

# Galapagos NV





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# The Galapagos Group

An overview of Galapagos and our performance in Q3 2015





## Letter from management

#### Dear Shareholders,

Galapagos reached another milestone in its development as a leading biotechnology company this quarter: after confirming the best-in-class potential of filgotinib at 24 weeks in the Phase 2B DARWIN 1 and DARWIN 2 studies in rheumatoid arthritis, we regained full rights to filgotinib, thereby accelerating our transformation into a Phase 3 company and opening up discussions with multiple potential partners. Meanwhile, our development team is working diligently to prepare for Phase 3 studies in rheumatoid arthritis, in time for our planned start in the first half of 2016. We look forward to bringing filgotinib into Phase 3, preferably together with a strong pharma partner to ensure fastest route to market introduction. We also await the topline 10 week results from the FITZROY Phase 2 study with filgotinib in Crohn's disease, which are expected before year end.

In October, Galapagos reported promising data from our cystic fibrosis programs at the NACFC in Phoenix. Innovative assays and models arising from the CF collaboration with AbbVie helped us to characterize and categorize interactions between the compounds in our portfolio. External laboratories confirmed the contribution of our potentiators to CFTR rescue and demonstrated how our potentiators restored CFTR in the nonsense (Class I) mutation *in vitro*. Furthermore, we reported that our novel potentiator GLPG1837 was well tolerated and demonstrated favorable drug-like properties in a Phase 1 study.

Galapagos has progressed in implementing a multiple-program strategy to manage development risk in cystic fibrosis. Importantly, GLPG2665 was selected as a first of an anticipated multiple second corrector portfolio, to complete a potential triple combination therapy for Class II mutation patients. The Company now has lead compounds in place for all components of a potential triple combination therapy for Class II mutation patients, with a backup potentiator as well. Backup C1 and C2 correctors are expected to be selected before year end. Combinations of our lead compounds *in vitro* resulted in a range of efficacies up to a six-fold greater restoration of CFTR activity in homozygous F508del cells,

compared to Orkambi $^{\circ}$ , the current standard of care for this class of patients. We look forward to bringing GLPG2665 into Phase 1 studies by mid 2016.

We continue to move our other programs forward. Galapagos completed recruitment for GLPG1205 early and expects to report topline results from a Phase 2A study in ulcerative colitis patients by early 2016. Preparations are underway to file an exploratory Phase 2 study of GLPG1690 in idiopathic pulmonary fibrosis before year end. Both '1205 and '1690 target new modes of action and are fully proprietary to Galapagos.

#### **Operational overview Q3 2015**

#### ■ Rheumatoid arthritis

- Galapagos reported promising efficacy and a potentially differentiated safety profile in its topline week 24 results for DARWIN 1 (594 rheumatoid arthritis patients, methotrexate add-on) and DARWIN 2 (283 RA patients, monotherapy) with filgotinib in July and August 2015
- AbbVie terminated the agreement for filgotinib, returning full global rights to filgotinib to Galapagos

#### ■ Inflammatory bowel disease

- In August, Galapagos completed patient recruitment for the FITZROY Phase 2 study with filgotinib in Crohn's disease. Management expects to report primary endpoint topline results from the first 10 weeks of treatment in FITZROY before end 2015
- Galapagos completed patient recruitment for ORIGIN, a Phase 2 Proof-of-Concept study with GLPG1205, a selective inhibitor of GPR84, in 60 ulcerative colitis patients. We expect to announce topline results from ORIGIN in Q1 2016

#### ■ Cystic fibrosis

- AbbVie and Galapagos presented novel assays and a new model used by both companies to screen for novel corrector-potentiator combinations at NACFC 2015
- Galapagos reported pharmacokinetic, safety and tolerability in Phase 1 with potentiator GLPG1837 at NACFC 2015
- GLPG2665 was nominated in October as the first C2 corrector to complete the discovery phase of the potential triple combination therapy



#### THE GALAPAGOS GROUP

- Nomination of second corrector candidate GLPG2665 in early October completed discovery phase of potential triple combination therapy in cystic fibrosis
- Further clinical trial initiations are expected in the CF program before end 2015

#### ■ IPF

■ At ERS in September, Galapagos presented preclinical data and promising safety and tolerability, and favorable drug-like properties from a Phase 1 First-In-Human study with GLPG1690, a selective autotaxin inhibitor fully owned by Galapagos. Filing of an exploratory Phase 2 study protocol for evaluation in patients with idiopathic pulmonary fibrosis is still expected before year end

#### ■ Other/corporate

- Galapagos licensed Organoid Technology from the HUB foundation for use in IBD and cystic fibrosis
- Galapagos raised a further €1.2 million from warrant exercises during the third quarter

#### Q3 2015 financial result

#### **Revenues**

Group revenues and other income for the first nine months of 2015 amounted to €47.2 million compared to €62.7 million in the same period of 2014. Revenues (€32.4 million vs €49.1 million last year) were lower due to a decrease in revenue recognition of upfront payments and reduced milestone payments, reflecting the increasingly proprietary nature of our pipeline programs. Other income (€14.8 million vs €13.6 million last year) increased in the first nine months of 2015, driven mainly by R&D incentives in Belgium and France.

#### **Results**

The Group realized a net loss for the first nine months of 2015 of  $\epsilon$ 61.4 million, compared to a net loss of  $\epsilon$ 27.0 million in the first nine months of 2014 for continuing operations.

Following the sale of the service division, the Group reported a net profit from discontinued operations of  $\epsilon$ 70.5 million in the first nine months of 2014. Galapagos recorded a result on divestment of  $\epsilon$ 67.5 million.

