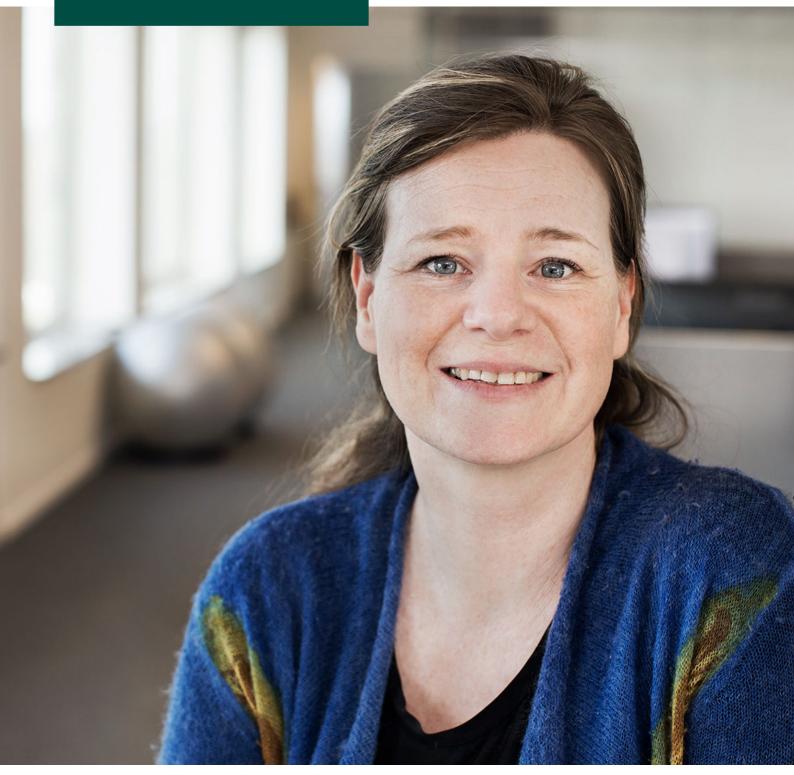


## **Galáp**agos

# Q3 Report 2017





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# The Galapagos group

An overview of Galapagos, its strategy and portfolio in the first nine months of 2017





## Letter from the management

Dear shareholders,

Galapagos is well on its way toward becoming an integrated biopharmaceutical company specialized in finding novel modes of action and developing therapies for patients with high medical need.

We reported a very eventful third quarter, showing that our platform delivers more than filgotinib. We announced outstanding results with our autotaxin inhibitor GLPG1690 in idiopathic pulmonary fibrosis patients, followed by antibody MOR106 (jointly owned with MorphoSys) targeting IL-17C in atopic dermatitis patients. We discovered the targets for these medicines the same way we found JAK1 for inflammation, using our unique target discovery engine. These additional proofs of platform come at a pivotal moment for us, as we prepare to start the commercial phase of the company. The promising Phase 2a results observed with GLPG1690 have fueled an ambition to build a proprietary, worldwide R&D and commercial franchise in fibrosis, next to inflammation.



We have built Galapagos step by step over the years, and we are now adding the last pieces to the puzzle: a Phase 3 study and a commercial organization. What a fantastic opportunity, being able to create the company we envision to be in 2020. To that end, we are actively recruiting more top development talent, growing and evolving the company to its next phase. Change has always been an inextricable part of Galapagos since our inception almost 19 years ago. We are pioneers in exploring biology, finding new modes of action and developing matching novel medicines. We are also pioneers in taking the company further while nourishing our innovative motor; our discovery platform will always be at the heart of Galapagos. So far we have shown the world what the combination of excellent science and strong business acumen can deliver.

Now we want to prove that an innovative core and being commercially successful can go together. It is in our DNA to evolve into a new company over and over again. We learn. We adapt. We step up - what a journey this is.

Our R&D engine continues to progress a large number of discovery and clinical candidate medicines. We anticipate updating the markets on the development of our cystic fibrosis triple combination therapies at the North American Cystic Fibrosis Conference in Indianapolis next month and expect to dose the first patient with the first triple by year end. We also plan to report the ALBATROSS Phase 2 study (GLPG2222 + Kalydeco<sup>1</sup> in Class II heterozygous patients) topline results before year-end. Our development teams are preparing the next stage studies with GLPG1690 in IPF and MOR106 in atopic dermatitis. We completed recruitment of a Phase 1b patient study with ADAMTS-5 inhibitor GLPG1972 in osteoarthritis and expect to report topline results in early 2018.

We reported a cash balance of  $\[ \in \]$ 1,220 million on 30 September 2017, retaining a solid financial position to invest in our promising R&D programs. With your continued support, we anticipate to keep reporting strong progress towards our goal of becoming a fully integrated biopharmaceutical company.

