Galápagos

Q3 Report 2016

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The Galapagos Group

An overview of Galapagos, its strategy and portfolio in the first nine months of 2016

Letter from the management

Dear Shareholders,

For Galapagos, there is no such thing as slow months of summer. We delivered robust progress in R&D and kept executing our plans on track. Our collaboration partner Gilead started the FINCH Phase 3 program with filgotinib in rheumatoid arthritis (RA), to be conducted in centers all over the world. We announced successful completion of discussions with regulatory authorities for the next studies with filgotinib in Crohn's disease and ulcerative colitis; these studies are expected to start before the end of 2016. Also on filgotinib, we reported endoscopic and histopathologic improvements that are consistent with clinical remission rates observed in patients with Crohn's disease in the FITZROY study, in an abstract submitted to UEG Week 2016.

In this third quarter, we received orphan status from the EU for our autotaxin inhibitor GLPG1690. Galapagos started a Phase 2a biomarker study with GLPG1690 in patients with idiopathic pulmonary fibrosis (IPF) earlier this year. Next step is filing for orphan drug designation with the FDA in the United States. GLPG1690 is fully proprietary to Galapagos. Galapagos and MorphoSys also disclosed the first dosing with MOR106 in atopic dermatitis patients and disclosed the target of MOR106, IL-17C, which was discovered by Galapagos to play a role in skin inflammation.

Galapagos has been working in cystic fibrosis (CF) since 2005, giving us 11 years' experience of developing new drugs in the field. We remain on track to evaluate a potential triple combination therapy in patient studies in mid-2017. Galapagos and AbbVie reported the results for the first-in-human study with GLPG2222 and for the Phase 2 SAPHIRA 2 study with GLPG1837 in S1251N mutation patients, and profiled much of our preclinical CF work at NACFC 2016 in Orlando.

We look forward to the last months of 2016. At the ACR conference in Washington we will present further modelling data on filgotinib and we will share our initial biomarker work from DARWIN on filgotinib. We will show patient reported outcomes from FITZROY at AIBD in December. In CF we will be starting Phase 1 with GLPG2737, our C2 corrector, which will bring us another step closer towards developing a triple combination therapy with the potential for transformative efficacy.

All these innovations could not have been possible without the continuous trust of our investors, and I thank you for that. But most of all, I want to thank my colleagues. Without their determination and ability to solve the most complex puzzles in biology, chemistry, and development, we would not have been where we are right now. And it is the Galapagos commitment to 'getting things done' that will bring us further along our way. The best is yet to come.

Operational overview Q3 2016

Rheumatoid arthritis

- Reported first patient dosing in the FINCH Phase 3 program with filgotinib in rheumatoid arthritis

Inflammatory bowel disease

- Reported that endoscopic improvements with filgotinib are consistent with clinical remission rates in patients with Crohn's disease, in an abstract submitted to UEG Week 2016

- Announced successful completion of discussions with regulatory authorities for the next studies with filgotinib in Crohn's disease (DIVERSITY) and ulcerative colitis (SELECTION). Both studies will recruit approximately 1,300 patients each from the US, Europe, Latin America, Canada, and Asia/Pacific. The SELECTION Phase 2b/3 study in ulcerative colitis will include a futility analysis, serving as the Phase 2b part of this integrated Phase 2b/3 study. The filgotinib Phase 3 program will also contain a dedicated male patient testicular safety study. First dosing in DIVERSITY and SELECTION is expected in Q4'16

Atopic dermatitis

- Galapagos and MorphoSys disclosed the first dosing with MOR106 in atopic dermatitis patients and disclosed the target of MOR106, IL-17C, which was discovered by Galapagos to play a role in skin inflammation.
- Topline results from the Phase 1 study with MOR106 are expected in the second half of 2017

Cystic fibrosis (CF)

- We remain on track to have a potential triple combination therapy in patient studies in mid-2017
- Galapagos and AbbVie reported the results for the First-in-Human study with GLPG2222 and for the Phase 2 SAPHIRA 2 study with GLPG1837 in S1251N mutation patients at NACFC 2016

Fibrosis

- Received orphan status from the EU for autotaxin inhibitor GLPG1690. Galapagos started a Phase 2a biomarker study with GLPG1690 in patients with idiopathic pulmonary fibrosis (IPF) earlier this year. Topline results are expected in Q2 2017

Q3 2016 financial result

Revenues and other income

Our revenues and other income for the first nine months of 2016 amounted to €65.0 million, compared to €47.2 million in the same period of 2015. Revenues (€50.0 million vs €32.4 million for the same period last year) were higher due to an increase of milestone payments received and contractually agreed costs recharges on partnered programs (i.e. reimbursement income). Other income was stable (€15.0 million vs €14.8 million for the same period last year).

Results

We realized a net profit of €8.1 million for the first nine months of 2016, compared to a net loss of €61.4 million in the first nine months of 2015. This evolution was primarily driven by €57.5 million fair value gain from the re-measurement of the financial asset triggered by the recent Share Subscription Agreement with Gilead.

We reported an operating loss amounting to €48.5 million for the first nine months of 2016, compared to an operating loss of €63.3 million for the same period last year.

Our R&D expenses in the first nine months of 2016 were €96.7 million, compared to €96.9 million for the same period in 2015.

Our G&A and S&M expenses were €16.8 million in the first nine months of 2016, compared to €13.6 million in the first nine months of 2015. This increase mainly resulted from higher costs recognized in relation to the warrant plans as a result of the increase of our share price in the past year as well as a slight headcount increase and higher other operational costs.

Financial results were primarily driven by the fair value re-measurement of the Share Subscription Agreement, which is explained under the next caption below. Net other financial costs in the first nine months of 2016 amounted to €0.9 million, compared to a net other financial income of €0.4 million in the first nine months of 2015, and were primarily attributable to €2.4 million of exchange loss on our cash position in USD due to the fluctuation of the USD exchange rate in the first nine months of 2016.