R&D expenses for the Group in the first nine months of 2015 were €96.9 million compared to €77.2 million in 2014. This planned increase is mainly due to increased efforts on the filgotinib and cystic fibrosis programs.

G&A and S&M expenses of the Group were €13.6 million in the first nine months of 2015, compared to €10.8 million in the first nine months of 2014. This increase is primarily due to a higher provision for short term and long term management bonus as well as higher costs for warrant plans, amongst other as a result of the recent evolution of Galapagos share price change relative to the Next Biotech Index.

Finally, for one subsidiary, a deferred tax asset was set up for an amount of  $\[mathebox{\ensuremath{\mathfrak{e}}1.8}$  million on 30 September 2015, of which  $\[mathebox{\ensuremath{\mathfrak{e}}1.5}$  million was additionally recognized in the first nine months of 2015.

#### Liquid assets position

Cash, cash equivalents and restricted cash totalled €374.4 million on 30 September 2015.

A net increase of €178.8 million in cash and cash equivalents was recorded during the first nine months of 2015, compared to an increase of €67.7 million during the same period last year. Net cash flows from financing activities generated €259.9 million through a recent global offering and concurrent listing on NASDAQ, as well as €11.4 million from warrant exercises. Furthermore, Galapagos continued to intensify its R&D investments, with a net cash outflow from operating activities of €90.3 million in the first nine months of 2015.

Restricted cash amounted to  $\in$ 10.7 million at the end of September 2014, and decreased to  $\in$ 7.9 million at the end of September 2015. This decrease is mainly related to the release of the  $\in$ 3 million bank guarantee issued in 2013 for the rental of the new premises in France which expired on 30 June 2015 following the move to the new offices.

Furthermore, Galapagos' balance sheet holds an unconditional and unrestricted receivable from the French government (Crédit d'Impôt Recherche) [1] now amounting to €37.5 million, payable in 4.75 yearly tranches. Galapagos' balance sheet also holds a receivable from the Belgian Government for R&D incentives now amounting to €23.7 million, payable as from 2016 in 5.75 yearly tranches.

[1] Crédit d'Impôt Recherche refers to an innovation incentive system underwritten by the French government.



#### Outlook 2015

The fourth quarter of 2015 promises to be an exciting one, with topline results expected from filgotinib's Phase 2 study in Crohn's disease, an update planned on the progress of our negotiations with potential new partners for filgotinib, and multiple anticipated clinical study initiations.

Based on the forecast for the remainder of the year, management retains 2015 guidance for operational cash burn:  $\in$ 110 -  $\in$ 130 million.

We thank you again for your support of Galapagos. With filgotinib's compelling results in the DARWIN program, we have proven our approach delivered a potential best-in-class new therapy for RA patients. With your continued support, we will bring our other programs into patients to investigate their potential as well.

Onno van de Stolpe Raj Parekh

CEO Chairman of the Board of

Directors



# At a glance

#### Key figures (IFRS) Galapagos Group

(thousands of €, if not stated otherwise)	30/09/2015	30/09/2014
Results <sup>1</sup>		
Revenues and other income	47,219	62,675
R&D expenditure	(96,873)	(77,200)
S, G&A expenses	(13,600)	(10,812)
Restructuring and integration costs	-	(594)
Personnel expenses (including share-based compensation)	(34,053)	(29,241)
Capital expenditure	4,543	4,233
Depreciation and amortization of (in)tangible assets	2,518	2,823
EBIT	(63,254)	(25,931)
EBITDA	(65,773)	(28,754)
Net loss from continuing operations	(61,406)	(27,005)
Net income from discontinued operations	-	70,514
Net income / loss (-)	(61,406)	43,509
Galapagos share		
Number of shares issued on 30 September	39,012,842	30,292,604
Basic and diluted loss per share from continuing operations (in €)	(1.78)	(0.89)
Dividend (in €)	-	-
Share price on 30 September (in €)	36.54	11.98
Personnel data		
Total Group employees on 30 September (Number)	427	417

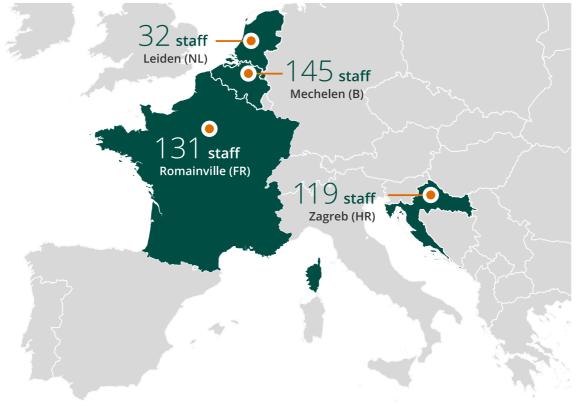
<sup>&</sup>lt;sup>1</sup> Service activities (sold to Charles River on 1 April 2014) for the nine months ended 30 September 2014 are shown on the line item "Net income from discontinued operations". All other line items consist of amounts from continuing operations, except for line item "Net income / loss (-)", which includes both continuing and discontinued operations.