## Operational overview H1 2017

We refer to our H1 2017 report.

 $<sup>^1\,</sup>$  Kalydeco  $^{\rm o}$  is a registered drug of Vertex Pharmaceuticals.



## Operational overview Q3 2017

## Inflammation

- Our collaboration partner Gilead initiated studies to investigate proof-of-concept with filgotinib in uveitis and lupus membranous nephropathy
- Our collaboration partner Servier inlicensed the non-U.S. commercial rights to novel ADAMTS-5 inhibitor GLPG1972 for osteoarthritis. This triggered a €6 million license fee payment to Galapagos. Servier and Galapagos will make joint decisions about co-development of GLPG1972
- We completed recruitment of osteoarthritis patients for a Phase 1b study with GLPG1972 in the U.S.
- We reported promising signs of clinical activity with MOR106, a human monoclonal antibody targeting IL-17C, in a Phase 1b study in atopic dermatitis patients

## Idiopathic pulmonary fibrosis (IPF)

■ We announced that GLPG1690 halted disease progression and was reported to be well tolerated in the Phase 2a FLORA study in patients with moderate-to-severe IPF

## Cystic fibrosis (CF)

- We progressed as planned in discussions with U.K. regulatory authorities for the initiation of a first triple combination evaluation in CF patients in Q4 2017
- We completed recruitment for the FLAMINGO patient study with GLPG2222

## Corporate

■ We announced the appointment of Michele Manto as Senior VP Commercial Operations

## Q3 2017 financial result

## Revenues and other income

Our revenues and other income for the first nine months of 2017 amounted to  $\[ \in \]$  65.0 million in the first nine months of 2016. Revenues for the first nine months of 2017 ( $\[ \in \]$  87.9 million vs.  $\[ \in \]$  50.0 million for the first nine months of 2016) were higher due to increased revenue recognition of upfront payments, which were related to our filgotinib program with Gilead, and due to an increase in milestone payments. Other income for the first nine months of 2017 increased ( $\[ \in \]$  18.5 million vs.  $\[ \in \]$  15.0 million for the first nine months of 2016), mainly driven by higher income from R&D incentives.

#### Results

We realized a net loss of  $\in$ 85.9 million for the first nine months of 2017, compared to a net profit of  $\in$ 8.1 million in the first nine months of 2016. Last year's net profit was primarily driven by a  $\in$ 57.5 million non-cash 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  $\in$ 62.6 million for the first nine months of 2017, compared to an operating loss of  $\in$ 48.5 million for the first nine months of 2016.

Our R&D expenses for the first nine months of 2017 were  $\[ ext{e} 149.2 ext{ million}, compared to \[ ext{e} 96.7 ext{ million} for the first nine months of 2016. This planned increase was due mainly to an increase of \[ ext{e} 37.0 ext{ million} in subcontracting costs, mostly for our filgotinib and cystic fibrosis programs. Furthermore, personnel costs increased in 2017, 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  $\in$ 19.7 million for the first nine months of 2017, compared to  $\in$ 16.8 million for the first nine months 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 nine months of 2017 amounted to  $\[ \in \]$ 23.1 million, compared to net other financial expenses of  $\[ \in \]$ 0.9 million for the same period last year, and were primarily attributable to  $\[ \in \]$ 24.8 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, cash equivalents and restricted cash totaled €1,220.1 million at 30 September 2017.

A net increase of  $\[ \in \]$ 245.6 million in cash and cash equivalents was recorded during the first nine months of 2017, compared to an increase of  $\[ \in \]$ 590.5 million during the first nine months of 2016. Net cash flows used in operating activities amounted to  $\[ \in \]$ 86.2 million during the first nine months of 2017. Furthermore  $\[ \in \]$ 3.6 million was generated in investing activities primarily driven by the release of restricted cash to cash and cash equivalents for  $\[ \in \]$ 6.6 million. Financing activities generated  $\[ \in \]$ 353.0 million of cash, consisting of  $\[ \in \]$ 348.1 million proceeds from the U.S. public offering and  $\[ \in \]$ 4.9 million proceeds from warrant exercises. Finally  $\[ \in \]$ 24.8 million of unrealized negative exchange rate differences were reported on cash and cash equivalents.

On 30 September 2017, our balance sheet held a receivable from the French government ( $Crédit\ d'Impôt\ Recherche^2$ ) amounting to  $\ensuremath{\in} 42.0$  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  $\ensuremath{\in} 34.2$  million, to be received in yearly tranches from 2018 to 2027.

