

**Galáp**agos

# Q1 Report 2017





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# The Galapagos group

An overview of Galapagos, its strategy and portfolio in Q1 2017





### Letter from the management

Dear shareholders.

The Galapagos team continues to push the limits, with progress in our inflammation, cystic fibrosis, and other pipeline programs in the first quarter of 2017.

In addition to the FINCH, DIVERSITY, and SELECTION Phase 3 programs initiated last year with filgotinib, Gilead started additional Phase 2 studies in small bowel and fistulizing Crohn's disease as well as in Sjögren's syndrome and cutaneous lupus erythematosus. Adding the Phase 2 studies in psoriatic arthritis and ankylosing spondylitis that we initiated this quarter, filgotinib currently is being investigated in nine different inflammation indications. We expect more studies with filgotinib in new indications to be initiated throughout 2017. We now have in excess of 1,500 patient years' experience with filgotinib in RA patients, as DARWIN 3 continues; we expect to report the first longer term interim readout from DARWIN 3 at EULAR in June this year.



We delivered on our promise to show strong progress in cystic fibrosis, with several study starts in the first quarter, including the Phase 1 study with a combination of novel potentiator GLPG2451 and novel corrector GLPG2222 in healthy volunteers. We plan to initiate a patient evaluation of a potential triple combination therapy by mid this year.

We also completed recruitment for the FLORA Phase 2a study with fully proprietary autotaxin inhibitor GLPG1690 in IPF patients this quarter. Topline for this study is expected in the second half of this year.

Also this quarter, we welcomed Walid Abi-Saab to our executive committee, in the role of Chief Medical Officer. Walid is building his team and has taken over operations for filgotinib within Galapagos. Walid

comes at a great time for Galapagos, as we grow the late-stage pipeline and move closer to running our own Phase 3 programs in the future.

We look forward to updating you on execution of our strategy this year, on our way to becoming a fully integrated biopharmaceutical company.

### Operational overview Q1 2017

#### Inflammation

 Our collaboration partner Gilead initiated new Phase 2 studies with filgotinib in small bowel Crohn's disease and fistulizing Crohn's disease

#### Cystic fibrosis (CF)

- We plan to initiate a patient evaluation with a potential triple combination therapy in mid-2017
- We reported dosing of the first patient with Class III (F508del and a gating mutation like G551D) with novel CF corrector GLPG2222 as an add-on to Kalydeco<sup>®1</sup> in a Phase 2a study
- We opened an Investigational New Drug application with the US Federal Drug Administration for novel corrector GLPG2222 triggering a \$10 million payment from our collaboration partner AbbVie
- We initiated a Phase 1 study with a combination of GLPG2451 and GLPG2222

 $<sup>^1\,</sup>$  Kalydeco $^{\!\circ}$  is a potentiator drug marketed by Vertex Pharmaceuticals.



■ We initiated a Phase 1 study with novel potentiator GLPG3067, triggering a \$7.5 million milestone payment from our collaboration partner AbbVie

#### Idiopathic pulmonary fibrosis (IPF)

■ We completed patient recruitment for the FLORA Phase 2a study with GLPG1690 in IPF

#### Corporate & other

- Dr Walid Abi-Saab joined as Chief Medical Officer of Galapagos
- We were awarded a €1.4 million grant from Flanders Innovation & Entrepreneurship (VLAIO) for research efforts towards the identification of new strategies in the management of autosomal dominant polycystic kidney disease

#### Recent events

- On 4 April 2017, we announced that our collaboration partner Gilead will initiate a Phase 2 study with filgotinib in Sjögren's syndrome
- On 5 April 2017, we announced the start of a Phase 2 study with with filgotinib in ankylosing spondylitis and psoriatic arthritis; the initiation of the latter triggered a \$10 million milestone payment from Gilead to Galapagos
- On 6 April 2017, 247,070 warrants were exercised at various exercise prices (with an average exercise price of €16.33 per warrant) resulting in a share capital increase (including issuance premium) of €4 million and the issuance of 247,070 new shares. The closing price of the Galapagos share at this date was €84.60. The exercise price of these warrants was received from the warrantholders end of March 2017 and was classified as restricted cash in the Q1 financials
- On 21 April 2017, we announced the closing of our underwritten public offering of 4,312,500 American Depositary Shares ("ADSs"), at a price of \$90.00 per ADS, before underwriting discounts, for gross proceeds of €363.9 million. This includes the full exercise of the underwriter's option to purchase additional ADSs. Each of the ADSs offered represents the right to receive one ordinary share. The estimated net proceeds of this public offering after underwriting discounts and offering expenses amount to €348.0 million
- On 25 April 2017, we announced that our collaboration partner Gilead will initiate a Phase 2 study with filgotinib in CLE

#### Q1 2017 financial result

#### Revenues and other income

Our revenues and other income for the first three months of 2017 amounted to  $\in$ 39.9 million, compared to  $\in$ 14.8 million in the same period of 2016. Revenues ( $\in$ 34.0 million vs  $\in$ 10.1 million for the same period last year) were higher thanks to increased milestone revenues and revenue recognition of upfront payments. The milestone revenues were related to our cystic fibrosis program with AbbVie, whereas the revenue recognition of upfront payments related to our filgotinib program with Gilead. Other income increased slightly ( $\in$ 5.9 million vs  $\in$ 4.7 million for the same period last year), mainly driven by higher income from R&D incentives.

