,912
Deferred income	(416)
Effect on total equity and liabilities	25,912

We applied the following practical expedients, as permitted by IFRS 16, on transition date:

- Reliance on the previous definition of a lease (as provided by IAS 17) for all contracts that existed on the date of initial application;
- The use of a single discount rate to a portfolio of leases with reasonably similar characteristics;
- Reliance on previous assessments on whether leases are onerous instead of performing an impairment review;
- The accounting for operating leases with a remaining lease term of less than 12 months as at 1 January 2019 as short-term leases.

Other new standards and interpretations applicable for the annual period beginning on 1 January 2019 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.

Change in accounting policies with effect from 1 January 2019 as a result of the adoption of IFRS 16:

Whereas until the end of 2018, we made a distinction between finance leases (presented on the balance sheet) and operating leases (off-balance sheet commitments), we recognized as from 1 January 2019 right-of-use assets on the balance sheet and corresponding lease liabilities (measured on a present value basis). These liabilities reflect the expected lease payments to be made in the future, estimated at the commencement date of the leases. After initial recognition, these lease liabilities are measured at amortized cost.

The right-of-use assets (mainly comprising the initial lease liability) are measured at cost and depreciated over their useful life on a straight-line basis. The right-of-use assets are presented in the statement of financial position under the caption "Property, plant and equipment" and the lease liabilities are presented as current and non-current lease liabilities.

Each lease payment is allocated between the lease liability and financial expenses.

Management judgments and estimates

Preparing interim financial statements in compliance with IFRS requires management to make judgments and estimates and to use assumptions that may significantly influence the reported amounts of assets and liabilities, the notes on contingent assets and liabilities on the date of the financial statements and the reported amounts of income and expenses during the reporting period. Actual results may differ from these estimates. We refer to our [annual report 2018](#), except for the judgments and estimates as a result of the application of IFRS 16.



Details of the unaudited condensed consolidated interim results

Revenues and other income

Revenues

The following table summarizes our revenues for the six months ended 30 June 2019 and 2018.

(thousands of €)	Six months ended 30 June	
	2019	2018
Recognition of non-refundable upfront payments and license fees	42,113	52,753
Gilead collaboration agreement for filgotinib	41,069	49,331
AbbVie collaboration agreement for CF	1,044	3,422
Milestone payments	33,383	28,567
Gilead collaboration agreement for filgotinib	10,034	16,023
AbbVie collaboration agreement for CF	23,349	12,544
Reimbursement income	11,344	558
Novartis collaboration agreement for MOR106	10,595	-
AbbVie collaboration agreement for CF	749	558
Other revenues	4,944	5,705
Fee-for-services revenues	4,878	5,641
Other	66	64
Total revenues	91,785	87,583

Revenues (€91.8 million for the first six months of 2019 vs €87.6 million for the first six months of 2018) were higher due to a milestone achieved in June 2019 related to the CF program with AbbVie and higher reimbursement income mainly from Novartis in the scope of our collaboration for MOR106. This was partly compensated by a lower over time recognition in revenue of the upfront payments and milestone payments related to the filgotinib program with Gilead.

For the first six months of 2019, €51.1 million of deferred income related to the Gilead collaboration agreement was recognized in revenue in function of costs incurred, applying the percentage of completion method. This consisted of the over time revenue recognition of (i) €36.0 million related to the upfront license fee, (ii) €5.1 million related to the deferred income triggered by the accounting treatment of the share subscription agreement under IAS 39 Financial Instruments: recognition and measurement, at the time of signing of the agreement in 2015, and (iii) €10.0 million related to milestone payments. The outstanding balance of deferred income from the Gilead collaboration agreement at 30 June 2019 amounted to €94.7 million all reported as current deferred income, as we expect to reach, at the end of 2019, the predetermined level of development study costs further described hereafter.

In December 2015, we entered into a license and collaboration agreement to co-develop filgotinib with Gilead in rheumatoid arthritis, Crohn's disease, ulcerative colitis and other indications. We are responsible for funding 20% of the associated global development costs of the program. We have retained certain mechanisms to give us cost protection as filgotinib advances in clinical development. We can defer our portion of the global co-development study costs if they exceed a predetermined level, which we expect to reach at the end of 2019, and this deferment would be credited against future milestones, royalties or profit sharing at our option. If there are no future amounts to be paid by Gilead, we will not be obligated to make any payments to Gilead for such deferment.



