



Think big.



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# The Galapagos group

An overview of Galapagos, its strategy and portfolio in Q1 2019



## Letter from the management

Dear shareholders.

The first quarter of 2019 was one of the most historic ones in our nearly 20 year existence: our Phase 3 FINCH 1 and 3 results with our lead program, selective JAK1 inhibitor filgotinib, show competitive efficacy and safety potential in rheumatoid arthritis (RA). In particular, the safety data from the FINCH program, demonstrated in more than 3,000 patients during six months of treatment, supported the long-term safety data seen with filgotinib in the DARWIN 3 study, as reported at week 156. The large body of filgotinib results to date points to its promising risk/ benefit profile, and we expect our collaboration partner Gilead to discuss submissions for approval in RA with regulatory authorities in the coming months.

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 that Gilead will report topline results with filgotinib in Sjögren's syndrome and cutaneous lupus, and initiate a Phase 3 trial in psoriatic arthritis.



We are also making steady progress with regard to the other programs in our broad and growing pipeline. We opened new centers for the global Phase 3 ISABELA trial with our fully proprietary autotaxin inhibitor GLPG1690 in idiopathic pulmonary fibrosis (IPF). It is noteworthy that recruitment per center is currently above target. This reflects the enthusiasm we hear from investigators on this innovative trial, as GLPG1690 has the potential to address the high unmet medical need for IPF patients world-wide. Recruitment for the Phase 2 NOVESA trial with GLPG1690 in systemic sclerosis (SSc) and for the Phase 2 PINTA trial with GPR84 inhibitor GLPG1205 in IPF is on track. We initiated the GECKO Phase 2 trial with antibody MOR106 for atopic dermatitis acting on novel target IL-17C. We opened an IND for this trial with the FDA in the U.S.

Furthermore, we note excellent progress in recruitment for the Phase 2b ROCCELLA trial for osteoarthritis with ADAMTS-5 inhibitor GLPG1972, which we develop together with our collaboration partner Servier.

At the same time, we continue to leverage our unique target discovery engine, as we keep pushing forward to discover novel targets and develop new mode of action molecules. This includes our Toledo class of novel targets for inflammation, for which we brought a first compound, GLPG3312, into the clinic in early 2019, with a second one expected to follow in the second half of the year.

Galapagos ended the first quarter 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. The Galapagos proprietary late stage development is growing, leading to increased costs for our company. This year we expect to execute over 40 clinical trials. Our financial guidance for operational cash burn between  $\leq$  320 and  $\leq$  340 million for full year 2019 remains unchanged.

<sup>1</sup> 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.



#### Operational overview Q1 2019

#### Inflammation

- Reported positive results with filgotinib in the Phase 3 FINCH 1 and 3 trials in RA, with collaboration partner Gilead
- Gilead completed recruitment for the SELECTION Phase 3 trial in UC, as well for the Phase 2 trials in Sjögren's disease and cutaneous lupus
- Initiated a Phase 1 trial with GLPG3312, a first compound from our Toledo class of novel targets for inflammation

#### **Fibrosis**

- Initiated the NOVESA Phase 2 trial with GLPG1690 in SSc
- Inlicensed compounds from Fibrocor and Evotec for fibrosis

#### Corporate & other

■ Raised €3.5 million from warrant exercises

#### Recent events

- Initiated a Phase 1 trial with GLPG3121, a novel JAK1/TYK2 inhibitor aimed at inflammation
- Initiated the GECKO Phase 2 trial with MOR106 together with collaboration partners MorphoSys and Novartis

#### Q1 2019 financial result

#### Revenues and other income

Our revenues and other income for the first three months of 2019 amounted to  $\in$ 40.9 million, compared to  $\in$ 44.8 million in the first three months of 2018. Revenues ( $\in$ 33.0 million for the first three months of 2019 vs  $\in$ 37.9 million for the first three months of 2018) were lower due to lower over time recognition in revenue of the upfront payments and milestone payments related to the filgotinib program with Gilead, as well as for the CF program as we are transitioning the activities to AbbVie. This was partly compensated by higher reimbursement income mainly from Novartis in the scope of our collaboration for MOR106.

