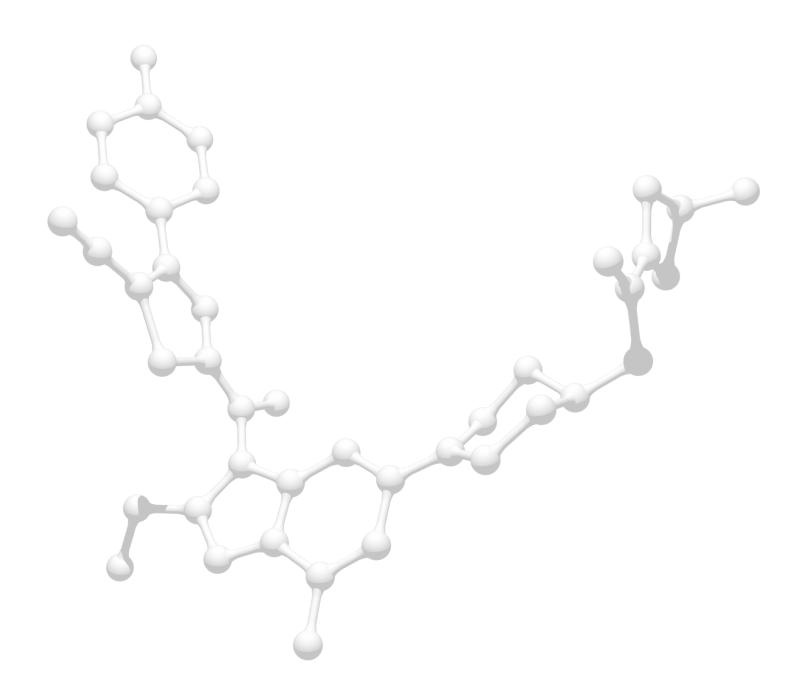


## **Galáp**agos

# Q1 Report 2018







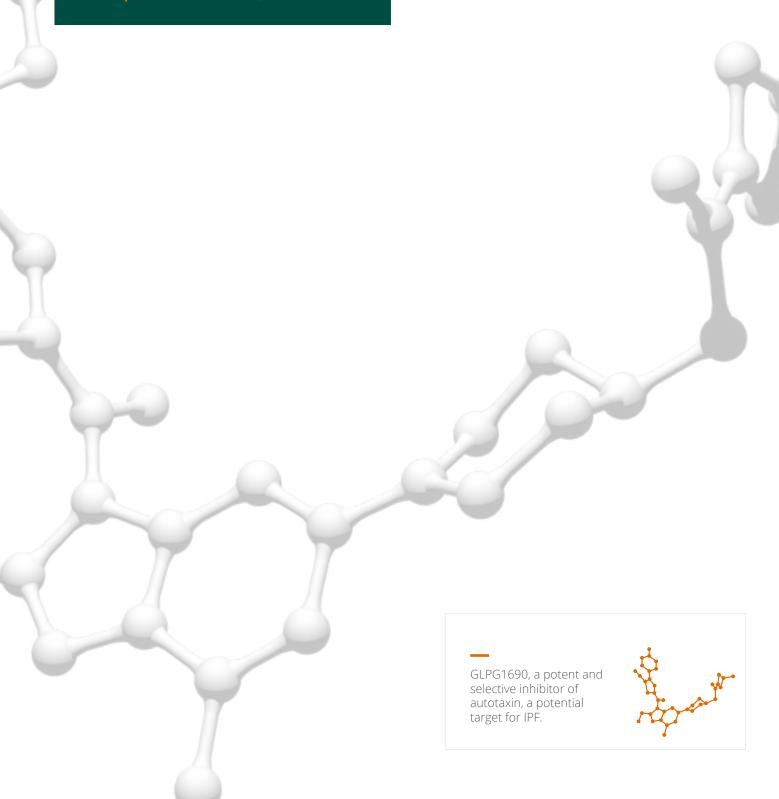
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# The Galapagos group

An overview of Galapagos, its strategy and portfolio in Q1 2018





## Letter from the management

Dear shareholders.

We reported another quarter of solid pipeline progress in the first quarter of 2018, as we prepared for the next wave of late stage studies, finished up execution on several other patient studies, and moved our early pipeline forward.

In our osteoarthritis, atopic dermatitis, and cystic fibrosis programs, we are preparing for the next patient studies in the second quarter. Importantly, we received feedback from regulatory authorities for our ISABELA global pivotal studies with GLPG1690 in idiopathic pulmonary fibrosis, expected to start in the second half of 2018. We await the next round of filgotinib clinical study results, starting with the EQUATOR studies in psoriatic arthritis in the second quarter.



The coming year will be data-rich, as we expect the first Phase 3 data with filgotinib in rheumatoid arthritis, along with an interim decision to move to Phase 3 in the ulcerative colitis trial and readouts in our trials in ankylosing spondylitis and psoriatic arthritis. In cystic fibrosis, we will see topline results from the PELICAN trial and a first interim readout with FALCON, a patient study of our first triple combination therapy. We expect to launch pivotal trials with GLPG1690 in IPF, building our fully proprietary IPF franchise. And with our planned start of Phase 2 studies for GLPG1205, GLPG1972, MOR106, and a second CF triple combination, we set the foundations for the next set of clinical results. Meanwhile, we continue to expand our organization to be able to execute the increasing number of clinical studies and to be ready for the anticipated market introduction of our drug candidates.

Galapagos ended the first quarter of 2018 with a strong balance sheet. We are continuing to grow our late stage development organization to execute on our successful programs. The Galapagos share of proprietary late stage development is growing, leading to increased costs for our company. During 2018 we expect to be running 13 Phase 2 studies. All this will contribute to our financial guidance for operational cash burn between €220 and €240 million for full year 2018.