We refer to the section 'Events after the end of the reporting period' of this interim report for the latest development in our collaboration with Gilead, which did not affect our financial statements for the first six months of 2019.

For the first six months of 2019, €2.2 million of the remaining deferred income related to the AbbVie collaboration agreement was recognized in revenue in function of costs incurred, applying the percentage of completion method. This consisted of the over time revenue recognition of (i) €1.1 million related to the upfront license fees, and (ii) €1.1 million related to milestone payments received in previous years. Additionally we achieved a milestone of \$25 million (€22.4 million) of which €22.2 million were recognized in revenue in the first half of 2019. The remaining outstanding balance of current deferred income from the AbbVie collaboration agreement at 30 June 2019 amounted to €1.2 million.

For the first six months of 2019, €10.6 million of reimbursement income was recognized as revenue related to our R&D activities in the scope of our collaboration agreement with Novartis and MorphoSys for MOR106.

Other revenues amounting to €4.9 million mainly consisted of service revenues from our fee-for-service business.

Other income

Other income increased to €16.7 million in the first six months of 2019 compared to €14.3 million in the first six months of 2018, mainly driven by higher income from R&D incentives.

Results

We realized a net loss of €95.9 million for the first six months of 2019, compared to a net loss of €59.1 million in the first six months of 2018.

We reported an operating loss amounting to €97.6 million for the first six months of 2019, compared to an operating loss of €65.8 million for the first six months of 2018.

Our R&D expenditure in the first six months of 2019 amounted to €177.6 million, compared to €151.4 million in the first six months of 2018. This planned increase was mainly due to an increase of €10.2 million in subcontracting costs primarily related to our IPF program and other proprietary programs. Furthermore, personnel costs increased explained by a planned headcount increase and higher costs related to warrant plans as a result of the increase in the number of beneficiaries and of the Galapagos share price.

The table below summarizes our R&D expenditure for the six months ended 30 June 2019 and 2018, broken down by program.

(thousands of €)	Six months ended 30 June	
	2019	2018
Filgotinib program (partnered)	(30,406)	(32,210)
CF program (partnered)	(1,793)	(21,014)
IPF program on GLPG1690 (proprietary)	(41,668)	(24,107)
OA program on GLPG1972 (partnered)	(9,733)	(7,621)
AtD program on MOR106 (partnered)	(12,460)	(7,661)
Other	(81,507)	(58,832)
Total R&D expenditure	(177,567)	(151,444)



FINANCIAL STATEMENTS

Our G&A and S&M expenses were €28.6 million in the first six months of 2019, compared to €16.2 million in the first six months of 2018. This increase mainly resulted from higher personnel costs due to a planned headcount increase as well as higher costs for warrant plans as a result of the increase in the number of beneficiaries and of the Galapagos share price.

Net financial income in the first six months of 2019 amounted to €1.8 million compared to net financial income of €6.9 million in the first six months of 2018, and was primarily attributable to €1.9 million of unrealized exchange gain on our cash position in U.S. dollars (€5.3 million of unrealized exchange gain on our cash position in U.S. dollars in the first six months of 2018).

Segment information

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

(thousands of €)	Six months ended 30 June 2019			Group
	R&D	Fee-for-services	Inter-segment elimination	
External revenue	86,907	4,878		91,785
Internal revenue		3,581	(3,581)	-
Other income	16,717	7		16,724
Revenues & other income	103,624	8,466	(3,581)	108,509
Segment result	(81,269)	410		(80,859)
Unallocated expenses ⁽¹⁾				(16,751)
Operating loss				(97,610)
Financial (expenses)/income				1,834
Result before tax				(95,776)
Income taxes				(129)
Net loss				(95,905)

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

(thousands of €)	Six months ended 30 June 2018			Group
	R&D	Fee-for-services	Inter-segment elimination	
External revenue	81,942	5,641		87,583
Internal revenue		4,126	(4,126)	-
Other income	14,287	2		14,289
Revenues & other income	96,229	9,770	(4,126)	101,872
Segment result	(57,446)	2,200		(55,246)
Unallocated expenses ⁽¹⁾				(10,540)
Operating loss				(65,786)
Financial (expenses)/income				6,867
Result before tax				(58,919)
Income taxes				(137)
Net loss				(59,056)

(1) Unallocated expenses consist 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 totaled €1,147.9 million on 30 June 2019.