Other income increased ( $\epsilon$ 7.9 million for the first three months of 2019 vs  $\epsilon$ 6.9 million for the first three months of 2018), mainly driven by higher income from R&D incentives.

#### Results

We realized a net loss of  $\in$ 48.7 million for the first three months of 2019, compared to a net loss of  $\in$ 37.3 million for the first three months of 2018.

We reported an operating loss amounting to  $\in$ 53.2 million for the first three months of 2019, compared to an operating loss of  $\in$ 32.0 million for the first three months of 2018.

Our R&D expenditure in the first three months of 2019 amounted to  $\in$ 83.2 million, compared to  $\in$ 69.8 million for the first three months of 2018. This planned increase was mainly due to an increase of  $\in$ 5.5 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 of the Galapagos share price. These also explained the increase in our G&A and S&M expenses which were  $\in$ 11.0 million in the first three months of 2019, compared to  $\in$ 7.1 million in the first three months of 2018.



Net financial income in the first three months of 2019 amounted to €4.7 million, compared to net financial expenses of €5.2 million for the first three months of 2018, which was primarily attributable to €5.0 million of unrealized exchange gain on our cash position in U.S. dollars (€5.6 million of unrealized exchange loss on our cash position in U.S. dollars in the first three months of 2018).

#### Liquid assets position

Cash and cash equivalents totaled €1,222.9 million on 31 March 2019.

A net decrease of  $\in$ 67.9 million in cash and cash equivalents was recorded during the first three months of 2019, compared to a net decrease of  $\in$ 43.0 million during the first three months of 2018. This net decrease was composed of  $\in$ 76.3 million of operational cash burn, offset by (i)  $\in$ 3.5 million of cash proceeds from capital and share premium increase from exercise of warrants in the first three months of 2019 and (ii)  $\in$ 5.0 million of unrealized positive exchange rate differences.

Finally, our balance sheet as at 31 March 2019 held a receivable from the French government ( $Crédit\ d'Impôt\ Recherche^2$ ), payable in 4 yearly tranches, and a receivable from the Belgian Government for R&D incentives, for a total of &87.7 million.

#### Outlook 2019

Following on the positive Phase 3 FINCH trial results, Gilead plans to discuss submissions for approval of filgotinib in RA with regulatory authorities in 2019. Also for filgotinib, in the second half of the year, we expect Gilead to report topline results for the proof-of-concept studies in Sjögren's syndrome and cutaneous lupus, and to launch a Phase 3 trial in PsA.

We also plan to fully recruit our Phase 2 PINTA trial for our IPF compound GLPG1205 as well as for our ROCCELLA study in OA, together with collaboration partner Servier. For GLPG1690, we plan to continue recruitment in our ISABELA trials as well as the NOVESA Phase 2 trial in SSc, for which a first patient was dosed in early 2019.

For MOR106, together with our collaboration partners MorphoSys and Novartis, we plan to continue recruiting the Phase 2 trial in AtD with MOR106 in combination with topical corticosteroids (the GECKO trial), for which a first patient was dosed post-period, and to prepare further for the Japanese ethno-bridging study. We will also continue the IGUANA Phase 2 trial in AtD as well as the subcutaneous Phase 1 bridging study with MOR106. Pending positive results, these four studies combined should offer a solid data package for our collaboration partner Novartis to move into Phase 3.

With regard to our earlier and fully proprietary programs, we expect Phase 1 readouts of a number of trials, including for GLPG3312, the first Toledo compound that entered the clinic in early 2019. This molecule is scheduled to be dosed in patients in a first proof-of-concept study in ulcerative colitis before the end of the year. We also plan to initiate a Phase 1 trial with our second generation Toledo compound, GLPG3970, in the second half of the year.

Given the large number of maturing proprietary clinical programs and the expansion of our R&D and commercial team, we retain our guidance for an operational cash burn between €320 and €340 million in 2019.

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

<sup>&</sup>lt;sup>2</sup> Crédit d'Impôt Recherche refers to an innovation incentive system underwritten by the French government.