## Operational overview Q1 2018

#### **Inflammation**

- Completed recruitment for the EQUATOR and TORTUGA Phase 2 Proof-of-Concept trials with filgotinib
- Reported good tolerability and dose-dependent decreases of biomarker ARGS neoepitope in the blood serum of osteoarthritis patients treated with GLPG1972
- Presented the key findings of the Phase 1b trial in atopic dermatitis patients with MOR106 at AAD 2018

#### Cystic fibrosis (CF)

- Reported activity and good tolerability with C1 corrector GLPG2222 in homozygous Class II patients in the FLAMINGO Phase 2 trial
- Completed Phase 1 with the second triple combination therapy comprising GLPG3067, GLPG2222, and GLPG2737
- Completed recruitment for the Phase 2 PELICAN trial with C2 corrector GLPG2737 in combination with Orkambi<sup>®</sup>1 in Class II homozygous patients

<sup>&</sup>lt;sup>1</sup> A combination potentiator-corrector therapy marketed by Vertex Pharmaceuticals



#### Corporate & other

■ Raised €3.9 million from warrant exercises

#### Recent events

- Announced ISABELA, a global Phase 3 program with GLPG1690 in IPF based on feedback from FDA and EMA
- Announced initiation of FALCON, our first clinical trial with an investigational triple combination therapy in CF patients

#### Q1 2018 financial result

#### Revenues and other income

Our revenues and other income for the first three months of 2018 amounted to  $\in$ 44.8 million, compared to  $\in$ 39.9 million in the same period of 2017. Revenues ( $\in$ 37.9 million vs  $\in$ 34.0 million for the same period last year) were higher due to an increased recognition in revenue of the upfront payment related to the filgotinib program with Gilead, in line with the increased spending, but also due to the adoption of IFRS 15 – Revenue from contract with customers, on 1 January 2018, resulting in the recognition for the first quarter of 2018 of  $\in$ 10.4 million of deferred revenues related to previously recognized upfront and milestones under the former applicable standards of IAS 18. We refer to the notes to this interim consolidated financial report for additional information on the impact of the adoption of IFRS 15 on our consolidated financial statements.

Other income increased ( $\le 6.9$  million vs  $\le 5.9$  million for the same period last year), mainly driven by higher income from R&D incentives.

#### Results

We realized a net loss of  $\in$ 37.3 million for the first three months of 2018, compared to a net loss of  $\in$ 13.6 million in the first three months of 2017.

We reported an operating loss amounting to  $\in$ 32.0 million for the first quarter of 2018, compared to an operating loss of  $\in$ 11.2 million for the same period last year.

Our R&D expenses in the first three months of 2018 were  $\epsilon$ 69.8 million, compared to  $\epsilon$ 44.9 million for the first quarter of 2017. This planned increase was due mainly to an increase of  $\epsilon$ 20.4 million in subcontracting costs primarily on our filgotinib and GLPG1690 programs. Furthermore, personnel costs increased explained by a planned headcount increase. Our G&A and S&M expenses were  $\epsilon$ 7.1 million in the first quarter of 2018, compared to  $\epsilon$ 6.2 million in the first quarter of 2017. This increase mainly resulted from higher personnel costs due to a planned headcount increase.

Net financial expenses in the first three months of 2018 amounted to  $\epsilon$ 5.2 million, compared to net financial expenses of  $\epsilon$ 2.4 million for the same period last year, and were primarily attributable to  $\epsilon$ 5.6 million of unrealized exchange loss on our cash position in U.S. dollars. We expect to use this cash held in U.S. dollars to settle our future payables in U.S. dollars, which will be primarily linked to our global collaboration with Gilead for the development of filgotinib.

#### Liquid assets position

Cash and cash equivalents totaled €1,108.2 million on 31 March 2018.

A net decrease of  $\epsilon$ 43.0 million in cash and cash equivalents was recorded during the first three months of 2018, compared to a net decrease of  $\epsilon$ 19.9 million during the same period last year. Net cash flows used in operating activities amounted to  $\epsilon$ 39.8 million in the first three months of 2018. Exercise of warrants in the first quarter of 2018 generated a financing cash inflow of  $\epsilon$ 3.9 million. Furthermore,  $\epsilon$ 1.5 million was used in investing activities and  $\epsilon$ 5.6 million unrealized negative exchange rate differences were reported on cash and cash equivalents.



Finally, our balance sheet held a receivable from the French government ( $Cr\acute{e}dit\ d'Imp\^{o}t\ Recherche^2$ ) amounting to €39.1 million, payable in 4 yearly tranches. Our balance sheet also held a receivable from the Belgian Government for R&D incentives amounting to €41.7 million.

#### Outlook 2018

We aim to report topline results with the FINCH 2 (rheumatoid arthritis), EQUATOR (psoriatic arthritis), TORTUGA (ankylosing spondylitis) filgotinib trials as well as a decision to continue to Phase 3 in SELECTION (ulcerative colitis). Our collaboration partner Gilead expects to complete recruitment of FINCH 1 and FINCH 3, the remaining RA Phase 3 trials with filgotinib. In cystic fibrosis we anticipate the readout of the PELICAN patient trial and an interim readout in FALCON. We recently announced the design for the ISABELA pivotal trials with GLPG1690 in IPF. We expect to start dosing ISABELA and initiate Phase 2 trials with GLPG1205 (IPF), an additional CF triple combination, GLPG1972 (osteoarthritis), and MOR106 (atopic dermatitis) later in 2018.

The company expects an operational cash burn between €220 and €240 million in 2018.