#### Results

We realized a net loss of  $\in$ 13.6 million for the first three months of 2017, compared to a net profit of  $\in$ 35.9 million in the first three months of 2016. Last year's result was primarily driven by a  $\in$ 57.5 million fair value gain from the re-measurement of the financial asset triggered by the share subscription agreement with Gilead.

We reported an operating loss amounting to  $\in$ 11.2 million for the first quarter of 2017, compared to an operating loss of  $\in$ 17.4 million for the same period last year.



Our R&D expenses in the first three months of 2017 were  $\in$ 44.9 million, compared to  $\in$ 27.8 million for the first quarter of 2016. This planned increase was due mainly to an increase of  $\in$ 11.7 million in subcontracting costs for our filgotinib and cystic fibrosis programs. Furthermore, personnel costs increased explained by a planned headcount increase, as well as higher costs for warrants and bonus plans as a result of the increase of our share price.

Our G&A and S&M expenses were  $\epsilon$ 6.2 million in the first quarter of 2017, compared to  $\epsilon$ 4.4 million in the first quarter of 2016. This increase primarily resulted from higher costs recognized for warrants and bonus plans as a result of the increase of our share price.

Net other financial expenses in the first three months of 2017 amounted to  $\[ \in \]$ 2.4 million, compared to net other financial expenses of  $\[ \in \]$ 4.1 million for the same period last year, and were primarily attributable to  $\[ \in \]$ 2.5 million of unrealized exchange loss on our cash position in U.S. dollar.

#### Liquid assets position

Cash, cash equivalents and restricted cash totaled €958.6 million at 31 March 2017.

A net decrease of  $\in$ 19.9 million in cash and cash equivalents was recorded during the first three months of 2017, compared to an increase of  $\in$ 638.0 million during the same period last year. Net cash flows used in operating activities amounted to  $\in$ 22.8 million in the first quarter of 2017. Furthermore  $\in$ 5.5 million was generated in investing activities primarily driven by the release of restricted cash to cash and cash equivalents for  $\in$ 6.6 million, and finally  $\in$ 2.5 million of unrealized negative exchange rate differences were reported on cash and cash equivalents.

On 31 March 2017, our balance sheet held a receivable from the French government ( $Crédit\ d'Impôt\ Recherche^2$ ) amounting to  $\epsilon$ 37.0 million, to be received in yearly tranches from 2017 to 2021. Our balance sheet also held a receivable from the Belgian Government for R&D incentives amounting to  $\epsilon$ 31.9 million, to be received in yearly tranches from 2017 to 2027.

#### Outlook 2017

In the first quarter of 2017, Galapagos executed as planned on its R&D strategy. We aim to initiate a CF patient evaluation of our triple combination therapy in mid-2017, as well as launching new clinical studies with CF candidates and combinations throughout the year. Together with our collaboration partner Gilead we plan to start additional proof-of-concept studies with filgotinib. Topline results from the FLORA Phase 2a study with GLPG1690 in IPF and from the Phase 1b study with MOR106 in atopic dermatitis patients are expected in the second half of 2017. We expect to initiate a Phase 1b study with GLPG1972 in osteoarthritis patients in the United States, as well as Phase 1 studies with GLPG2938 (IPF) and GLPG2534 (AtD). We expect an operational use of cash of €135-155 million during 2017.

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

#### Onno van de Stolpe

CEO

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



# At a glance

### Key figures (IFRS) Galapagos group (unaudited)

(in thousands of €, if not stated otherwise)	31/03/2017	31/03/2016
Results		
Revenues and other income	39,863	14,817
R&D expenditure	(44,930)	(27,818)
S, G&A expenses	(6,158)	(4,394)
Personnel expenses (including share-based compensation)	(16,280)	(11,251)
Capital expenditure	1,036	1,065
Depreciation and amortization of (in)tangible assets	(1,050)	(964)
Operating loss	(11,225)	(17,395)
Net financial results	(2,380)	53,345
Taxes	-	-
Net income / loss (-)	(13,605)	35,950
Galapagos share		
Number of shares issued on 31 March	46,256,078	45,837,043
Basic income / loss (–) per share (in €)	(0.29)	0.81
Diluted income / loss (-) per share (in €)	(0.29)	0.79
Share price on 31 March (in €)	81.58	36.99
Personnel data		
Total group employees on 31 March (number)	530	447

#### Balance sheet

(thousands of €)	31/03/2017	31/12/2016
Total assets	1,072,814	1,083,338
Cash, cash equivalents and restricted cash	958,557	980,909
Total liabilities	324,665	324,637
Stockholders' equity	748,150	758,701



#### Employees per site as of 31 March 2017





#### **Risk factors**

We refer to the description of risk factors in the 2016 annual report, pp. 42-50, as supplemented by the description of risk factors in our annual report on Form 20-F filed with the U.S. Securities and Exchange Commission, pp. 5-47. In summary, the principal risks and uncertainties faced by us relate to: product development, regulatory approval and commercialization; our reliance on third parties; our financial position and need for additional capital; 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 2016 annual report, pp. 130-134, 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 to the public free of charge and upon request:

#### 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 2017", guidance from management regarding the expected operational use of cash during financial year 2017, statements regarding the development of a potential triple combination therapy for Class II cystic fibrosis patients and the possible activity and clinical utility of such potential triple combination therapy, statements regarding the expected timing, design and readouts of ongoing and planned clinical trials (i) with filgotinib in inflammatory indications (including but not limited to rheumatoid arthritis, Crohn's disease and ulcerative colitis), (ii) with our CF modulators (including but not limited to GLPG1837, GLPG2222, GLPG2737, GLPG2851, GLPG2451, and GLPG3067) in cystic fibrosis, (iii) with GLPG1690 in IPF, (iv) with GLPG1972 in osteoarthritis, (v) with MOR106 in atopic dermatitis, (vi) with GLPG2938 in IPF and (vii) with GLPG2534 in atopic dermatitis. 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, performance or achievements, 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 2017 operating expenses may be incorrect (including because one or more of our assumptions underlying our 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, cystic fibrosis, idiopathic pulmonary fibrosis, osteoarthritis, and other inflammatory indications may not support registration or further development of our product candidates due to safety, efficacy or other reasons), our reliance on collaborations with third parties (including our collaboration partner for filgotinib, Gilead, and our collaboration partner for cystic fibrosis, AbbVie), 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 filing and reports, including in our most recent annual report on Form 20-F filed with the SEC and our subsequent filings and reports filed with the SEC. We also refer to the "Risk Factors" section of this report. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. We expressly disclaim any obligation to update any such forward-looking statements in this document to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements, unless specifically required by law or regulation.





# Consolidated interim financial statements

# Consolidated statements of income and comprehensive income (unaudited)

#### Consolidated income statement

	Three months e	nded 31 March
(thousands of €, except share and per share data)	2017	2016
Revenues	33,992	10,121
Other income	5,871	4,696
Total revenues and other income	39,863	14,817
Research and development expenditure	(44,930)	(27,818)
General and administrative expenses	(5,603)	(3,972)
Sales and marketing expenses	(556)	(422)
Total operating expenses	(51,088)	(32,212)
Operating loss	(11,225)	(17,395)
Fair value re-measurement of share subscription agreement	-	57,479
Other financial income	894	626
Other financial expenses	(3,274)	(4,761)
Profit / loss (–) before tax	(13,605)	35,950
Income taxes	-	-
Net income / loss (-)	(13,605)	35,950
Net income / loss (-) attributable to:		
Owners of the parent	(13,605)	35,950
Basic income / loss (-) per share	(0.29)	0.81
Diluted income / loss (-) per share	(0.29)	0.79
Weighted average number of shares – basic (in thousands of shares)	46,256	44,425
Weighted average number of shares – diluted (in thousands of shares)	48,330	45,492



## Consolidated statements of comprehensive income

	Three months e	nded 31 March
(thousands of €)	2017	2016
Net income / loss (-)	(13,605)	35,950
Items that may be reclassified subsequently to profit or loss:		
Fair value adjustment of available-for-sale financial assets	(8)	
Translation differences, arisen from translating foreign activities	39	(382)
Other comprehensive income, net of income tax	31	(382)
Total comprehensive income attributable to:		
Owners of the parent	(13,574)	35,567



# Consolidated statements of financial position (unaudited)

	31 March	31 December
(thousands of €)	2017	2016
Assets		
Intangible assets	963	1,023
Property, plant and equipment	15,064	14,961
Deferred tax assets	1,957	1,957
Non-current R&D incentives receivables	58,693	54,188
Non-current restricted cash	1,137	1,098
Other non-current assets	2,878	2,880
Non-currents assets	80,692	76,107
Inventories	324	300
Trade and other receivables	16,010	9,728
Current R&D incentives receivables	10,154	10,154
Cash and cash equivalents	953,385	973,241
Current restricted cash	4,034	6,570
Other current assets	8,215	7,239
Current assets	992,122	1,007,232
Total assets	1,072,814	1,083,338
Equity and liabilities		
Share capital	223,928	223,928
Share premium account	649,135	649,135
Other reserves	(1,008)	(1,000)
Translation differences	(1,051)	(1,090)
Accumulated losses	(122,854)	(112,272)
Total equity	748,150	758,701
Description Publishers	2.502	2.520
Pension liabilities	3,592	3,520
Provisions	64	63
Finance lease liabilities		9
Other non-current liabilities	1,697	2,469
Non-current deferred income	191,328	214,785
Non-current liabilities	196,681	220,846



	31 March	31 December
(thousands of €)	2017	2016
Finance lease liabilities	50	54
Trade and other payables	46,964	31,269
Current tax payable	1,023	1,022
Accrued charges	921	619
Deferred income	79,026	70,827
Current liabilities	127,984	103,791
Total liabilities	324,665	324,637
Total equity and liabilities	1,072,814	1,083,338