# At a glance

#### **Consolidated Key Figures**

	Three months ended	Three months ended	Forth 2040
(thousands of €, if not stated otherwise)	31 March 2019	31 March 2018	Full year 2018
Income statement			
Revenues	33,047	37,907	288,836
Other income	7,872	6,931	29,009
R&D expenditure	(83,195)	(69,765)	(322,875)
S, G&A expenses	(10,966)	(7,110)	(39,776)
Operating expenses	(94,161)	(76,875)	(362,652)
Operating loss	(53,242)	(32,036)	(44,807)
Net financial results	4,655	(5,184)	15,598
Taxes	(68)	(62)	(50)
Net loss	(48,656)	(37,283)	(29,259)
Balance sheet			
Cash and cash equivalents	1,222,901	1,108,186	1,290,796
R&D incentives receivables	87,674	80,870	84,646
Assets <sup>(1)</sup>	1,400,200	1,229,864	1,439,496
Shareholders' equity <sup>(1)</sup>	1,175,755	899,345	1,214,249
Deferred income	123,822	268,654	149,801
Other liabilities <sup>(1)</sup>	100,624	61,865	75,446
Cash flow			
Operational cash burn <sup>(2)</sup>	(76,344)	(41,354)	(158,384)
Cash flow used in operating activities <sup>(1)</sup>	(71,698)	(39,804)	(142,466)
Cash flow used in investing activities	(3,398)	(1,531)	(15,914)
Cash flow generated in financing activities <sup>(1)</sup>	2,233	3,905	287,876
Increase / decrease (-) in cash and cash equivalents	(72,863)	(37,430)	129,497
Effect of currency exchange rate fluctuation on cash and cash equivalents	4,968	(5,595)	10,089
Cash and cash equivalents at the end of the period	1,222,901	1,108,186	1,290,796
Financial ratios			
Number of shares issued at the end of the period	54,614,791	51,234,962	54,465,421
Basic and diluted loss per share (in €)	(0.89)	(0.73)	(0.56)
Share price at the end of the period (in €)	103.90	81.30	80.56
Total group employees at the end of the period (number)	779	634	725

Our assets, shareholders' equity, other liabilities, cash flow used in operating activities and cash flow generated in financing activities for the period ended 31 March 2019 were influenced by the adoption of the new standard IFRS 16 – Leases, on 1 January 2019. We refer to the notes of this condensed consolidated interim financial report for additional information.
 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:

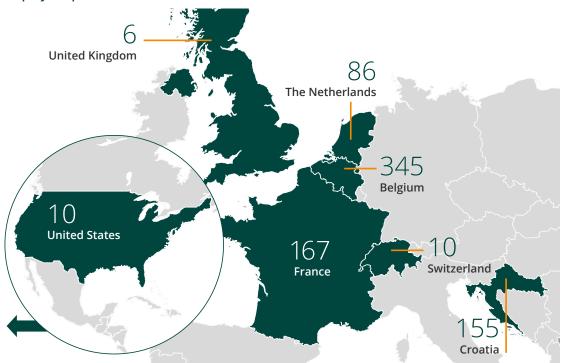
This alternative performance measure is in our view an important metric for a biotech company in the development stage.

<sup>(</sup>i) the net proceeds, if any, from share capital and share premium increases included in the net cash flows generated / used (-) in financing

<sup>(</sup>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.



#### Employees per site as of 31 March 2019



## **Risk factors**

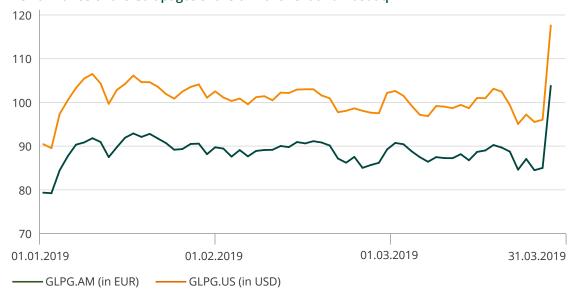
We refer to the description of risk factors in the 2018 annual report, pp. 57-66, as supplemented by the description of risk factors in our Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission, pp. 4-45. In summary, the principal risks and uncertainties faced by us relate to: product development, regulatory approval and commercialization; our financial position and need for additional capital; our reliance on third parties; our competitive position; our intellectual property; our organization, structure and operation (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.