#### Outlook 2017

Looking to the remainder of the year, we aim to dose the first CF patient with our first triple combination investigational therapy in Q4, to disclose the ALBATROSS study topline results, and to launch new clinical studies with CF candidates and combinations. We aim to prepare the next late-stage study design with GLPG1690 in IPF patients and with MOR106 in Phase 2 in atopic dermatitis patients. We expect to end the year 2017 at the lower end of the guided range between €135-155 million operational use of cash.

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

#### Onno van de Stolpe

CEO

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



## At a glance

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

(in thousands of €, if not stated otherwise)	30/09/2017	30/09/2016
Results		
Revenues and other income	106,354	65,040
R&D expenditure	(149,226)	(96,739)
S, G&A expenses	(19,681)	(16,784)
Personnel expenses (including share-based compensation)	(53,922)	(38,785)
Capital expenditure	3,219	3,876
Depreciation and amortization of (in)tangible assets	(3,211)	(3,077)
Operating loss	(62,552)	(48,482)
Net financial result	(23,142)	56,621
Taxes	(161)	(71)
Net income / loss (-)	(85,855)	8,067
Galapagos share		
Number of shares issued on 30 September	50,895,778	46,169,828
Basic income / loss (–) per share (in €)	(1.75)	0.18
Diluted income / loss (–) per share (in €)	(1.75)	0.17
Share price on 30 September (in €)	86.19	57.13
Personnel data		
Total group employees on 30 September (number)	578	479

## Balance sheet

(thousands of €)	30/09/2017	31/12/2016
Total assets	1,331,373	1,083,338
Cash, cash equivalents and restricted cash	1,220,072	980,909
Total liabilities	294,440	324,637
Stockholders' equity	1,036,932	758,701



## Employees per site as of 30 September 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 most recent 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 inconsistencies 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 addressed to:

#### Galapagos NV

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Email: ir@glpg.com

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

We will use reasonable efforts to ensure the accuracy of the digital version, but do not assume responsibility 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 and our financial results, including timing of the release thereof, statements regarding interactions with regulators, statements regarding the expected timing, design and readouts of ongoing and planned preclinical and clinical studies and the potential activity of filgotinib in inflammatory indications, the further development, anticipated timing of clinical studies and potential activity of GLPG2222, GLPG2451, GLPG2737, GLPG3067, GLPG2851, GLPG3221, GLPG1837 and of potential triple combinations including any of these compounds for cystic fibrosis, the anticipated timing of clinical studies and the potential activity of GLPG1972 for osteoarthritis, the further development of GLPG1690 and GLPG3499 for idiopathic pulmonary fibrosis, MOR106 and GLPG2534 for atopic dermatitis, GLPG3121 and GLPG3312 in inflammation, GLPG3535, GLPG1205, and GLPG2384, and build-up and development of commercial operations. 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 study 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, 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 osteoarthritis, 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 (SEC) filings and reports, including in our most recent annual report on Form 20-F filed with the SEC and our subsequent filings and reports filed with the SEC. We also refer to the "Risk Factors" section of this report. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. We expressly disclaim any obligation to update any such forward-looking statements in this document to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements, unless specifically required by law or regulation.

# Financial statements

Consolidated interim financial statements for the first nine months of 2017





## Consolidated interim financial statements

# Consolidated statements of income and comprehensive income (unaudited)

## Consolidated income statement

	Nine months ended 30 September		
(thousands of €, except share and per share data)	2017	2016	
Revenues	87,870	50,009	
Other income	18,484	15,031	
Total revenues and other income	106,354	65,040	
Research and development expenditure	(149,226)	(96,739)	
General and administrative expenses	(17,783)	(15,511)	
Sales and marketing expenses	(1,898)	(1,272)	
Total operating expenses	(168,907)	(113,522)	
Operating loss	(62,552)	(48,482)	
Fair value re-measurement of share subscription agreement	-	57,479	
Other financial income	3,663	2,642	
Other financial expenses	(26,805)	(3,500)	
Profit / loss (–) before tax	(85,694)	8,138	
Income taxes	(161)	(71)	
Net income / loss (-)	(85,855)	8,067	
Net income / loss (-) attributable to:			
Owners of the parent	(85,855)	8,067	
Basic income / loss (-) per share	(1.75)	0.18	
Diluted income / loss (-) per share	(1.75)	0.17	
Weighted average number of shares – basic (in thousands of shares)	48,996	45,527	
Weighted average number of shares – diluted (in thousands of shares)	48,996	47,054	



