
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the month of November 2021

Commission File Number: 001-37384

GALAPAGOS NV
(Translation of registrant's name into English)

**Generaal De Wittelaan L11 A3
2800 Mechelen, Belgium**
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F. Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

Third Quarter 2021 Results

On November 4, 2021, the Registrant announced its unaudited third quarter results for 2021, which are further described in a Q3 2021 report.

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release dated November 4, 2021
99.2	Q3 Report 2021

The information contained in this Report on Form 6-K, including the exhibits, except for the quotes of Onno van de Stolpe and the quote of Bart Filius contained in Exhibit 99.1, is hereby incorporated by reference into the Company's Registration Statements on Forms F-3 (File No. 333-230639) and S-8 (File Nos. 333-204567, 333-208697, 333-211834, 333-215783, 333-218160, 333-225263, 333-231765, 333-249416 and 333-260500).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: November 8, 2021

GALAPAGOS NV

(Registrant)

/s/ Marie-Théodora Vandewiele

Marie-Théodora Vandewiele

Company Secretary



Galapagos reports commercial and operational progress at Q3 financial results

- **First nine months 2021 financial results:**
 - **Group revenues of €317.9 million**
 - **Operating loss of €175.7 million**
 - **Net loss of €119.6 million**
 - **Cash and current financial investments of €4.9 billion on 30 September 2021**
- **Filgotinib launch in RA on track with reimbursement secured in 14 countries**
- **Reduced 2021 cash burn guidance by €50 million to €530-€570 million**

Webcast presentation tomorrow, 5 November 2021, at 13.00 CET / 8 AM ET, www.glp.com, +32 2 793 38 47, code 4987105

Mechelen, Belgium; 4 November 2021, 22.01 CET; regulated information – Galapagos NV (Euronext & NASDAQ: GLPG) is pleased to report on its commercial launch of filgotinib in Europe. The company is moving forward with its revised R&D strategy and operational restructuring announced in May, resulting in a downward adjustment of the cash burn by €50 million. The unaudited Q3 financial and operational results are further detailed in the Q3 2021 report available on the website, www.glp.com.

“This quarter we achieved key steps in our growing commercial business in Europe, while moving earlier-stage R&D programs forward. We continue to deliver on our revised strategy, accelerating the savings program announced at the first quarter results. We are focused on nominating a successor to lead our company going forward following my eventual retirement as CEO,” said Onno van de Stolpe, CEO of Galapagos. “Supported by our strong balance sheet and long-term R&D collaboration with Gilead, we believe that Galapagos remains well-positioned for future growth.”

“After years of hard work by so many, we are very excited to bring Jyseleca to market as a new treatment option for people living with rheumatoid arthritis (RA). As per 30 September 2021, we booked €6.1 million in net sales for Jyseleca, for a total of €15.8 million together with Gilead. Encouraged by these sales of our first commercial product and its positioning in the growing JAK market in Europe, we are confident in the commercial potential of our Jyseleca franchise in Europe. Following the positive CHMP opinion for filgotinib for the treatment of patients with ulcerative colitis (UC), we expect a decision by the European Commission (EC) before year-end, and if granted, we are ready to go full steam ahead with the commercial roll-out in a second indication,” added Bart Filius, President and COO of Galapagos. “Following our strategic operational review in March 2021, we implemented a cost savings program of €150 million on a full year basis. As a result of an acceleration of this program, we revise our guidance for full year 2021 operational cash burn¹ from €580 to €620 million to €530 to €570 million.”

Key figures third quarter report 2021 (unaudited)
 (€ millions, except basic & diluted loss per share)

	30 September 2021 group total	30 September 2020 group total (*)
Product net sales	6.1	—
Collaboration revenues	311.7	321.9
Total revenues	317.9	321.9
Cost of sales	(0.7)	—
R&D expenditure	(378.0)	(392.2)
G&A ⁱⁱ and S&M ⁱⁱⁱ expenses	(151.3)	(132.4)
Other operating income	36.3	35.0
Operating loss	(175.7)	(167.7)
Fair value re-measurement of financial instruments	3.0	(8.1)
Net other financial result	30.6	(75.3)
Income taxes	0.3	(0.7)
Net loss from continuing operations	(141.8)	(251.8)
Net profit from discontinued operations	22.2	4.2
Net loss of the period	(119.6)	(247.6)
Basic and diluted loss per share (€)	(1.83)	(3.81)
Current financial investments and cash and cash equivalents	4,874.2	5,308.6

(*) The 2020 comparatives have been restated to consider the impact of classifying the Fidelta business as discontinued operations in 2020.

Details of the financial results

Due to the sale of our fee-for-service business (Fidelta) to Selvita on 4 January 2021 for a total consideration of €37.1 million (including customary adjustments for net cash and working capital), the results of Fidelta are presented as “Net profit from discontinued operations” in our unaudited condensed consolidated income statements for the nine months ended 30 September 2021 and 30 September 2020.

Revenues from continuing operations

Our revenues from continuing operations for the first nine months of 2021 amounted to €317.9 million compared to €321.9 million in the first nine months of 2020.

We reported net sales of Jyseleca for the first nine months of 2021 amounting to €6.1 million (€5.7 million in the third quarter of 2021), which reflects the sales booked by Galapagos after the transition from Gilead. Total sales of Jyseleca in Europe by both companies for the first nine months of 2021 is €15.8 million.

Collaboration revenues amounted to €311.7 million for the first nine months of 2021, compared to €321.9 million for the same period last year. This was mainly driven by the recognition of upfront consideration and milestone payments received in the scope of the collaboration with Gilead for filgotinib, amounting to €136.4 million for the first nine months of 2021 (€145.9 million for the same period last year). The decrease in revenue recognition was primarily due to a negative cumulative catch up of revenue triggered by the recent agreement under which Galapagos will assume operational and financial responsibility for the ongoing DIVERSITY clinical study. This decrease was partly compensated by additional consideration from Gilead related to the renegotiated collaboration, when compared to the same period last year. The revenue recognition related to the exclusive access rights for Gilead to our drug discovery platform amounted to €173.3 million for the first nine months of 2021 (€170.7 million for the same period last year).

Our deferred income balance on 30 September 2021 includes €1.8 billion allocated to our drug discovery platform that is recognized linearly over 10 years, and €0.7 billion allocated to the filgotinib development that is recognized over time until the end of the development period.

Results from continuing operations

We realized a net loss from continuing operations of €141.8 million for the first nine months of 2021, compared to a net loss of €251.8 million for the first nine months of 2020.

We reported an operating loss amounting to €175.7 million for the first nine months of 2021, compared to an operating loss of €167.7 million for the same period last year.

Cost of sales related to Jyseleca net sales in the first nine months of 2021 amounted to €0.7 million.

Our R&D expenditure in the first nine months of 2021 amounted to €378.0 million, compared to €392.2 million for the first nine months of 2020. This decrease was primarily explained by winding down of our ziritaxestat (IPF), MOR106 (atopic dermatitis), and GLPG1972 (OA) programs and by reduced spend on our other programs. This was partly offset by costs increases for our filgotinib and Toledo (SIKi) programs, on a nine months comparison basis. Personnel costs increased primarily because of an increased average headcount compared to the same period last year, and increased costs of our subscription right plans.

Our S&M and G&A expenses were respectively €46.6 million and €104.7 million in the first nine months of 2021, compared to respectively €44.1 million and €88.3 million in the first nine months of 2020. This increase was primarily due to an increase in personnel costs and other operating expenses mainly driven by the commercial launch of filgotinib in Europe. This increase was partly compensated by higher cost recharges from us to Gilead in the scope of our commercial cost sharing for filgotinib in Europe.

Other income (€36.3 million vs €35.0 million for the same period last year) increased, mainly driven by higher grant income.

We reported a non-cash fair value gain from the re-measurement of initial warrant B issued to Gilead, amounting to €3.0 million, mainly due to the decreased implied volatility of the Galapagos share price and its evolution between 31 December 2020 and 30 September 2021.

Net other financial income in the first nine months of 2021 amounted to €30.6 million, compared to net other financial loss of €75.3 million for the first nine months of 2020, which was primarily attributable to €54.9 million of currency exchange gain on our cash and cash equivalents and current financial investments in U.S. dollars, to €10.1 million of negative changes in (fair) value of current financial investments and financial assets and to €8.5 million of interest expenses. The other financial expenses also contained the effect of discounting our long term deferred income of €7.2 million.

Results from discontinued operations

The net profit from discontinued operations for the nine months ended 30 September 2021 consisted of the gain on the sale of Fidelta, our fee-for-services business, for €22.2 million.

Group net results

We reported a group net loss for the first nine months of 2021 of €119.6 million, compared to a group net loss of €247.6 million for the first nine months of 2020.

Cash position

Current financial investments and cash and cash equivalents totaled €4,874.2 million on 30 September 2021, as compared to €5,169.3 million on 31 December 2020.

Total net decrease in cash and cash equivalents and current financial investments amounted to €295.2 million during the first nine months of 2021, compared to a net decrease of €472.2 million during the first nine months of 2020. This net decrease was composed of (i) €376.7 million of operational cash burn, (ii) offset by €2.7 million of cash proceeds from capital and share premium increase from exercise of subscription rights in the first nine months of 2021, (iii) €7.2 million negative changes in (fair) value of current financial investments and €57.3 million of mainly positive exchange rate differences, (iv) €28.7 million cash in from disposal of subsidiaries, net of cash disposed.

Our balance sheet on 30 September 2021 also held a receivable from the French government (Crédit d'Impôt Rechercheiv) and a receivable from the Belgian Government for R&D incentives, for a total of both receivables of €149.3 million.

Outlook 2021

Going forward, we continue to build our filgotinib franchise throughout Europe, and remain on track to complete the transition of the full European commercial operations for filgotinib from our collaboration partner Gilead to us by year-end. We anticipate an approval decision from the EC and Great Britain's Medicines and Healthcare products Regulatory Agency (MHRA) for filgotinib for the treatment of UC, which, if approved, would add a second indication to our growing commercial footprint in Europe.

Following the positive topline Phase 1b data from our TYK2 inhibitor GLPG3667, we are running an extended dose escalation study in healthy volunteers, and we are preparing to launch a Phase 2b trial in Psoriasis and a Phase 2 trial in UC in 2022.

We are advancing our SIK3 inhibitor GLPG4399 in healthy volunteers this year, and we aim to move a follow-up SIK2/3 preclinical candidate into the clinic in 2022.

By year-end we also intend to finalize recruitment into the GLPG2737 Phase 2a trial in autosomal dominant polycystic kidney disease (ADPKD), an indication with important unmet medical need.

Meanwhile we continue to apply lessons learned from the strategic exercise announced at Q1 to the development of our deep pipeline, and we diligently evaluate business development opportunities in our core therapeutic areas of inflammation and fibrosis.

Following our strategic review of operations in March 2021, we implemented a cost savings program of €150 million on a full year basis. As a result of an acceleration of this program, we revise our guidance for full year 2021 operational cash burn from €580 to €620 million to €530 to €570 million.

Third quarter report 2021

Galapagos' financial report for the first nine months ended 30 September 2021, including details of the unaudited consolidated results, is accessible via www.glp.com/financial-reports.

Conference call and webcast presentation

Galapagos will conduct a conference call open to the public tomorrow, 5 November 2021, at 13:00 CET / 8 AM ET, which will also be webcasted. To participate in the conference call, please call one of the following numbers ten minutes prior to commencement:

CODE: 4987105

Standard International:	+44 2071 928338
USA:	+1 646 741 3167
UK:	+44 844 481 9752
Netherlands:	+31 207 95 66 14
France:	+33 1 70 70 0781
Belgium:	+32 2 793 38 47

A question and answer session will follow the presentation of the results. Go to www.glp.com to access the live audio webcast. The archived webcast will also be available for replay shortly after the close of the call.