#### Balance sheet

(thousands of €, if not stated otherwise)	30/09/2015	31/12/2014
Total assets	461,049	270,467
Cash, cash equivalents and restricted cash	374,447	198,440
Total liabilities	42,258	64,332
Stockholders' equity	418,791	206,135
Equity ratio (in %)	91%	76%



### Employees per site as of 30 September 2015





### **Risk factors**

Management refers to its description of risk factors in the 2014 Annual Report, pp. 26-32, as updated and supplemented by its description of risk factors in the prospectus filed with the U.S. Securities and Exchange Commission on 14 May 2015 (and included in the listing prospectus approved by the FSMA on 18 May 2015), pp. 11-51. In summary, the principal risks and uncertainties faced by the Group relate to: Galapagos' financial position and need for additional capital; product development, regulatory approval and commercialization; Galapagos' reliance on third parties; Galapagos' competitive position; Galapagos' intellectual property; Galapagos' organization, structure and operation (including but not

limited to certain risks related to its status as a U.S. publicly listed company following the public offering of its shares (in the form of ADSs) and listing on NASDAQ in May 2015) and market risks relating to the Galapagos shares and ADSs.

Management also refers to the description of the Group's financial risk management given in the 2014 Annual Report, pp. 108-110, which remains valid.

In addition, because Galapagos' reporting currency is the euro, the operations and financial position of entities operating in other currencies needs to be translated into euros in the consolidation process. As there is an ongoing fluctuation between these foreign currencies and the euro, a negative impact might occur on the consolidated financial results.

# The Galapagos share

#### Performance of the Galapagos share on Euronext





# Disclaimer and other information

Galapagos NV is a limited liability company organized under the laws of Belgium and has its registered office at Generaal De Wittelaan L11 A3, 2800 Mechelen, Belgium. Throughout this report, the term "Galapagos NV" refers solely to the nonconsolidated Belgian company and references to "the Group" or "Galapagos" include Galapagos NV and its subsidiaries.

Galapagos publishes its Q3 Report 2015 in Dutch and in English. In case of differences in interpretation, the Dutch version will take precedence. Galapagos is responsible for the translation and conformity between the Dutch and English versions.

This document is available to the public free of charge and upon request:

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

Email: ir@glpg.com

A digital version of the Q3 Report 2015 is available on the website of Galapagos, www.glpg.com

Galapagos will use reasonable efforts to ensure the accuracy of the digital version, but does not assume responsibility if inaccuracies or inconsistencies with the printed document arise as a result of any electronic transmission. Therefore, Galapagos considers only the printed version of the Q3 Report 2015 to be legally valid. Other information on the website of Galapagos or on other websites does not form a part of this Q3 Report 2015.

#### Listings

Euronext Amsterdam and Brussels: GLPG NASDAQ: GLPG

#### Financial calendar 2015

Full year results 2015 4 March 2016 Annual Shareholders' 26 April 2016

Meeting

#### **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 Berkenlaan 8b 1831 Diegem, Belgium

#### **Forward-looking statements**

This Q3 Report 2015 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 "believes," "anticipates," "expects," "intends," "plans," "seeks," "estimates," "may," "will," "could," "stands to," "continues," "we believe," "we intend," as well as similar expressions. Forward-looking statements contained in this report include, but are not limited to, the first four paragraphs of the Letter from Management, the information provided in the section captioned "Outlook 2015", statements regarding a potential new partnership for the further development of filgotinib, statements regarding the development of a potential triple combination therapy for Class II cystic fibrosis patients, and statements regarding the expected timing, design and readouts of ongoing and planned clinical trials (i) with filgotinib in rheumatoid arthritis (Phase 3) and Crohn's disease (Phase 2), (ii) with the compounds in the cystic fibrosis program, (iii) with GLPG1205 in ulcerative colitis (Phase 2) and (iv) with GLPG1690 in IPF (Phase 2). Galapagos cautions 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 the actual results, financial condition and liquidity, performance or achievements of Galapagos, or the development of the industry in which it operates, to be



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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 Galapagos' results of operations, financial condition and liquidity, and the development of the industry in which it operates 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 Galapagos' expectations regarding its 2015 revenues and financial results and its 2015 operating expenses may be incorrect (including because one or more of its assumptions underlying its 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 the company's development programs may not support registration or further development of its compounds due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties (including its collaboration partner for cystic fibrosis, AbbVie), and estimating the commercial potential of our product candidates. A further list and description of these risks, uncertainties and other risks can be found in Galapagos' Securities and Exchange Commission filing and reports, including in the prospectus filed with the SEC on May 14, 2015 and future filings and reports by Galapagos. Galapagos also refers 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. Galapagos expressly disclaims any obligation to update any such forward-looking statements in this document to reflect any change in its 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 forwardlooking statements, unless specifically required by law or regulation.



# Financial statements

Consolidated interim financial statements for the third quarter 2015





# Consolidated statements of income and comprehensive income

#### (unaudited)

Consolidated income statement

	Nine months ended 30 September,		
(thousands of €, except share and per share data)	2015	2014	
Revenues	32,371	49,122	
Other income	14,848	13,553	
Total revenues and other income	47,219	62,675	
Research and development expenditure	(96,873)	(77,200)	
General and administrative expenses	(12,882)	(9,975)	
Sales and marketing expenses	(718)	(838)	
Restructuring and integration costs	-	(594)	
Total operating costs	(110,473)	(88,606)	
Operating loss	(63,254)	(25,931)	
Finance income	1,636	1,834	
Finance expense	(1,198)	(1,092)	
Loss before tax	(62,816)	(25,189)	
Income taxes	1,411	(1,816)	
Net loss from continuing operations	(61,406)	(27,005)	
Net income from discontinued operations	-	70,514	
Net income / loss (-)	(61,406)	43,509	
Net income / loss (-) attributable to:			
Owners of the parent	(61,406)	43,509	
Basic and diluted income / loss (–) per share (in €)	(1.78)	1.44	
Basic and diluted loss per share from continuing operations (in €)	(1.78)	(0.89)	
Weighted average number of shares (in thousands of shares)	34,578	30,218	



#### FINANCIAL STATEMENTS

#### Consolidated statement of comprehensive income

Nine months and	led 30 September.