## Consolidated statements of comprehensive income

Nino	months	andad	20	Santami	201
wine	months	enaea	30	Septemi	ber

(thousands of €)	2017	2016
Net income / loss (–)	(85,855)	8,067
Items that may be reclassified subsequently to profit or loss:		
Fair value adjustment of available-for-sale financial assets	(62)	(122)
Translation differences, arisen from translating foreign activities	(569)	(816)
Other comprehensive income, net of income tax	(631)	(938)
Total comprehensive income attributable to:		
Owners of the parent	(86,486)	7,129



# Consolidated statements of financial position (unaudited)

	30 September	31 December
(thousands of €)	2017	2016
Assets		
Intangible assets	747	1,023
Property, plant and equipment	15,279	14,961
Deferred tax assets	1,957	1,957
Non-current R&D incentives receivables	65,894	54,188
Non-current restricted cash	1,215	1,098
Other non-current assets	2,442	2,880
Non-currents assets	87,535	76,107
Inventories	304	300
Trade and other receivables	7,481	9,728
Current R&D incentives receivables	10,259	10,154
Cash and cash equivalents	1,218,856	973,241
Current restricted cash	-	6,570
Other current assets	6,939	7,239
Current assets	1,243,838	1,007,232
Total assets	1,331,373	1,083,338
Equity and liabilities		
Share capital	233,192	223,928
Share premium account	992,893	649,135
Other reserves	(1,062)	(1,000)
Translation differences	(1,659)	(1,090)
Accumulated losses	(186,432)	(112,272)
Total equity	1,036,932	758,701
Pension liabilities	3,734	3,520
Provisions	56	63
Finance lease liabilities	-	9
Other non-current liabilities	1,534	2,469
Non-current deferred income	134,586	214,785
Non-current liabilities	139,910	220,846



	30 September	31 December
(thousands of €)	2017	2016
Finance lease liabilities	23	54
Trade and other payables	48,437	31,269
Current tax payable	835	1,022
Accrued charges	1,391	619
Deferred income	103,845	70,827
Current liabilities	154,530	103,791
Total liabilities	294,440	324,637
Total equity and liabilities	1,331,373	1,083,338



## Consolidated cash flow statements (unaudited)

(thousands of €)	2017	2016
Cash and cash equivalents at beginning of year	973,241	340,314
Net income / loss (-)	(85,855)	9.067
Net Income / ioss (-)	(85,855)	8,067
Adjustments for:		
Tax expense	161	71
Other net financial expenses	23,142	858
Fair value re-measurement of share subscription agreement	-	(57,479)
Depreciation of property, plant and equipment	2,701	2,428
Amortization of intangible fixed assets	510	649
Net realized loss on foreign exchange transactions and net other financial expenses paid	(503)	(192)
Share-based compensation	11,697	7,201
Decrease in provisions	(8)	(5)
Increase in pension liabilities	214	183
Gain on sale of fixed assets	-	(14)
Operating cash flows before movements in working capital	(47,942)	(38,232)
Increase in inventories	(3)	(1)
Increase in receivables	(8,240)	(14,727)
Increase / decrease (–) in payables	16,464	(1,841)
Increase / decrease (–) in deferred income	(47,180)	258,878
Cash generated / used (-) in operations	(86,901)	204,077
Interest paid	(42)	(37)
Interest received	903	726
Income taxes paid	(191)	(477)
Net cash flows generated / used (-) in operating activities	(86,231)	204,289
Purchase of property, plant and equipment	(2,986)	(3,627)
Purchase of and expenditure in intangible fixed assets	(233)	(250)
Proceeds from disposal of property, plant and equipment	-	23
Increase (–) / decrease in restricted cash	6,453	(54)
Acquisition of (-) / proceeds from sale of available-for-sale financial assets	372	(2,750)
Net cash flows generated / used (-) in investing activities	3,605	(6,657)
.,	-,	(-,)



## Nine months ended 30 September

(thousands of €)	2017	2016
Repayment of obligations under finance leases and other debts	(50)	(41)
Proceeds from capital and share premium increases, net of issue costs	348,133	391,785
Proceeds from capital and share premium increases from exercise of warrants	4,935	3,489
Net cash flows generated in financing activities	353,018	395,233
Effect of exchange rate differences on cash and cash equivalents	(24,777)	(2,371)
Increase in cash and cash equivalents	245,615	590,493
Cash and cash equivalents at end of the period	1,218,856	930,807



# 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 income					8,067	8,067
Other comprehensive income			(816)	(122)		(938)
Total comprehensive income			(816)	(122)	8,067	7,129
Share-based compensation					7,201	7,201
Issue of new shares	36,575	289,696				326,271
Share issue costs	(269)					(269)
Exercise of warrants	1,756	1,732				3,489
On 30 September 2016	223,462	648,830	(1,283)	(140)	(162,048)	708,822
On 1 January 2017	223,928	649,135	(1,090)	(1,000)	(112,272)	758,701
Net loss					(85,855)	(85,855)
Other comprehensive income			(569)	(62)		(631)
Total comprehensive income			(569)	(62)	(85,855)	(86,486)
Share-based compensation					11,697	11,697
Issue of new shares	23,331	340,593				363,924
Share issue costs	(15,837)					(15,837)
Exercise of warrants	1,770	3,165				4,935
On 30 September 2017	233,192	992,893	(1,659)	(1,062)	(186,432)	1,036,932



## **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' 2016 annual report.

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 nine months ended 30 September 2017 and 2016.