A net decrease of €142.9 million in cash and cash equivalents was recorded during the first six months of 2019, compared to a net decrease of €84.4 million during the first six months of 2018. This net decrease was composed of €152.5 million of operational cash burn, offset by (i) €7.8 million of cash proceeds from capital and share premium increases from exercise of warrants in the first six months of 2019 and (ii) €1.9 million of unrealized positive exchange rate differences.

Cash and cash equivalents amounted to €1,147.9 million at the end of June 2019 and comprised cash and cash at banks, short term bank deposits and money market funds that 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 €514.7 million of term deposits with an original maturity longer than three months but which are available upon one 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 €199.0 million and aim at meeting short-term cash commitments, while reducing the counterparty risk of investment.

	30 June	31 December
(thousands of €)	2019	2018
Cash at banks	434,228	358,016
Term deposits	514,701	733,537
Money market funds	198,993	199,243
Total cash and cash equivalents	1,147,923	1,290,796

On 30 June 2019, our cash and cash equivalents included \$279.4 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.

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 €94.3 million as at 30 June 2019.



Capital increase

On 30 June 2019, Galapagos NV's share capital was represented by 54,823,101 shares. All shares were issued, fully paid up and of the same class. The below table summarizes our capital increases for the half-year ended 30 June 2019.

(thousands of €, except share data)	Number of shares	Share capital	Share premium	Share capital and share premium	Average exercise price warrants	Closing share price on date of capital increase
On 1 January 2019	54,465,421	236,540	1,277,780	1,514,320		
20 March 2019: exercise of warrants	149,370	808	2,673	3,481	23.30	90.32
20 June 2019: exercise of warrants	208,310	1,127	3,198	4,325	20.76	113.55
On 30 June 2019	54,823,101	238,475	1,283,650	1,522,125		

Note to the cash flow statement

(thousands of €)	Six months ended 30 June	
	2019	2018
Adjustment for non-cash transactions		
Depreciation and amortization	5,653	3,684
Share-based compensation	16,751	10,540
Increase in retirement benefit liabilities and provisions	168	149
Unrealised exchange gains (-) / losses and non-cash other financial expenses	(1,424)	(5,241)
Fair value adjustment financial assets held at fair value through profit or loss	2,130	(154)
Total adjustment for non-cash transactions	23,278	8,978
Adjustment for items to disclose separately under operating cash flow		
Interest expense	452	415
Interest income	(3,445)	(1,892)
Tax expense	129	137
Total adjustment for items to disclose separately under operating cash flow	(2,864)	(1,340)
Adjustment for items to disclose under investing and financing cash flows		
Gain on sale of assets	(3)	-
Total adjustment for items to disclose under investing and financing cash flows	(3)	-
Change in working capital other than deferred income		
Decrease in inventories	3	12
Increase in receivables	(32,895)	(3,204)
Increase in payables	16,974	21,357
Total change in working capital other than deferred income	(15,918)	18,165



Contingencies and commitments

Contractual obligations and commitments

We entered into lease agreements for offices, laboratories and cars. As a consequence of the adoption of IFRS 16 Leases, on 1 January 2019, lease obligations in the scope of the new standard are presented as lease liabilities in the statements of financial position and no longer disclosed separately as off-balance sheet commitments.

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

On 30 June 2019 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	237,242	150,649	75,174	9,792	1,627

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 €48.4 million at 30 June 2019 for which we have direct purchase commitments of €19.1 million at 30 June 2019 reflected in the table above.

We refer to the section "Events after the end of the reporting period" of this interim report for the latest development in our collaboration with Gilead, which did not affect our financial statements for the first six months of 2019.

Contingent liabilities and assets

We refer to our [annual report 2018](#) for a description of our contingent liabilities and assets as no material change is to be disclosed for the first six months of 2019.

Related party transactions

On 10 April 2019, the members of the board of directors and the executive committee were offered new warrants under Warrant Plan 2019, subject to acceptance. The final number of accepted warrants under Warrant Plan 2019 was enacted by notary deed on 12 July 2019. The members of the board and the executive committee accepted all warrants offered to them. Under Warrant Plan 2019, the warrants have an exercise term of eight years as of the date of the offer. The exercise price of the warrants is €95.11. Each warrant gives the right to subscribe for one new Galapagos share. As regards the directors, the warrants vest over a period of 36 months at a rate of 1/36th per month. As regards the other beneficiaries, the warrants vest only and fully on the first day of the fourth calendar year following the calendar year in which the grant was made. The warrants are not transferable and can in principle not be exercised prior to 1 January 2023.