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>&</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**

#### (thousands of €, if not stated otherwise)

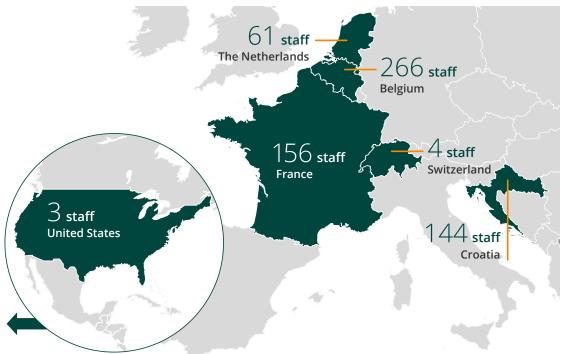
Income statement	31/03/2018	31/03/2017
Revenues <sup>(1)</sup>	37,907	33,992
Other income	6,931	5,871
R&D expenditure	(69,765)	(44,930)
S, G&A expenses	(7,110)	(6,158)
Operating expenses	(76,875)	(51,088)
Operating loss	(32,036)	(11,225)
Net financial results	(5,184)	(2,380)
Taxes	(62)	-
Net loss	(37,283)	(13,605)
Balance sheet	31/03/2018	31/12/2017
Cash and cash equivalents	1,108,186	1,151,211
R&D incentives receivables	80,870	75,783
Assets	1,229,864	1,286,274
Shareholders' equity <sup>(1)</sup>	899,345	1,011,983
Deferred income <sup>(1)</sup>	268,654	219,892
Other liabilities	61,865	54,399
Cash flow	31/03/2018	31/03/2017
Operational cash burn <sup>(2)</sup>	(41,335)	(23,878)
Cash flow generated / used (-) in financing activities	3,905	(14)
Effect of currency exchange rate fluctuation on cash and cash equivalents	(5,595)	(2,496)
Decrease in cash and cash equivalents	(43,025)	(19,856)
Cash and cash equivalents on 31 March	1,108,186	953,385
Financial ratios	31/03/2018	31/03/2017
Number of shares issued on 31 March	51,234,962	46,256,078
Basic and diluted loss per share (in €)	(0.73)	(0.29)
Share price on 31 March (in €)	81.30	81.58
Total group employees on 31 March (number)	634	530

<sup>(1)</sup> Our revenues, shareholders' equity and deferred income for the period ended 31 March 2018 were influenced by the adoption of the new standard IFRS 15 – Revenue from contract with customers, on 1 January 2018. We refer to the notes of this interim consolidated financial report for additional information.

<sup>(2)</sup> The operational cash burn (or operational cash flow if this performance measure is positive) is equal to the sum of the net cash flows generated / used (-) in operating activities and the net cash flows generated / used (-) in investing activities minus (i) the proceeds or cash used, if any, in acquisitions or disposals of businesses; and (ii) the movement in restricted cash, if any. This alternative performance measure is in our view an important metric for a biotech company in the development stage.



#### Employees per site as of 31 March 2018



## **Risk factors**

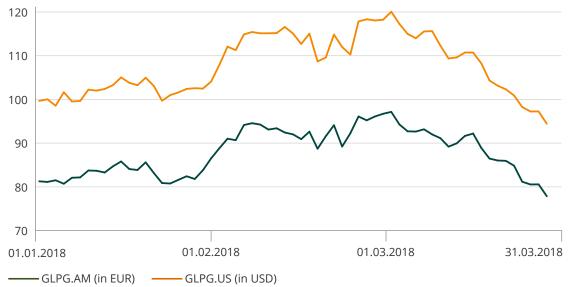
We refer to the description of risk factors in the 2017 annual report, pp. 48-56, as supplemented by the description of risk factors in our annual report on Form 20-F filed with the U.S. Securities and Exchange Commission, pp. 5-45. In summary, the principal risks and uncertainties faced by us relate to: our financial position and need for additional capital; product development, regulatory approval and commercialization; 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 2017 annual report, pp. 132-135, 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:

#### Galapagos NV

Investor Relations Generaal De Wittelaan L11 A3 2800 Mechelen, Belgium Tel: +32 15 34 29 00

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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 NASDAO: GLPG

#### Forward-looking statements

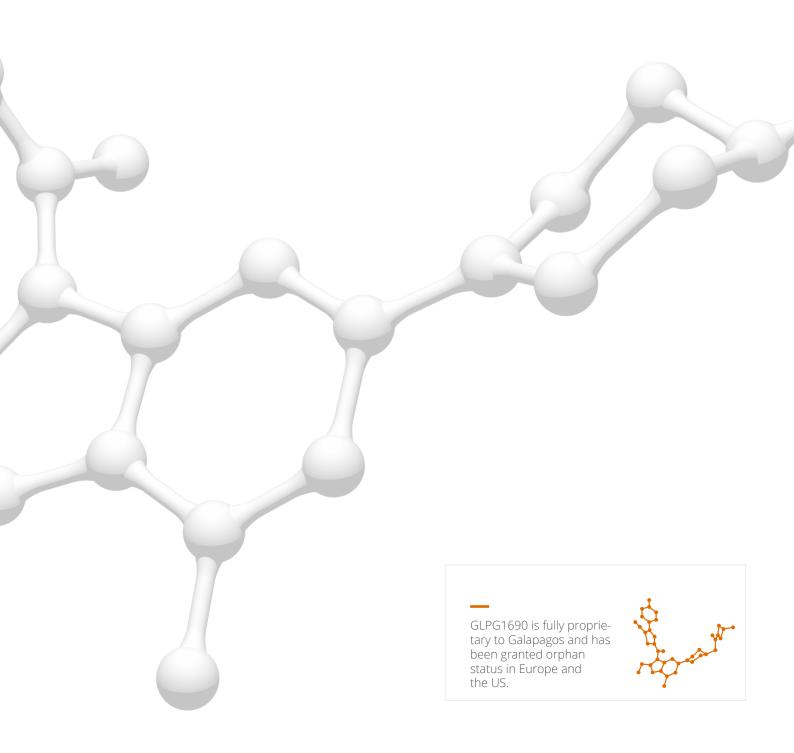
This report contains forward-looking statements, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "believe," "anticipate," "expect," "intend," "plan," "seek," "estimate," "may," "will," "could," "stand 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 2018", guidance from management regarding the expected operational use of cash during financial year 2018, 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 rheumatoid arthritis, Crohn's disease, ulcerative colitis and other indications, (ii) with GLPG2222, GLPG2737, GLPG2851, GLPG2451, and GLPG3067 or combinations thereof in cystic fibrosis, (iii) with GLPG1690 and GLPG1205 in IPF, (iv) with GLPG1972 in osteoarthritis, and (v) with MOR106 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, 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 2018 revenues and financial results and our 2018 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, cystic fibrosis, idiopathic pulmonary fibrosis, 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 cystic fibrosis, AbbVie, our collaboration partner for GLPG1972, Servier, and our collaboration partner for MOR106, MorphoSys), and estimating the commercial potential of our product candidates. A further list and description of these risks, uncertainties and other risks can be found in our Securities and Exchange Commission filings and reports, including in our most recent annual report on Form 20-F filed with the SEC and our other filings and reports. We also refer to the "Risk Factors" section of this report. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. We expressly disclaim any obligation to update any such forward-looking statements in this document to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements, unless specifically required by law or regulation.