# Consolidated cash flow statements (unaudited)

	Three months ended 3	1 March
(thousands of €)	2017	2016
Cash and cash equivalents at beginning of year	973,241	340,314
A	(40.505)	25.050
Net income / loss (–)	(13,605)	35,950
Adjustments for:		
Other net financial expenses	2,380	4,134
Fair value re-measurement of share subscription agreement	-	(57,479)
Depreciation of property, plant and equipment	870	755
Amortization of intangible fixed assets	180	209
Net realized loss on foreign exchange transactions and net other financial expenses paid	(338)	(724)
Share-based compensation	3,023	1,902
Increase in pension liabilities	72	61
Gain on sale of fixed assets	-	(13)
Operating cash flows before movements in working capital	(7,418)	(15,206)
Increase in inventories	(24)	(23)
Increase in receivables	(11,586)	(5,209)
Increase in payables	11,092	928
Increase / decrease (-) in deferred income	(15,259)	270,926
Cash generated / used (-) in operations	(23,196)	251,416
Interest paid	(16)	(13)
Interest received	370	144
Net cash flows generated / used (–) in operating activities	(22,843)	251,547
Purchase of property, plant and equipment	(916)	(1,024)
Purchase of and expenditure in intangible fixed assets	(120)	(41)
Proceeds from disposal of property, plant and equipment	1	16
Decrease in restricted cash	6,531	_
Net cash flows generated / used (-) in investing activities	5,497	(1,050)



#### Three months ended 31 March

(thousands of €)	2017	2016
Repayment of obligations under finance leases and other debts	(14)	(17)
Proceeds from capital and share premium increases, net of issue costs	-	392,044
Net cash flows generated/ used (-) in financing activities	(14)	392,027
Effect of exchange rate differences on cash and cash equivalents	(2,496)	(4,505)
Increase / decrease (–) in cash and cash equivalents	(19,856)	638,020
		-
Cash and cash equivalents at end of the period	953,385	978,334



# Consolidated statements of changes in equity (unaudited)

(thousands of €)	Share capital	Share premium account	Translation differences	Other reserves	Accumul. losses	Total
On 1 January 2016	185,399	357,402	(467)	(18)	(177,317)	364,999
Net loss					35,950	35,950
Other comprehensive income			(382)			(382)
Total comprehensive income			(382)	-	35,950	35,567
Share-based compensation					1,902	1,902
Issue of new shares	36,575	289,696				326,271
Share issue costs	(195)					(195)
On 31 March 2016	221,779	647,098	(849)	(18)	(139,465)	728,545
On 1 January 2017	223,928	649,135	(1,090)	(1,000)	(112,272)	758,701
Net income					(13,605)	(13,605)
Other comprehensive income			39	(8)		31
Total comprehensive income			39	(8)	(13,605)	(13,574)
Share-based compensation					3,023	3,023
On 31 March 2017	223,928	649,135	(1,051)	(1,008)	(122,854)	748,150



#### **Notes**

#### **Basis of preparation**

These condensed interim financial statements have been prepared in accordance with IAS 34 'Interim Financial Reporting' as adopted by the European Union. The condensed interim financial statements do not contain all information required for an annual report and should therefore be read in conjunction with Galapagos' annual report 2016.

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

#### Details of the unaudited interim results

#### Revenues and other income

#### Revenues

The following table summarizes our revenues for the three months ended 31 March 2017 and 2016.

	Three months e	ths ended 31 March	
(thousands of €)	2017	2016	
Recognition of non-refundable upfront payments	15,225	4,843	
Milestone payments	16,564	-	
Reimbursement income	104	3,950	
Other revenues	2,099	1,327	
Total revenues	33,992	10,121	

Revenues ( $\in$ 34.0 million vs  $\in$ 10.1 million for the same period last year) were higher due to increased milestone revenues from AbbVie for our CF program and to an increase in revenue recognition of the upfront payment from Gilead related to the filgotinib program, which is recognized in function of the costs incurred.

The following table summarizes the upfront payments revenue recognition for the three months ended 31 March 2017 and 2016.

Agreement	Upfront received	Upfront received	Date of receipt	Revenue recognized, three months ended 31 March 2017	Revenue recognized, three months ended 31 March 2016	Outstanding balance in deferred income as at 31 March 2017
	(thousands of \$)	(thousands of €)		(thousands of €)		
Gilead collaboration agreement for filgotinib	300,000	275,558	January 2016	13,337	4,243	236,600
Gilead collaboration agreement for filgotinib	N.A.	39,003 <sup>(*)</sup>	January 2016	1,888	600	33,488
Total recognition o	of non-refundable up	front payments		15,225	4,843	270,088

<sup>(\*)</sup> deferred income of €39 million recognized upon signing of the share subscription agreement with Gilead as required under IAS 39.



For the three first months of 2017,  $\in$ 15.2 million of deferred income related to the Gilead collaboration agreement were recognized in revenue in function of costs incurred, applying the percentage of completion method. This revenue recognition consisted of  $\in$ 13.3 million related to the upfront license fee and  $\in$ 1.9 million related to the deferred income triggered by the accounting treatment of the share subscription agreement under IAS 39. The outstanding balance of deferred income from the Gilead collaboration agreement at the end of March 2017 amounted to  $\in$ 270.1 million of which  $\in$ 191.3 million reported as non-current deferred income.

#### Other income

The following table summarizes our other income for the three months ended 31 March 2017 and 2016.