Fair value re-measurement of Share Subscription Agreement

On 16 December 2015, Gilead and Galapagos entered into a global collaboration for the development and commercialization of filgotinib, in the framework of which Gilead committed to an upfront payment of $725 million consisting of a license fee of $300 million and a $425 million equity investment in Galapagos NV by subscribing to new shares at a price of €58 per share, including issuance premium. This agreement was effectively completed and entered into force on 19 January 2016 and the full payment was received.

In connection with this agreement, we recognized in December 2015 a short term financial asset (derivative) and an offsetting deferred income of €39 million upon signing of the Share Subscription Agreement with Gilead as required under IAS 39. This financial asset initially reflected the share premium that Gilead committed to pay above our closing share price on the day of entering into the Share Subscription Agreement. Under IAS 39 the fair value of the financial asset was re-measured at year-end and again upon closing of the Share Subscription Agreement on 19 January 2016, when the financial asset expired. Variations in fair value of the financial asset are recorded in the income statement.

The decrease in the fair value of the financial asset resulting from the increase in the Galapagos share price between signing of the Share Subscription Agreement and 31 December 2015 resulted in a negative, non-cash fair value adjustment of €30.6 million in the financial results of 2015.

The subsequent increase in the fair value of the financial asset resulting from the decrease in our share price between 1 January 2016 and 19 January 2016 resulted in a positive non-cash adjustment of €57.5 million in the financial result of the first quarter of 2016.

On 19 January 2016, the value of the financial asset at maturity amounted to €65.9 million, reflecting the share premium that Gilead paid above our closing share price on the day of the capital increase. This financial asset expired on the effective date of the Share Subscription Agreement.

Liquid assets position

Cash, cash equivalents and restricted cash totaled €938.8 million on 30 September 2016.

A net increase of €590.5 million in cash and cash equivalents was recorded during the first nine months of 2016, compared to an increase of €178.8 million during the same period last year. Net cash flows from financing activities generated €395.2 million mainly through the share subscription by Gilead. Furthermore, a net cash inflow from operating activities was realized for €204.3 million in the first nine months of 2016 resulting from the license fee of $300 million (€275.6 million) received from Gilead and, by difference, from an operating cash burn of €71.3 million. Finally, €6.7 million was used in investing activities and €2.4 million negative exchange rate differences were generated on cash and cash equivalents.

Finally, our balance sheet holds an unconditional and unrestricted receivable from the French government (*Crédit d'Impôt Recherche*[1]) now amounting to €39.0 million, to be received in yearly tranches from 2016 to 2020. Our balance sheet also holds a receivable from the Belgian Government for R&D incentives now amounting to €28.3 million, to be received in yearly tranches from 2017 to 2026.

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

Outlook 2016

In the first nine months of 2016, Galapagos continued to execute as planned on its R&D strategy. The full year 2016 is expected to deliver more data, with topline results expected from GLPG1837 in the SAPHIRA 1 Phase 2 program in patients with the G551D mutation. In addition, we expect to initiate a Phase 1 study with novel C2 corrector GLPG2737 in CF, and our collaboration partner Gilead is expected to start dosing with filgotinib in a Phase 3 program in Crohn's disease, and Phase 2b/3 in ulcerative colitis.

Based on the forecast for the remainder of the year, management retains 2016 guidance for operational cash burn (excluding payments received from our collaboration partner Gilead for filgotinib) of €100-120 million.

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

Onno van de Stolpe
CEO

At a glance

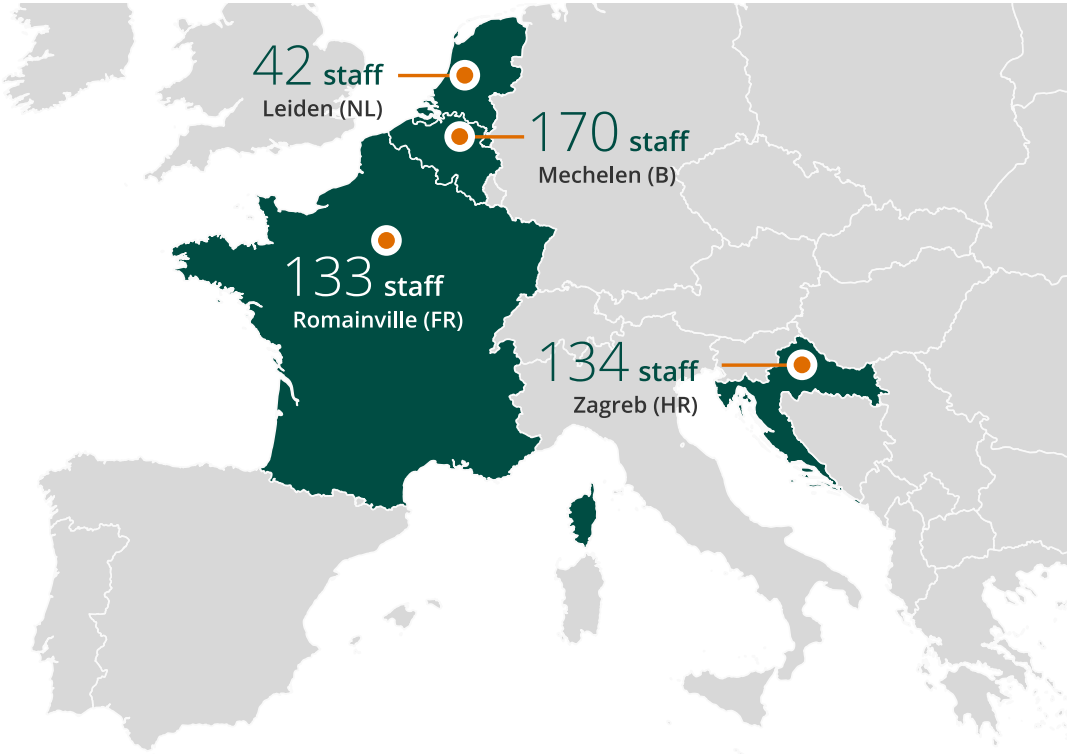
Key figures (IFRS) Galapagos Group (unaudited)