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





#### 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.

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:

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#### Listings

Euronext Amsterdam and Brussels: GLPG Nasdaq: GLPG

#### Forward-looking statements

This report contains forward-looking statements, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "believe," "anticipate," "expect," "intend," "plan," "seek," "estimate," "may," "will," "could," "stand to," "continue," as well as similar expressions. Forward-looking statements contained in this report include, but are not limited to, statements made in the "Letter from the management", the information provided in the section captioned "Outlook 2019", guidance from management regarding the expected operational use of cash during financial year 2019, statements regarding the 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 and GLPG3121 for inflammation. We caution the reader that forward-looking statements are not guarantees of future performance. Forward-looking statements may involve known and unknown risks, uncertainties and other factors which might cause our actual results, financial condition and liquidity, performance or achievements, or the development of the industry in which we operate, to be materially different from any historic or future results, financial conditions, performance or achievements expressed or implied by such forward-looking statements. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. Among the factors that may result in differences are that our expectations regarding our 2019 revenues and financial results and our 2019 operating



expenses may be incorrect (including because one or more of our assumptions underlying our revenue or expense expectations may not be realized), the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including that data from our clinical research programs in rheumatoid arthritis, Crohn's disease, ulcerative colitis, idiopathic pulmonary fibrosis, systemic sclerosis, osteoarthritis, atopic dermatitis, 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, 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 forwardlooking 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 2019



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

# Consolidated statements of income and comprehensive income (unaudited)

#### Consolidated income statement

	Three months ended 31 March		
(thousands of €, except per share data)	2019	2018	
Revenues	33,047	37,907	
Other income	7,872	6,931	
Total revenues and other income	40,919	44,838	
Research and development expenditure	(83,195)	(69,765)	
General and administrative expenses	(9,221)	(6,697)	
Sales and marketing expenses	(1,746)	(413)	
Total operating expenses	(94,161)	(76,875)	
Operating loss	(53,242)	(32,036)	
Et a control to a	6.000	1.640	
Financial income	6,999	1,610	
Financial expenses	(2,345)	(6,794)	
Loss before tax	(48,588)	(37,221)	
Income taxes	(68)	(62)	
Net loss	(48,656)	(37,283)	
Net loss attributable to:			
Owners of the parent	(48,656)	(37,283)	
Basic and diluted loss per share	(0.89)	(0.73)	

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



## Consolidated statement of comprehensive income / loss (-)

Three months ended 31 March

(thousands of €)	2019	2018
Net loss	(48,656)	(37,283)
Items that may be reclassified subsequently to profit or loss:		
Translation differences, arisen from translating foreign activities	267	(3)
Other comprehensive income / loss (-), net of income tax	267	(3)
Total comprehensive income / loss (-) attributable to:		
Owners of the parent	(48,389)	(37,286)

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



# Consolidated statements of financial position (unaudited)

	31 March	31 December
(thousands of €)	2019	2018
Intangible assets	6,497	3,632
Property, plant and equipment	49,542	23,137
Deferred tax assets	2,511	2,514
Non-current R&D incentives receivables	76,029	73,443
Other non-current assets	6,377	7,919
Non-current assets	140,956	110,645
Trade and other receivables	15,347	18,609
Current R&D incentives receivables	11,645	11,203
Cash and cash equivalents	1,222,901	1,290,796
Other current assets	9,351	8,244
Current assets	1,259,244	1,328,851
Total assets	1,400,200	1,439,496
Equity and liabilities		
Share capital	237,348	236,540
Share premium account	1,280,452	1,277,780
Other reserves	(735)	(735)
Translation differences	(1,290)	(1,557)
Accumulated losses	(340,020)	(297,779)
Total equity	1,175,755	1,214,249
Retirement benefit liabilities	3,851	3,764
Non-current lease liabilities	20,409	
Other non-current liabilities	736	1,578
Non-current liabilities	24,996	5,342
Current lease liabilities	4,580	
Trade and other liabilities	69,880	68,928
Current tax payable	1,168	1,175
Current deferred income	123,822	149,801
Current liabilities	199,450	219,905
Total liabilities	224,445	225,247
Total equity and liabilities	1,400,200	1,439,496