Financial calendar

24 February 2022	Full year 2021 results	(webcast 25 February 2022)
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About Galapagos

Galapagos NV discovers, develops, and commercializes small molecule medicines with novel modes of action. Our pipeline comprises discovery through Phase 3 programs in inflammation, fibrosis and other indications. Our ambition is to become a leading global biopharmaceutical company focused on the discovery, development, and commercialization of innovative medicines. More information at www.glp.com.

Except for filgotinib's approval for the treatment of rheumatoid arthritis by the European Commission, Great Britain's Medicines and Healthcare products Regulatory Agency and Japanese Ministry of Health, Labour and Welfare, our drug candidates are investigational; their efficacy and safety have not been fully evaluated by any regulatory authority.

Jyseleca® is a trademark of Galapagos NV and Gilead Sciences, Inc. or its related companies.

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Forward-looking statements

This release may contain forward-looking statements, including, among other things, statements regarding the global R&D collaboration with Gilead, the amount and timing of potential future milestones, opt-in and/or royalty payments by Gilead, Galapagos' strategic R&D ambitions, including progress on our fibrosis portfolio and SIK platform, and potential changes of such ambitions, the guidance from management (including guidance regarding the expected operational use of cash during financial year 2021), financial results, statements regarding the expected timing, design and readouts of ongoing and planned clinical trials, including recruitment for trials and topline results for our trials and studies in our inflammation portfolio, statements regarding the strategic re-evaluation, statements relating to interactions with regulatory authorities, the timing or likelihood of additional regulatory authorities' approval of marketing authorization for filgotinib for RA, UC or any other indication, including UC and IBD indications for filgotinib in Europe, Great-Britain, Japan, and the U.S., such additional regulatory authorities requiring additional studies, statements regarding changes in our management board and key personnel, our ability to effectively transfer knowledge during this period of transition, the search and recruitment of a suitable successor to lead our organization and a CSO, the risk that Galapagos will be unable to successfully achieve the anticipated benefits from its leadership transition plan, the possibility that Galapagos will encounter challenges retaining or attracting talent, the timing or likelihood of pricing and reimbursement interactions for filgotinib, statements relating to the build-up of our commercial organization, statements and expectations regarding commercial sales for filgotinib, the expected impact of COVID-19, and our strategy, business plans and focus. Galapagos cautions the reader that forward-looking statements are not guarantees of future performance. Forward-looking statements 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 industry results, to be materially different from any historic or future results, financial conditions and liquidity, performance or achievements expressed or implied by such forward-looking statements. In addition, even if Galapagos' results, performance, 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 our expectations regarding our 2021 revenues and financial results and our 2021 operating expenses may be incorrect (including because one or more of its assumptions underlying its expense expectations may not be realized), Galapagos' expectations regarding its development programs may be incorrect, the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including the risk that data from Galapagos' ongoing and planned clinical research programs in rheumatoid arthritis, Crohn's disease, ulcerative colitis, idiopathic pulmonary fibrosis, osteoarthritis, other inflammatory indications and kidney disease may not support registration or further development of its product candidates due to safety or efficacy concerns or other reasons), Galapagos' reliance on collaborations with third parties (including our collaboration partner Gilead), the timing of and the risks related to the implementation of the transition of the European commercialization responsibility of filgotinib from Gilead to us, the risk that the transition will not be completed on the currently contemplated timeline or at all, including the transfer of the supply chain, and the risk that the transition will not have the currently expected results for our business and results of operations, estimating the commercial potential of our product candidates and Galapagos' expectations regarding the costs and revenues associated with the transfer of European commercialization rights to filgotinib may be incorrect, the risk that Galapagos will not be able to continue to execute on its currently contemplated business plan and/or will revise its business plan, and the uncertainties

relating to the impact of the COVID-19 pandemic. A further list and description of these risks, uncertainties and other risks can be found in Galapagos' Securities and Exchange Commission (SEC) filings and reports, including in Galapagos' most recent annual report on Form 20-F filed with the SEC and other filings and reports filed by Galapagos with the SEC. 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 forward-looking statements, unless specifically required by law or regulation.

- i The operational cash burn (or operational cash flow if this performance measure is positive) is equal to the increase or decrease in our cash and cash equivalents (excluding the effect of exchange rate differences on cash and cash equivalents), minus:
- the net proceeds, if any, from share capital and share premium increases included in the net cash flows generated from/used in (-) financing activities
 - the net proceeds or cash used, if any, in acquisitions or disposals of businesses; the movement in restricted cash and movement in current financial investments, if any, included in the net cash flows generated from/used in (-) investing activities.

This alternative performance measure is in our view an important metric for a biotech company in the development stage. The operational cash burn for the nine months ended 30 September 2021 amounted to €376.7 million and can be reconciled to our cash flow statement by considering the increase in cash and cash equivalents of €650.7 million, adjusted by (i) the cash proceeds from capital and share premium increase from the exercise of subscription rights by employees for €2.7 million, (ii) the net sale of current financial investments amounting to €996.0 million, and (iii) the cash in from sale of subsidiaries, net of cash disposed, of €28.7 million.

- ii General and administrative
- iii Sales and marketing
- IV Crédit d'Impôt Recherche refers to an innovation incentive system underwritten by the French government

Forward with confidence

Q3 Report 2021

Galápagos
Pioneering for patients



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The Galapagos group

An overview of
Galapagos, its strategy
and portfolio in the first
nine months of 2021

Forward with confidence

Letter from the management

Dear shareholders,

This quarter we achieved key steps in our growing commercial business in Europe, while moving earlier-stage R&D programs forward. We continue to deliver on our revised strategy, while accelerating the savings program announced at the first quarter results.

We are proud of the progress made with our filgotinib (Jyseleca®) franchise. One year after receiving approval for filgotinib in Europe in rheumatoid arthritis (RA), we secured reimbursement in 14 countries, including Germany, France, Spain, Italy, and Great Britain. Meanwhile, the process of transitioning all commercial activities for filgotinib, including the European marketing authorization (MA) for Jyseleca, from Gilead to us is on track to be completed by year-end. After years of hard work by so many, we are very excited to bring a new treatment option to patients living with RA, and for the first time in the history of our company, we report on sales achieved without our own commercial organization. As per 30 September 2021, we booked €6.1 million in net sales for Jyseleca, for a total of €15.8 million together with Gilead, building confidence in the potential of our filgotinib franchise in Europe and in Galapagos' commercial capabilities.

Recently, we received the positive opinion issued by the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) for filgotinib as treatment for adults with moderately to severely active ulcerative colitis (UC). We anticipate a decision for filgotinib in UC from the European Commission (EC) and Great Britain's Medicines and Healthcare products Regulatory Agency (MHRA) before year-end. If granted, this would add a second indication for filgotinib, and we are ready to go full steam ahead with the commercial roll out in UC throughout Europe.

On the clinical development side of filgotinib, we recently announced the completion of patient enrollment for our DIVERSITY Phase 3 program in patients with Crohn's disease (CD), with 1,374 patients enrolled across 369 sites globally. This study evaluates the efficacy and safety of filgotinib on clinical remission and endoscopic response in a 10-week induction study, followed by a 47-week maintenance study, with topline results anticipated in the first half of 2023. The full recruitment is an important milestone for the DIVERSITY program, which has the potential to provide robust evidence to assess the use of filgotinib as a new treatment option for people suffering from CD.

We recently announced that we will be solely responsible for all development activities for the ongoing DIVERSITY study and its long-term extension study starting on 1 April 2022. Gilead will make a one-time payment of \$15 million to support Galapagos with the remaining DIVERSITY trial costs, and should the European Commission (EC) grant regulatory approval of filgotinib for the treatment of CD based on data from the DIVERSITY trial, royalties payable by Galapagos to Gilead will be reduced by 30% across all filgotinib indications, or 5.6% to 10.5% of net sales in Europe. These royalties are payable as of 2024.

In early Q3, we also announced positive topline data from the Phase 1b trial with GLPG3667, our proprietary selective tyrosine kinase 2 (TYK2) compound in psoriasis (Pso). We are currently running a further dose escalation study in healthy volunteers, and we aim to launch both a Phase 2b dose finding study in Pso and a Phase 2 study in UC with GLPG3667 in 2022.

Our earlier-stage inflammation pipeline continues to progress as well, and in particular our salt inducible kinase (SIK) program. At UEGW¹, we presented additional preclinical data showing evidence of the potential dual mode of action of SIK2/3. We plan to bring an SIK2/3 molecule with optimized pharmacology into a healthy volunteer Phase 1 study in 2022.

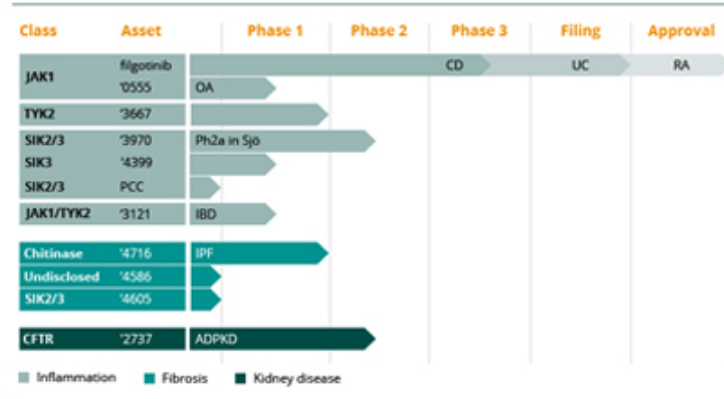
¹ United European Gastroenterology Week

Moving beyond inflammation, we are on track to complete recruitment for the Phase 2 MANGROVE study with GLPG2737 in patients with autosomal dominant polycystic kidney disease (ADPKD) by year-end. ADPKD remains a high unmet medical need, and we look forward to reporting topline results in the first half of 2023.

This quarter we also announced key management changes. After 23 years of leading this company, my time as CEO at the helm of Galapagos will come to an end. I plan to retire after achieving a seamless hand over to a new CEO. The supervisory board is conducting an external search for my replacement, while we continue our search for a new CSO. I am convinced that great candidates will be selected to lead Galapagos into a successful future.

Meanwhile we continue to progress with our differentiated, refocused portfolio of novel target-based assets in our core areas of inflammation, fibrosis, and kidney disease:

Differentiated pipeline



Operational overview H1 2021

We refer to our [H1 2021 report](#).