# Financial statements

Consolidated interim financial statements for the first quarter 2018





# Consolidated interim financial statements for the first three months of 2018

# Consolidated statements of income and comprehensive income (unaudited)

#### Consolidated income statement

	Three months ended 3	31 March	
(thousands of €, except share and per share data)	2018	201	
Revenues	37,907	33,992	
Other income	6,931	5,871	
Total revenues and other income	44,838	39,863	
Research and development expenditure	(69,765)	(44,930)	
General and administrative expenses	(6,697)	(5,603)	
Sales and marketing expenses	(413)	(556)	
Total operating expenses	(76,875)	(51,088)	
Operating loss	(32,036)	(11,225)	
Financial income	1,610	894	
Financial expenses	(6,794)	(3,274)	
Loss before tax	(37,221)	(13,605)	
Income taxes	(62)	-	
Net loss	(37,283)	(13,605)	
Net loss attributable to:			
Owners of the parent	(37,283)	(13,605)	
Basic and diluted loss per share	(0.73)	(0.29)	
Weighted average number of shares – Basic and diluted (in thousands of shares)	50,973	46,256	



## Consolidated statements of comprehensive income

Owners of the parent

	Three months e	Three months ended 31 March			
(thousands of €)	2018	2017			
Net loss	(37,283)	(13,605)			
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	(3)	39			
Other comprehensive income, net of income tax	(3)	31			
Total comprehensive income attributable to:					

(37,286)

(13,574)



## Consolidated statements of financial position

## (unaudited)

	31 March	31 December
(thousands of €)	2018	2017
Assets		
Intangible assets	2,555	2,495
Property, plant and equipment	16,971	16,692
Deferred tax assets		1,978
Non-current R&D incentives receivables	1,979	64,001
	1,158	
Non-current restricted cash		1,158
Other non-current assets	2,182	2,303
Non-currents assets	94,129	88,627
Inventories	293	279
Trade and other receivables	8,501	27,966
Current R&D incentives receivables	11,585	11,782
Cash and cash equivalents	1,108,186	1,151,211
Other current assets	7,171	6,409
Current assets	1,135,735	1,197,647
Total assets	1,229,864	1,286,274
Equity and liabilities		
Equity and natifices		
Share capital	235,027	233,414
Share premium account	995,336	993,025
Other reserves	(641)	(1,260)
Translation differences	(1,757)	(1,754)
Accumulated losses	(328,620)	(211,441)
Total equity	899,345	1,011,983
Pension liabilities	3,660	3,582
Provisions	5,000	5,362
Other non-current liabilities	677	
Non-current deferred income		1,597
Non-current liabilities	102,486 106,888	97,348 <b>102,592</b>



	31 March	31 December
(thousands of €)	2018	2017
Finance lease liabilities	-	9
Trade and other payables	55,657	47,122
Current tax payable	862	865
Accrued charges	943	1,159
Current deferred income	166,168	122,544
Current liabilities	223,631	171,699
Total liabilities	330,519	274,291
Total equity and liabilities	1,229,864	1,286,274



## Consolidated cash flow statements

## (unaudited)

(thousands of €)	2018	2017
Cash and cash equivalents at beginning of year	1,151,211	973,241
Net loss	(37,283)	(13,605)
Adjustments for:		
Tax expense	62	_
Net financial expense	5,184	2,380
Depreciation of property, plant and equipment	914	870
Amortization of intangible fixed assets	283	180
Net realized gain / loss (–) on foreign exchange transactions	63	(338)
Share-based compensation	3,943	3,023
Increase in pension liabilities	78	72
	(26.755)	(7.440)
	(26,755)	(7,418)
Increase in inventories	(14)	(24)
Decrease / Increase (-) in receivables	12,928	(11,586)
Increase in payables	7,568	11,092
Decrease in deferred income	(34,458)	(15,259)
Cash used in operations	(40,732)	(23,196)
Interest paid	(500)	(16)
Interest received	1,428	370
Net cash flows used in operating activities	(39,804)	(22,843)
Purchase of property, plant and equipment	(1,192)	(916)
Purchase of and expenditure in intangible fixed assets	(340)	(120)
Proceeds from disposal of property, plant and equipment	1	1
Decrease in restricted cash	-	6,531
Net cash flows generated / used (-) in investing activities	(1,531)	5,497



(thousands of €)	2018	2017
Repayment of obligations under finance leases and other debts	(19)	(14)
Proceeds from capital and share premium increases from exercise of warrants	3,924	-
Net cash flows generated /used (-) in financing activities	3,905	(14)
Effect of exchange rate differences on cash and cash equivalents	(5,595)	(2,496)
Decrease in cash and cash equivalents	(43,025)	(19,856)
Cash and cash equivalents at end of the period	1,108,186	953,385



## Consolidated statements of changes in equity

## (unaudited)

(thousands of €)	Share capital	Share premium account	Translation differences	Other reserves	Accumul. losses	Total
On 1 January 2017	223,928	649,135	(1,090)	(1,000)	(112,272)	758,701
Net loss					(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
On 31 December 2017	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)	(295,280)	928,764
Net loss					(37,283)	(37,283)
Other comprehensive income			(3)	-		(3)
Total comprehensive income			(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



# Notes to the unaudited consolidated interim financial statements for the first three months of 2018

### 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 2017.

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 2018 and 2017.