(in € thousands, if not stated otherwise)	30/09/2016	30/09/2015
Results		
Revenues and other income	65,040	47,219
R&D expenditure	(96,739)	(96,873)
S, G&A expenses	(16,784)	(13,600)
Personnel expenses (including share-based compensation)	(38,785)	(34,053)
Capital expenditure	3,876	4,543
Depreciation and amortization of (in)tangible assets	(3,077)	(2,518)
Operating loss	(48,482)	(63,254)
Net financial results	56,621	438
Taxes	(71)	1,411
Net income / loss (–)	8,067	(61,406)
Galapagos share		
Number of shares issued on 30 September	46,169,828	39,012,842
Basic income / loss (–) per share (in €)	0.18	(1.78)
Diluted income / loss (–) per share (in €)	0.17	(1.78)
Share price on 30 September (in €)	57.13	36.54
Personnel data		
Total Group employees on 30 September (Number)	479	427

Balance sheet

(thousands of €)	30/09/2016	31/12/2015
Total assets	1,043,093	442,514
Cash, cash equivalents and restricted cash	938,764	348,216
Total liabilities	334,272	77,515
Stockholders' equity	708,822	364,999

Employees per site as of 30 September 2016



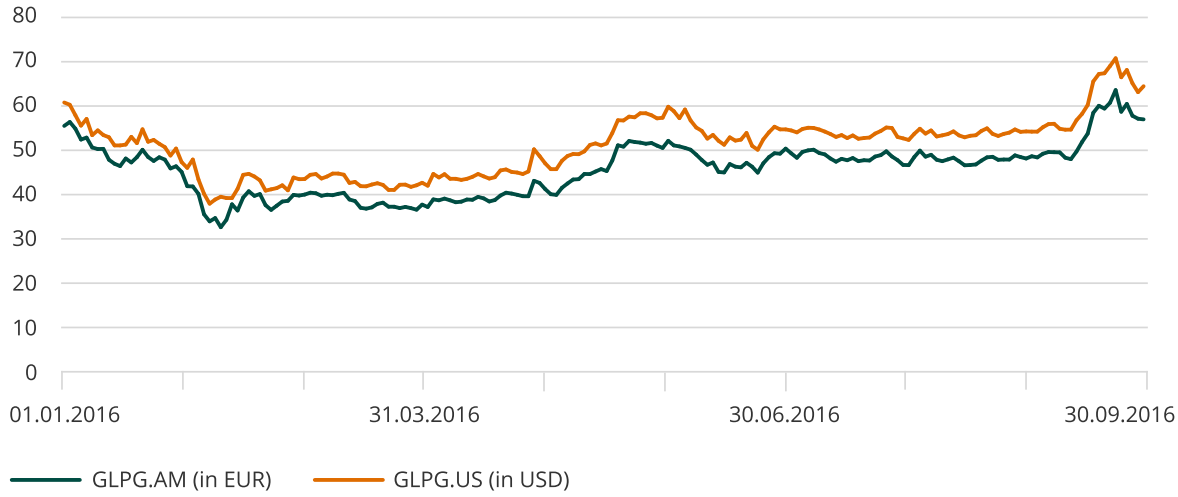
Risk factors

We refer to the description of risk factors in the 2015 Annual Report, pp. 53-59, as supplemented by the description of risk factors in our annual report on Form 20-F filed with the U.S. Securities and Exchange Commission, pp. 5-45. In summary, the principal risks and uncertainties faced by us relate to: our financial position and need for additional capital; product development, regulatory approval and commercialization; our reliance on third parties; our competitive position; our intellectual property; our organization, structure and operation (including but not limited to certain risks related to our status as a U.S. publicly listed company following the public offering of shares (in the form of ADSs) and listing on NASDAQ in May 2015) and market risks relating to our shares and ADSs.

We also refer to the description of the Group's financial risk management given in the 2015 Annual Report, pp. 131-134, which remains valid.

The Galapagos share

Performance of the Galapagos share on Euronext and NASDAQ



Disclaimer and other information

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

This report is published in Dutch and in English. In case of inconsistency between the Dutch and the English versions, the Dutch version shall prevail. Galapagos is responsible for the translation and conformity between the Dutch and English versions.

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

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Listings

Euronext Amsterdam and Brussels: GLPG
NASDAQ: GLPG

Forward-looking statements

This report contains forward-looking statements, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "believe," "anticipate," "expect," "intend," "plan," "seek," "estimate," "may," "will," "could," "stand to," "continue," as well as similar expressions. Forward-looking statements contained in this report include, but are not limited to, statements made in the "Letter from the management", the information provided in the section captioned "Outlook 2016", guidance from management regarding the expected operational use of cash during financial year 2016, statements regarding the development of a potential triple combination therapy for Class II cystic fibrosis patients and the possible activity and clinical utility of such potential triple combination therapy, statements regarding the expected timing, design and readouts of ongoing and planned clinical trials (i) with filgotinib in rheumatoid arthritis, Crohn's disease and ulcerative colitis, (ii) with GLPG2222, GLPG2737, GLPG2851, and GLPG2451 in cystic fibrosis, (iii) with GLPG1837 in Class III cystic fibrosis patients, (iv) with GLPG1690 in IPF, (v) with GLPG1972 in osteoarthritis, and (vi) with MOR106 in atopic dermatitis. We caution the reader that forward-looking statements are not guarantees of future performance. Forward-looking statements may involve known and unknown risks, uncertainties and other factors which might cause our actual results, financial condition and liquidity, performance or achievements, or the development of the industry in which we operate, to be materially different from any historic or future results, financial conditions, performance or achievements expressed or implied by such forward-looking statements. In addition, even if our results of operations, financial condition

and liquidity, and the development of the industry in which we operate are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. Among the factors that may result in differences are that our expectations regarding our 2016 revenues and financial results and our 2016 operating expenses may be incorrect (including because one or more of our assumptions underlying our revenue or expense expectations may not be realized), the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including that data from our clinical research programs in rheumatoid arthritis, Crohn's disease, ulcerative colitis, cystic fibrosis, idiopathic pulmonary fibrosis, osteoarthritis, atopic dermatitis, and other inflammatory indications may not support registration or further development of our product candidates due to safety, efficacy or other reasons), our reliance on collaborations with third parties (including our collaboration partner for filgotinib, Gilead, and our collaboration partner for cystic fibrosis, AbbVie), and estimating the commercial potential of our product candidates. A further list and description of these risks, uncertainties and other risks can be found in our Securities and Exchange Commission filings and reports, including in our most recent annual report on Form 20-F filed with the SEC and our other filings and reports. We also refer to the "Risk Factors" section of this report. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. We expressly disclaim any obligation to update any such forward-looking statements in this document to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements, unless specifically required by law or regulation.