Operational overview Q3 2021

In inflammation

- We observed activity with TYK2 inhibitor GLPG3667 in Pso, with a generally safe and well tolerated profile, and launched a dose escalation study in healthy volunteers, with the aim to start a Phase 2b study in Pso and a Phase 2 study in UC in 2022
- We reported on biological activity with SIK2/3 inhibitor GLPG3970 in inflammation, and more particularly in the CALOSOMA Phase 1b study in Pso and the SEA TURTLE Phase 2a study in UC
- We nominated a new preclinical SIK2/3 candidate for early development in inflammation

Corporate & other

- We announced the planned retirement of Onno van de Stolpe, our founder and CEO, and the initiation of the search for an external successor, in addition to the previously announced search for a new CSO
- We raised €0.15 million from subscription right exercises

Recent events

- We received a positive CHMP opinion for filgotinib for the treatment of moderate to severe UC
- Following the first read-outs with GLPG3970, we decided to terminate the TAPINOMA Phase 1b study with GLPG3970 in systemic lupus erythematosus due to low likelihood of success and poor recruitment in the trial. We continue to execute on the GLIDER Phase 2a study in Sjögren's disease, with data expected in 2022
- We announced that Galapagos will assume operational and financial responsibility for the ongoing DIVERSITY clinical study in CD and its long-term extension study. Gilead will make a one-time payment of \$15 million to Galapagos to support the costs of the DIVERSITY clinical program, and if the EC grants regulatory approval of filgotinib for the treatment of CD based on data from the DIVERSITY trial, royalties payable by Galapagos to Gilead will be reduced by 30% across all filgotinib indications

Q3 2021 financial result

Details of financial results

Due to the sale of our fee-for-service business (Fidelta) to Selvita on 4 January 2021 for a total consideration of €37.1 million (including customary adjustments for net cash and working capital), the results of Fidelta are presented as "Net profit from discontinued operations" in our unaudited condensed consolidated income statement.

Revenues from continuing operations

Our revenues from continuing operations for the first nine months of 2021 amounted to €317.9 million, compared to €321.9 million for the first nine months of 2020.

We reported net sales of Jyseleca for the first nine months of 2021 amounting to €6.1 million (€5.7 million in the third quarter of 2021), which reflects the sales booked by Galapagos after the transition from Gilead. Total sales of Jyseleca in Europe by both companies for the first nine months of 2021 are €15.8 million.

Collaboration revenues amounted to €311.7 million for the first nine months of 2021, compared to €321.9 million for the same period last year. This was mainly driven by the recognition of upfront consideration and milestone payments received in the scope of the collaboration with Gilead for filgotinib, amounting to €136.4 million for the first nine months of 2021 (€145.9 million for the same period last year). The decrease in revenue recognition was primarily due to a negative cumulative catch up of revenue triggered by the recent agreement under which Galapagos will assume operational and financial responsibility for the ongoing DIVERSITY clinical study. This decrease was partly compensated by additional consideration from Gilead related to the renegotiated collaboration when compared to the same period last year. The revenue recognition related to the exclusive access rights for Gilead to our drug discovery platform amounted to €173.3 million for the first nine months of 2021 (€170.7 million for the same period last year).

Results from continuing operations

We realized a net loss from continuing operations of €141.8 million for the first nine months of 2021, compared to a net loss of €251.8 million for the first nine months of 2020.

We reported an operating loss amounting to €175.7 million for the first nine months of 2021, compared to an operating loss of €167.7 million for the same period last year.

Cost of sales related to Jyseleca net sales in the first nine months of 2021 amounted to €0.7 million.

Our R&D expenditure in the first nine months of 2021 amounted to €378.0 million, compared to €392.2 million for the first nine months of 2020. This decrease was primarily explained by winding down of our ziritaxestat (IPF), MOR106 (atopic dermatitis), and GLPG1972 (OA) programs and by reduced spend on our other programs. This was partly offset by costs increases for our filgotinib and Toledo (SIK) programs, on a nine months comparison basis. Personnel costs increased primarily because of an increased average headcount compared to the same period last year, and increased costs of our subscription right plans.

Our S&M and G&A expenses were €151.3 million in the first nine months of 2021, compared to €132.4 million in the first nine months of 2020. This increase is primarily due to an increase in personnel costs and other operating expenses mainly driven by the commercial launch of filgotinib in Europe. This increase was partly compensated by higher cost recharges from us to Gilead in the scope of our commercial cost sharing for filgotinib in Europe.

Other income (€36.3 million vs €35.0 million for the same period last year) increased, mainly driven by higher grant income.

We reported a non-cash fair value gain from the re-measurement of initial warrant B issued to Gilead, amounting to €3.0 million, mainly due to the decreased implied volatility of the Galapagos share price as well as its evolution between 31 December 2020 and 30 September 2021.

Net other financial income in the first nine months of 2021 amounted to €30.6 million, compared to net other financial loss of €75.3 million for the first nine months of 2020. This is primarily attributable to €54.9 million of currency exchange gain on our cash and cash equivalents and current financial investments in U.S. dollars, to €10.1 million of negative changes in (fair) value of current financial investments and financial assets and to €8.5 million of interest expenses. The other financial expenses also contained the effect of discounting our long term deferred income of €7.2 million.

Results from discontinued operations

The net profit from discontinued operations for the nine months ended 30 September 2021 consisted of the gain on the sale of Fidelta, our fee-for-services business, for €22.2 million.

Group net results

The group realized a net loss for the first nine months of 2021 amounting to €119.6 million, compared to a net loss of €247.6 million for the same period in 2020.

Cash position

Current financial investments and cash and cash equivalents totaled €4,874.2 million on 30 September 2021 (€5,169.3 million on 31 December 2020, including the cash and cash equivalents included in the assets classified as held for sale).

A net decrease in current financial investments and cash and cash equivalents amounted to €295.2 million in the first nine months of 2021, compared to a net decrease of €472.2 million during the first nine months of 2020. This net decrease is composed of (i) €376.7 million of operational cash burn,² offset by (ii) €2.7 million of cash proceeds from capital and share premium increase from exercise of subscription rights in the first nine months of 2021, (iii) €7.2 million of negative changes in (fair) value of current financial investments and €57.3 million of mainly positive exchange rate differences, (iv) €28.7 million cash in from the disposal of Fidelta, net of cash disposed.

Our balance sheet on 30 September 2021 also held a receivable from the French government (*Credit d'Impôt Recherche*) and a receivable from the Belgian Government for R&D incentives, for a total of €149.3 million.

² We refer to the [note](#) on the cash position of our condensed consolidated interim financial statements for an explanation and reconciliation of this alternative performance measure.

³ *Credit d'Impôt Recherche* refers to an innovation incentive system underwritten by the French government.

Outlook 2021

Going forward, we continue to build our filgotinib franchise throughout Europe, and remain on track to complete the transition of the full European commercial operations for filgotinib from our collaboration partner Gilead to us by year-end. We anticipate an approval decision from the EC and Great Britain's MHRA of filgotinib for the treatment of UC, which, if approved, would add a second indication to our growing commercial footprint in Europe.

Following the positive topline Phase 1b data from our TYK2 inhibitor GLPG3667, we are running an extended dose escalation study in healthy volunteers, and we are preparing to launch a Phase 2b trial in Pso and a Phase 2 trial in UC in 2022.

We are advancing our SIK3 inhibitor GLPG4399 in healthy volunteers this year, and we aim to move a follow-up SIK2/3 preclinical candidate into the clinic in 2022.

By year-end we also intend to finalize recruitment into the GLPG2737 Phase 2a trial in ADPKD, an indication with important unmet medical need.

Meanwhile we continue to apply lessons learned from the strategic exercise announced at Q1 to the development of our deep pipeline, and we diligently evaluate business development opportunities in our core therapeutic areas of inflammation and fibrosis.

Following our strategic review of operations in March 2021, we implemented a cost savings program of €150 million on a full year basis. As a result of an acceleration of this program, we revise our guidance for full year 2021 operational cash burn from €580 to €620 million to €530 to €570 million.

We thank you for your continued support as we make filgotinib available to patients across Europe and execute on our strategy to develop novel mode-of-action drugs. The supervisory board is focused on the selection of new leadership, and we have no doubt that excellent successors to the CEO and CSO will be nominated. Supported by our strong balance sheet and long-term R&D collaboration with Gilead, we believe that Galapagos remains well positioned for future growth.

Respectfully,

Onno van de Stolpe
CEO

Bart Fillus
President & COO

COVID-19 impact

Given the impact of the COVID-19 pandemic, we sustain our efforts towards improving our understanding of people and business needs, and as such we have executed plans to accommodate for the current situation and minimize the impact to operations. We closely follow local governmental regulations and apply these as appropriate within our organization, guided and supported by our dedicated COVID-19 task force teams. All local and global task force teams meet regularly and make recommendations directly to the COO.

We report the following impacts:

- **Staff**

We continue to follow the strict measures put in place to help prevent the spread of the COVID-19 virus and protect the health of our staff. We rolled out our global and site-specific business continuity plans and continue to take appropriate recommended precautions.

During lock-down periods, we arranged for essential tasks to be carried out within our facilities. Consequently, the majority of our Research staff continues to work from the office/labs, with periodic exceptions for local lockdowns during which no staff is allowed into the facilities. For those employees coming to the office, we have stringent cleaning and sanitation protocols in place, and we strictly respect social distancing policies at all times in order to minimize risk of exposure.

As the global pandemic has prevailed into 2021, we continue to sustain our efforts to maintain our strict measures and protocols to ensure safety and good health of our employees. Strictly following local governmental measures, we have started to welcome our employees back on site.

- **Research portfolio**

By prioritizing the most advanced projects very early on and increasing the flexibility of our dedicated research staff in the labs within projects, we sustain our research progress, and continue our early drug research and the implementation of new modalities for target or drug discovery.

So far, we note no material impact of the COVID-19 pandemic on our research portfolio.

- **Διαγνωστικό**

We have a business continuity plan for our clinical development programs. We closely monitor each program in the context of the current global and local situation of the pandemic and the associated specific regulatory, institutional, and government guidance and policies related to COVID-19. Within the boundaries of these guidances and policies, and in consultation with our CROs and clinical trial sites, we applied various measures to minimize the impact of the COVID-19 pandemic on our clinical development programs, with the primary aim to ensure the safety of our trial participants and to preserve the data integrity and scientific validity of our trials. These measures continue to be implemented on a case-by-case basis, tailored to the specific study and geographic needs at any given time, with specific attention paid to vulnerable populations and the use of investigational medicines with immunosuppressive properties. The measures include, among others, increased, transparent communication to all stakeholders and the direct supply of investigational medicines to patients. For each clinical trial, we actively monitor and document the impact of COVID-19 where necessary and facilitate the interpretation and reporting of results.

Following the global increase of COVID-19 testing and vaccinations, we issued an internal guidance on the impact of testing and vaccinations on clinical trials.

- *Filgotinib filing process UC*

On 16 September 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the addition of UC as a new indication to the marketing authorization of Jyseleca. The Commission decision on this change to the marketing authorization is pending. In addition, the assessment of this new indication in Great Britain by the MHRA is ongoing as well.

As of publication of this Q3 report, our collaboration partner Gilead has not been informed by regulatory agencies of approval timeline delays related to the pandemic.

- *Manufacturing operations*

To date, there has been no COVID-19 impact to the commercial supply of filgotinib. Gilead also confirmed that all sites involved in the manufacturing of filgotinib are established sites that currently manufacture other Gilead marketed products and are in good standing with the FDA and are GMP certified. Under the revised agreement with Gilead for filgotinib in Europe, Galapagos plans to become the marketing authorization holder of filgotinib in Europe by year-end 2021, and then become responsible for manufacturing. We plan to work with the same manufacturing sites as Gilead except for secondary packaging and labelling for which a new vendor has been selected.

- *Commercial organization*

The form of outreach of our commercial teams to physicians and hospitals was impacted by the COVID-19 pandemic and consequent travel restrictions, and thus became partially virtual. The teams invested in digital channels as part of the overall commercial build strategy, and these channels are being utilized during our ongoing commercial launch. Thus far we note no material impact on our commercial operations due to travel restrictions, nor has there been an impact of COVID-19 on our ability to engage in market access discussions. Nevertheless, healthcare systems are under pressure across Europe, increasing the volatility in reimbursement procedures and potentially reducing the number of new therapy options initiated by healthcare providers.