(thousands of €)	2015	2014
Net income / loss (-)	(61,406)	43,509
Items that may be reclassified subsequently to profit or loss:		
Translation differences, arisen from translating foreign activities	591	658
Translation differences, arisen from the sale of service division		(1,787)
Other comprehensive income, net of income tax	591	(1,129)
Total comprehensive income attributable to:		
Owners of the parent	(60,814)	42,381



# Consolidated statements of financial position

#### (unaudited)

(thousands of €)	As at 30 September 2015	As at 31 December 2014
Assets		
Intangible assets	1,517	2,015
Property, plant and equipment	12,577	10,091
Deferred tax assets	1,761	293
Non-current R&D incentives receivables	46,038	43,944
Non-current restricted cash	1,046	306
Other non-current assets	549	215
Non-currents assets	63,487	56,864
Inventories	344	281
Trade and other receivables	3,987	3,211
Current R&D incentives receivables	15,176	7,351
Cash and cash equivalents	366,545	187,712
Current restricted cash	6,856	10,422
Other current assets	4,653	4,625
Current assets	397,561	213,603
Total assets	461,049	270,467



#### FINANCIAL STATEMENTS

(thousands of €)	As at 30 September 2015	As at 31 December 2014
Equity and liabilities		
Share capital	185,055	157,274
Share premium account	357,155	114,182
Other reserves	(220)	(220)
Translation differences	(566)	(1,157)
Accumulated losses	(122,634)	(63,944)
Total equity	418,791	206,135
Pension liabilities	3,085	2,865
Provisions	66	72
Finance lease liabilities	76	115
Other non-current liabilities	1,781	923
Non-current liabilities	5,008	3,976
Provisions	35	105
Finance lease liabilities	51	52
Trade and other payables	32,775	30,007
Current tax payable	2,640	2,582
Accrued charges	470	585
Deferred income	1,279	27,026
Current liabilities	37,251	60,356
Total liabilities	42,258	64,332
Total equity and liabilities	461,049	270,467



# Consolidated cash flow statements

(unaudited)

	Nine months ended 30 September,		
(thousands of €)	2015	2014	
Cash and cash equivalents at beginning of period	187,712	138,175	
Net income / loss (–)	(61,406)	43,509	
Adjustments for:			
Tax income (-) / expenses	(1,411)	2,050	
Financial income (-) / expenses	(438)	(1,159)	
Depreciation of property, plant and equipment	1,708	2,826	
Amortization and impairment of intangible fixed assets	811	870	
Net realized gain / loss (–) on foreign exchange transactions	(257)	268	
Share based compensation	2,716	2,245	
Decrease in provisions	(80)	(52)	
Increase in pension liabilities	220	219	
Gain on sale of service division	-	(67,508)	
Operating cash flows before movements in working capital	(58,137)	(16,732)	
Increase in inventories	(63)	(34)	
Increase in receivables	(9,468)	(5,048)	
Decrease in payables	(23,430)	(37,061)	
Cash used in operations	(91,097)	(58,876)	
Interest paid	(38)	(100)	
Interest received	870	606	
Income taxes received	-	86	
Net cash flows used in operating activities	(90,265)	(58,284)	
Purchase of property, plant and equipment	(4,231)	(3,999)	
Purchase of and expenditure in intangible fixed assets	(312)	(461)	
Proceeds from disposal of property, plant and equipment	49	2,681	
Disposals of subsidiaries, net of cash disposed	_	130,787	
Increase (–) / decrease in restricted cash	2,259	(7,422)	
Net cash flows generated / used (-) in investing activities	(2,235)	121,586	



#### FINANCIAL STATEMENTS

#### Nine months ended 30 September,

(thousands of €)	2015	2014
Repayment of obligations under finance leases and other debts	(34)	(206)
Proceeds from Capital and Share premium increases	290,114	4,374
Issue costs of capital increase paid	(18,844)	-
Net cash flows generated in financing activities	271,236	4,168
Effect of exchange rate differences on cash and cash equivalents	96	222
Increase in cash and cash equivalents	178,832	67,693
Cash and cash equivalents at end of period	366,545	205,869



# Consolidated statements of changes in equity

(unaudited)

(thousands of €)	Share capital	Share premium account	Translation differences	Other reserves	Accumul. losses	Total
On 1 January 2014	154,542	112,484	170	47	(100,107)	167,137
Net income					43,509	43,509
Other comprehensive income			(1,129)			(1,129)
Total comprehensive income			(1,129)	-	43,509	42,381
Share-based compensation					2,245	2,245
Exercise of warrants	2,697	1,677				4,374
On 30 September 2014	157,239	114,161	(959)	47	(54,353)	216,135
On 1 January 2015	157,274	114,182	(1,157)	(220)	(63,944)	206,135
Net loss					(61,406)	(61,406)
Other comprehensive income			591			591
Total comprehensive income			591	-	(61,406)	(60,814)
Share-based compensation					2,716	2,716
Issue of new shares	40,751	237,952				278,703
Share issue costs	(19,360)					(19,360)
Exercise of warrants	6,390	5,021				11,411
On 30 September 2015	185,055	357,155	(566)	(220)	(122,634)	418,791



# Notes

Notes to the unaudited consolidated interim financial statements





# Basis of preparation

The condensed financial statements have been prepared in accordance with IAS 34 'Interim Financial Reporting' as adopted by the European Union. The condensed financial statements do not contain all information required for an annual report and should therefore be read in conjunction with Galapagos' Annual Financial Report of 2014.