Financial statements

Consolidated interim financial statements for the first nine months of 2016

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)	**2016**	**2015**
Revenues	50,009	32,371
Other income	15,031	14,848
Total revenues and other income	**65,040**	**47,219**
Research and development expenditure	(96,739)	(96,873)
General and administrative expenses	(15,511)	(12,882)
Sales and marketing expenses	(1,272)	(718)
Operating loss	**(48,482)**	**(63,254)**
Fair value re-measurement of Share Subscription Agreement	57,479	–
Other financial income	2,642	1,636
Other financial expenses	(3,500)	(1,198)
Profit / loss (–) before tax	**8,138**	**(62,816)**
Income taxes	(71)	1,411
Net income / loss (–)	**8,067**	**(61,406)**
Net income / loss (–) attributable to:		
Owners of the parent	8,067	(61,406)
Basic income / loss (–) per share	**0.18**	**(1.78)**
Diluted income / loss (–) per share	**0.17**	**(1.78)**
Weighted average number of shares – Basic (in thousands of shares)	45,527	34,578
Weighted average number of shares – Diluted (in thousands of shares)	47,054	34,578

Consolidated statements of comprehensive income

	Nine months ended 30 September	
(thousands of €)	**2016**	2015
Net income / loss (–)	**8,067**	**(61,406)**
Items that may be reclassified subsequently to profit or loss:		
Fair value adjustment of financial assets available for sale	(122)	
Translation differences, arisen from translating foreign activities	(816)	591
Other comprehensive income, net of income tax	**(938)**	**591**
Total comprehensive income attributable to:		
Owners of the parent	7,129	(60,814)

Consolidated statements of financial position
(unaudited)

(thousands of €)	As at 30 September 2016	As at 31 December 2015
Assets		
Intangible assets	1,150	**1,550**
Property, plant and equipment	15,032	13,782
Deferred tax assets	1,756	1,726
Non-current R&D incentives receivables	57,928	49,384
Non-current restricted cash	1,098	1,046
Other non-current assets	3,162	557
Non-current assets	**80,127**	**68,044**
Inventories	326	325
Trade and other receivables	8,686	3,931
Current R&D incentives receivables	9,441	9,161
Cash and cash equivalents	930,807	340,314
Current restricted cash	6,859	6,857
Current financial asset from Share Subscription Agreement	–	8,371
Other current assets	6,847	5,512
Current assets	**962,967**	**374,470**
Total assets	**1,043,093**	**442,514**
Equity and liabilities		
Share capital	223,462	185,399
Share premium account	648,830	357,402
Other reserves	(140)	(18)
Translation differences	(1,283)	(467)
Accumulated losses	(162,048)	(177,317)
Total equity	**708,822**	**364,999**
Pension liabilities	2,876	2,693
Provisions	51	55
Finance lease liabilities	23	63
Other non-current liabilities	1,984	2,291
Non-current deferred income	199,512	–
Non-current liabilities	**204,446**	**5,103**

	As at 30 September	As at 31 December
(thousands of €)	2016	2015
Finance lease liabilities	53	52
Trade and other payables	27,749	29,482
Current tax payable	2,108	2,583
Accrued charges	742	490
Deferred income	99,173	39,806
Current liabilities	**129,826**	**72,412**
Total liabilities	**334,272**	**77,515**
Total equity and liabilities	**1,043,093**	**442,514**

Consolidated cash flow statements
(unaudited)

	Nine months ended 30 September	
(thousands of €)	**2016**	2015
Cash and cash equivalents at beginning of year	**340,314**	**187,712**
Net income / loss (–)	8,067	(61,406)
Adjustments for:		
Tax expense / income (–)	71	(1,411)
Other net financial expense / income (–)	858	(438)
Fair value re-measurement of Share Subscription Agreement	(57,479)	–
Depreciation of property, plant and equipment	2,428	1,708
Amortization of intangible fixed assets	649	811
Net realized loss on foreign exchange transactions	(192)	(257)
Share-based compensation	7,201	2,716
Decrease in provisions	(5)	(80)
Increase in pension liabilities	183	220
Gain on sale of fixed assets	(14)	–
Operating cash flows before movements in working capital	**(38,232)**	**(58,137)**
Increase in inventories	(1)	(63)
Increase in receivables	(14,727)	(9,468)
Increase / decrease (–) in payables	(1,841)	2,317
Increase / decrease (–) in deferred income	258,878	(25,747)
Cash generated / used (–) in operations	**204,077**	**(91,097)**
Interest paid	(37)	(38)
Interest received	726	870
Income taxes paid	(477)	–
Net cash flows generated / used (–) in operating activities	**204,289**	**(90,265)**
Purchase of property, plant and equipment	(3,627)	(4,231)
Purchase of and expenditure in intangible fixed assets	(250)	(312)
Proceeds from disposal of property, plant and equipment	23	49
Increase (–) / decrease in restricted cash	(54)	2,259
Acquisition of shares available for sale	(2,750)	

	Nine months ended 30 September	
(thousands of €)	2016	2015
Net cash flows used in investing activities	**(6,657)**	**(2,235)**
Repayment of obligations under finance leases and other debts	(41)	(34)
Proceeds from capital and share premium increases, net of issue costs	391,785	259,859
Proceeds from capital and share premium increases from exercise of warrants	3,489	11,411
Net cash flows generated in financing activities	**395,233**	**271,236**
Effect of exchange rate differences on cash and cash equivalents	**(2,371)**	**96**
Increase in cash and cash equivalents	**590,493**	**178,832**
Cash and cash equivalents at end of reporting period	**930,807**	**366,545**

Consolidated statements of changes in equity
(unaudited)

(thousands of €)	Share capital	Share premium account	Translation differences	Other reserves	Accumul. losses	Total
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**
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**

Notes

Basis of preparation

These condensed interim financial statements have been prepared in accordance with IAS 34 *'Interim Financial Reporting,'* as adopted by the European Union. The condensed interim financial statements do not contain all information required for an annual report and should therefore be read in conjunction with Galapagos' Annual Report 2015.