	Three months ended 31 March		
(thousands of €)	2017	2016	
Grant income	293	594	
Other income	5,578	4,102	
Total other income	5,871	4,696	

Other income increased slightly ( $\epsilon$ 5.9 million vs  $\epsilon$ 4.7 million last year) in the first three months of 2017, mainly driven by higher income from R&D incentives.

#### Results

We realized a net loss of  $\in$ 13.6 million for the first three months of 2017, compared to a net profit of  $\in$ 35.9 million in the first three months of 2016. Last year's result was primarily driven by  $\in$ 57.5 million fair value gain from the re-measurement of the financial asset triggered by the share subscription agreement with Gilead.

We reported an operating loss amounting to  $\in$ 11.2 million for the first quarter of 2017, compared to an operating loss of  $\in$ 17.4 million for the same period last year.

Our R&D expenses in the first three months of 2017 were  $\epsilon$ 44.9 million, compared to  $\epsilon$ 27.8 million in 2016. This planned increase was due mainly to an increase of  $\epsilon$ 11.7 million in subcontracting costs for our filgotinib and cystic fibrosis programs. Furthermore, personnel costs increased, explained by a planned increase in headcount, as well as higher costs for warrants and bonus plans as a result of the increase of our share price.

Our G&A and S&M expenses were  $\epsilon$ 6.2 million in the first quarter of 2017, compared to  $\epsilon$ 4.4 million in the first quarter of 2016. This increase mainly resulted from higher costs recognized in relation to the warrants and bonus plans as a result of the increase of the Galapagos share price, as well as a planned slight headcount increase.

Net other financial expenses in the first three months of 2017 amounted to  $\[mathcal{\in}\]$ 2.4 million compared to net other financial expenses of  $\[mathcal{\in}\]$ 4.1 million in 2016, and were primarily attributable to  $\[mathcal{\in}\]$ 2.5 million of unrealized exchange loss on our cash position in U.S. dollar as a consequence of the fluctuation of the U.S. dollar exchange rate in the first quarter of 2017.

Financial results in 2016 were primarily driven by the fair value re-measurement of the share subscription agreement.



#### Segment information

#### Segment information for the three months ended 31 March 2017

R&D	Fee-for-services	Inter-segment elimination	Group
31,950	2,042	-	33,992
-	1,005	(1,005)	-
5,859	12	-	5,871
37,809	3,059	(1,005)	39,863
(7,745)	(457)		(8,202)
			(3,023)
			(11,225)
			(2,380)
			(13,605)
			-
			(13,605)
	31,950 - 5,859 37,809	31,950 2,042  - 1,005  5,859 12  37,809 3,059	R&D         Fee-for-services         elimination           31,950         2,042         -           -         1,005         (1,005)           5,859         12         -           37,809         3,059         (1,005)

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

#### Segment information for the three months ended 31 March 2016

(thousands of €)	R&D	Fee-for-services	Inter-segment elimination	Group
External revenue	8,840	1,281	-	10,121
Internal revenue	-	1,310	(1,310)	-
Other income	4,636	60	-	4,696
Revenues & other income	13,476	2,651	(1,310)	14,817
Segment result	(14,624)	(869)		(15,493)
Unallocated expenses <sup>(1)</sup>				(1,902)
Operating loss				(17,395)
Financial (expenses) / income				53,345
Result before tax				35,950
Income taxes				-
Net income				35,950

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

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, cash equivalents and restricted cash totaled €958.6 million at 31 March 2017.

A net decrease of  $\le$ 19.9 million in cash and cash equivalents was recorded during the first three months of 2017, compared to an increase of  $\le$ 638.0 million during the same period last year. Net cash used in operating activities amounted to  $\le$ 22.8 million in the first quarter of 2017.



Restricted cash amounted to  $\[ \in \]$ 7.7 million at the end of December 2016, and decreased by  $\[ \in \]$ 2.5 million to  $\[ \in \]$ 5.2 million at the end of March 2017. This decrease was explained by the full release of the escrow account containing the remaining  $\[ \in \]$ 6.6 million of proceeds from the sale of the service division in 2014, as final agreement between the parties was reached. However, this was largely offset by an increase of  $\[ \in \]$ 4.0 million from the proceeds received as a consequence of warrant exercises. This amount remained on a blocked bank account until 6 April 2017, being the date of the notary deed formally establishing the capital increase.

On 31 March 2017, restricted cash was composed of  $\in$ 0.5 million and  $\in$ 0.7 million bank guarantees on real estate lease obligations in Belgium and in the Netherlands respectively, and  $\in$ 4.0 million advances on capital increase from warrant exercises.

Cash and cash equivalents amounted to  $\in$ 953.4 million at the end of March 2017 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  $\in$ 661.5 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  $\in$ 99.9 million and aim at meeting short-term cash commitments, while reducing the counterparty risk of investment.

	31 March	31 December
(thousands of €)	2017	2016
Cash at banks	191,937	357,630
Term deposits	661,496	515,632
Money market funds	99,949	99,977
Cash on hand	3	2
Total cash and cash equivalents	953,385	973,241

On 31 March 2017, our cash and cash equivalents included \$201.6 million held in U.S. dollar which could generate unrealized exchange gain or loss in our financial results in accordance with the fluctuation of the EUR/U.S. dollar exchange rate as our functional currency is EUR. We expect to use this cash held in U.S. dollar to settle our future payables in U.S. dollar which will be primarily linked to our global collaboration with Gilead for the development of filgotinib.