At a glance

Consolidated Key Figures

(thousands of €, if not stated otherwise)	Third quarter of 2021	Third quarter of 2020	Nine months ended 30 September 2021	Nine months ended 30 September 2020	Year ended 31 December 2020
Income statement⁽¹⁾					
Product net sales	5,691	-	6,147	-	-
Collaboration revenues	58,503	127,519	311,711	321,923	478,053
Cost of sales	(529)	-	(660)	-	-
R&D expenditure	(109,196)	(129,298)	(378,022)	(392,199)	(523,667)
S, G&A expenses	(45,448)	(43,716)	(151,267)	(132,412)	(185,225)
Other operating income	12,781	12,201	36,345	35,003	52,207
Operating loss	(78,199)	(33,294)	(175,747)	(167,685)	(178,632)
Net financial results	13,743	(49,211)	33,659	(83,355)	(131,143)
Taxes	(157)	(14)	316	(723)	(1,226)
Net loss from continuing operations	(64,613)	(82,519)	(141,772)	(251,763)	(311,001)
Net profit from discontinued operations, net of tax	-	614	22,191	4,215	5,565
Net loss	(64,613)	(81,905)	(119,581)	(247,548)	(305,436)
Balance sheet					
Cash and cash equivalents	2,834,378	2,087,797	2,834,378	2,087,797	2,135,187
Current financial investments	2,039,787	3,220,805	2,039,787	3,220,805	3,026,278
R&D incentives receivables	149,271	122,878	149,271	122,878	135,728
Assets	5,331,987	5,721,086	5,331,987	5,721,086	5,717,731
Shareholders' equity	2,617,383	2,712,082	2,617,383	2,712,082	2,670,355
Deferred income	2,520,652	2,789,183	2,520,652	2,789,183	2,809,133
Other liabilities	193,952	219,821	193,952	219,821	238,242
Cash flow					
Operational cash burn ⁽²⁾	(153,546)	(202,784)	(376,743)	(433,270)	(517,404)
Cash flow used in operating activities	(136,925)	(180,340)	(340,056)	(390,169)	(427,336)
Cash flow generated from/used in (-) investing activities	311,138	(81,084)	993,191	631,720	757,288
Cash flow generated from/used in (-) financing activities	(964)	353	(2,438)	20,599	22,040
Increase/decrease (-) in cash and cash equivalents	173,249	(261,073)	650,697	262,149	351,994
Effect of currency exchange rate fluctuation on cash and cash equivalents	18,489	(35,351)	40,610	(35,968)	(70,539)
Cash and cash equivalents at end of the period	2,834,378	2,087,797	2,834,378	2,087,797	2,143,071

⁽¹⁾ The comparatives of 30 September 2020 and the third quarter of 2020 have been restated to consider the impact of classifying the Fidelta business as discontinued operations in 2020.

⁽²⁾ We refer to the note on our **cash position** of our condensed consolidated interim financial statements for an explanation and reconciliation of this alternative performance measure.

⁽³⁾ The number of employees on 31 December 2020 and on 30 September 2020 included respectively 185 and 174 employees of Fidelta, which has been sold to Selvita on 4 January 2021.

(thousands of €, if not stated otherwise)	Third quarter of 2021	Third quarter of 2020	Nine months ended 30 September 2021	Nine months ended 30 September 2020	Year ended 31 December 2020
Cash and cash equivalents from continuing operations	2,834,378	2,087,797	2,834,378	2,087,797	2,135,187
Cash and cash equivalents classified as assets held for sale	-	-	-	-	7,884
Current financial investments at the end of the period	2,039,787	3,220,805	2,039,787	3,220,805	3,026,278
Total current financial investments and cash and cash equivalents at the end of the period	4,874,165	5,308,602	4,874,165	5,308,602	5,169,349
Financial ratios					
Number of shares issued at the end of the period	65,530,121	65,340,842	65,530,121	65,340,842	65,411,767
Basic and diluted loss per share (in €)	(0.99)	(1.25)	(1.83)	(3.81)	(4.69)
Share price at the end of the period (in €)	45.16	121.20	45.16	121.20	80.48
Total group employees at the end of the period (number) ¹⁾	1,319	1,407	1,319	1,407	1,489

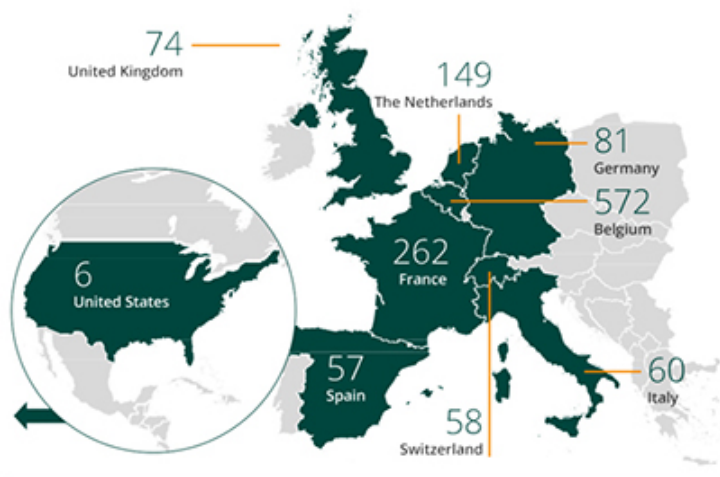
¹⁾ The comparatives of 30 September 2020 and the third quarter of 2020 have been restated to consider the impact of classifying the Fidelta business as discontinued operations in 2020.

²⁾ We refer to the note on our cash position of our condensed consolidated interim financial statements for an explanation and reconciliation of this alternative performance measure.

³⁾ The number of employees on 31 December 2020 and on 30 September 2020 included respectively 185 and 174 employees of Fidelta, which has been sold to Selvita on 4 January 2021.

Employees per site as of 30 September 2021

(total: 1,319 employees)



Risk factors

We refer to the [description of risk factors in the 2020 annual report](#), pp. 51-61, 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. 8-48. In summary, the principal risks and uncertainties faced by us relate to: commercialization, product development and regulatory approval; our financial position and need for additional capital; our reliance on third parties; our competitive position; our intellectual property; our organization, structure and operation (including the emergence of epidemics such as COVID-19); 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 2020 annual report](#), pp. 193-196, 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.

With the exception of filgotinib's approval for the treatment of rheumatoid arthritis by the European Commission, Great Britain's Medicines and Healthcare Products Regulatory Agency and Japanese Ministry of Health, Labour and Welfare, our drug candidates mentioned in this report are investigational; their efficacy and safety have not been fully evaluated by any regulatory authority.

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

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

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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 2021", guidance from management regarding the expected operational use of cash during financial year 2021, statements regarding the amount and timing of potential future milestones, opt-in and/or royalty payments by Gilead, Galapagos' strategic R&D ambitions, including progress on our fibrosis portfolio and our SIK platform, and potential changes of such ambitions, statements regarding the strategic re-evaluation, our statements and expectations regarding commercial sales of filgotinib, statements regarding the global R&D collaboration

with Gilead and regarding the amendment of our arrangement with Gilead for the commercialization and development of filgotinib, statements regarding the expected timing, design and readouts of ongoing and planned clinical trials (i) with filgotinib in rheumatoid arthritis, ulcerative colitis and Crohn's disease, (ii) with GLPG4716 in IPF, (iii) with GLPG3970 in ulcerative colitis, rheumatoid arthritis, psoriatic arthritis and primary Sjögren's syndrome, (iv) with GLPG0555 in osteoarthritis, (v) with GLPG4399 in inflammation, (vi) with GLPG3667 in psoriasis and ulcerative colitis, (vii) with GLPG2737 in ADPKD, (viii) with GLPG3121 in IBD, and (ix) with GLPG4586 and GLPG4605 in fibrosis, statements relating to interactions with regulatory authorities, the timing or likelihood of additional regulatory authorities' approval of marketing authorization for filgotinib for RA, UC or any other indication, including the UC and IBD indications for filgotinib in Europe, Great Britain, Japan, and the U.S., such additional regulatory authorities requiring additional studies, statements regarding changes in our management board and key personnel, our ability to effectively transfer knowledge during this period of transition, the search and recruitment of a suitable successor to lead our organization and of a CSO, the risk that Galapagos will be unable to successfully achieve the anticipated benefits from its leadership transition plan, the possibility that Galapagos will encounter challenges retaining or attracting talent, the timing or likelihood of pricing and reimbursement interactions for filgotinib, statements relating to the build-up of our commercial organization, commercial sales for filgotinib and rollout in Europe, the expected impact of COVID-19, and our strategy, business plans and focus. 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 2021 revenues and financial results and our 2021 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 the risk that data from our ongoing and planned clinical research programs in rheumatoid arthritis, Crohn's disease, ulcerative colitis, idiopathic pulmonary fibrosis, osteoarthritis, other inflammatory indications and kidney disease may not support registration or further development of our product candidates due to safety, or efficacy concerns, or other reasons), our reliance on collaborations with third parties (including our collaboration partner, Gilead), the timing of and the risks related to the implementation of the transition of the European commercialization responsibility of filgotinib from Gilead to us, the risk that the transition will not be completed on the currently contemplated timeline or at all, including the transition of the supply chain, and the risk that the transition will not have the currently expected results for our business and results of operations, estimations regarding our filgotinib development program and the commercial potential of our product candidates and Galapagos' expectations regarding the costs and revenues associated with the transfer of European commercialization rights to filgotinib may be incorrect, the risk that Galapagos will not be able to continue to execute on its currently contemplated business plan and/or will revise its business plan, and the uncertainties relating to the impact of the COVID-19 pandemic. A further list and description of these risks, uncertainties and other risks can be found in our Securities and Exchange Commission filing and reports, including in our most recent annual report on Form 20-F filed with the SEC and our subsequent filings and reports filed with the SEC. We also refer to the "Risk Factors" section of this report. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. We expressly disclaim any obligation to update any such forward-looking statements in this document to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements, unless specifically required by law or regulation.

Financial statements

Unaudited condensed
consolidated interim
financial statements for the
first nine months of 2021

Forward with confidence

Unaudited condensed consolidated interim financial statements for the first nine months of 2021

Consolidated statements of income and comprehensive income/loss (-)

Consolidated income statement

(thousands of €, except per share data)	Third quarter of		Nine months ended 30 September	
	2021	2020 ¹	2021	2020 ¹
Product net sales	5,691	-	6,147	-
Collaboration revenues	58,503	127,519	311,711	321,923
Total revenues	64,194	127,519	317,858	321,923
Cost of sales	(529)	-	(660)	-
Research and development expenditure	(109,196)	(129,298)	(378,022)	(392,199)
Sales and marketing expenses	(17,655)	(17,187)	(46,616)	(44,109)
General and administrative expenses	(27,793)	(26,529)	(104,651)	(88,303)
Other operating income	12,781	12,201	36,345	35,003
Operating loss	(78,199)	(33,294)	(175,747)	(167,685)
Fair value re-measurement of warrants	197	13,033	3,025	(8,085)
Other financial income	23,694	(295)	60,267	13,919
Other financial expenses	(10,148)	(61,950)	(29,633)	(89,190)
Loss before tax	(64,456)	(82,505)	(142,088)	(251,040)
Income taxes	(157)	(14)	316	(723)
Net loss from continuing operations	(64,613)	(82,519)	(141,772)	(251,763)
Net profit from discontinued operations, net of tax	-	614	22,191	4,215
Net loss	(64,613)	(81,905)	(119,581)	(247,548)
Net loss attributable to:				
Owners of the parent	(64,613)	(81,905)	(119,581)	(247,548)
Basic and diluted loss per share	(0.99)	(1.25)	(1.83)	(3.81)
Basic and diluted loss per share from continuing operations	(0.99)	(1.26)	(2.16)	(3.87)

¹ The comparatives of 30 September 2020 and the third quarter of 2020 have been restated to consider the impact of classifying the Fidelia business as discontinued operations in 2020.