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



# Consolidated cash flow statements (unaudited)

	Three months ended 31 March			
(thousands of €)	2019	2018		
Net loss of the period	(48,656)	(37,283)		
Adjustment for non-cash transactions	5,524	11,057		
Adjustment for items to disclose separately under operating cash flow	(1,517)	(530)		
Adjustment for items to disclose under investing and financing cash flows	(3)	-		
Change in working capital other than deferred income	(2,294)	20,482		
Decrease in deferred income	(25,979)	(34,458)		
Cash used in operations	(72,925)	(40,732)		
Interest paid	(327)	(500)		
Interest received	1,565	1,428		
Corporate taxes paid	(11)	-		
Net cash flows used in operating activities	(71,698)	(39,804)		
Purchase of property, plant and equipment	(2,103)	(1,192)		
Purchase of intangible fixed assets	(1,201)	(340)		
Proceeds from disposal of property, plant and equipment	1	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	(3,398)	(1,531)		
Payment of lease liabilities	(1,248)	(19)		
Proceeds from capital and share premium increases from exercise of warrants	3,481	3,924		
Net cash flows generated in financing activities	2,233	3,905		
Net tash nows generated in imancing activities	2,255	3,903		
Decrease in cash and cash equivalents	(72,863)	(37,430)		
Cash and cash equivalents at beginning of the period	1,290,796	1,151,211		
Decrease in cash and cash equivalents	(72,863)	(37,430)		
Effect of exchange rate differences on cash and cash equivalents	4,968	(5,595)		
Cash and cash equivalents at end of the period	1,222,901	1,108,186		

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



# 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					(37,283)	(37,283)
Other comprehensive loss			(3)			(3)
Total comprehensive loss	-	-	(3)	-	(37,283)	(37,286)
Share-based compensation					3,943	3,943
Exercise of warrants	1,613	2,311				3,924
On 31 March 2018	235,027	995,336	(1,757)	(641)	(328,620)	899,345
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			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

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



# Notes to the unaudited consolidated interim financial statements for the first three 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	
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



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 three months ended 31 March 2019 and 2018.

	Three months e	Three months ended 31 March		
(thousands of €)	2019	2018		
Recognition of non-refundable upfront payments and license fees	20,231	25,824		
Gilead collaboration agreement for filgotinib	19,787	23,874		
AbbVie collaboration agreement for CF	444	1,950		
Milestone payments	5,302	8,809		
Gilead collaboration agreement for filgotinib	4,834	4,891		
AbbVie collaboration agreement for CF	468	3,918		
Reimbursement income	5,136	192		
Novartis collaboration agreement for MOR106	4,680	-		
AbbVie collaboration agreement for CF	456	192		
Other revenues	2,378	3,081		
Fee-for-services revenues	2,312	3,019		
Other	66	63		
Total revenues	33,047	37,907		

Revenues ( $\in$ 33.0 million for the first three months of 2019 vs  $\in$ 37.9 million for the first three months of 2018) were lower due to lower over time recognition in revenue of the upfront payments and milestone payments related to the filgotinib program with Gilead, as well as for the CF program as we are transitioning the activities to AbbVie. This was partly compensated by higher reimbursement income mainly from Novartis in the scope of our collaboration for MOR106.

For the first three months of 2019,  $\in$ 24.6 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)  $\in$ 17.3 million related to the upfront license fee, (ii)  $\in$ 2.5 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)  $\in$ 4.8 million related to milestone payments. The outstanding balance of deferred income from the Gilead collaboration agreement at the end of March 2019 amounted to  $\in$ 121.2 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.



For the first three months of 2019, €4.7 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

Other revenues amounting to  $\in$ 2.4 million mainly consisted of service revenues from our fee-for-service business for  $\in$ 2.3 million.

#### Other income

The following table summarizes our other income for the three months ended 31 March 2019 and 2018.

	nded 31 March	
(thousands of €)	2019	2018
Grant income	351	549
Other income	7,520	6,382
Total other income	7,872	6,931

Total other income increased to €7.9 million in the first three months of 2019 compared to €6.9 million in the first three months of 2018, mainly driven by higher income from R&D incentives.