Furthermore, our balance sheet held R&D incentives receivables from the French government ( $Crédit d'Impôt Recherche^3$ ) amounting to €37.0 million as of 31 March 2017, to be received in yearly tranches from 2017 to 2021. Our balance sheet also held R&D incentives receivables from the Belgian Government amounting to €31.9 million as of 31 March 2017, to be received in yearly tranches from 2017 until 2027.

<sup>&</sup>lt;sup>3</sup> Crédit d'Impôt Recherche refers to an innovation incentive system underwritten by the French government.



#### Contingencies and commitments

#### Contractual obligations and commitments

We entered into lease agreements for offices and laboratories which qualify as operating leases. We also have certain purchase commitments principally with CRO subcontractors.

On 31 March 2017, we had outstanding obligations for future minimum rent payments and purchase commitments, which become due as follows:

(thousands of €)	Total	Less than 1 year	1–3 years	3–5 years	More than 5 years
Operating lease obligations	26,386	4,186	6,202	5,512	10,485
Purchase commitments	44,617	41,877	2,740	-	-
Total contractual obligations & commitments	71,003	46,063	8,943	5,512	10,485

On 31 December 2016, we had outstanding obligations for future minimum rent payments and purchase commitments, which become due as follows:

(thousands of €)	Total	Less than 1 year	1–3 years	3–5 years	More than 5 years
Operating lease obligations	27,263	4,114	6,494	5,504	11,151
Purchase commitments	27,579	27,084	495	-	-
Total contractual obligations & commitments	54,842	31,198	6,989	5,504	11,151

#### Contingent liabilities and assets

On 13 March 2014, we announced the signing of a definitive agreement to sell the service division operations to Charles River Laboratories International, Inc., or CRL, for a total consideration of up to  $\epsilon$ 134 million. CRL agreed to pay us an immediate cash consideration of  $\epsilon$ 129 million. The potential earn-out of  $\epsilon$ 5 million due upon achievement of a revenue target 12 months after transaction closing has not been obtained. Approximately 5% of the total consideration, including price adjustments, was being held on an escrow account. Four claims have been introduced by CRL, which all have been settled for a total amount of  $\epsilon$ 1.3 million. In the first quarter of 2017, the remaining balance of  $\epsilon$ 6.6 million was released in full as final agreement between the parties has been reached.

Following the divestment, we remained guarantor until early February 2017 in respect of the lease obligations for certain U.K. premises. Finally, following common practice, we have given representations and warranties which are capped and limited in time (since 1 April 2016, CRL can only introduce a claim covered by the Tax Deed (during a period of 5 years), other claims related to the sale cannot be submitted anymore).

In the course of 2008, a former director of one of the subsidiaries sued for wrongful termination and seeks damages of €1.5 million. We believe that the amount of damages claimed is unrealistically high. In 2014, the court requested an external advisor to evaluate the exact amount of damages. On 29 January 2016, the court made a 1st degree judgment, dismissing all claims in full. In appeal, the 2nd degree court instructed the 1st degree court to conduct a new trial, which is currently pending. So far, the first hearing is scheduled on 12 July 2017, no decisions have yet been made. Considering the defense elements provided, as well as the fact that so far the court has made no decision indicating that the claim would be sustained, our board and management evaluated the risk to be remote to possible, but not likely. Accordingly, it was decided not to record any provision as the exposure was considered to be limited.



#### 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 financial statements of 2016, except for the adoption of new standards and interpretations described below.

# New standards and interpretations applicable for the annual period beginning on 1 January 2017

- Amendments to IAS 12 Recognition of Deferred Tax Assets for Unrealized Losses
- Amendments to IAS 7 Disclosure Initiative
- Annual Improvements to IFRS Standards 2014–2016 Cycle Amendments to IFRS 12

The nature and the effect of these changes were taken into consideration, but the above amendments did not affect the interim condensed consolidated financial statements. We have not early adopted any other standard, interpretation, or amendment that has been issued but is not yet effective.

#### Seasonality

The impact of seasonality or cyclicality on our operations is not regarded as applicable to the unaudited interim condensed consolidated financial statements.

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

On 5 April 2017, we announced the dosing of the first patient in an additional Phase 2 study with filgotinib in psoriatic arthritis (EQUATOR), led by Galapagos, which triggered a \$10 million milestone payment from Gilead to Galapagos.

On 6 April 2017, 247,070 warrants were exercised at various exercise prices (with an average exercise price of  $\le$ 16.33 per warrant) resulting in a share capital increase (including issuance premium) of  $\le$ 4 million and the issuance of 247,070 new shares. The closing price of the Galapagos share at this date was  $\le$ 84.60. The exercise price of these warrants was received from the warrantholders end of March 2017 and was classified as restricted cash.

On 21 April 2017, we announced the closing of our underwritten public offering of 4,312,500 American Depositary Shares ("ADSs"), at a price of \$90.00 per ADS, before underwriting discounts, for gross proceeds of  $\epsilon$ 363.9 million. This includes the full exercise of the underwriter's option to purchase additional ADSs. Each of the ADSs offered represents the right to receive one ordinary share. The estimated net proceeds of this public offering after underwriting discounts and offering expenses payable by us, amount to  $\epsilon$ 348.0 million.