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

# Significant accounting policies

There were no significant changes in accounting policies applied by the Group in these condensed consolidated interim financial statements compared to those used in the most recent annual financial statements of 2014, except for the adoption of new standards and interpretations described below.

#### **New standards**

Standards and interpretations applicable for the annual period beginning on 1 January 2015

- Improvements to IFRS (2011-2013) (applicable for annual periods beginning on or after 1 January 2015)
- IFRIC 21 Levies (applicable for annual periods beginning on or after 17 June 2014)

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. The Group has 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 the Galapagos' operations is not regarded as applicable to the unaudited interim condensed consolidated financial statements.



# Details of the unaudited Q3 2015 results

#### **General information**

Galapagos sold its service division to Charles River Laboratories International, Inc. on 1 April 2014. As a result of this sale the service division is reported as discontinued operations. Group results of 2014 include both continuing and discontinued operations. The components of the operating result of 2014 discussed below are for the continuing operations only, as per IFRS 5 presentation. Following the sale of the service division on 1 April 2014, the continuing operations relate primarily to R&D activities. Consequently there is one reportable segment.

#### **Revenues and other income**

#### **Revenues**

The following table summarizes our revenues for the nine months ended 30 September 2015 and 2014.

	Nine	months	ended	30	September,
ī					

(thousands of €)	2015	2014
Milestone payments	2,101	10,981
Recognition of non-refundable upfront payments	26,419	35,503
Other revenues	3,851	2,638
Total revenues	32,371	49,122

Revenues ( $\leqslant$ 32.4 million vs  $\leqslant$ 49.1 million last year) were lower due to a decrease in revenue recognition of upfront payments and reduced milestone payments, reflecting the increasing proprietary nature of our pipeline programs. Revenue recognized from upfront non-refundable payments related to the CF collaboration agreement with AbbVie signed in September 2013 and to the contract signed with AbbVie in February 2012 for the filgotinib program.

#### Other income

The following table summarizes our other income for the nine months ended 30 September 2015 and 2014.

Nine	months	ended	30	September,
IAIIIG	1110111113	ciiucu	20	september,

(thousands of €)	2015	2014
Grant income	2,430	3,759
Other income	12,418	9,794
Total other income	14,848	13,553

Other income ( $\in$ 14.8 million vs  $\in$ 13.6 million last year) increased in the first nine months of 2015, driven mainly by R&D incentives in Belgium and France.

#### Results

The Group realized a net loss for the first nine months of 2015 of €61.4 million, compared to a net loss of €27.0 million in the first nine months of 2014 for continuing operations.



Following the sale of the service division, the Group reported a net profit from discontinued operations of  $\epsilon$ 70.5 million in the first nine months of 2014. Galapagos recorded a result on divestment of  $\epsilon$ 67.5 million.

R&D expenses for the Group in the first nine months of 2015 were €96.9 million compared to €77.2 million in 2014. This planned increase is mainly due to increased efforts on the filgotinib and cystic fibrosis programs.

G&A and S&M expenses of the Group were  $\in$  13.6 million in the first nine months of 2015, compared to  $\in$  10.8 million in the first nine months of 2014. This increase is primarily due to a higher provision for short term and long term management bonus as well as higher costs for warrant plans, amongst other as a result of the recent evolution of Galapagos share price change relative to the Next Biotech Index.

Finally, for one subsidiary, a deferred tax asset was set up for an amount of  $\in$ 1.8 million on 30 September 2015, of which  $\in$ 1.5 million was additionally recognized in the first nine months of 2015. Income taxes recorded in the first nine months of 2014 for an amount of  $\in$ 1.8 million primarily relate to a tax provision for one subsidiary, triggered by a change in estimate.

#### Liquid assets position

Cash, cash equivalents and restricted cash totalled €374.4 million on 30 September 2015.

A net increase of  $\in$  178.8 million in cash and cash equivalents was recorded during the first nine months of 2015, compared to an increase of  $\in$  67.7 million during the same period last year. Net cash flows from financing activities generated  $\in$  259.9 million through a recent global offering and concurrent listing on NASDAQ, as well as  $\in$  11.4 million from warrant exercises. Furthermore, Galapagos continued to intensify its R&D investments, with a net cash outflow from operating activities of  $\in$  90.3 million in the first nine months of 2015.

Restricted cash amounted to  $\in$ 10.7 million at the end of September 2014, and decreased to  $\in$ 7.9 million at the end of September 2015. This decrease is related to (i) the release of the  $\in$ 3 million bank guarantee issued in 2013 for the rental of the new premises in France which expired on 30 June 2015 following the move to the new offices, (ii) the payment of a claim to Charles River by decrease of the escrow account, and (iii) a  $\in$ 0.7 million bank guarantee issued in September 2015 for the rental of new premises in the Netherlands (to replace the current premises) which will expire on 1 October 2025. Restricted cash on 30 September 2015 is related to  $\in$ 0.3 million and  $\in$ 0.7 million bank guarantees on real estate lease obligations in Belgium and in the Netherlands respectively, and to  $\in$ 6.9 million escrow account containing part of the proceeds from the sale of the service division in 2014 for which the release will be possible after final agreement between the parties on the exposure regarding one outstanding claim. An amount of  $\in$ 0.3 million has been accrued in March 2015 based on a preliminary estimate of the exposure.