	Inree months e	nded 31 March
(thousands of €)	2018	2017
Recognition of non-refundable upfront payments and license fees	25,824	15,225
Milestone payments	8,809	16,564
Reimbursement income	192	104
Other revenues	3,081	2,099
Total revenues	37,907	33,992

Revenues (€37.9 million vs €34.0 million for the same period last year) were higher due to an increase in the recognition of the upfront payment from Gilead related to the filgotinib program, which is recognized in function of the costs incurred for this program, but also due to the adoption of IFRS 15 – Revenue from contract with customers, on 1 January 2018, resulting in the recognition for the first quarter of 2018 of €10.4 million of deferred revenues related to previously recognized upfront and milestones under the former applicable standards of IAS 18.

The following table summarizes the recognition of the upfront, license fees and milestones payments received for the three months ended 31 March 2018 and 2017.



				IAS 18		IFRS 15	IFRS 15	IAS 18	IAS 18	IFRS 15
Agreement	Consideration received	Consideration received	Collaboration start date	Outstanding balance in deferred income as at 31 December 2017	Deferred income reclassified from equity following adoption of IFRS 15	Outstanding balance in deferred income as at 1 January 2018	months ended		Revenue recognized, three months ended 31 March 2017	Outstanding balance in deferred income as at 31 March 2018
	(thousands of \$)	(thousands of €)					(thousands of	:€)	*	
Gilead collaboration agreement for filgotinib – Upfront payment	300,000	275,558	January 2016	187,449		187,449	20,914	20,914	13,337	166,535
Gilead collaboration agreement for filgotinib - Sub- scription agreement <sup>(1)</sup>	N.A.	39,003	January 2016	26,532		26,532	2,960	2,960	1,888	23,572
Servier collaboration agreement for osteo- arthritis – License fee	N.A.	6,000	June 2010	5,362	(5,362)	-		383		-
AbbVie collaboration agreement for CF – Upfront payments	45,000	34,001	September 2013		14,872	14,872	1,950			12,922
Total upfron	t and license fee	es:		219,343	9,510	228,853	25,824	24,257	15,225	203,028
Gilead collaboration agreement for filgotinib – Milestone payments	70,000	64,435	January 2016		43,832	43,832	4,891			38,941
AbbVie collaboration agreement for CF – Milestone payments	77,500	68,310	September 2013		29,878	29,878	3,918		16,564	25,960
Total milesto	nes:			-	73,710	73,710	8,809	-	16,564	64,901
Total:				219,343	83,220	302,563	34,633	24,257	31,789	267,929

<sup>(1)</sup> deferred income of €39 million booked upon signing of the share subscription agreement with Gilead as required under IAS 39 Financial instruments: recognition and measurement

The first adoption of IFRS 15 Revenue from contracts with customers negatively impacted the accumulated losses and increased the amount of deferred income (contract liabilities) with an amount of &83.2 million, as shown in the table above (column "Deferred income reclassified from equity following adoption of IFRS 15"). We elected the modified retrospective method for the transition which foresees that prior period figures remain as reported under the previous standard and the cumulative effect of applying IFRS 15 is recognized as an adjustment to the opening balance of equity as at the date of initial application (beginning of the year 2018).

The revenues recognized for the three months ended 31 March 2018 are presented in the table above under IFRS 15 standard as well as under IAS 18 standard, with a comparison to last year's period under IAS 18 standard.



We applied the five step model detailed in the IFRS 15 standard to determine when, how and at what amount revenue is to be recognized depending on whether certain criteria are met. The significant judgements made in applying this standard are detailed below:

The substance of our current arrangements is that Galapagos is licensing its IP to collaborative partner entities and conducts research and development ("R&D") activities. Such activities result in a service that is the output of Galapagos' ordinary activities. We generate revenue through a number of these arrangements which include license fees, milestone payments, reimbursement income and future sales based milestones and sales based royalties. We assessed that the revenues from our current material licensing and collaboration agreements are in the scope of IFRS 15.

#### Collaboration with Gilead

We concluded as follows:

- We assessed that there is one single performance obligation under the new standards of IFRS 15; the transfer of a license combined with performance of R&D activities. This is because we considered that the license is not distinct in the context of the contract.
- The transaction price of our agreement is currently composed of a fixed part, being an upfront license fee and a variable part, being milestone payments and cost reimbursements for R&D activities delivered. Milestone payments are included in our revenues only when achieved. Sales based milestones and sales based royalties are a part of our arrangement but are not yet included in our revenues as our program is still in phase 3 of development.
- The transaction price has been allocated to the single performance obligation and revenues have been recognized over the estimated service period based on a pattern that reflects the transfer of the license and progress to complete satisfaction of the R&D activities. This is because we considered that there is a transformational relationship between the license and the R&D activities to be delivered.
- We have chosen an input model to measure the satisfaction of the single performance obligation that considers percentage of costs incurred for this program that are completed each period (% of completion method).
- Costs reimbursements received from Gilead are to be recognized in revenues when costs are incurred and agreed by the parties as we are acting as a principal in the scope of our stake of the R&D activities of our ongoing license and collaboration agreements.