The accompanying notes form an integral part of these condensed consolidated financial statements.

Consolidated statement of comprehensive income / loss (-)

(thousands of €)	Third quarter of		Nine months ended 30 September	
	2021	2020	2021	2020
Net loss	(64,613)	(81,905)	(119,581)	(247,548)
Items that may be reclassified subsequently to profit or loss:				
Translation differences, arisen from translating foreign activities	(32)	(688)	171	(350)
Realization of translation differences upon sale of foreign operations	-	(1,023)	731	(1,023)
Other comprehensive income/loss (-), net of income tax	(32)	(1,711)	902	(1,373)
Total comprehensive loss attributable to:				
Owners of the parent	(64,645)	(83,616)	(118,679)	(248,920)
Total comprehensive loss attributable to owners of the parent arises from:				
Continuing operations	(64,645)	(84,244)	(141,601)	(252,906)
Discontinued operations	-	628	22,922	3,985
Total comprehensive loss	(64,645)	(83,616)	(118,679)	(248,920)

⁽¹⁾ The comparatives of 30 September 2020 and the third quarter of 2020 have been restated to consider the impact of classifying the Fidelta business as discontinued operations in 2020.

The accompanying notes form an integral part of these condensed consolidated financial statements.

Consolidated statements of financial position

(thousands of €)	30 September 2021	31 December 2020
Assets		
Intangible assets	59,623	67,565
Property, plant and equipment	123,637	103,378
Deferred tax assets	4,471	4,475
Non-current trade receivables	-	50,000
Non-current R&D incentives receivables	123,804	111,624
Other non-current assets	4,455	11,343
Non-current assets	315,990	348,384
Trade and other receivables	101,335	148,418
Current R&D incentives receivables	25,467	24,104
Current financial investments	2,039,787	3,026,278
Cash and cash equivalents	2,834,378	2,135,187
Other current assets	15,029	11,953
Current assets from continuing operations	5,015,997	5,345,941
Assets classified as held for sale	-	23,406
Total current assets	5,015,997	5,369,347
Total assets	5,331,987	5,717,731
Equity and liabilities		
Share capital	291,953	291,312
Share premium account	2,729,935	2,727,840
Other reserves	(10,885)	(10,907)
Translation differences	(2,309)	(3,189)
Accumulated losses	(391,311)	(334,701)
Total equity	2,617,383	2,670,355
Retirement benefit liabilities	15,256	14,996
Non-current lease liabilities	19,128	23,035
Other non-current liabilities	6,453	8,096
Non-current deferred income	2,098,273	2,365,974
Non-current liabilities	2,139,110	2,412,101

	30 September	31 December
(thousands of €)	2021	2020
Current lease liabilities	7,262	6,401
Trade and other liabilities	145,260	172,386
Current tax payable	454	1,248
Current financial instruments	139	3,164
Current deferred income	422,379	443,159
Current liabilities from continuing operations	575,494	626,357
Liabilities directly associated with assets classified as held for sale	-	8,917
Total current liabilities	575,494	635,274
Total liabilities	2,714,604	3,047,375
Total equity and liabilities	5,331,987	5,717,731

The accompanying notes form an integral part of these condensed consolidated financial statements.

Consolidated cash flow statements

(thousands of €)	Nine months ended 30 September	
	2021	2020
Net loss of the period	(119,581)	(247,548)
Adjustment for non-cash transactions	59,050	159,802
Adjustment for items to disclose separately under operating cash flow	6,013	1,668
Adjustment for items to disclose under investing and financing cash flows	(28,845)	(2,551)
Change in working capital other than deferred income	46,642	(77,466)
Decrease in deferred income	(295,651)	(224,308)
Cash used in operations	(332,372)	(390,401)
Interest paid	(9,436)	(6,591)
Interest received	2,049	8,125
Corporate taxes paid	(297)	(1,302)
Net cash flows used in operating activities	(340,056)	(390,169)
Purchase of property, plant and equipment	(33,907)	(25,252)
Purchase of and expenditure in intangible fixed assets	(1,661)	(20,208)
Proceeds from disposal of property, plant and equipment	-	4
Purchase of current financial investments	(905,124)	(4,272,252)
Interest received related to current financial investments	10	3,483
Sale of current financial investments	1,901,132	4,942,000
Cash in from disposal of subsidiaries, net of cash disposed of	28,696	-
Acquisition of financial assets	-	(2,681)
Proceeds from sale of financial assets held at fair value through profit or loss	4,045	6,626
Net cash flows generated from investing activities	993,191	631,720
Payment of lease liabilities	(5,174)	(5,073)
Proceeds from capital and share premium increases from exercise of subscription rights	2,735	25,672
Net cash flows generated from/used in (-) financing activities	(2,438)	20,599
Increase in cash and cash equivalents	650,697	262,149

(thousands of €)	Nine months ended 30 September	
	2021	2020
Cash and cash equivalents at beginning of the period	2,143,071	1,861,616
Increase in cash and cash equivalents	650,697	262,149
Effect of exchange rate differences on cash and cash equivalents	40,610	(35,968)
Cash and cash equivalents at end of the period	2,834,378	2,087,797

The accompanying notes form an integral part of these condensed consolidated financial statements.

(thousands of €)	30 September	
	2021	2020
Current financial investments	2,039,787	3,220,805
Cash and cash equivalents	2,834,378	2,087,797
Current financial investments and cash and cash equivalents	4,874,165	5,308,602

The accompanying notes form an integral part of these condensed consolidated financial statements.

Consolidated statements of changes in equity

(thousands of €)	Share capital	Share premium account	Translation differences	Other reserves	Accumul. losses	Total
On 1 January 2020	287,282	2,703,583	(1,142)	(4,842)	(109,223)	2,875,658
Net loss					(247,548)	(247,548)
Other comprehensive loss			(1,358)	(14)		(1,373)
Total comprehensive loss			(1,358)	(14)	(247,548)	(248,921)
Share-based compensation					59,673	59,673
Exercise of subscription rights	3,647	22,026				25,672
On 30 September 2020	290,929	2,725,608	(2,500)	(4,856)	(297,098)	2,712,082
On 1 January 2021	291,312	2,727,840	(3,189)	(10,907)	(334,701)	2,670,355
Net loss					(119,581)	(119,581)
Other comprehensive income			880	22		902
Total comprehensive income/ loss (-)			880	22	(119,581)	(118,679)
Share-based compensation					62,971	62,971
Exercise of subscription rights	640	2,095				2,735
On 30 September 2021	291,953	2,729,935	(2,309)	(10,885)	(391,311)	2,617,383

The accompanying notes form an integral part of these condensed consolidated financial statements.

Notes to the unaudited condensed consolidated interim financial statements for the first nine months of 2021

Basis of preparation

These condensed consolidated interim financial statements have been prepared in accordance with IAS 34 'Interim Financial Reporting' as adopted by the European Union and as issued by the IASB. The condensed consolidated interim financial statements do not contain all information required for an annual report and should therefore be read in conjunction with our [Annual Report 2020](#).

Impact of COVID-19 on the financial statements

To date, we have experienced limited impact on our financial performance, financial position, cash flows and significant judgements and estimates, although we continue to face additional risks and challenges associated with the impact of the outbreak.

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 consolidated financial statements of 31 December 2020.

New standards and interpretations applicable for the annual period beginning on 1 January 2021 did not have any impact on our condensed consolidated interim financial statements.

We have not early adopted any other standard, interpretation, or amendment that has been issued but is not yet effective.

New accounting policies as a result of recent transactions

Product net sales

Product net sales is the net amount of revenue recognized resulting from transferring control over our products (Jyseleca) to our customer (for example wholesalers, pharmacies and hospitals). Product sales revenue is recognized at a point in time when control of the goods has transferred to the customer. This is generally when the goods are delivered to the customer depending on the specific incoterms in the contract with a customer.

The amount of revenue recognized is the amount allocated to the satisfied performance obligation taking into account variable consideration. The estimated amount of variable consideration is included in the transaction price only to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Variable consideration that is included in the transaction price is primarily composed of rebates, cash discounts and chargebacks granted to various customers that are part of commercial and governmental contractual arrangements or other reimbursement programs. A liability is recognized for expected rebates, cash discounts, chargebacks or other reimbursements payable directly or indirectly to customers in relation to sales made until the end of the reporting period. The amount of variable consideration is estimated using several elements such as third-party market data, product pricing and the specific terms in the individual agreements. Net sales are presented net of value added tax and other sales related taxes.

The related cost of sales are recorded on a separate line in our consolidated income statement.

Details of the unaudited condensed consolidated interim results

Revenues

Our revenues from continuing operations for the first nine months of 2021 amounted to €317.9 million, compared to €321.9 million for the first nine months of 2020.

Product net sales

We reported net sales of Jyseleca for the first nine months of 2021 amounting to €6.1 million (€5.7 million in the third quarter of 2021), which reflects the sales booked by Galapagos after the transition from Gilead.

Collaboration revenues

The following table summarizes our collaboration revenues for the nine months ended 30 September 2021 and 2020 and for the third quarter of 2021 and 2020.

(thousands of €)			Third quarter of		Nine months ended 30 September	
	Over time	Point in time	2021	2020	2021	2020
Recognition of non-refundable upfront payments and license fees			58,928	92,698	291,370	273,409
Gilead collaboration agreement for filgotinib	✓		1,277	34,736	118,021	102,728
Gilead collaboration agreement for drug discovery platform	✓		57,651	57,962	173,348	170,681
Milestone payments			(978)	36,195	18,391	43,191
Gilead collaboration agreement for filgotinib	✓		(978)	36,195	18,391	43,191
Reimbursement income			-	(1,372)	-	5,256
Novartis collaboration agreement for MOR106	✓		-	(1,370)	-	5,289
AbbVie collaboration agreement for CF	✓		-	(2)	-	(33)
Royalties			553	(1)	1,950	68
Gilead royalties on Jyseleca		✓	557	-	1,907	-
Other royalties		✓	(4)	(1)	43	68
Total collaboration revenues			58,503	127,519	311,711	321,923

Collaboration revenues (€311.7 million for the first nine months of 2021, compared to €321.9 million for the first nine months of 2020) were lower mainly driven by the decrease in revenue recognition of upfront consideration and milestone payments received in the scope of the collaboration with Gilead for filgotinib amounting to €136.4 million for the first nine months of 2021 (€145.9 million for the same period last year). The decrease in revenue recognition was primarily due to a negative cumulative catch up of revenue triggered by the recent agreement under which Galapagos will assume operational and financial responsibility for the ongoing DIVERSITY clinical study. This decrease was partly compensated by additional consideration from Gilead related to the renegotiated collaboration compared to the same period last year. The revenue recognition related to the exclusive access rights for Gilead to our drug discovery platform amounted to €173.3 million for the first nine months of 2021 (€170.7 million for the same period last year).