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 2016 and 2015.

	Nine months ended 30 September	
(thousands of €)	2016	2015
Recognition of non-refundable upfront payments	17,562	26,419
Milestone payments	17,567	200
Reimbursement income	9,238	1,901
Other revenues	5,641	3,851
Total revenues	**50,009**	**32,371**

Revenues (€50.0 million vs €32.4 million for the same period last year) were higher due to milestone payments received from AbbVie for our CF program and to an increase of contractually agreed costs recharges on partnered programs (i.e. reimbursement income).

In the first nine months of 2016, reimbursement income amounting to €9.2 million mainly comprised of the reimbursement of certain research and development costs related to the development work under the Galapagos' collaboration agreements for our CF program with AbbVie for €5.6 million and for filgotinib with Gilead for €3.6 million.

Cost reimbursements resulting from Research & Development collaborations are recognized as reimbursement income in revenue as the related costs are incurred. The corresponding R&D expenses are included in the Research & Development expenditures in the consolidated financial statements.

The following table summarizes the upfront payments recognition for the nine months ended 30 September 2016 and 2015.

Agreement	Upfront received	Upfront received	Date of receipt	Revenue recognized, nine months ended 30 September 2016	Revenue recognized, nine months ended 30 September 2015	Outstanding balance in deferred income as at 30 September 2016
	(thousands of $)	(thousands of €)		(thousands of €)		
AbbVie Collaboration Agreement for CF	45,000	34,001	September 2013		11,401	
AbbVie Collaboration Agreement for RA and CD (filgotinib)	150,000	111,582	February 2012		12,045	
First Amendment to AbbVie Collaboration Agreement for RA and CD (filgotinib)	20,000	15,619	March 2013		2,973	
Gilead Collaboration Agreement for filgotinib	300,000	275,558	January 2016	14,500		261,058
Gilead Collaboration Agreement for filgotinib	N.A.	39,003(*)	January 2016	2,052		36,950
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		
Total recognition of non-refundable upfront payments				**17,562**	**26,419**	**298,008**

(*) deferred income of €39 million booked upon signing of the Share Subscription Agreement with Gilead as required under IAS 39.

Revenue recognized in 2015 from upfront non-refundable payments related to the CF collaboration agreement with AbbVie signed in September 2013 and the contract signed with AbbVie in February 2012 for our filgotinib program (including the extension signed in March 2013). Those upfront payments were fully recognized into revenues by the end of August 2015.

In September 2015 AbbVie decided not to opt in, which ended the collaboration agreement regarding our filgotinib program and consequently the period of our involvement. There are no outstanding commitments for us regarding this terminated collaboration for our filgotinib program.

On 16 December 2015, we entered into a global collaboration with Gilead Sciences, Inc. for the development and commercialization of the JAK1-selective inhibitor filgotinib for inflammatory indications. On 19 January 2016, we completed the closing of the global collaboration agreement with Gilead, in the framework of which Gilead made a $425 million (or €392 million) equity investment in Galapagos NV by subscribing to new shares at a price of €58 per share, including issuance premium. This resulted in Gilead owning 6,760,701 ordinary shares of Galapagos NV, representing 14.75% percent of the then-outstanding share capital of Galapagos. We also received a license fee of $300 million. In addition, we are eligible for payments of up to $755 million in development and regulatory milestones and $600 million in sales milestones, with tiered royalties starting at 20% and a profit split in co-promotion territories.

Finally, we agreed on a 20-80 cost split for development costs of the licensed product, i.e. we will support 20% of all development costs. As we do not expect to have a statutory taxable base in the foreseeable future, we did not recognize any additional deferred tax asset following the signing of this new collaboration.

The global collaboration with Gilead foresees continuous involvement from us, since we will perform certain R&D activities in the development phase of the filgotinib program; therefore, management assessed that the upfront payment of $300 million (or €275.6 million) received in January 2016 from Gilead should be spread as a function of the costs incurred for this program, applying the percentage of completion method. In the first nine months of 2016, €14.5 million revenues were recognized regarding this upfront payment.

In connection with the agreement with Gilead, we recognized a deferred income and an offsetting short-term financial asset (derivative) of €39 million upon signing of the Share Subscription Agreement with Gilead, as required under IAS 39. We refer to the note below for further detail. The deferred income will be recognized in function of the costs incurred for this program, applying the percentage of completion method, along with the upfront payment. In the first nine months of 2016, €2.1 million revenues were recognized in the income statement.

In 2016, Galapagos signed a license agreement with Thrombogenics for an integrin antagonist (formerly GLPG0187), for which an upfront payment of €1 million was invoiced and fully recognized, as Galapagos has no further involvement or obligation in the contract.

Other income

The following table summarizes our other income for the nine months ended 30 September 2016 and 2015.

	Nine months ended 30 September	
(thousands of €)	2016	2015
Grant income	1,451	2,430
Other income	13,581	12,418
Total other income	**15,031**	**14,848**

Other income was stable (€15.0 million vs €14.8 million last year) in the first nine months of 2016.

Results

We realized a net profit of €8.1 million for the first nine months of 2016, compared to a net loss of €61.4 million in the first nine months of 2015.

We reported an operating loss amounting to €48.5 million for the first nine months of 2016, compared to an operating loss of €63.3 million for the same period last year.

Our R&D expenses in the first nine months of 2016 were €96.7 million, compared to €96.9 million in 2015.