Furthermore, Galapagos' balance sheet holds an unconditional and unrestricted receivable from the French government (Crédit d'Impôt Recherche)  $^{[1]}$  now amounting to  $\in$ 37.5 million, payable in 4.75 yearly tranches. Galapagos' balance sheet also holds a receivable from the Belgian Government for R&D incentives now amounting to  $\in$ 23.7 million, payable as from 2016 in 5.75 yearly tranches.

#### **Capital increase**

On 26 March 2015, warrants were exercised at various exercise prices with an average exercise price of  $\le$ 10.18 per warrant resulting in a share capital increase of  $\le$ 3,092 thousand (plus  $\le$ 2,727 thousand in issuance premium) and the issuance of 571,548 new ordinary shares.

On 19 May 2015, Galapagos successfully completed a global offering of 7,532,499 ordinary shares consisting of a concurrent public offering in the US and private placement in Europe. Galapagos offered 5,746,000 ordinary shares through a public offering in the US in the form of American Depositary Shares, or ADSs, at a price of \$42.05 per ADS, before underwriting discounts. The ADSs were evidenced by American Depositary Receipts, or ADRs, and each ADS represents the right to receive one ordinary share.

[1] Crédit d'Impôt Recherche refers to an innovation incentive system underwritten by the French government.



The ADSs are listed on the NASDAQ Global Select Market under the symbol "GLPG." Galapagos offered 1,786,499 ordinary shares through a European private placement at price of €37.00 per share, before underwriting discounts.

Galapagos received €278.7 million of gross proceeds from the global offering, decreased by €19.4 million of underwriter discounts and commission, and offering expenses, of which €18.8 million has been paid at 30 September 2015 and €0.5 million remains to be settled in cash. Total net cash proceeds from the global offering after remaining settlements will amount to €259.3 million.

On 19 June 2015, following warrant exercises at an average exercise price of €8.94 per warrant, Galapagos issued 491,406 new ordinary shares for a total capital increase (including issuance premium) of €4,395 thousand.

On 25 September 2015, following warrant exercises at an average exercise price of  $\in$ 10.13 per warrant, Galapagos issued 118,260 new ordinary shares for a total capital increase (including issuance premium) of  $\in$ 1,198 thousand.

(thousands of €, except share data)	Number of Shares	Share Capital	Share Premium	Share Capital and Share Premium	
On 1 January 2015	30,299,129	157,274	114,182	271,456	
26 March 2015: Exercise of Warrants	571,548	3,092	2,727	5,819	
19 May 2015: Global Offering					
Ordinary shares (fully paid)	1,786,499	9,665	56,436	66,100	
ADSs (fully paid)	5,746,000	31,086	181,516	212,602	
Underwriter discounts and offering expenses (fully paid)		(18,844)		(18,844)	
Offering expenses not yet settled in cash at 30 September 2015		(516)		(516)	
Total Global Offering	7,532,499	21,391	237,952	259,343	
19 June 2015: Exercise of Warrants	491,406	2,659	1,737	4,395	
25 September 2015: Exercise of Warrants	118,260	640	558	1,198	
On 30 September 2015	39,012,842	185,055	357,155	542,211	

#### **Discontinued operations**

The following disclosure illustrates the results from our discontinued operations reported in the 30 September 2014 interim financial statements. In the first nine months of 2015, Galapagos does not hold discontinued operations to be disclosed in its financial statements.

On 1 April 2014, the Group sold its service division – comprising all service operations of BioFocus and Argenta in the UK and The Netherlands – to Charles River Laboratories International, Inc. In particular, the Group disposed of following companies which were previously fully consolidated: BioFocus DPI (Holdings) Ltd. and BioFocus DPI Ltd. (Saffron Walden, UK), Argenta Discovery 2009 Ltd. (Harlow, UK) and its subsidiary Cangenix Ltd. (Canterbury, UK). In addition, also certain assets from the Galapagos B.V. (Leiden, The Netherlands) have been acquired by Charles River Laboratories International, Inc.



#### **Consideration received**

Consideration received	
	1 April,
(thousands of €)	2014
Consideration received in cash and cash equivalents	137,760
Correction on consideration still to settle	(650)
Total consideration	137,110
Analysis of assets and liabilities over which control was lost	
Analysis of assets and habilities over which control was lose	1 April,
(thousands of €)	2014
Cash	6,115
Trade and other receivables	18,165
Current assets	24,280
Goodwill	39,246
Fixed assets	13,397
Deferred tax assets	4,588
Non-current assets	57,231
Trade payables	(2,569)
Other payables	(5,263)
Current liabilities	(7,832)
Provisions	(604)
Deferred tax liabilities	(1,996)
Other non-current liabilities	(549)
Non-current liabilities	(3,149)
Net assets disposed of	70,531
Gain on disposal of subsidiaries	1 April,
(thousands of €)	2014
Total consideration	137,110
Net assets disposed of	(70,531)
Effect from cumulative translation adjustments reclassified from equity	1,787
Costs associated to sale	(858)
Gain on disposal	67,508

The gain on disposal is included in the profit from discontinued operations for the nine months ended 30 September 2014.