The rollforward of the outstanding balance of the current and non-current deferred income between 1 January 2021 and 30 September 2021 can be summarized as follows:

(thousands of €)	Total	Gilead col- laboration agree- ment for filgotinib	Gilead col- laboration agree- ment for drug discovery platform ¹⁾	Other deferred income (grants)
On 31 December 2020	2,809,133	818,654	1,990,412	67
Upfront payments	12,643	12,643		
Significant financing component ²⁾	7,170	7,170		
Revenue recognition of upfront	(291,370)	(118,021)	(173,348)	
Revenue recognition of milestones	(18,391)	(18,391)		
Other movements	1,467			1,467
On 30 September 2021	2,520,652	702,055	1,817,063	1,534

¹⁾ The outstanding balance at 30 September 2021 and at 31 December 2020 comprises the issuance liability for the subsequent warrant B and the upfront payment allocated to the drug discovery platform.

²⁾ With regard to the additional consideration received for the extended cost sharing for filgotinib, we assume the existence of a significant financing component reflecting the time value of money on the estimated recognition period.

Results from continuing operations

We realized a net loss from continuing operations of €141.8 million for the first nine months of 2021, compared to a net loss of €251.8 million in the first nine months of 2020.

We reported an operating loss amounting to €175.7 million for the first nine months of 2021, compared to an operating loss of €167.7 million for the same period last year.

Cost of sales related to Jyseleca net sales in the first nine months of 2021 amounted to €0.7 million.

Our R&D expenditure in the first nine months of 2021 amounted to €378.0 million, compared to €392.2 million for the first nine months of 2020. This decrease was primarily explained by winding down of our ziritaxestat (IPF), MOR106 (atopic dermatitis), and GLPG1972 (OA) programs and by reduced spend on our other programs. This was partly offset by costs increases for our filgotinib and Toledo (SIK1) programs, on a nine months comparison basis. Personnel costs increased by €14.0 million from €120.3 million for the first nine months of 2020 to €134.3 million for the first nine months of 2021. This increase is primarily explained by a higher average headcount compared to the same period last year, and increased costs of our subscription right plans.

The table below summarizes our R&D expenditure for the nine months ended 30 September 2021 and 2020 and for the third quarter of 2021 and 2020, broken down by program.

(thousands of €)	Third quarter of		Nine months ended 30 September	
	2021	2020	2021	2020
Filgotinib program	(40,656)	(31,451)	(128,496)	(96,992)
Ziritaxestat program	(4,002)	(9,886)	(23,420)	(39,676)
OA program with GLPG1972	(445)	(5,474)	(1,686)	(17,973)
Toledo program	(19,625)	(23,599)	(71,860)	(61,156)
AtD program with MOR106	(37)	902	(89)	(8,616)
Other programs	(44,430)	(59,790)	(152,470)	(167,787)
Total research and development expenditure	(109,196)	(129,298)	(378,022)	(392,199)

Our G&A and S&M expenses were €151.3 million in the first nine months of 2021, compared to €132.4 million in the first nine months of 2020. This increase was primarily due to an increase in personnel costs (€95.7 million for the first nine months of 2021 compared to €75.1 million for the same period last year) and other operating expenses mainly driven by the commercial launch of filgotinib in Europe. This increase was partly compensated by higher cost recharges from us to Gilead in the scope of our commercial cost sharing for filgotinib in Europe.

Other operating income (€36.3 million for the first nine months of 2021, compared to €35.0 million for the first nine months of 2020) increased by €1.3 million, mainly driven by higher grant income.

In the first nine months of 2021, we reported a non-cash fair value gain from the re-measurement of initial warrant B issued to Gilead, amounting to €3.0 million, mainly due to the decreased implied volatility of the Galapagos share price as well as its evolution between 31 December 2020 and 30 September 2021.

Net other financial income in the first nine months of 2021 amounted to €30.6 million (as compared to net other financial loss of €75.3 million in the same period last year), which was primarily attributable to €54.9 million of currency exchange gain on our cash and cash equivalents and current financial investments in U.S. dollars (as compared to €51.3 million currency exchange losses in the first nine months of 2020) and €7.2 million negative changes in (fair) value of current financial investments (€13.3 million in the same period last year). The other financial expenses also contained the effect of discounting our long term deferred income of €7.2 million (€12.8 million in the same period last year), the fair value loss of financial assets held at fair value through profit or loss of €2.9 million (€0.7 million in the same period last year), as well as interest expenses of €8.5 million (€6.9 million in the same period last year).

Cash position

Cash and cash equivalents and current financial investments totaled €4,874.2 million on 30 September 2021 (€5,169.3 million on 31 December 2020, including the cash and cash equivalents included in the assets classified as held for sale).

A net decrease of €295.2 million in cash and cash equivalents and current financial investments was recorded during the first nine months of 2021, compared to a net decrease of €472.2 million during the first nine months of 2020. This net decrease was composed of (i) €376.7 million of operational cash burn, (ii) offset by €2.7 million of cash proceeds from capital and share premium increase from exercise of subscription rights in the first nine months of 2021, (iii) €7.2 million of negative changes in (fair) value of current financial investments and €57.3 million of mainly positive exchange rate differences, and (iv) €28.7 million cash in from disposal of subsidiaries, net of cash disposed.

The operational cash burn (or operational cash flow if this performance measure is positive) is a financial measure that is not calculated in accordance with IFRS. Operational cash burn/cash flow is defined as the increase or decrease in our cash and cash equivalents (excluding the effect of exchange rate differences on cash and cash equivalents), minus:

- i. the net proceeds, if any, from share capital and share premium increases included in the net cash flows generated from/used in (-) financing activities
- ii. the net proceeds or cash used, if any, in acquisitions or disposals of businesses; the movement in restricted cash and movement in current financial investments, if any, included in the net cash flows generated from/used in (-) investing activities.

This alternative performance measure is in our view an important metric for a biotech company in the development stage.

The following table represents a reconciliation of the operational cash burn:

(thousands of €)	Nine months ended 30 September	
	2021	2020
Increase in cash and cash equivalents (excluding effect of exchange differences)	650,697	262,149
Less:		
Net proceeds from capital and share premium increases	(2,735)	(25,672)
Net sale of current financial investments	(996,008)	(669,747)
Cash in from disposal of subsidiaries, net of cash disposed of	(28,696)	-
Total operational cash burn	(376,743)	(433,270)

Cash and cash equivalents and current financial investments comprised cash at banks, short-term bank deposits, treasury bills 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 monitors and optimizes our liquidity position. Our cash management strategy allows short-term deposits with an original maturity exceeding three months while monitoring all liquidity aspects. Cash and cash equivalents comprised €1,684.0 million of term deposits which all had an original maturity longer than three months. All cash and cash equivalents are available upon maximum three months notice period and without significant penalty. Cash at banks were mainly composed of notice accounts. Our credit risk is mitigated by selecting a panel of highly rated financial institutions for our deposits.

Cash invested in highly liquid money market funds represented €1,061.8 million (€1,571.9 million on 31 December 2020) and are presented as current financial investments on 30 September 2021. The current financial investments also include treasury bills, amounting to €978.0 million on 30 September 2021 (€1,454.4 million on 31 December 2020). Our portfolio of treasury bills contains only AAA rated paper, issued by Germany. Our money market funds portfolio consists of AAA short-term money market funds with a diversified and highly rated underlying portfolio managed by established fund management companies with a proven track record leading to an insignificant risk of changes in value.

(thousands of €)	30 September	31 December
	2021	2020
Cash at banks	1,150,381	1,239,993
Term deposits	1,683,997	895,194
Cash and cash equivalents from continuing operations	2,834,378	2,135,187
Cash and cash equivalents included in assets classified as held for sale	-	7,884
Total cash and cash equivalents	2,834,378	2,143,071

On 30 September 2021, our cash and cash equivalents and current financial investments included \$966.6 million held in U.S. dollars (\$1,418.9 million on 31 December 2020) which could generate foreign exchange gains or losses in our financial results in accordance with the fluctuation of the EUR/U.S. dollar exchange rate as our functional currency is EUR. The foreign exchange loss (-)/gain in case of a 10% change in the EUR/U.S. dollar exchange rate amounts to €83.5 million.

Our balance sheet also held R&D incentives receivables from the French government (*Credit d'Impôt Recherche*) to be received in four yearly tranches, and R&D incentives receivables from the Belgian Government, for a total of €149.3 million as at 30 September 2021.

Capital increase

On 30 September 2021, Galapagos NV's share capital was represented by 65,530,121 shares. All shares were issued, fully paid up and of the same class. The below table summarizes our capital increases for the period ended 30 September 2021.

(thousands of €, except share data)	Number of shares	Share capital	Share premium	Share capital and share premium	Average exercise price subscription rights (in €/subscription right)	Closing share price on date of capital increase (in €/share)
On 1 January 2021	65,411,767	291,312	2,727,840	3,019,153		
19 March 2021: exercise of subscription rights	99,814	540	1,718	2,258	22.62	68.48
7 June 2021: exercise of subscription rights	10,940	59	266	325	29.73	61.78
20 September 2021: exercise of subscription rights	7,600	41	111	152	19.97	46.93
On 30 September 2021	65,530,121	291,953	2,729,935	3,021,888		

Note to the cash flow statement

(thousands of €)	Nine months ended 30 September	
	2021	2020
Adjustment for non-cash transactions		
Depreciations and impairment	29,050	13,237
Share-based compensation expenses	62,971	59,673
Increase in retirement benefit obligations and provisions	285	264
Unrealized exchange gains (-)/losses and non-cash other financial result	(47,975)	51,361
Discounting effect of deferred income	7,170	12,849
Fair value re-measurement of warrants	(3,025)	8,085
Net change in (fair) value of current financial investments	7,206	13,277
Fair value adjustment financial assets held at fair value through profit or loss	2,913	669
Other non-cash expenses	455	387
Total adjustment for non-cash transactions	59,050	159,802
Adjustment for items to disclose separately under operating cash flow		
Interest expense	8,474	6,876
Interest income	(2,146)	(6,304)
Tax expense	(316)	1,096
Total adjustment for items to disclose separately under operating cash flow	6,013	1,668
Adjustment for items to disclose under investing and financing cash flows		
Gain on disposal of subsidiaries	(22,191)	-
Loss on sale of fixed assets	1	84
Realized exchange gain on sale of current financial investments	(6,645)	-
Interest income on current financial assets	(10)	(2,634)
Total adjustment for items to disclose separately under investing and financing cash flow	(28,845)	(2,551)
Change in working capital other than deferred income		
Increase in inventories	(2,060)	(84)
Increase (-)/decrease in receivables	82,008	(88,953)
Increase/decrease (-) in liabilities	(33,306)	11,571
Total change in working capital other than deferred income	46,642	(77,466)

Discontinued operations

The following disclosure illustrates the result from our discontinued operations, related to the sale of our fee-for-service business (Fidelta) to Selvita on 4 January 2021.