As a result of this analysis, for the first three months of 2018,  $\[ \in \]$  28.8 million of deferred income related to the Gilead collaboration agreement were recognized in revenue under IFRS 15 in function of costs incurred, applying the percentage of completion method. This revenue recognition consisted of (i)  $\[ \in \]$  20.9 million related to the upfront license fee, (ii)  $\[ \in \]$  3.0 million related to the deferred income triggered by the accounting treatment of the share subscription agreement under IAS 39 Financial Instruments: recognition and measurement, and (iii)  $\[ \in \]$  4.9 million related to milestone payments received. The outstanding balance of deferred income from the Gilead collaboration agreement at the end of March 2018 amounted to  $\[ \in \]$  229.0 million of which  $\[ \in \]$  83.9 million reported as non-current deferred income.

As reflected in the table above, the impact of the IFRS 15 adoption on our revenues generated from our collaboration with Gilead was only related to the deferral of previously recognized milestones.

#### Collaboration with AbbVie

We concluded as follows:

■ We assessed that there is one single performance obligation under the new standards of IFRS 15; the transfer of a license combined with performance of R&D activities. This is because we considered that the license is not capable of being distinct and is not distinct in the context of the contract.



- The transaction price of our agreement is currently composed of a fixed part, being an upfront license fee, and a variable part, being milestone payments and cost reimbursements for R&D activities delivered. Milestone payments are included in our revenues only when achieved. Sales based milestones and sales based royalties are a part of our arrangement but are not yet included in our revenues as our program is still in phase 1 & 2 of development.
- The transaction price has been allocated to the single performance obligation and revenues have been recognized over the estimated service period based on a pattern that reflects the transfer of the license and progress to complete satisfaction of the R&D activities. This is because we considered that there is a transformational relationship between the license and the R&D activities to be delivered.
- We have chosen an input model to measure the satisfaction of the single performance obligation that considers a percentage of costs incurred for this program that are completed each period (% of completion method).
- Costs reimbursements received from AbbVie could be recognized in revenues when costs are incurred and agreed by the parties as we are acting as a principal in the scope of our stake of the R&D activities of our ongoing license and collaboration agreements.

As a result of this analysis, for the first three months of 2018,  $\in$ 5.9 million of deferred income related to the AbbVie collaboration agreement were recognized in revenue under IFRS 15 in function of costs incurred, applying the percentage of completion method. This revenue recognition consisted of (i)  $\in$ 2.0 million related to the upfront license fee and (ii)  $\in$ 3.9 million related to milestone payments received in previous years. The outstanding balance of deferred income from the AbbVie collaboration agreement at the end of March 2018 amounted to  $\in$ 38.9 million of which  $\in$ 18.6 million reported as non-current deferred income.

As reflected in the table above, the impact of the IFRS 15 adoption on our revenues generated from our collaboration with AbbVie was related to the deferral of previously recognized upfront fee and milestones.

Finally, the deferred income balance on 31 December 2017 related to the license fee received from Servier in the scope of our license and collaboration agreement in the field of osteoarthritis ( $\in$ 5.4 million) was fully reclassified to equity as a consequence of the adoption of the new standard.

#### Other revenues

Other revenues mainly consisted in service revenues from our fee-for-service business for  $\in$  3.0 million, as reported under the segment information disclosure below.

#### Other income

The following table summarizes our other income for the three months ended 31 March 2018 and 2017.

	Three months ended 31 Marc		
(thousands of €)	2018	2017	
Grant income	549	293	
Other income	6,382	5,578	
Total other income	6,931	5,871	

Other income increased ( $\epsilon$ 6.9 million vs  $\epsilon$ 5.9 million last year) in the first three months of 2018, mainly driven by higher income from R&D incentives.

#### Results

We realized a net loss of  $\in$ 37.3 million for the first three months of 2018, compared to a net loss of  $\in$ 13.6 million in the first three months of 2017.



We reported an operating loss amounting to  $\leq$ 32.0 million for the first three months of 2018, compared to an operating loss of  $\leq$ 11.2 million for the same period last year.

Our R&D expenses in the first three months of 2018 were  $\epsilon$ 69.8 million, compared to  $\epsilon$ 44.9 million in 2017. This planned increase was due mainly to an increase of  $\epsilon$ 20.4 million in subcontracting costs primarily on our filgotinib and GLPG1690 programs. Furthermore, personnel costs increased, explained by a planned headcount increase.

Our G&A and S&M expenses were  $\[ \in \]$ 7.1 million in the first quarter of 2018, compared to  $\[ \in \]$ 6.2 million in the first quarter of 2017. This increase mainly resulted from higher personnel costs due to a planned headcount increase.

Net financial expenses in the first three months of 2018 amounted to  $\[ \in \]$ 5.2 million compared to net financial expenses of  $\[ \in \]$ 2.4 million in 2017, and were primarily attributable to  $\[ \in \]$ 5.6 million of unrealized exchange loss on our cash position in U.S. dollars. We expect to use this cash held in U.S. dollars to settle our future payables in U.S. dollars, which will be primarily linked to our global collaboration with Gilead for the development of filgotinib.

#### **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 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 <sup>(2)</sup>				(5,184)				
Result before tax				(37,221)				
Income taxes <sup>(2)</sup>				(62)				
Net loss				(37,283)				

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

<sup>(2)</sup> Financial results and taxes information are not being provided to management in our management reporting as segment results and therefore, their aggregate amount is disclosed at the level of the group in our segment reporting.



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 <b>37,809</b>	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 Share based payments.

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

#### Liquid assets position

Cash and cash equivalents totaled €1,108.2 million on 31 March 2018.