#### Net cash inflow on disposal of subsidiaries

	1 April,
(thousands of €)	2014
Consideration received in cash and cash equivalents	137,760
Less: cash and cash equivalent balances disposed	(6,115)
Total consideration received	131,645
Costs associated to sale	(858)
Cash in from disposal of subsidiaries, net of cash disposed	130,787

#### Result from discontinued operations for nine months ended 30 September

·	Nine Months ended September 30,
(thousands of €, except share and per share data)	2014
Service revenues	17,502
Other income	669
Total revenues and other income	18,171
Services cost of sales	(11,283)
General and administrative expenses	(3,772)
Sales and marketing expenses	(255)
Restructuring and integration costs	(38)
Gain on sale of service division	67,508
Operating income	70,331
Finance income	417
Income before tax	70,748
Income taxes	(234)
Net income from discontinued operations	70,514
Basic and diluted income per share from discontinued operations (in €)	2.33
Weighted average number of shares (in thousands of shares)	30,218

#### Cash flows from discontinued operations for nine months ended 30 september

	Nine Months ended September 30,
(thousands of €)	2014
Net cash flows used in operating activities	(1,722)
Net cash flows generated in investing activities	122,580
Net cash flows generated in financing activities	-
Net cash generated	120,858



# **Contingencies and commitments**

#### **Contractual obligations and commitments**

The Group entered into lease agreements for office and laboratories which qualify as operating leases. The Group also has certain purchase commitments with CRO subcontractors principally. On 30 September 2015, the Group had outstanding obligations for future minimum rent payments and purchase commitments, which become due as follows:

		Payments due by period			
(thousands of €)	Total	Less than 1 year	1–3 years	3–5 years	More than 5 years
Operating lease obligations	33,112	4,306	7,991	5,553	15,262
Purchase commitments	21,601	18,625	2,976		
Total contractual obligations & commitments	54,713	22,931	10,967	5,553	15,262

The purchase commitments are mainly comprised of engagements related to clinical studies for  $\epsilon$ 9.9 million (or 46% of our total purchase commitments). Other purchase commitments relate to contracts with CROs and academics for R&D activities such as chemistry work, biology work and batch production.

#### **Contingent liabilities and assets**

On 13 March 2014, the Group announced the signing of a definitive agreement to sell the service division operations to Charles River Laboratories International, Inc. (the "Buyer") for a total consideration of up to  $\epsilon$ 134 million. Charles River agreed to pay Galapagos an immediate cash consideration of  $\epsilon$ 129 million. The potential earn out of  $\epsilon$ 5 million due upon achievement of a target 12 months after transaction closing has not been achieved.

Approximately 5% of the total price consideration, including price adjustments, is being held on an escrow account which would have been released on 30 June 2015 if no claim had been introduced by the Buyer. To date, four claims have been introduced by the Buyer, of which three claims have been settled for a total amount of €1.0 million. One claim, which has been introduced by the Buyer in March 2015, is still being investigated. An amount of €0.3 million has been accrued in March 2015 based on a preliminary estimate of the exposure. The release of the escrow account will be possible after final agreement between the parties on the amounts at stake.

Following the divestment, we remain a guarantor for a limited transitional period in respect of the lease obligations for certain U.K. premises amounting to £40 million future rent payments. The Buyer will fully indemnify Galapagos NV against all liabilities arising in connection with the lease obligation. We evaluated the risk to be remote.

Finally, following common practice, Galapagos NV has given customary representations and warranties which are capped and limited in time.

In the course of 2008, a former director of one of our subsidiaries sued for wrongful termination and seeks damages of €1.1 million. Galapagos believes that the amount of damages claimed is unrealistically high. In 2014, the Court requested an external advisor to evaluate the exact amount of damages. This analysis is still ongoing. Considering the defense elements provided in favor of Galapagos and also the latest evolution in the Court, the 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 is considered to be limited.

# Events after the end of the reporting period

There was no material event subsequent to the end of the interim reporting period that has not been reflected in the financial statements for the interim period.

# Approval of interim financial statements

The interim financial statements were approved by the Board of Directors on 3 November 2015.



# Report on review of the consolidated interim financial information for the nine-month period ended 30 September 2015

#### To the board of directors

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 2015, 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 461.049 (000) EUR and the consolidated condensed income statement shows a consolidated loss for the period then ended of 61.406 (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.

Diegem, 4 November 2015 **The statutory auditor** 

DELOITTE Bedrijfsrevisoren / Reviseurs d'Entreprises

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



# Glossary of terms

#### **ACR**

American College of Rheumatology

#### ADR

American Depositary Receipt; Certificate representing an American Depositary Share

#### ADS

American Depositary Share; One Galapagos ADS represents the right to receive, and to exercise the beneficial ownership interests in, one ordinary share in Galapagos NV on deposit with depositary Citibank, N.A.; Galapagos' ADSs are listed on NASDAQ under the symbol "GLPG"

#### **Bioavailability**

Assessment of the amount of (candidate) drug that reaches a body's systemic circulation after administration

#### **Candidate drug**

Substance that has satisfied the requirements of pre-clinical testing and has been selected for clinical testing for the treatment of a certain disorder in humans

#### CFTR

Cystic fibrosis transmembrane conductance regulator protein. CFTR is a protein involved in the transport of chloride ions across cell membranes. Cystic fibrosis patients have a genetic mutation resulting in absence of or dysfunction of CFTR

#### CIR

Crédit d'Impôt Recherche, or research credit. Under the CIR, the French government refunds up to 30% of the annual investment in French R&D operations, over a period of three years. Galapagos benefits from the CIR through its operations in Romainville, just outside Paris

#### **Clinical Proof of Concept (PoC)**

Point in the drug development process where the candidate drug shows efficacy in a therapeutic setting