The table below sets forth the number of warrants offered under Warrant Plan 2019 to each member of the board and executive committee in office during the first six months of 2019:

Name	Title	Number of 2019 warrants offered
Onno van de Stolpe	Chief Executive Officer; Executive director	100,000
Raj Parekh	Non-executive director; Chairman of the board	15,000
Peter Guenter	Non-executive director	7,500
Howard Rowe	Non-executive director	7,500
Katrine Bosley	Non-executive director	7,500
Mary Kerr	Non-executive director	7,500
Piet Wigerinck	Chief Scientific Officer	50,000
Bart Filius	Chief Operating Officer; Chief Financial Officer	65,000
Andre Hoekema	Chief Business Officer	50,000
Walid Abi-Saab	Chief Medical Officer	50,000

We note that Mr. Peter Guenter was appointed as a non-executive, independent director by the shareholders' meeting on 30 April 2019 and the board mandates of Dr. Werner Cautreels and Dr. Christine Mummery ended on 30 April 2019.

During the first six months of 2019, there were no changes to related party transactions disclosed in the 2018 annual report that potentially had a material impact on the financials of the first six months of 2019.

Events after the end of the reporting period

On 14 July 2019 we and Gilead announced that we have entered into a 10-year global research and development collaboration. Through this agreement, Gilead will gain access to our innovative portfolio of compounds, including six molecules currently in clinical trials, more than 20 preclinical programs and a proven drug discovery platform.

We will receive a \$3.95 billion upfront payment and a \$1.1 billion equity investment from Gilead. We will use the proceeds to expand and accelerate our research and development programs. Gilead will receive an exclusive product license and option rights to develop and commercialize all current and future programs in all countries outside Europe. In addition, we and Gilead have agreed to amend certain terms in the agreement governing filgotinib, to provide a broader commercialization role for us in Europe.

Gilead will also nominate two individuals to our board of directors following the closing of the transaction.

As part of the collaboration, Gilead gains rights to GLPG1690, our Phase 3 candidate for idiopathic pulmonary fibrosis. Gilead also receives option rights for GLPG1972, a Phase 2b candidate for osteoarthritis, in the United States. In addition, Gilead receives option rights on all of our other current and future clinical programs outside of Europe.

Terms of the collaboration

We will fund and lead all discovery and development autonomously until the end of Phase 2. After the completion of a qualifying Phase 2 study, Gilead will have the option to acquire an expanded license to the compound. If the option is exercised, we and Gilead will co-develop the compound and share costs equally. Gilead will maintain option rights to our programs through the 10-year term of the collaboration and for up to an additional three years thereafter for those programs that have entered clinical development prior to the end of the collaboration term.



If GLPG1690 is approved in the United States, Gilead will pay us an additional \$325 million milestone fee. For GLPG1972, Gilead has the option to pay a \$250 million fee to license the compound in the United States after the completion of the ongoing Phase 2b study in osteoarthritis. If certain secondary efficacy endpoints are met, Gilead would pay us up to an additional \$200 million. Following opt in, we would be eligible to receive up to \$550 million in regulatory and commercial milestones.

For all other programs resulting from the collaboration, Gilead will make a \$150 million opt-in payment per program and will owe no subsequent milestones. We will receive tiered royalties ranging from 20-24% on net sales of all our products licensed by Gilead as part of the agreement.

Filgotinib collaboration

Under the amended agreement, we will have greater involvement in filgotinib's global strategy and participate more broadly in the commercialization of the product in Europe, providing the opportunity to build a commercial presence on an accelerated timeline. We and Gilead will co-commercialize filgotinib in France, Germany, Italy, Spain and the United Kingdom and retain the 50/50 profit share in these countries that was part of the original filgotinib license agreement, and under the revised agreement, we will have an expanded commercial role. We retain exclusive rights in Belgium, the Netherlands and Luxembourg, where the 50/50 profit share also applies. The companies will share future global development costs for filgotinib equally, in lieu of the 80/20 cost split provided by the original agreement. Other terms of the original license agreement remain in effect, including the remaining \$1.27 billion in total potential milestones and tiered royalties ranging from 20-30% payable in territories outside of Belgium, France, Germany, Italy, Luxembourg, the Netherlands, Spain and the United Kingdom.