	Nine months end	Nine months ended 30 September		
(thousands of €)	2017	2016		
Recognition of non-refundable upfront payments and license fees	53,526	17,562		
Milestone payments	25,918	17,567		
Reimbursement income	2,319	9,238		
Other revenues	6,108	5,641		
Total revenues	87,870	50,009		

Revenues for the nine months ended 30 September 2017 ( $\epsilon$ 87.9 million vs.  $\epsilon$ 50.0 million for the nine months ended 30 September 2016) were higher due to increased revenue recognition of the upfront payment from Gilead related to the filgotinib program, which is recognized in function of the costs incurred, and due to an increase in milestone payments.

The following table summarizes the revenue recognition of upfront payments and license fees for the nine months ended 30 September 2017 and 2016.



Agreement	Upfront received	Upfront and license fees received	Recognition as from	Revenue recognized, nine months ended 30 September 2017	Revenue recognized, nine months ended 30 September 2016	Outstanding balance in deferred income as at 30 September 2017
	(thousands of \$)	(thousands of €)		(thousands of €)		
Gilead collaboration agreement for filgotinib	300,000	275,558	January 2016	46,632	14,500	203,305
Gilead collaboration agreement for filgotinib	N.A.	39,003 <sup>(*)</sup>	January 2016	6,600	2,052	28,776
ThromboGenics license agreement for integrin antagonists	N.A.	1,000	April 2016		1,000	
Sirion Biotech license agreement for RNA interference (RNAi) technologies	N.A.	10	June 2016		10	
Servier collaboration agreement for osteoarthritis	N.A.	6,000	August 2017	293		5,707
Total recognition of non-refundable upfront payments and license fees			53,526	17,562	237,788	

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

For the first nine months of 2017,  $\[ \in \]$  53.2 million of deferred income related to the Gilead collaboration agreement was recognized as revenue in function of costs incurred, applying the percentage of completion method. This revenue recognition consisted of  $\[ \in \]$  46.6 million related to the upfront license fee and  $\[ \in \]$  6.6 million related to the deferred income triggered by the accounting treatment of the share subscription agreement with Gilead under IAS 39. The outstanding balance of deferred income from the Gilead collaboration agreement at 30 September 2017 amounted to  $\[ \in \]$  232.1 million, of which  $\[ \in \]$  313.6 million reported as non-current deferred income.

Under the collaboration agreement with Servier for osteoarthritis, we received a license fee payment of €6.0 million end of July 2017. The license fee revenue is recognized over the estimated period of our involvement. As such, an amount of €0.3 million was recognized as license revenue for the nine months ended 30 September 2017.

## Other income

The following table summarizes our other income for the nine months ended 30 September 2017 and 2016.

	Nine months en	ded 30 September
(thousands of €)	2017	2016
Grant income	690	1,451
Other income	17,794	13,581
Total other income	18,484	15,031

Other income increased in the first nine months of 2017 ( $\in$ 18.5 million vs.  $\in$ 15.0 million in the first nine months of 2016), mainly driven by higher income from R&D incentives.



## Results

We realized a net loss of  $\epsilon$ 85.9 million for the first nine months of 2017, compared to a net profit of  $\epsilon$ 8.1 million for the first nine months of 2016. Last year's net profit was primarily driven by  $\epsilon$ 57.5 million non-cash 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  $\in$ 62.6 million for the first nine months of 2017, compared to an operating loss of  $\in$ 48.5 million for the first nine months of 2016.

Our R&D expenses for the first nine months of 2017 were  $\[ \]$ 149.2 million, compared to  $\[ \]$ 96.7 million for the first nine months of 2016. This planned increase was due mainly to an increase of  $\[ \]$ 37.0 million in subcontracting costs, mostly for our filgotinib and cystic fibrosis programs. Furthermore, personnel costs increased in 2017, 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 €19.7 million for the first nine months of 2017, compared to €16.8 million for the first nine months 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 for the first nine months of 2017 amounted to  $\[mathcal{e}\]$ 23.1 million, compared to net other financial expenses of  $\[mathcal{e}\]$ 0.9 million for the first nine months of 2016, and were primarily attributable to  $\[mathcal{e}\]$ 24.8 million of unrealized exchange loss on our cash position in U.S. dollars as a consequence of the fluctuation of the EUR / U.S. dollar exchange rate in the first nine months of 2017. 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.