Our G&A and S&M expenses were €16.8 million in the first nine months of 2016, compared to €13.6 million in the first nine months of 2015. This increase mainly resulted from higher costs recognized in relation to the warrant plans as a result of the increase of our share price in the past year as well as a slight headcount increase and higher other operational costs

Financial results were primarily driven by the fair value re-measurement of the Share Subscription Agreement, which is explained under the next caption below. Net other financial costs in the first nine months of 2016 amounted to €0.9 million compared to a net other financial income of €0.4 million in 2015; this increase was primarily attributable to €2.4 million of exchange loss on our cash position in USD due to the fluctuation of the USD exchange rate in the first nine months of 2016.

Finally, the income tax expense in the first nine months of 2016 represented a tax expense in a French subsidiary while the income tax profit of €1.4 million in the first nine months of 2015 mainly reflected the setup of an additional deferred tax asset for a French subsidiary for €1.5 million. We had a total of €1.7 million deferred tax assets on the balance sheet for two subsidiaries at the end of the first nine months of 2015 and 2016.

Fair value re-measurement of Share Subscription Agreement

On 16 December 2015, Gilead and Galapagos entered into a global collaboration for the development and commercialization of filgotinib, in the framework of which Gilead committed to an upfront payment of $725 million consisting of a license fee of $300 million and a $425 million equity investment in Galapagos NV by subscribing to new shares at a price of €58 per share, including issuance premium. This agreement was effectively completed and entered into force on 19 January 2016, and the full payment was received.

In connection with this agreement, we recognized in December 2015 a short term financial asset (derivative) and an offsetting deferred income of €39 million upon signing of the Share Subscription Agreement with Gilead as required under IAS 39. This financial asset initially reflected the share premium that Gilead committed to pay above our closing share price on the day of entering into the Share Subscription Agreement. Under IAS 39 the fair value of the financial asset was re-measured at year-end and again upon closing of the Share Subscription Agreement on 19 January 2016, when the financial asset expired. Variations in fair value of the financial asset are recorded in the income statement.

The decrease in the fair value of the financial asset resulting from the increase in the Galapagos share price between signing of the Share Subscription Agreement and 31 December 2015 resulted in a negative, non-cash adjustment fair value charge of €30.6 million in the financial results of 2015.

The subsequent increase in the fair value of the financial asset resulting from the decrease in our share price between 1 January 2016 and 19 January 2016 resulted in a positive non-cash gain of €57.5 million in the financial result of the first quarter of 2016.

On 19 January 2016, the value of the financial asset at maturity amounted to €65.9 million, reflecting the share premium that Gilead paid above our closing share price on the day of the capital increase. This amount was composed of (1) the initial measurement on the day of entering into the Share Subscription Agreement for an amount of €39 million which was reported in deferred income and (2) the subsequent re-measurements of the financial asset, reported as financial result under IAS 39: €30.6 million fair value loss reported in the year 2015 and €57.5 million fair value gain reported in the first quarter of 2016, together a net fair value gain of €26.8 million. This financial asset expired on the effective date of the Share Subscription Agreement.

Segment information

Since the last quarter of 2015, the IFRS 8 threshold of 10% of the combined revenues, external and intersegment, of all segments was met by the external and internal revenues reported by our fee-for-service business Fidelta, located in Croatia. Consequently, there are two reportable segments: R&D and fee-for-service business.

	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[1]				(7,201)
Operating loss				**(48,482)**
Financial (expenses) / income				56,621
Result before tax				**8,138**
Income taxes				(71)
Net income / loss (–)				**8,067**

(1) Unallocated expenses consist mainly of expenses for warrant plans under IFRS 2.

	Segment information for the nine months ended 30 September 2015			
(thousands of €)	R&D	Fee-For-Services	Inter-segment elimination	Group
External revenue	28,580	3,791	–	32,371
Internal revenue	–	3,872	(3,872)	–
Other income	14,654	194	–	14,848
Revenues & other income	**43,234**	**7,857**	**(3,872)**	**47,219**
Segment result	**(58,894)**	**(2,014)**		**(60,908)**
Unallocated expenses[1]				(2,346)
Operating loss				**(63,254)**
Financial (expenses) / income				438
Result before tax				**(62,816)**
Income taxes				1,411
Net income / loss (–)				**(61,406)**

(1) Unallocated expenses consist of €2,716 thousand of expenses for warrant plans under IFRS 2 and €370 thousand of positive adjustment on depreciation charges reported by Fee-For-Services reflecting the expected useful lifetime of certain fixed assets following the purchase accounting of the acquisition of Fidelta in 2010.

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 €938.8 million on 30 September 2016.

A net increase of €590.5 million in cash and cash equivalents was recorded during the first nine months of 2016, compared to an increase of €178.8 million during the same period last year. Net cash flows from financing activities were generated for €395.2 million mainly through the share subscription by Gilead. Furthermore, a net cash inflow from operating activities was realized for €204.3 million in the first nine months of 2016 resulting from the license fee

of $300 million (€275.6 million) received from Gilead and, by difference, from an operating cash burn of €71.3 million. Finally, €6.7 million was used in investing activities and €2.4 million negative exchange rate differences were generated on cash and cash equivalents.

Restricted cash amounted to €7.9 million at the end of December 2015, and remained stable at the end of September 2016.

Restricted cash on 30 September 2016 was composed of (1) €0.4 million and €0.7 million bank guarantees on real estate lease obligations in Belgium and in the Netherlands respectively, and (2) €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 €0.3 million was accrued in March 2015 based on a preliminary estimate of the exposure.

Cash and cash equivalents amounted to €930.8 million at the end of September 2016 and comprised 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 3 months while monitoring all liquidity aspects. Cash and cash equivalents comprised €387.5 million of term deposits with an original maturity longer than 3 months but which are available upon one month notice period. Cash at banks were mainly composed of savings accounts and current accounts. We maintain our bank deposits in highly rated financial institutions to reduce credit risk. Cash invested in highly liquid money market funds represented €100.0 million and was aimed at meeting short-term cash commitments, while reducing the counterparty risk of investment.