A net decrease of  $\[ \in \]$ 43.0 million in cash and cash equivalents was recorded during the first three months of 2018, compared to a decrease of  $\[ \in \]$ 19.9 million during the same period last year. Net cash flows used in operating activities amounted to  $\[ \in \]$ 39.8 million in the first quarter 2018. Exercise of warrants in the first quarter of 2018 generated a financing cash inflow of  $\[ \in \]$ 3.9 million. Furthermore  $\[ \in \]$ 1.5 million was used in investing activities and  $\[ \in \]$ 5.6 million unrealized negative exchange rate differences were reported on cash and cash equivalents.

Cash and cash equivalents amounted to €1,108.2 million at the end of March 2018 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 €662.4 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 €149.6 million and aim at meeting short-term cash commitments, while reducing the counterparty risk of investment.

	31 March	31 December
(thousands of €)	2018	2017
Cash at banks	296,226	288,052
Term deposits	662,355	713,446
Money market funds	149,602	149,711
Cash on hand	3	3
Total cash and cash equivalents	1,108,186	1,151,211

<sup>(2)</sup> Financial results and taxes information are not being provided to management in our management reporting as segment results and therefore, their aggregate amount is disclosed at the level of the group in our segment reporting.



On 31 March 2018, our cash and cash equivalents included \$247.4 million held in U.S. dollars which could generate foreign 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. dollars to settle our future payables in U.S. dollars which will be primarily linked to our global collaboration with Gilead for the development of filgotinib.

Finally, our balance sheet held R&D incentives receivables from the French government ( $Crédit\ d'Impôt\ Recherche$ ) amounting to €39.1 million as of 31 March 2018, to be received in four yearly tranches. Our balance sheet also held R&D incentives receivables from the Belgian Government amounting to €41.7 million as at 31 March 2018.

#### Capital increase

On 31 March 2018, Galapagos NV's share capital was represented by 51,234,962 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 2018.

(thousands of €, except share data)	Number of shares	Share capital	Share premium	Share capital and share premium	Average exercise price warrants	Closing share price on date of capital increase
On 1 January 2018	50,936,778	233,414	993,025	1,226,439		
20 March 2018: exercise of warrants	298,184	1,613	2,311	3,924	13.16	83.72
On 31 March 2018	51,234,962	235,027	995,336	1,230,363		

## Contingencies and commitments

#### Contractual obligations and commitments

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

On 31 March 2018 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	25,831	4,349	7,897	5,887	7,698
Purchase commitments	68,930	54,983	13,259	688	-
Total contractual obligations & commitments	94,761	59,332	21,156	6,575	7,698

On 31 December 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	26,346	4,150	7,820	6,010	8,366
Purchase commitments	65,246	53,010	11,233	1,002	-
Total contractual obligations & commitments	91,592	57,160	19,053	7,012	8,366



In addition to the tables above, we have a contractual cost sharing obligation related to our collaboration agreement with Gilead for filgotinib. The contractual cost sharing commitment amounted to  $\epsilon$ 111.6 million at 31 March 2018 ( $\epsilon$ 129.0 million at 31 December 2017), for which we have direct purchase commitments of  $\epsilon$ 6.4 million at 31 March 2018 ( $\epsilon$ 10.1 million at 31 December 2017) reflected in the tables above.

#### Contingent liabilities and assets

We refer to our annual report 2017 for contingent liabilities and assets.

### 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 2017, except for the adoption of new standards and interpretations described below.

- IFRS 15 Revenue from Contracts with Customers, and clarifications on this IFRS (applicable for annual periods beginning on or after 1 January 2018)
- IFRS 9 Financial Instruments, and subsequent amendments (applicable for annual periods beginning on or after 1 January 2018)

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

IFRS 15 Revenue from Contracts with Customers. As a consequence of the adoption of the new IFRS standard on 1 January 2018, our consolidated accumulated losses and deferred income were both increased for an amount of €83.2 million, reflecting the impact of the new standard on the revenue recognition of the considerations received related to our ongoing license and collaboration agreements. Differences in accounting treatment compared to the former standard were identified for (i) the milestones payments previously received in the scope of our license and collaboration agreement for filgotinib with Gilead, and (ii) the upfront and milestone payments received related to the license and collaboration agreement with AbbVie for cystic fibrosis, which were fully recognized in revenue in the previous years under the former applicable IFRS standard. Finally, the deferred income balance related to the license fee received from Servier in the scope of our license and collaboration agreement in the field of osteoarthritis was fully reclassified to equity as a consequence of the adoption of the new standard. We refer to the revenues disclosure for further detail.

IFRS 9 Financial Instruments. The only financial instrument held by the company subject to change in accounting treatment following the adoption of IFRS 9 – Financial Instruments, was the equity investments in a French biotech company classified as available-for-sale financial asset. At 31 December 2017, our balance sheet held shares of this company which were acquired in 2016. The closing price of the share on Euronext as at the end of the year 2017 led to cumulative fair value loss amounting to  $\epsilon$ 0.6 million recognized in other comprehensive income following the accounting treatment applied under IAS 39. Following the adoption of the new IFRS standard on 1 January 2018, and considering that the financial asset should be classified and measured at fair value, with changes in fair value recognized in profit and loss, the cumulative fair value loss of  $\epsilon$ 0.6 million previously recognized in other comprehensive income was reclassified to accumulated losses. Fair value loss amounting to  $\epsilon$ 0.1 million was additionally recognized in profit and loss for the first three months of 2018.

Other new standards and interpretations applicable for the annual period beginning on 1 January 2018 did not have any impact on our 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 19 April 2018, the board of directors of Galapagos approved the "Warrant Plan 2018," a warrant plan intended mainly for certain (future) employees of the company and its subsidiaries, and also for directors and an independent consultant of the company, and the "Warrant Plan 2018 RMV," a warrant plan intended for certain employees of its French subsidiary, Galapagos SASU, within the framework of the authorized capital. Under these warrant plans, 1,585,000 warrants were created, subject to acceptances, and offered to the beneficiaries of the plans. The warrants have an exercise term of eight years as of the date of the offer and have an exercise price of €79.88 (the average closing price of the share on Euronext Amsterdam and Brussels during the thirty days preceding the date of the offer). The warrants are not transferable and can in principle not be exercised prior to 1 January 2022. 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 2018.