#### Approval of interim financial statements

The interim financial statements were approved by the board of directors on 25 April 2017.



# Report on review of the consolidated interim financial information for the three-month period ended 31 March 2017

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 2017, 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 Financial Reporting Standard IAS 34 – *Interim Financial Reporting* as adopted by the European Union.

The consolidated condensed statement of financial position shows total assets of 1,072,814 (000) EUR and the consolidated condensed income statement shows a consolidated loss for the period then ended of 13,605 (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 2017

The statutory auditor

DELOITTE Bedrijfsrevisoren / Reviseurs d'Entreprises

BV o.v.v.e. CVBA / SC s.f.d. SCRL Represented by Gert Vanhees



### Glossary of terms

#### 100 points clinical response

Percentage of patients achieving a 100 point decrease in CDAI score during a clinical trial in Crohn's disease 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

#### **ADR**

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

#### **AFM**

Dutch Authority for the Financial Markets

#### **Anemia**

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

#### (anti-)TNF

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

#### 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 signalling molecule lypophosphatidic acid (LPA). GLPG1690 targets autotaxin for IPF

#### **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 candidate drug 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 mouse model

A pre-clinical model involving use of bleomycin (a cancer medication) to induce IPF symptoms

#### Candidate drug

Substance that has satisfied the requirements of early pre-clinical 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

#### CDAI

Crohn's Disease Activity Index, evaluating patients on 8 different factors, each of which has a pre-defined weight as a way to quantify the impact of Crohn's disease

#### **CFTR**

Cystic Fibrosis Transmembrane conductance Regulator protein. CFTR is an ion channel that transports chloride and thiocyanate ions across epithelial cell membranes. Mutations in the CFTR gene, that codes for the CFTR protein, cause cystic fibrosis

#### 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



#### Class II mutation

A genetic mutation in cystic fibrosis resulting in errors in CFTR folding, transport of functional CFTR to the cell membrane, and CFTR channel opening, whereby chloride ion flow at the cell surface in the membrane of affected organs is impacted negatively. More than 90% of cystic fibrosis patients are carriers of the Class II mutation. It is believed that a potentiator and multiple correctors will be needed to address the CFTR malfunction of Class II mutation patients. Orkambi is the only approved disease-modifying therapy for Class II mutation patients today

#### Class III mutation

A genetic mutation in cystic fibrosis resulting in errors in CFTR channel opening, whereby chloride ion flow at the cell surface in the membrane of affected organs is impacted negatively. Approximately 4% of cystic fibrosis patients are carriers of the Class III mutation. It is believed that a potentiator is needed to address the malfunction of Class III mutation patients. Kalydeco is the only approved disease-modifying therapy for Class III mutation patients today

#### Clinical Proof of Concept (PoC)

Point in the drug development process where the candidate drug 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

#### Corrector drug

Drug that restores the correct protein formation in cystic fibrosis patients. In most CF patients, a potentiator and corrector drug are needed in combination to restore the channel function of the CFTR. Galapagos and AbbVie are planning to combine a potentiator with two correctors to investigate in CF patients with the most prevalent mutation of CFTR

#### Crohn's disease (CD)

An inflammatory bowel disease 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

#### 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



#### **DARWIN**

Phase 2 program for filgotinib in rheumatoid arthritis: completed and reported in 2015 (except for the currently still ongoing DARWIN 3 study). DARWIN 1 explored three doses, in bid and qd 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 qd 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 c-reactive protein the 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 pre-clinical and clinical development research, chemical and pharmaceutical development and regulatory filings of drug 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 pre-clinical candidates

#### **Disease-modifying**

Addresses the cause of disease and modifying the disease progression, not just the symptoms of the disease

#### **DIVERSITY**

Phase 3 program evaluating filgotinib in Crohn's disease

#### 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



#### **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 authorization of new medication

#### Fee-for-service

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

#### 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 candidate drug

#### **Filgotinib**

Formerly known as GLPG0634. Small molecule selective JAK1 inhibitor which showed promising safety and activity profile in RA and Crohn's disease 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. Gilead initiated Phase 2 studies with filgotinib in small bowel Crohn's disease, fistulizing Crohn's disease, and Sjögren's syndrome; Galapagos initiated Phase 2 studies with filgotinib in ankylosing spondylitis and psoriatic arthritis. We expect to initiate more Phase 2 trials with filgotinib in new indications in the course of 2017. Filgotinib is an investigational drug and its efficacy and safety have not been established.