#### Results

We realized a net loss of  $\in$ 48.7 million for the first three months of 2019, compared to a net loss of  $\in$ 37.3 million in the first three months of 2018.

We reported an operating loss amounting to  $\in$ 53.2 million for the first three months of 2019, compared to an operating loss of  $\in$ 32.0 million for the first three months of 2018.

Our R&D expenditure in the first three months of 2019 amounted to  $\in$ 83.2 million, compared to  $\in$ 69.8 million in the first three months of 2018. This planned increase was mainly due to an increase of  $\in$ 5.5 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 of the Galapagos share price.



The table below summarizes our R&D expenditure for the three months ended 31 March 2019 and 2018, broken down by program.

Thron	months	andad	21	March

(thousands of €)	2019	2018
Filgotinib program (partnered)	(14,400)	(15,265)
CF program (partnered)	(1,343)	(11,761)
IPF program on GLPG1690 (proprietary)	(20,013)	(8,960)
OA program on GLPG1972 (partnered)	(3,861)	(2,233)
AtD program on MOR106 (partnered)	(5,490)	(4,494)
Other	(38,088)	(27,051)
Total R&D expenditure	(83,195)	(69,765)

Our G&A and S&M expenses were  $\in$  11.0 million in the first three months of 2019, compared to  $\in$  7.1 million in the first three 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 of the Galapagos share price.

Net financial income in the first three months of 2019 amounted to  $\epsilon$ 4.7 million compared to net financial expenses of  $\epsilon$ 5.2 million in the first three months of 2018, and was primarily attributable to  $\epsilon$ 5.0 million of unrealized exchange gain on our cash position in U.S. dollars ( $\epsilon$ 5.6 million of unrealized exchange loss on our cash position in U.S. dollars in the first three months of 2018).

#### **Segment information**

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

Segment information for the three months ended 31 March 2019

R&D	Fee-for-services	Inter-segment elimination	Group
30,735	2,312		33,047
	1,481	(1,481)	-
7,865	7		7,872
38,600	3,800	(1,481)	40,919
(46,967)	(276)		(47,242)
			(6,000)
			(53,242)
			4,655
			(48,588)
			(68)
			(48,656)
	7,865 38,600	30,735 2,312 1,481 7,865 7 38,600 3,800	R&D         Fee-for-services         elimination           30,735         2,312           1,481         (1,481)           7,865         7           38,600         3,800         (1,481)

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



Segment information for the three months ended 31 March 2018

(thousands of €)	R&D	Fee-for-services	Inter-segment elimination	Group
External revenue	34,888	3,019		37,907
Internal revenue		2,175	(2,175)	-
Other income	6,931			6,931
Revenues & other income	41,819	5,194	(2,175)	44,838
Segment result	(29,424)	1,330		(28,093)
Unallocated expenses <sup>(1)</sup>				(3,943)
Operating loss				(32,036)
Financial (expenses)/income				(5,184)
Result before tax				(37,221)
Income taxes				(62)
Net loss				(37,283)

<sup>(1)</sup> 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  $\ensuremath{\mbox{\ensuremath{$\mathfrak{e}}}}$ 1,222.9 million on 31 March 2019.

A net decrease of  $\in$ 67.9 million in cash and cash equivalents was recorded during the first three months of 2019, compared to a net decrease of  $\in$ 43.0 million during the first three months of 2018. This net decrease was composed of  $\in$ 76.3 million of operational cash burn, offset by (i)  $\in$ 3.5 million of cash proceeds from capital and share premium increase from exercise of warrants in the first three months of 2019 and (ii)  $\in$ 5.0 million of unrealized positive exchange rate differences.

Cash and cash equivalents amounted to €1,222.9 million at the end of March 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 €649.8 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 €199.1 million and aim at meeting short-term cash commitments, while reducing the counterparty risk of investment.

	31 March	31 December
(thousands of €)	2019	2018
Cash at banks	373,965	358,016
Term deposits	649,822	733,537
Money market funds	199,114	199,243
Total cash and cash equivalents	1,222,901	1,290,796



On 31 March 2019, our cash and cash equivalents included \$298.8 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.

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  $\in$ 87.7 million as at 31 March 2019.