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

## Segment information

Segment information for the nine months ended 30 September 2017

(thousands of €)	R&D	Fee-for-services	Inter-segment elimination	Group
External revenue	81,830	6,040		87,870
Internal revenue		4,024	(4,024)	
Other income	18,469	14		18,484
Revenues & other income	100,299	10,078	(4,024)	106,354
Segment result	(50,774)	(81)		(50,855)
Unallocated expenses <sup>(1)</sup>	. , ,	. , ,		(11,697)
Operating loss				(62,552)
Financial (expenses) / income				(23,142)
Result before tax				(85,694)
Income taxes				(161)
Net loss				(85,855)

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



#### Segment information for the nine months ended 30 September 2016

(thousands of €)	R&D	Fee-for-services	Inter-segment elimination	Group
External revenue	44,525	5,484		50,009
Internal revenue		3,901	(3,901)	
Other income	14,898	133		15,031
Revenues & other income	59,423	9,518	(3,901)	65,040
Segment result	(40,546)	(736)		(41,281)
Unallocated expenses <sup>(1)</sup>				(7,201)
Operating loss				(48,482)
Financial (expenses) / income				56,621
Result before tax				8,138
Income taxes				(71)
Net income				8,067

<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 €1,220.1 million at 30 September 2017.

A net increase of  $\[ \in \]$ 245.6 million in cash and cash equivalents was recorded during the first nine months of 2017, compared to an increase of  $\[ \in \]$ 590.5 million during the first nine months of 2016. Net cash used in operating activities amounted to  $\[ \in \]$ 86.2 million in the first nine months of 2017. Furthermore,  $\[ \in \]$ 3.6 million was generated in investing activities primarily driven by the release of restricted cash to cash and cash equivalents for  $\[ \in \]$ 6.6 million.

Financing activities generated €353.0 million of cash, consisting of €348.1 million proceeds from the U.S. public offering and €4.9 million proceeds from warrant exercises. Finally €24.8 million of negative unrealized exchange rate differences were reported on cash and cash equivalents.

Restricted cash amounted to  $\[ \in \]$ 7.7 million at 31 December 2016, and decreased by  $\[ \in \]$ 6.5 million to  $\[ \in \]$ 1.2 million at 30 September 2017. This decrease is primarily 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 to Charles River Laboratories International, Inc. in 2014, as a final agreement between the parties was reached.

On 30 September 2017, restricted cash was comprised of  $\in$ 0.5 million and  $\in$ 0.7 million bank guarantees on real estate lease obligations in Belgium and in the Netherlands, respectively.

Cash and cash equivalents amounted to €1,218.9 million at 30 September 2017 and were comprised of 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 €792.6 million of term deposits with an original maturity longer than three months but which are available upon one month's notice. Cash at banks was 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 €149.8 million, aim at meeting short-term cash commitments, while reducing the counterparty risk of investment.



	30 September	31 December
(thousands of €)	2017	2016
Cash at banks	276,502	357,630
Term deposits	792,551	515,632
Money market funds	149,801	99,977
Cash on hand	2	2
Total cash and cash equivalents	1,218,856	973,241

On 30 September 2017, our cash and cash equivalents included \$255.6 million held in U.S. dollars, 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. 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.

Furthermore, our balance sheet held R&D incentives receivables from the French government ( $Crédit d'Impôt Recherche^3$ ) amounting to €42.0 million as of 30 September 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 €34.2 million as of 30 September 2017, to be received in yearly tranches from 2018 until 2027.

## Capital increase

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  $\le$ 4.0 million and the issuance of 247,070 new shares. The closing price of the Galapagos share on that date was  $\le$ 84.60.

On 21 April 2017 our U.S. public offering of 4,312,500 American Depositary Shares ("ADSs") was fully underwritten, at a price of \$90.00 per ADS, before underwriting discounts, for gross proceeds of  $\epsilon$ 363.9 million. Underwriting discounts and offering expenses amounted to  $\epsilon$ 15.8 million. As such, net proceeds amounted to  $\epsilon$ 348.1 million.

On 20 June 2017, 52,030 warrants were exercised at various exercise prices (with an average exercise price of  $\le$ 12.14 per warrant) resulting in a share capital increase (including issuance premium) of  $\le$ 0.6 million and the issuance of 52,030 new shares. The closing price of the Galapagos share on that date was  $\le$ 70.66.