#### **FINCH**

Phase 3 program evaluating filgotinib in RA

#### Fistulizing Crohn's disease

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 are expected in  $H_2$  2017

#### **FSMA**

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



#### FTE

Fulltime equivalent; a way to measure a worker'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

#### **GLPG0634**

Molecule number currently known as filgotinib

#### **GLPG1690**

A novel product candidate targeting autotaxin, with potential application in idiopathic pulmonary fibrosis. Fully proprietary to Galapagos. Testing in Phase 2 proof-of-concept FLORA study in IPF underway, with topline results expected in  $\rm H_2$  2017

#### **GLPG1837**

A potentiator product candidate which showed activity and favorable safety in the SAPHIRA 1 and 2 trials in Phase 2 in Class III CF mutation patients

#### **GLPG1972**

A novel mode-of-action product candidate that is part of the OA alliance with Servier. GLPG1972 was well-tolerated and showed no emerging safety signals in a Phase 1 trial with healthy volunteers. In addition, GLPG1972 showed up to 60% reduction in a relevant OA biomarker within 14 days in these volunteers. Galapagos expects to initiate a Phase 1b trial with GLPG1972 in OA patients in the U.S. in 2017

#### GLPG2222

A C1 (early) corrector product candidate which showed favorable safety in Phase 1 and is currently being tested in the ALBATROSS Phase 2 study in combination with Kalydeco in Class III mutation patients. In February 2017 Galapagos announced first dosing of GLPG2222 with GLPG2451 in healthy volunteers

#### **GLPG2451**

A potentiator product candidate currently undergoing a Phase 1 safety trial. In February 2017 Galapagos announced first dosing of GLPG2222 with GLPG2451 in healthy volunteers

#### **GLPG2534**

A pre-clinical candidate with novel mode of action with potential application in AtD. GLPG2543 is expected to enter Phase 1 trials in 2017

#### **GLPG2737**

A C2 (late) corrector product candidate currently in a Phase 1 safety trial

#### **GLPG2851**

A C1 (early) corrector product candidate currently at the pre-clinical stage. GLPG2851 is expected to enter Phase 1 trials in 2017

#### **GLPG2938**

A pre-clinical candidate with novel mode of action with potential application in IPF. GLPG2938 is expected to enter Phase 1 trials in 2017



#### **GLPG3067**

A potentiator drug candidate. GLPG3067 started a Phase 1 trial in March 2017

#### **GLPG3221**

A C2 (late) corrector drug candidate currently at the pre-clinical stage. GLPG3221 is expected to enter Phase 1 trials in 2017

#### **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\*

\* Source: webmd.com/cholesterol-management/guide/hdl-cholesterol-the-good-cholesterol#1

#### 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

#### Heterozygous

Genetic term meaning a cell containing different alleles for a gene

#### Histopathology

Microscopic examination of tissues for manifestations of a disease

#### Homozygous

Genetic term meaning identical alleles of the gene are present on both homologous chromosomes

#### **IBD**

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

#### **IL-17C**

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

#### In-/out-licensing

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

#### In vitro

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



#### Inflammatory diseases

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

#### Intellectual property

Creations of the mind that have commercial value and are protected 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

#### 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 rheumatoid arthritis. Filgotinib is a selective JAK1 inhibitor

#### Kalydeco

A potentiator drug marketed by Vertex Pharmaceuticals

#### LDL

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

\* Source: webmd.com/cholesterol-management/guide/hdl-cholesterol-the-good-cholesterol#1

#### Liver enzymes

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

\* Source: Mayoclinic.org

#### **LPA**

Lysophosphatidic acid, or LPA, is a signaling molecule involved in fibrosis

#### Lymphocyte

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



#### Milestone

Major achievement in a project or program; in Galapagos' 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 being evaluated in AtD patients in a Phase 1b trial. MOR106 acts on IL-17C, a novel antibody target discovered by Galapagos. MOR106 is part of the alliance with MorphoSys

#### **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

#### 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

#### Orkambi

A combination potentiator-corrector therapy marketed by Vertex Pharmaceuticals

#### 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

#### Placebo-controlled

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

#### Potentiator drug

Drug that restores the CFTR ion channel opening in CF patients. In most CF patients, a potentiator and corrector drug are needed in combination to restore the genetic defect causing CF. Galapagos and AbbVie are planning to combine a potentiator with two correctors to investigate CF patients with the most prevalent mutation of CFTR

#### **Pre-clinical**

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

#### Pre-clinical candidate (PCC)

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

#### **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



#### QD dosing

Once daily dosing (quaque die)

#### **R&D** operations

Research and development operations; unit responsible for discovery and developing new candidate drugs 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

#### **SAPHIRA**

A Phase 2 trial of potentiator GLPG1837 in cystic fibrosis patients carrying a Class III mutation. Results were reported in 2016, showing activity and favorable safety in two Class III mutations

#### 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 2/3 program evaluating filgotinib in UC patients. Galapagos expects an interim readout for the Phase 2 portion of the program in late 2017

#### Service operations

Business unit primarily focused on delivering products and conducting fee-for-service work for clients. Galapagos' 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 Crohn's Disease, involving review of 5 pre-defined bowel segments, assigning values from 0 (unaffected) to 3 (highly affected)

#### Small bowel CD

Crohn's disease causes chronic inflammation and erosion of the intestines. It can affect different regions of GI 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 (SB), particularly the ileum, is common

#### Target

Protein that has been shown to be involved in a disease process and forms the basis of therapeutic intervention or drug discovery

#### 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)

#### Ulcerative colitis (UC)

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



### Financial calendar

#### 27 July 2017

First Half 2017 Results

#### 26 October 2017

Third Quarter 2017 Results

#### 22 February 2018

Full Year 2017 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

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#### Photography

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On our cover:

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