# Report on the review of the consolidated interim financial information for the three-month period ended 31 March 2018

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 condensed statement of financial position as at 31 March 2018, the consolidated condensed statement of income and comprehensive income, the consolidated condensed cash flow statement and the consolidated condensed 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 condensed statement of financial position shows total assets of 1 229 864 (000) EUR and the consolidated condensed income statement shows a consolidated loss (group share) for the period then ended of 37 283 (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, 23 April 2018 The statutory auditor

DELOITTE Bedrijfsrevisoren / Réviseurs d'Entreprises

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

The original text of this report is in Dutch



## **Glossary of terms**

Glossary of terms, to be read only in conjunction with this Q1 Report 2018.

#### 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

#### **ALBATROSS**

A Phase 2 trial to evaluate GLPG2222 in ivacaftor-treated CF patients with the Class II mutation on one allele

#### 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 measure 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

#### **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 pre-clinical 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

#### **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 CF



#### 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 CF 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. About 90% of CF 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 and Symdeko are the only approved disease-modifying therapies for Class II mutation patients today

#### Class III mutation

A genetic mutation in CF 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 8% of CF 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 product candidate 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 CF 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 be investigated in CF patients with the most prevalent mutation of CFTR

#### 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**

 $\hbox{$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

#### **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 will be 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 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 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 pre-clinical 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

#### **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 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

#### **FLAMINGO**

A Phase 2 study to evaluate GLPG2222 in patients with CF with the F508del mutation on both alleles

#### **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

#### **GLPG0634**

Molecule number currently known as filgotinib

#### **GLPG1205**

A GPR84 inhibitor fully proprietary to us. We plan to initiate a patient trial with GLPG1205 in IPF

#### **GLPG1690**

A novel drug targeting autotaxin, with potential application in IPF. Fully proprietary to Galapagos. Topline results from the Phase 2a FLORA trial were reported in August 2017

#### **GLPG1837**

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



#### **GLPG1972**

A novel mode-of-action product candidate that is part of the OA alliance with Servier. Galapagos reported positive results in a Phase 1b trial with GLPG1972 in OA patients in the United States in 2017

#### **GLPG2222**

A C1 (early) corrector drug candidate which showed favorable tolerability in Phase 1 and activity and favorable tolerability in the ALBATROSS Phase 2 trial in combination with Kalydeco in Class III mutation patients and in the FLAMINGO trial as monotherapy in Class II mutation patients

#### **GLPG2451**

A potentiator drug candidate which showed favorable tolerability in Phase 1, also in combination with C1 corrector GLPG2222

#### **GLPG2534**

A pre-clinical candidate with a novel mode of action. GLPG2534 is expected to enter Phase 1 trials in 2018

#### **GLPG2737**

A C2 (late) corrector drug candidate which showed favorable tolerability in a Phase 1 safety trial. GLPG2737 is currently being tested in the PELICAN trial in combination with Orkambi in Class II mutation CF patients

#### **GLPG2851**

A C1 (early) corrector drug candidate which entered Phase 1 trials in 2017

#### **GLPG3067**

A potentiator drug candidate which showed favorable tolerability in a Phase 1 trial in 2017, in combination with GLPG2222

#### **GLPG3121**

A pre-clinical candidate with undisclosed novel mode of action directed toward inflammation

#### **GLPG3221**

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

#### GI PG3312

A pre-clinical candidate with undisclosed mode of action directed toward inflammation

#### **GLPG3499**

A pre-clinical candidate with undisclosed mode of action in the IPF program

#### **GLPG3535**

A pre-clinical candidate with undisclosed mode of action directed toward pain in the alliance with Calchan

#### **GLPG3667**

A pre-clinical candidate with novel mode of action directed toward inflammation



#### **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

#### 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

#### 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

#### 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

#### Kalydeco

A potentiator drug (ivacaftor) marketed by Vertex Pharmaceuticals

#### 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

#### 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 which completed a Phase 1b trial in AtD patients. 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

#### **PELICAN**

Phase 2 trial of C2 corrector GLPG2737 in combination with Orkambi in Class II mutation CF patients

#### 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 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 in 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

#### **Product candidate**

Substance that has satisfied the requirements of early pre-clinical testing and has been selected for development, starting with formal pre-clinical 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**

Psoriatic arthritis 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

#### **SAPHIRA**

A Phase 2 trial of potentiator GLPG1837 in CF patients carrying a Class III mutation

#### 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

#### 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 measure spondylitis in the EQUATOR trial with filgotinib in psoriatic arthritis

#### Sweat chloride

The sweat test measures the concentration of chloride that is excreted in sweat. It is used to screen for CF. Due to defective chloride channels (CFTR), the concentration of chloride in sweat is elevated in individuals with CF



#### Symdeko

A corrector-potentiator combination for CF patients with the Class II mutation; marketed by Vertex Pharmaceuticals

#### **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)

#### **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 measure tendinitis in the EQUATOR trial with filgotinib in psoriatic arthritis

#### **Tezacaftor**

C1 corrector for CF therapy developed by Vertex Pharmaceuticals

#### **TORTUGA**

Phase 2 trial with filgotinib in patients with ankylosing spondylitis

#### 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

## 2 August 2018 (webcast 3 August)

Half Year 2018 Results

# 25 October 2018 (webcast 26 October)

Third quarter 2018 Results

# 21 February 2019 (webcast 22 February)

Full Year 2018 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

#### Photography & visuals

Aldo Allessi

Nicolas Triballeau

Visuals in this report are an artist impression, the purpose is not to represent reality.

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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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