1. Disposal of subsidiaries (discontinued operations)

1.1. Consideration received

(thousands of €)	
Consideration received in cash and cash equivalents	37,080
Total consideration received	37,080

1.2. Analysis of assets and liabilities over which control was lost

(thousands of €)	4 januari 2021
Intangible assets	21
Property, plant and equipment	10,050
Other non-current assets	160
Trade and other receivables	4,428
Cash and cash equivalents	7,884
Other current assets	863
Total assets	23,406
Non-current lease liabilities	4,115
Other non-current liabilities	70
Trade and other liabilities	4,479
Current lease liabilities	727
Income tax payable	356
Total liabilities	9,747
Net assets disposed of	13,658

1.3. Gain on disposal of subsidiaries

(thousands of €)	
Consideration received	37,080
Net assets disposed of	(13,658)
Effect of cumulative translation adjustments reclassified from equity on loss of control	(731)
Costs associated to the sale	(500)
Gain on disposal	22,191

1.4. Net cash inflow on disposal of subsidiaries

(thousands of €)	
Consideration received in cash and cash equivalents	37,080
Less: cash and cash equivalents balances disposed of	(7,884)
Total consideration received, net of cash disposed of	29,196
Costs associated to the sale	(500)
Cash in from disposal of subsidiaries, net of cash disposed of	28,696

2. Result from discontinued operations

(thousands of €, except share and per share data)	Nine months ended 30 September	
	2021	2020
Fee-for-service revenue	-	11,666
Total revenues	-	11,666
Gain on disposal of subsidiaries	22,191	
Research and development expenditure	-	(5,935)
General and administrative expenses	-	(1,200)
Operating profit	22,191	4,531
Other financial income	-	166
Other financial expenses	-	(108)
Profit before tax	22,191	4,588
Income taxes	-	(373)
Net profit	22,191	4,215
Basic income per share from discontinued operations	0.34	0.06
Diluted income per share from discontinued operations	0.34	0.06
Weighted average number of shares - Basic (in thousands of shares)	65,488	64,979
Weighted average number of shares - Diluted (in thousands of shares)	65,881	67,855

3. Cash flows from discontinued operations

(thousands of €)	Nine months ended 30 September	
	2021	2020
Net cash flows generated from operating activities	-	3,407
Net cash flows generated from/used in (-) investing activities	28,696	(1,582)
Net cash flows used in financing activities	-	(538)
Net cash flows from discontinued operations	28,696	1,287

Contingencies and commitments

Contractual obligations and commitments

We have certain purchase commitments principally with CRO subcontractors and certain collaboration partners.

On 30 September 2021, we had outstanding obligations for purchase commitments, which become due as follows:

(thousands of €)	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Purchase commitments	298,932	184,489	81,274	33,110	60

In addition to the table above, we have a contractual cost sharing obligation related to our collaboration agreement with Gilead for filgotinib. The contractual cost sharing commitment amounted to €454.6 million at 30 September 2021 for which we have direct purchase commitments of €118.7 million at 30 September 2021 reflected in the table above.

Contingent liabilities and assets

We refer to our [Annual Report 2020](#) for a description of our contingent liabilities and assets.

Related party transactions

On 30 April 2021, the members of the management board were offered new subscription rights under Subscription Right Plan 2021 BE, subject to acceptance. The final number of accepted subscription rights under Subscription Right Plan 2021 BE, Subscription Right Plan 2021 RMV and Subscription Right Plan 2021 ROW were enacted by notary deed on 2 July 2021 and on 18 August 2021. The subscription rights have an exercise term of eight years as of the date of the offer. The exercise price of the subscription rights is €64.76 (the closing price of the Galapagos share on Euronext Amsterdam and Brussels on the day preceding the date of the offer). Each subscription right gives the right to subscribe for one new Galapagos share. For all the beneficiaries under Subscription Right Plan 2021 BE the subscription rights vest only and fully on the first day of the fourth calendar year following the calendar year in which the grant was made. The subscription rights are not transferable and can in principle not be exercised prior to 1 January 2025. Subscription rights granted under Subscription Right Plan 2021 RMV and Subscription Right Plan 2021 ROW vest in instalments: with 25% of each grant being exercisable as of 1 January 2023, 25% as of 1 January 2024 and 50% (the remainder) as of 1 January 2025.

On 5 May 2021 and on 24 September 2021, the members of the management board were offered new restricted stock units ('RSUs'), subject to acceptance. The RSUs are offered for no consideration. Under the first RSU grant, four members of the management board accepted all RSUs offered to them. Under the second RSU grant, five members of the management board accepted all RSUs offered to them. Each RSU represents the right to receive, at Galapagos' discretion, one Galapagos share or a payment in cash of an amount equivalent to the volume-weighted average price of the Galapagos share on Euronext Brussels over the 30-calendar day period preceding the relevant vesting date. The first RSU grant will vest in full three years after the offer date. The second RSU grant has a four-year vesting period, with 25% vesting each year and a first vesting date on 1 May 2022. For the members of the management board, any vesting prior to the third anniversary of the offer date will always give rise to a payment in cash rather than a delivery of shares. The RSUs are not transferable.

The table below sets forth the number of subscription rights accepted under Subscription Right Plan 2021 BE and the total number of RSUs accepted by each member of the management board during the first nine months of 2021:

Name	Title	Number of 2021 subscription rights accepted	Number of 2021 RSUs accepted
Onno van de Stolpe	Chief Executive Officer	85,000	63,830
Bart Filius	President & Chief Operating Officer	50,000	62,730
Walid Abi-Saab	Chief Medical Officer	40,000	44,038
Piet Wigerinck	Chief Scientific Officer	40,000	-
Andre Hoekema	Chief Business Officer	30,000	51,433
Michele Manto	Chief Commercial Officer	30,000	31,694

During the first nine months of 2021, there were no changes to related party transactions disclosed in the 2020 annual report that potentially had a material impact on the financials of the first nine months of 2021.

Events after the end of the reporting period

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

Approval of interim financial statements

The interim financial statements were approved by the management board on 2 November 2021.

Glossary of terms

100 points clinical response

Percentage of patients achieving a 100-point decrease in CDAI score during a clinical trial in CD patients

ACR

American College of Rheumatology

ACR20 (ACR 20/50/70)

American College of Rheumatology 20% response rate signifies a 20% or greater improvement in the number of swollen and tender joints as well as a 20% or greater improvement in three out of five other disease-activity measures. ACR50 and ACR70 reflect the same, for 50% and 70% response rates, respectively

Adenovirus

A common virus that causes cold-like symptoms and is used as a research tool for the lab in the discovery of new drugs

ADPKD

Autosomal dominant polycystic kidney disease, a disease where typically both kidneys become enlarged with fluid-filled cysts, leading to kidney failure. Other organs may be affected as well

ADS

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

AFM

Dutch Authority for the Financial Markets

Anemia

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

Anti-TNF

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

Assays

Laboratory tests to determine characteristics

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 product candidate that reaches a body's systemic circulation after (oral) administration

Biomarker

Substance used as an indicator of a biological process, particularly to determine whether a product candidate has a biological effect

Black & Scholes model

A mathematical description of financial markets and derivative investment instruments that is widely used in the pricing of European options and subscription rights

Bridging trial

Clinical trial performed to "bridge" or extrapolate one dataset to that for another situation, i.e. to extrapolate data from one population to another for the same drug candidate, or to move from IV to subcutaneous dosing

CALOSOMA

Phase 1 program with GLPG3970 in psoriasis

Cash position

Current financial investments and cash and cash equivalents

CDAI

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

CDAI remission

In the FITZROY trial, the percentage of patients with CD who showed a reduction of CDAI score to <150

CFTR

Cystic fibrosis transmembrane conductance regulator (CFTR) is a membrane protein and chloride channel in vertebrates that is encoded by the CFTR gene. It is hypothesized that inhibition of the CFTR channel might reduce cyst growth and enlargement for patients with ADPKD. GLPG2737 is a CFTR inhibitor

CHIT1/AMCase

Chitinase (CHIT1) is a protein coding gene, and AMCase is an inactive acidic mammalian chitinase. CHIT1 is predominantly involved in macrophage activation. Inhibition of chitinase activity translates into a potential therapeutic benefit in lung diseases like IPF, as shown in preclinical models. GLPG4716 is a CHIT1/AMCase inhibitor targeting a key pathway in tissue remodeling

Chitinase

Chitinase is an enzyme that degrades chitin, involved in the human innate immunity. Inhibition of chitinase activity translates into a potential therapeutic benefit in lung diseases like IPF, as shown in preclinical models

CHMP

Committee for Medicinal Products for Human Use is the European Medicines Agency's (EMA) committee responsible for human medicines and plays a vital role in the authorization of medicines in the European Union (EU)

CIR

Credit 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 product candidate first shows efficacy in a therapeutic setting

Complete Response Letter (CRL)

A letter sent by the FDA to indicate that the review cycle for an application is complete and the application is not ready for approval in its present form

Compound

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

Contract research organization (CRO)

Organization which provides drug discovery and development services to the pharmaceutical, biotechnology and medical devices industry

Corticosteroids

Any of a group of steroid hormones produced in the adrenal cortex or made synthetically. They have various metabolic functions and some are used to treat inflammation

Crohn's disease (CD)

An IBD involving inflammation of the small and large intestines, leading to pain, bleeding, and ultimately in some cases surgical removal of parts of the bowel

CRP

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

Cytokine

A category of small proteins which play important roles in signaling in processes in the body

DARWIN

Phase 2 program for filgotinib in RA. DARWIN 1 explored three doses, in twice-daily and once-daily administration, for up to 24 weeks in RA patients with insufficient response to methotrexate (MTX) and who remained on their stable background treatment with MTX. DARWIN 2 explored three once-daily doses for up to 24 weeks in RA patients with insufficient response to methotrexate (MTX) and who washed out of their treatment with MTX. DARWIN 1 and 2 were double-blind, placebo-controlled trials which recruited approximately 900 patients globally and for which results were reported in 2015. DARWIN 3 is a long term extension trial in which all patients are on 200 mg filgotinib, except for U.S. males who are on 100 mg. The week 156 results from DARWIN 3 were reported in 2019

DAS28 (CRP)

DAS28 is an RA Disease Activity Score based on a calculation that uses tender and swollen joint counts of 28 defined joints, the physician's global health assessment and a serum marker for inflammation, such as C-reactive protein. DAS28 (CRP) includes the C-reactive protein score calculation: scores range from 2.0 to 10.0, with scores below 2.6 being considered remission

DDI study

Drug-drug interaction study. This type of study will assess if there is a change in the action or side effects of a drug caused by concomitant administration with another drug

Deep venous thrombosis (DVT)

The formation of one or more blood clots in one of the body's large veins, most commonly in the lower limbs. The blood clots can travel to the lung and cause a pulmonary embolism

Degradation

The process by which proteins are lost through the use of drugs such as PROTACs or small molecules

Development

All activities required to bring a new drug to the market. This includes preclinical and clinical development research, chemical and pharmaceutical development and regulatory filings of product candidates

Discovery

Process by which new medicines are discovered and/or designed. At Galapagos, this is the department that oversees target and drug discovery research through to nomination of preclinical candidates

Disease-modifying

Addresses the disease itself, modifying the disease progression, not just the symptoms of the disease

DIVERGENCE

Phase 2 programs with filgotinib in Crohn's disease. DIVERGENCE 1 was an exploratory study in small bowel CD and DIVERGENCE 2 in fistulizing CD

DIVERSITY

Phase 3 program evaluating filgotinib in CD

DMARDs

Disease modifying anti rheumatic drugs; these drugs address the disease itself rather than just the symptoms

Dose-range finding study

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

Double-blind

Term to characterize a clinical trial in which neither the physician nor the patient knows if the patient is taking placebo or the treatment being evaluated

EC

European Commission

Efficacy

Effectiveness for intended use

EMA

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

Endoscopy

A non-surgical procedure involving use of an endoscope to examine a person's digestive tract

Fast Track

A designation by the FDA of an investigational drug for expedited review to facilitate development of drugs which treat a serious or life-threatening condition and fill an unmet medical need

FDA

The U.S. Food and Drug Administration is an agency responsible for protecting and promoting public health and in charge of American market approval of new medications