	As at 30 September	As at 31 December
(thousands of €)	2016	2015
Cash at banks	443,307	240,292
Term deposits	387,520	100,000
Money market funds	99,979	–
Cash on hand	2	22
Total cash and cash equivalents	**930,807**	**340,314**

On 30 September 2016, our cash and cash equivalents included $124 million held in USD which could generate unrealized exchange gain or loss in our financial results in accordance with the fluctuation of the EUR/USD exchange rate as our functional currency is EUR. We expect to use this cash held in USD to settle our future payables in USD which will be primarily linked to our global collaboration with Gilead for the development of filgotinib.

Furthermore, our balance sheet holds an unconditional and unrestricted receivable from the French government (*Crédit d'Impôt Recherche*[2]) amounting to €39.0 million as of 30 September 2016, to be received in yearly tranches from 2016 to 2020. Our balance sheet also holds a receivable from the Belgian Government for R&D incentives amounting to €28.3 million as of 30 September 2016, to be received in yearly tranches from 2017 until 2026.

Capital increase

On 19 January 2016, Gilead made a $425 million equity investment in Galapagos NV by subscribing to 6,760,701 new ordinary shares at a price of €58 per share, including issuance premium.

Galapagos received €392.1 million of gross proceeds, decreased by €0.26 million of expenses, of which all has been paid at 30 September 2016. The total net cash proceeds from the share subscription by Gilead amounts to €391.9 million.

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

The €65.9 million current financial asset from the Share Subscription Agreement reflecting the premium that Gilead paid compared to the closing price of our shares on 19 January 2016 were derecognized via the share premium account.

On 1 April 2016, warrants were exercised at various exercise prices (with an average exercise price of €10.70 per warrant) resulting in a share capital increase (including issuance premium) of €1,409.3 thousand and the issuance of 131,695 new shares. The closing price of the Galapagos share on this date was €36.64.

On 19 May 2016, warrants were exercised at various exercise prices (with an average exercise price of €10.49 per warrant) resulting in a share capital increase (including issuance premium) of €1,476.4 thousand and the issuance of 140,770 new shares. The closing price of the Galapagos share on this date was €45.41.

On 19 September 2016, warrants were exercised at various exercise prices (with an average exercise price of €10.00 per warrant) resulting in a share capital increase (including issuance premium) of €603.3 thousand and the issuance of 60,320 new shares. The closing price of the Galapagos share on this date was €58.62.

On 30 September 2016, Galapagos NV's share capital was represented by 46,169,828 shares. All shares were issued, fully paid up and of the same class.

(thousands of €, except number of shares)	Number of shares	Share capital	Share premium	Share capital and share premium
On 1 January 2016	**39,076,342**	**185,399**	**357,402**	**542,801**
19 January 2016: share subscription from Gilead				
Ordinary shares (fully paid)	6,760,701	36,575	355,546	392,121
Derecognition of financial asset from Share Subscription Agreement			(65,850)	(65,850)
Capital increase expenses (fully paid)		(269)		(269)
Total share subscription by Gilead	**6,760,701**	**36,306**	**289,696**	**326,002**
1 April 2016: exercise of warrants	**131,695**	**668**	**741**	**1,409**
19 May 2016: exercise of warrants	**140,770**	**762**	**715**	**1,476**
19 September 2016: exercise of warrants	**60,320**	**326**	**277**	**603**
On 30 September 2016	**46,169,828**	**223,462**	**648,830**	**872,292**

The number of warrants outstanding per 30 September 2016 amounted to 3,552,657, of which 755,954 were exercisable. During the third quarter of 2016, 634,250 warrants were granted, 2,500 warrants were forfeited and 60,320 were exercised. All warrants offered to the members of the Board of Directors and of the Executive Committee during the third quarter of 2016 (i.e. an aggregate amount of 327,500 warrants) were accepted as per 30 September 2016.

Contingencies and commitments

Contractual obligations and commitments

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

On 30 September 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	28,412	4,150	6,780	5,666	11,816
Purchase commitments	21,784	21,103	681	–	–
Total contractual obligations & commitments	**50,196**	**25,253**	**7,461**	**5,666**	**11,816**

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. (the "Buyer") for a total consideration of up to €134 million. The Buyer 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 closing of the transaction was not obtained. Approximately 5% of the total consideration, including price adjustments, is being held on an escrow account. 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 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 guarantor for a limited transitional period in respect of the lease obligations for certain U.K. premises amounting to £4 million future rent payments. The Buyer will fully indemnify us against all liabilities arising in connection with the lease obligation. We evaluated the risk to be remote. Finally, following common practice, we have given representations and warranties which are capped and limited in time (since 1 April 2016, the Buyer can only introduce a claim covered by the Tax Deed (during a period of 5 years), other claims related to the sale cannot be submitted anymore).

In the course of 2008, a former director of one of the subsidiaries sued for wrongful termination and sought damages of €1.1 million. We believe that the amount of damages claimed is unrealistically high. Considering the defense elements provided and the recent court judgment in our favor, our Board and management evaluated the risk to be remote to possible, but not likely. Accordingly, it was decided not to record any provision in 2016, 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 2015, except for the adoption of new standards and interpretations described below.

New standards and interpretations applicable for the annual period beginning on 1 January 2016

- Improvements to IFRS (2012-2014) (applicable for annual periods beginning on or after 1 January 2016)
- Amendments to IFRS 11 Joint Arrangements – Accounting for Acquisitions of Interests in Joint Operations (applicable for annual periods beginning on or after 1 January 2016)
- Amendments to IAS 1 Presentation of Financial Statements – Disclosure Initiative (applicable for annual periods beginning on or after 1 January 2016)
- Amendments to IAS 16 and IAS 38 Property, Plant and Equipment and Intangible Assets – Clarification of Acceptable Methods of Depreciation and Amortization (applicable for annual periods beginning on or after 1 January 2016)

- Amendment to IAS 27 Separate Financial Statements – Equity Method (applicable for annual periods beginning on or after 1 January 2016)

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

Seasonality

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

Events after the end of the reporting period

They 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 25 October 2016.