On 21 September 2017, 28,100 warrants were exercised at various exercise prices (with an average exercise price of  $\[ \in \]$ 9.55 per warrant) resulting in a share capital increase (including issuance premium) of  $\[ \in \]$ 0.3 million and the issuance of 28,100 new shares. The closing price of the Galapagos share on that date was  $\[ \in \]$ 84.62.

On 30 September 2017, Galapagos NV's share capital was represented by 50,895,778 shares. All shares were issued, fully paid up and of the same class.

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



(thousands of €, except share data)	Number of shares	Share capital	Share premium	Share capital and share premium
On 1 January 2017	46,256,078	223,928	649,135	873,063
6 April 2017: exercise of warrants	247,070	1,337	2,697	4,034
21 April 2017: U.S. public offering				
ADSs (fully paid)	4,312,500	23,331	340,593	363,924
Underwriter discounts and offering expenses (paid)		(15,790)		(15,790)
Offering expenses still to be paid at 30 September 2017		(47)		(47)
Total U.S. public offering	4,312,500	7,494	340,593	348,087
20 June 2017 : exercise of warrants	52,030	281	350	632
21 September 2017: exercise of warrants	28,100	152	117	269
On 30 September 2017	50,895,778	233,192	992,893	1,226,085

## **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 30 September 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	27,523	4,183	8,030	6,159	9,152
Purchase commitments	36,722	32,649	2,576	1,497	_
Total contractual obligations & commitments	64,245	36,832	10,606	7,655	9,152

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. (CRL) for a total consideration of up to €134 million. CRL agreed to pay us an immediate cash consideration of €129 million. The potential earn-out of €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 were introduced by CRL, which all have been settled for a total amount of €1.3 million. In the first quarter of 2017, the remaining balance of the escrow account of €6.6 million was released in full, as final agreement between the parties was reached.

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

In the course of 2008, a former director of one of our 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 2<sup>nd</sup> degree court instructed the 1<sup>st</sup> degree court to conduct a new trial, which is currently pending. A first hearing, initially scheduled on 12 July 2017, was postponed to an undefined date. We recently filed a motion petitioning for expedient procedure in consideration of the value of the claim, overall duration of the dispute and duration of the re-trial. 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.

The assessment of the impact of IFRS 15 Revenue from Contracts with Customers (applicable for annual periods beginning on or after 1 January 2018) is still ongoing as the company assesses all contracts, performance obligations and allocation of revenues. We plan to adopt IFRS 15 on its effective date.

We are currently evaluating the guidance to determine the impact of IFRS 16 Leases (applicable for annual periods beginning on or after 1 January 2019). We plan to adopt IFRS 16 on its effective date.

## 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

There were no adjusting events nor material non-adjusting events to be reported.

## Approval of interim financial statements

The interim financial statements were approved by the board of directors on 23 October 2017.



# Report on the review of the consolidated interim financial information for the nine-month period ended 30 September 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 30 September 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 nine 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 1 331 373 (000) EUR and the consolidated condensed income statement shows a consolidated loss for the period then ended of 85 855 (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, 24 October 2017

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

## 100 points clinical response

Percentage of patients achieving a 100 point decrease in CDAI score during a clinical study 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

#### **ADAMTS-5**

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

#### **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

#### **ALBATROSS**

A Phase 2 study to evaluate GLPG2222 in ivacaftor-treated cystic fibrosis patients with the Class II mutation on one allele

#### **Anemia**

Condition in which there are 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

## 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 lysophosphatidic 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 pre-clinical 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

## Cutaneous lupus erythematosus (CLE)

Lupus is an autoimmune disease affecting multiple organs and systems in the body, resulting in a wide variety of signs and symptoms. CLE is a form of lupus in the skin which can be triggered or exacerbated by exposure to sunlight



## 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 studies which recruited approximately 900 patients globally. DARWIN 3 is a long term extension study 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 in 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 study 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 study, 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 was evaluated in RA and Crohn's disease patients in Phase 2 studies. Filgotinib is partnered with Gilead. Galapagos and Gilead are running Phase 3 studies with filgotinib in RA, CD and UC. Gilead initiated Phase 2 studies with filgotinib in small bowel Crohn's disease, fistulizing Crohn's disease, Sjögren's syndrome, cutaneous lupus erythematosus, uveitis, and lupus membranous nephropathy; Galapagos initiated Phase 2 studies with filgotinib in ankylosing spondylitis and psoriatic arthritis. We expect to initiate more Phase 2 studies with filgotinib in new indications. 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 study 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 cystic fibrosis with the Class II mutation on both alleles