Terms of the equity investment

Gilead's equity investment will consist of a subscription for new Galapagos shares at a price of €140.59 per share, representing at 14 July 2019 a 20% premium to Galapagos' 30-day, volume-weighted average price. This will increase Gilead's stake in Galapagos from approximately 12.3% to 22.1% of the issued and outstanding shares in Galapagos. In addition, we intend to seek shareholder approval to issue two warrants allowing Gilead to further increase its ownership of Galapagos to up to 29.9% of the company's issued and outstanding shares. The agreement also includes a 10-year standstill restricting Gilead's ability to seek to acquire Galapagos or increase its stake in Galapagos beyond 29.9% of the company's issued and outstanding shares, subject to limited exceptions.

The transaction, which is expected to close late in the third quarter of 2019, is subject to certain closing conditions, including the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and receipt of merger control approval from the Austrian Federal Competition Authority.

Approval of interim financial statements

The interim financial statements were approved by the board of directors on 22 July 2019.



Report on the review of the consolidated interim financial information for the six-month period ended 30 June 2019

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 30 June 2019, 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 six 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 1 357 848 (000) EUR and the consolidated income statement shows a consolidated loss (group share) for the period then ended of 95 905 (000) EUR.

The board of directors 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, 25 July 2019

The statutory auditor

DELOITTE Bedrijfsrevisoren CVBA/ Réviseurs d'Entreprises SCRL

Represented by Gert Vanhees

The original text of this report is in Dutch



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

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 spondyloarthritis 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

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

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

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 lysophosphatidic 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

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

Crohn's 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

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. Completed and reported in 2015 (except for the currently still ongoing DARWIN 3 study). 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. DARWIN 3 is a long term extension trial currently ongoing; all patients are on 200 mg filgotinib, except for U.S. males who are on 100 mg

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



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



OTHER INFORMATION

FALCON

A phase 1b, open-label, non-randomized study to assess the safety, tolerability, pharmacokinetics, and efficacy of a novel combination treatment in up to 24 adult patients with CF

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 which showed activity and favorable tolerability in RA, PsA, AS and CD patients in Phase 2 trials. Filgotinib is partnered with Gilead. Galapagos and Gilead are running Phase 3 trials with filgotinib in RA, CD, and UC and Phase 2 trials with filgotinib in additional indications. Filgotinib is an investigational drug and its efficacy and safety have not been established

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



OTHER INFORMATION

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

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

GECKO

A Phase 2 trial evaluating a subcutaneous formulation of MOR106 in combination with topical corticosteroids. This Phase 2 trial was initiated early 2019

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

A novel drug 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

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 are recruiting the ROCCELLA global Phase 2b trial with GLPG1972/S201086

GLPG2534

A preclinical candidate with undisclosed mode of action. GLPG2534 is expected to enter Phase 1 trials in 2020

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 currently in Phase 1 with an undisclosed mode of action directed towards inflammation (IBD). GLPG3312 is a Toledo compound and the first one to enter Phase 1

GLPG3667

A preclinical candidate with undisclosed mode of action directed toward inflammation. GLPG3667 is expected to enter Phase 1 trials in 2019

GLPG3970

A preclinical candidate with a undisclosed mode of action directed toward inflammation. GLPG3970, which is part of the Toledo target family, is expected to enter Phase 1 trials in 2019

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

IGUANA

Phase 2 trial together with our partners MophoSys and Novartis, investigating MOR106 in AtD patients

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

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

MANTA

A Phase 2 trial with filgotinib to evaluate male testicular safety in patients with UC and CD



MANTA-RAY

A Phase 2 trial with filgotinib to evaluate male testicular safety in patients with RA, PsA and AS

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

A novel mode-of-action antibody product candidate currently in a Phase 2 trial in AtD patients. MOR106 acts on IL-17C, a novel antibody target discovered by Galapagos. MOR106 is part of the alliance with MorphoSys and Novartis

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

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

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

PINTA

Phase 2 trial with GPR84 inhibitor GLPG1205 in IPF patients

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 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

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

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)

Sjögren's 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

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

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



Financial calendar

24 October 2019
(webcast 25 October 2019)

Third quarter 2019 Results

20 February 2020
(webcast 21 February 2020)

Full Year 2019 Results

Financial year

The financial year starts on 1 January and ends on 31 December.

Auditor

Deloitte Bedrijfsrevisoren CVBA,
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Colophon

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