Report on review of the consolidated interim financial information for the nine-month period ended 30 September 2016

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 2016, 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 1,043,093 (000) EUR and the consolidated condensed income statement shows a consolidated profit for the period then ended of 8,067 (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, 26 October 2016
The Statutory Auditor

DELOITTE Bedrijfsrevisoren / Réviseurs 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

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. ACR 50 and ACR70 reflect the same, for 50% and 70% response rates, respectively

ADR

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

Atherogenic index

Total cholesterol over HDL ratio. Improvement of the atherogenic index may be a forecast of cardiovascular health

Atopic dermatitis

Also known as atopic eczema. A type of inflammation of the skin resulting in itchy, red, swollen, and cracked skin

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

BID dosing

Twice daily dosing (bis in die)

Bioavailability

Assessment of the amount of (candidate) drug 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 (desired) 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

Candidate drug

Substance that has satisfied the requirements of early pre-clinical testing and has been selected for development, starting with formal preclinical safety evaluation followed by clinical testing for the treatment of a certain disorder in humans

CFTR

Cystic **F**ibrosis **T**ransmembrane conductance **R**egulator 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 (such as lungs and bowels) 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

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 (such as lungs and bowels) 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

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 surface expression of the CFTR protein 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 treat CF patients with the most prevalent mutation of CFTR

Crohn's disease (CD)

See IBD

CRP

C-reactive protein is a protein found in the blood, the levels of which rise in response to inflammation

Cystic fibrosis (CF)

A life-threatening genetic disease that affects approximately 80,000 people worldwide. Although the disease affects the entire body, difficulty breathing is the most serious symptom as a result of clogging of the airways due to mucus build-up and frequent lung infections

DAS28

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

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

Dose-range finding study

Phase 2 clinical study exploring the trade-offs between efficacy and safety among various doses of treatment in patients. Results are used to determine doses for later studies

Drug development

See: Development

Drug discovery

See: Discovery

Efficacy

Effectiveness for intended use

EMA

European Medicines Agency, in charge of European market authorization of new medication

FDA

The U.S. Food and Drug Administration is an agency responsible for protecting and promoting public health, assessing whether drug candidates can be tested in clinical studies in the U.S. 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

FIH

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

Filgotinib

Formerly known as GLPG0634. Small molecule selective JAK1 inhibitor which showed excellent results in rheumatoid arthritis and Crohn's disease patients in Phase 2 trials. Filgotinib is partnered with Gilead. Galapagos and Gilead started a Phase 3 trials with filgotinib in RA and expect to start first dosing in Ph 3 in Crohn's disease and Phase 2/3 in ulcerative colitis in Q4 2016

FSMA

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

FTE

Full-time equivalent; a way to measure 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

Drug candidate known as filgotinib

GLPG1690

A novel drug candidate targeting autotaxin, with potential applications in idiopathic pulmonary fibrosis. Fully proprietary to Galapagos. A Phase 2a proof-of-concept study in IPF is ongoing

GLPG1837

A potentiator drug candidate currently in Phase 2 in Class III cystic fibrosis mutation patients

GLPG1972

A novel mode-of-action drug candidate that is part of the osteoarthritis alliance with Servier. GLPG1972 was well-tolerated and showed no emerging safety signals in a Phase 1 study with healthy volunteers. In addition, GLPG1972 showed a 50% reduction in a relevant osteoarthritis biomarker within 14 days in these volunteers

GLPG2222

A corrector drug candidate that was well-tolerated, with no emerging safety signals observed in healthy volunteers in a Phase 1 study

GLPG2451

A potentiator drug candidate currently in Phase 1 in healthy volunteers

GLPG2534

A preclinical candidate with an undisclosed mechanism-of-action to be developed in atopic dermatitis

GLPG2737

A second-generation corrector drug candidate (C2) currently in preclinical development

GLPG2851

A preclinical candidate (C1) currently in preclinical development

GLPG2938

A preclinical candidate with an undisclosed mechanism-of-action to be developed in IPF

IBD

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

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

Intersegment

Occurring between the different operations of a company

Investigational New Drug (IND) application

United States Federal law requires a pharmaceutical company to obtain an exemption to ship an experimental drug across state lines, usually to clinical investigators, before a marketing application for the drug has been approved. The IND is the means by which the sponsor technically obtains this exemption, allowing them to perform clinical studies

IPF

Idiopathic pulmonary fibrosis. A chronic and ultimately fatal disease characterized by a progressive decline in lung function. Pulmonary fibrosis involves scarring of lung tissue and is the cause of shortness of breath. Fibrosis is usually associated with a poor prognosis. The term "idiopathic" is used because the cause of pulmonary fibrosis is still unknown

JAK

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

Milestone

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

MTX

Methotrexate; a first-line therapy for inflammatory diseases

Molecule collections

Chemical libraries, usually consisting of drug-like small molecules that are designed to interact with to specific target classes. These collections can be screened against a target to generate initial "hits" in a drug discovery program

MOR106

A novel antibody targeting IL-17C that is being developed in atopic dermatitis and is part of the alliance with MorphoSys. MOR106 will readout Phase 1 results in H2 2017

NDA

New Drug Application

Oral dosing

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

Osteoarthritis

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 a potential new treatment 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 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 and/or placebo; serves as the principal basis for regulatory approval

Placebo-controlled

A clinical study can only show statistical significance when the effect of a candidate drug is measured against that of a placebo, a substance having no pharmacological effect but administered as a control in testing experimentally or clinically the efficacy of a biologically active preparation

Potentiator drug

Drug that restores the CFTR 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. Galapagos and AbbVie are planning to combine a potentiator with two correctors to treat CF patients with the most prevalent mutation of CFTR

Pre-clinical

Stage of drug research development, undertaken prior to the administration of the drug to humans. Consists of in vitro and in vivo screening, pharmacokinetics, toxicology, chemical upscaling and de development of a pharmacological delivery mechanism

Pre-clinical candidate (PCC)

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

Proof-of-concept (POC)

First study in patients to investigate the efficacy and safety of a candidate drug

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 collaboration 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

Technology access fee

License payment made in return for access to specific technology (e.g. compound or virus collections)

TNF

Tumor necrosis factor

Ulcerative colitis (UC)

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

Financial calendar

3 March 2017

Full Year 2016 Results

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

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