## **FLORA**

A double-blind, placebo-controlled exploratory Phase 2a study with GLPG1690 in 24 IPF patients; we announced that GLPG1690 halted lung function decline and was reported to be generally well tolerated in this study

#### **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

### **GLPG1205**

A GPR84 inhibitor fully proprietary to us. We plan to initiate a patient study with GLPG1205 in an undisclosed indication

## **GLPG1690**

A novel product candidate targeting autotaxin, with potential application in idiopathic pulmonary fibrosis. Fully proprietary to us. We announced that GLPG1690 halted lung function decline and was reported to be well tolerated in the Phase 2a FLORA study in patients with moderate to severe IPF. GLPG1690 is an investigational drug and its efficacy and safety have not been established

#### **GLPG1837**

A potentiator product candidate which was evaluated in the SAPHIRA 1 and 2 studies 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, who inlicensed the non-U.S. rights to GLPG1972 in July 2017. Servier and Galapagos will make joint decisions on further co-development of GLPG1972. GLPG1972 was reported to be well- tolerated and showed no emerging safety signals in a Phase 1 study with healthy volunteers. In addition, GLPG1972 showed up to a 60% reduction in a relevant OA biomarker within 14 days in these volunteers. We completed recruitment for a Phase 1b study with GLPG1972 in OA patients in the U.S.



#### **GLPG2222**

A C1 (early) corrector product candidate which was evaluated in Phase 1 and is currently being tested in the ALBATROSS Phase 2 study in combination with Kalydeco in Class III mutation patients and in the FLAMINGO Phase 2 study in Class II mutation patients. In June 2017 we announced that the study of GLPG2222 in combination with GLPG2451 in healthy volunteers was successfully completed. GLPG2222 is expected to be combined with a potentiator and C2 (late) corrector in future triple combination investigational therapies

## **GLPG2384**

A pre-clinical candidate molecule targeting GPR84. The indication for GLPG2384 remains undisclosed

## **GLPG2451**

A potentiator product candidate. In June 2017 we announced that the study of GLPG2222 in combination with GLPG2451 in healthy volunteers was successfully completed. GLPG2451 is expected to be combined with a C1 (early) corrector and C2 (late) corrector in future triple combination investigational therapies

#### **GLPG2534**

A pre-clinical candidate with novel mode of action with potential application in AtD

## **GLPG2737**

A C2 (late) corrector product candidate. In June 2017 we announced the successful completion of Phase 1 studies with GLPG2737. GLPG2737 is expected to be combined with a potentiator and a C1 (early) corrector in future triple combination investigational therapies

## **GLPG2851**

A C1 (early) corrector product candidate currently at the pre-clinical stage

## **GLPG3067**

A potentiator drug candidate in Phase 1. GLPG3067 is expected to be combined with C1 and C2 corrector in future triple combination investigational therapies

## **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

#### **GLPG3312**

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



#### **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

## 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

U.S. 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

## IAK

Janus kinases (JAKs) 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 in CF 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, or LPA, is a signaling molecule involved in fibrosis

## Lupus membranous nephropathy

Membranous nephropathy is a subtype of kidney disease that occurs in 10-20% of Systemic Lupus Erythematosus patients with nephritis and that manifests itself as excess protein in the urine. Patients with LMN are at risk of developing end-stage renal disease due to longstanding protein leak via kidneys into the urine

## 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 which showed promising signs of activity and was reported to be well tolerated in AtD patients in a Phase 1b study. 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 in CF 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 evaluate efficacy, tolerability and the dose to use

## Phase 3

Large clinical studies, 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

## **Preclinical**

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

## Preclinical candidate (PCC)

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

## **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 percent of psoriasis 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 collaboration 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 study of potentiator GLPG1837 in cystic fibrosis patients carrying a Class III mutation. Results were reported in 2016, showing activity and presenting safety data 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

## 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)

## 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

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

## Systemic lupus erythematosus (SLE)

SLE is an autoimmune disease. In autoimmune diseases, the immune system turns against parts of the body it is designed to protect. This leads to inflammation and damage to various body tissues. Lupus can affect many parts of the body, including the joints, skin, kidneys, heart, lungs, blood vessels, and brain. Although people with lupus may have many different symptoms, some of the most common ones include extreme fatigue, painful or swollen joints (arthritis), unexplained fever, skin rashes, and kidney problems



## **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)

## **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

## **22 February 2018**

Full year 2017 results

## 24 April 2018

Annual Shareholders' Meeting in Mechelen

#### 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

Frank van Delft

On our cover:

Annegret van der Aa, Head of Development

Copy deadline: 26 October 2017

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>

## **Contact**





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