#### Colitis ulcerosa/ulcerative colitis (UC)

see IBD

#### Compound

A chemical substance, often a small molecule with drug-like properties

#### **Corrector drug**

Drug that restores the protein forming the ion channel opening in cystic fibrosis patients. In most CF patients, a potentiator and corrector drug are needed in combination to restore the genetic defect causing CF. GLPG2222 and GLPG2665 are corrector drugs with different mechanisms of action

#### Crohn's (CD)

see IBD

#### 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 frequent lung infections

#### Development

Process of bringing a new drug to the market. At Galapagos, this is the department which performs pre-clinical and clinical development research, clinical batch scale-up, and regulatory filings of Galapagos' 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

#### **Drug development**

Process of bringing a new drug to the market; includes both pre-clinical development and human clinical trials

#### **Drug discovery**

Process by which a (potential) therapeutic is either discovered or designed

#### **Efficacy**

Effectiveness for intended use

#### Fee-for-service

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



#### **FIH**

First-in-human clinical trial, usually conducted in healthy volunteers with the aim to assess the safety, tolerability and bioavailability of the candidate drug

#### filgotinib

Also known as GLPG0634. Small molecule selective JAK1 inhibitor which showed excellent efficacy and safety in rheumatoid arthritis patients in Phase 2 trials in November 2011, November 2012, and DARWIN 1 & 2 studies reported in 2015. Currently being prepared by Galapagos to enter a Phase 3 study in rheumatoid arthritis, with a Phase 2 study topline result in Crohn's disease expected before end 2015

#### **FSMA**

The Belgian market authority: Financial Services and Markets Authority

#### **GLPG0634**

See filgotinib

#### **GLPG1205**

Novel mode of action medicine in inflammatory bowel disease, fully owned by Galapagos, currently in a Phase 2 Proof-of-Concept study in ulcerative colitis

#### **GLPG1690**

A novel drug targeting autotaxin, with potential applications in idiopathic pulmonary fibrosis. Fully proprietary to Galapagos. Currently in preparations for the start of a Phase 2 Proof of concept study in IPF

#### **GLPG1837**

A potentiator drug which completed Phase 1 in 2015

#### **GLPG2222**

A corrector drug currently in pre-clinical candidate stage, which is expected to enter Phase 1 before end 2015

#### **GLPG2665**

A corrector drug currently in pre-clinical candidate stage

#### **IBD**

Inflammatory Bowel Disease. This is a general term for autoimmune disease affecting the bowel, including Crohn's disease and ulcerative colitis. Crohn's disease affects the small intestine primarily, while ulcerative colitis affects the large intestine. Both diseases involve inflammation of the intestinal wall, leading to pain, bleeding, and ultimately in some cases removal of bowel tissue

#### **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

#### Inflammatory diseases

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

#### 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

#### Intellectual property

Creations of the mind that have commercial value and are protected by patents, trademarks or copyrights

#### **JAK**

Janus kinases (JAK) are critical components of signaling mechanisms utilized by a number of cytokines and growth factors, including those that are elevated in rheumatoid arthritis

#### Milestone

Major achievement in a project or program; in Galapagos' alliances, this is usually associated with a payment

#### MTX

Methotrexate

#### **Oral dosing**

Administration of medicine by the mouth, either as a solution or solid (capsule, pill) form

#### Orkambi<sup>®</sup>

Orkambi is a prescription medicine sold by Vertex Pharmaceuticals Incorporated, used for the treatment of cystic fibrosis (CF) in patients age 12 years and older who have two copies of the F508del mutation (F508del/F508del) in their CFTR gene

#### Pharmacokinetics (PK)

Study of what a body does to a drug; the fate of a substance delivered to a body



#### Phase 1

First stage of clinical testing of a potential new treatment designed to assess the safety and tolerability of a drug, usually performed in a small number of healthy human volunteers

#### Phase 2

Second stage of clinical testing, usually performed in 20-300 patients, in order to determine efficacy, tolerability and the most effective dose to use

#### Phase 3

Large clinical trials, usually conducted in 300-3000 patients to gain a definitive understanding of the efficacy and tolerability of the candidate treatment by comparing it to the "gold standard" treatment; serves as the principal basis for regulatory approval

#### **Potentiator drug**

Drug that restores the ion channel opening in cystic fibrosis patients. In most CF patients, a potentiator and corrector drug are needed in combination to restore the genetic defect causing CF. GLPG1837 is a potentiator drug

#### **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, pharmaco-kinetics, toxicology, and chemical upscaling

#### Pre-clinical candidate (PCC)

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

#### Rheumatoid arthritis (RA)

A chronic, systemic inflammatory disease that causes joint inflammation, and usually leads to cartilage destruction, bone erosion and disability

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

Research and development operations; unit responsible for discovery and developing new candidate drugs for internal pipeline or as part of risk/reward sharing alliances with partners

#### 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

#### **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

#### **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



# Financial calendar

#### 4 March 2016

Full year results 2015

#### 26 April 2016

Annual Shareholders' Meeting

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



# Colophon

#### Concept, design, and online programming

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

www.nexxar.com

#### Photography

Frank van Delft

Copy deadline 12 November 2015

This Q3 Report 2015 is also available in Dutch and available for download in the Downloads section of this report or at www.glpg.com

## **Contact**



#### Elizabeth Goodwin

VP Investor Relations & Corporate Communications Galapagos NV Generaal De Wittelaan L11 A3 B-2800 Mechelen, Belgium Tel. +32 15 34 29 00

Mob. +1 781 460 1784 Email: ir@glpg.com