#### **Capital increase**

On 31 March 2019, Galapagos NV's share capital was represented by 54,614,791 shares. All shares were issued, fully paid up and of the same class. The below table summarizes our capital increases for the quarter ended 31 March 2019.

(thousands of €, except share data)	Number of shares	Share capital	Share premium	Share capital and share premium	exercise price	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
On 31 March 2019	54,614,791	237,348	1,280,452	1,517,801		

#### Note to the cash flow statement

_	Three months ended 31 March		
(thousands of €)	2019	2018	
Adjustment for non-cash transactions			
Depreciation and amortization	2,758	1,197	
Share-based compensation	6,000	3,943	
Increase in retirement benefit obligations and provisions	87	78	
Unrealised exchange gains (-) /losses and non-cash other financial expenses	(4,777)	5,716	
Fair value adjustment financial assets held at fair value through profit or loss	1,455	123	
Total adjustment for non-cash transactions	5,524	11,057	
Adjustment for items to disclose separately under operating cash flow			
Interest expense	237	208	
Interest income	(1,822)	(800)	
Tax expense	68	62	
Total adjustment for items to disclose separately under operating cash flow	(1,517)	(530)	
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 / increase (-) in inventories	2	(14)	
Decrease / increase (-) in receivables	(1,239)	12,928	
Increase / decrease (-) in payables	(1,057)	7,568	
Total change in working capital other than deferred income	(2,294)	20,482	



#### 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 31 March 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	229,290	137,148	77,139	13,377	1,625

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  $\epsilon$ 02.7 million at 31 March 2019 for which we have direct purchase commitments of  $\epsilon$ 20.7 million at 31 March 2019 reflected in the table above.

#### 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 three months of 2019.

#### Events after the end of the reporting period

On 10 April 2019, the board of directors of Galapagos approved "Warrant Plan 2019," a warrant plan intended mainly for the employees of the company and its subsidiaries, and also for directors and an independent consultant of the company, and "Warrant Plan 2019 RMV," a warrant plan intended for the employees of its French subsidiary, Galapagos SASU, within the framework of the authorized capital. Under these warrant plans, 2,070,000 warrants were created, subject to acceptances, and offered to the beneficiaries of the plans. The offer of warrants to directors remains subject to approval of the annual shareholders' meeting of 30 April 2019. The warrants have an exercise term of eight years as of the date of the offer and have an exercise price of €95.11 (the average closing price of the share on Euronext Amsterdam and Brussels during the thirty days preceding the date of the offer). In principle, the warrants are not transferable and cannot be exercised prior to 1 January 2023. Each warrant gives the right to subscribe to one new Galapagos share.

#### Approval of interim financial statements

The interim financial statements were approved by the board of directors on 23 April 2019.



# Report on the review of the consolidated interim financial information for the three-month period ended 31 March 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 31 March 2019, the consolidated statement of income and comprehensive income, the consolidated cash flow statement and the consolidated statement 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 1 400 200 (000) EUR and the consolidated income statement shows a consolidated loss (group share) for the period then ended of 48 656 (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 April 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 spondyoloarthropathy 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 pruritis 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 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

#### 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

#### 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

#### 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

#### 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 subcutaneaous formulation of MOR106 in combination with topical corticosteroids. This Phase 2 trial was initiated early 2019

#### **GLPG0555**

A preclinical 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. Fully proprietary to Galapagos. 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 2019

#### **GLPG2737**

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

#### **GLPG3121**

A compound currently in Phase 1 with a novel mode of action directed towards inflammation. GLPG3121 is a JAK1/TYK2 inhibitor

#### **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  $% \left( 1\right) =\left( 1\right) \left( 1\right)$ 

#### 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

#### 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**

Proteïn 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

25 July 2019 (webcast 26 July 2019)

Half Year 2019 Results

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 B.V. o.v.v.e. CVBA, represented by Gert Vanhees Luchthaven Nationaal 1, bus J, 1930 Zaventem, Belgium

## Colophon

Concept, design and online programming

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

www.nexxar.com

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Aldo Allessi

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This report is also available in Dutch and available for download in the Downloads section of this report or at <a href="https://www.glpg.com">www.glpg.com</a>

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