Fee-for-service

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

FIH

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

Filgotinib

Formerly known as GLPG0634, commercial name is Jyseleca. Small molecule preferential JAK1 inhibitor, approved in RA in Europe and Japan. Application for approval for ulcerative colitis was filed in Europe and Japan. Filgotinib is partnered with Gilead. Filgotinib currently is in Phase 3 trials in CD, and in a Phase 4 trial in RA

FILOSOPHY

Phase 4 program evaluating filgotinib in RA

FINCH

Phase 3 program evaluating filgotinib in RA

Fistulizing CD

Fistulae are inflammatory tracts that most often occur between the distal colon and the perianal region. Fistulae are one of the most severe sequelae of luminal CD and the lifetime risk of occurrence is close to 50% of those with active CD

FITZROY

A double-blind, placebo controlled Phase 2 trial with filgotinib in 177 CD patients for up to 20 weeks. Full results were published in The Lancet in 2016

FORM 20-F

Form 20-F is an SEC filing submitted to the US Securities and Exchange Commission

FSMA

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

FTE

Full-time equivalent; a way to measure an employee's involvement in a project. For example, an FTE of 1.0 means that the equivalent work of one full-time worker was used on the project

Futility analysis

Analysis of the likelihood of a trial to meet its primary endpoint, based on a subset of the total information to be gathered. The term 'futility' is used to refer to the low likelihood of a clinical trial to achieve its objectives. In particular, stopping a clinical trial when the interim results suggest that it is unlikely to achieve statistical significance can save resources that could be used on more promising research

G&A expenses

General & administrative expenses

Genome

An organism's complete set of genetic information needed to build that organism and allow it to grow and develop

GLIDER

Phase 2 Proof of Concept trial with SIK2/3 inhibitor GLPG3970 in Sjögren's syndrome

GLPG0555

A JAK1 inhibitor currently in Phase 1b in osteoarthritis

GLPG0634

Molecule number currently known as filgotinib and Jyseleca

GLPG1690

Autotaxin inhibitor discovered by us and currently known as ziritaxestat. All development with ziritaxestat was discontinued in February 2021

GLPG2737

A compound currently in Phase 2 in ADPKD. This compound is part of the CF collaboration with AbbVie but Galapagos retained rights outside of CF

GLPG3121

A compound currently in Phase 1 targeting JAK1/TYK2 directed toward inflammation (IBD)

GLPG3667

A TYK2 kinase inhibitor discovered by us, topline results from the Phase 1b in psoriasis reported in July 2021

GLPG3970

A SIK2/3 inhibitor currently in multiple Phase 2 Proof of Concept studies. Topline results from the studies in UC, psoriasis and RA reported in July 2021

GLPG4399

A SIK3 inhibitor currently in Phase 1 directed toward inflammation

GLPG4586

A compound with undisclosed mode of action currently in the preclinical phase directed toward fibrosis. This is the first preclinical candidate to emerge from the collaboration with Fibrocor

GLPG4605

A SIK2/3 inhibitor in the preclinical phase, currently directed toward fibrosis

GLPG4716

A chitinase inhibitor inlicensed from OncoArendi in preparation for Phase 2 in IPF

HDL

High-density lipoprotein. HDL scavenges and reduces low-density lipoprotein (LDL) which contributes to heart disease at high levels. High levels of HDL reduce the risk for heart disease, while low levels of HDL increase the risk of heart disease

Hemoglobin

A protein inside red blood cells that carries oxygen from the lungs to tissues and organs in the body and carries carbon dioxide back to the lungs

Histology

Study of the microscopic structures of tissues

Histopathology

Microscopic examination of tissues for manifestations of a disease

IBD

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

In-/out-licensing

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

In vitro

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

In vivo

Studies performed with animals in a laboratory setting

Inflammatory diseases

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

Intellectual property

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

Intersegment

Occurring between the different operations of a company

Investigational New Drug (IND) Application

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

IPF

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

JAK

Janus kinases (JAK) are critical components of signaling mechanisms utilized by a number of cytokines and growth factors, including those that are elevated in RA. Filgotinib is a preferential JAK1 inhibitor

Jyseleca®

Jyseleca® is the brand name for filgotinib

LADYBUG

Phase 2 program with GLPG3970 in rheumatoid arthritis

LDL

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

Lipoprotein

Lipoproteins are substances made of protein and fat that carry cholesterol through your bloodstream. There are two main types of cholesterol: High-density lipoprotein (HDL), or "good" cholesterol and Low-density lipoprotein (LDL), or "bad" cholesterol

Liver enzymes

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

Lymphocyte

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

MACE

Major adverse cardiovascular events; a composite endpoint frequently used in cardiovascular research

MANGROVE

Phase 2 program with GLPG2737 in autosomal dominant polycystic kidney disease

MANTA

A Phase 2 semen parameter trial with filgotinib in male patients with CD or UC

MANTA-RAY

Phase 2 semen parameter trial with filgotinib in male patients with RA, PsA, or AS

Mayo Score

Mayo Score is a Disease Activity Score for ulcerative colitis. It is a composite of subscores from four categories, including stool frequency, rectal bleeding, findings of flexible proctosigmoidoscopy or colonoscopy, and physician's global assessment, with a total score ranging from 0–12

MHLW

Japanese Ministry of Health, Labor and Welfare (MHLW), in charge of Japanese market authorization of new medications

MHRA

Medicines and Healthcare products Regulatory Agency in Great Britain

Milestone

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

Modulation

The process by which the function of proteins is changed through the use of drugs such as small molecules, peptides, antibodies or cell therapy

Molecule collections

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

MTX

Methotrexate; a first-line therapy for inflammatory diseases

NDA

New Drug Application

Neutrophil

Type of immune system cell which is one of the first cell types to travel to the site of an infection in the body. Neutrophils are another type of white blood cell which fight infection by ingesting and killing microorganisms

NICE

The National Institute for Health and Care Excellence; an independent public body that provides national guidance and advice to improve health and social care in the UK

NK cells

Natural killer cells, type of white blood cell with granules of enzymes which can attack tumors or viruses

Oligonucleotide

Short DNA or RNA molecule that can be used as research tools or therapeutic drug to change protein expression

Oral dosing

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

Osteoarthritis (OA)

The most common form of arthritis, usually occurring after middle age, marked by chronic breakdown of cartilage in the joints leading to pain, stiffness, and swelling

Outsourcing

Contracting work to a third party

PASI

Psoriasis Area and Severity Index; an index used to express the severity of psoriasis. It combines the severity (erythema, induration and desquamation) and percentage of affected area

PCKD

Polycystic kidney disease is a genetic disorder in which the renal tubules become structurally abnormal, resulting in the development and growth of multiple cysts within the kidney

Pharmacokinetics (PK)

Study of what a body does to a drug; the fate of a substance delivered to a body. This includes absorption, distribution to the tissues, metabolism and excretion. These processes determine the blood concentration of the drug and its metabolite(s) as a function of time from dosing

Phase 1

First stage of clinical testing of an investigational drug designed to assess the safety and tolerability, pharmacokinetics of a drug, usually performed in a small number of healthy human volunteers

Phase 2

Second stage of clinical testing, usually performed in no more than several hundred patients, in order to determine efficacy, tolerability and the dose to use

Phase 3

Large clinical trials, usually conducted in several hundred to several thousand patients to gain a definitive understanding of the efficacy and tolerability of the candidate treatment; serves as the principal basis for regulatory approval

Phenotypic screening

Phenotypic screening is a strategy used in drug discovery to identify molecules with the ability to alter a cell's disease characteristics. Animal models and cell-based assays are both strategies used to identify these molecules. In contrast to target-based drug discovery, phenotypic screening does not rely on knowing the identity of the specific drug target or its hypothetical role in the disease. A key benefit this approach has over target-based screening, is its capacity to capture complex biological mechanisms that are not otherwise achievable

Pivotal trials

Registrational clinical trials

Placebo

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

Preclinical

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

Preclinical candidate (PCC)

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

Product candidate

Substance that has satisfied the requirements of early preclinical 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

Proof of Concept (POC)

A clinical trial in which first evidence for efficacy of a candidate drug is gathered. A Proof of Concept trial is usually with a small number of patients and for short duration to get a first impression of drug activity

Proof of Concept study

Phase 2 patient study in which activity as well as safety in patients is evaluated, usually for a new mechanism of action

PROTAC

Proteolysis targeting chimera, a special small molecule capable of removing unwanted proteins that play a role in disease processes

Psoriasis

A chronic skin disease which results in scaly, often itchy areas in patches

Psoriatic arthritis (PsA)

Psoriatic arthritis or PsA is an inflammatory form of arthritis, affecting up to 30% of psoriasis patients. Psoriatic arthritis can cause swelling, stiffness and pain in and around the joints, and cause nail changes and overall fatigue

Pulmonary embolism

A blockage in one of the pulmonary arteries in the lungs

QD dosing

Once-daily dosing (qd from the Latin quaque die)

R&D operations

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

Replication

The process by which DNA is copied to produce two identical DNA molecules during the process of cell division

Rheumatoid arthritis (RA)

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

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

SEA TURTLE

Phase 2 program with GLPG3970 in ulcerative colitis

SEC

Securities and Exchange Commission in the US

SELECTION

Phase 3 program evaluating filgotinib in UC patients. Full results were published in The Lancet in 2021

SES-CD scores

Simple endoscopic score for CD, involving review of five pre-defined bowel segments, assigning values from 0 (unaffected) to 3 (highly affected)

Short interfering RNA

A research tool that is used to silence the activity of specific genes

SIK

Salt-inducible kinase. This is the target family for the portfolio of molecules in the Toledo program

Sjögrens syndrome

Sjögren's Syndrome is a systemic inflammatory disease which can be felt throughout the body, often resulting in chronic dryness of the eyes and mouth

S&M expenses

Sales and marketing expenses

Small bowel CD (SBCD)

CD causes chronic inflammation and erosion of the intestines. It can affect different regions of gastrointestinal tract including the stomach and small and large intestines. While isolated SBCD is an uncommon presentation of CD, involvement of some portion of the small bowel, particularly the ileum, is common

Statin

Statins are a class of lipid-lowering medications that reduce illness and mortality in those who are at high risk of cardiovascular disease. They are the most common cholesterol-lowering drugs. Low-density lipoprotein (LDL) carriers of cholesterol play a key role in the development of atherosclerosis and coronary heart disease via the mechanisms described by the lipid hypothesis

Systemic lupus erythematosus

An autoimmune disease, with systemic manifestations including skin rash, erosion of joints or even kidney failure

TAPINOMA

Phase 1b Proof of Concept trial with SIK2/3 inhibitor GLPG3970 in SLE. The study was terminated in October 2021

Target

Protein that has been shown to play a role in a disease process and that forms the basis of a therapeutic intervention or discovery of a medicine

Target discovery

Identification and validation of proteins that have been shown to play a role in a disease process

TEAE

Treatment Emergent Adverse Event, is any event not present prior to the initiation of the treatments or any event already present that worsens in either intensity or frequency following exposure to the treatments

Technology access fee

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

Toledo

Toledo is the program name for the target family of SIK inhibitors

Topical corticosteroids

Corticosteroids which are administered through the skin using an ointment

Transcription

The process of making an RNA copy of a DNA gene sequence

Translation

The process by which a protein is synthesized from mRNA

TYK

Tyrosine kinase is an enzyme that can transfer a phosphate group from ATP to the tyrosine residues of specific proteins inside a cell. It functions as an "on" or "off" switch in many cellular functions. Tyrosine kinases belong to a larger class of enzymes known as protein kinases which also attach phosphates to other amino acids such as serine and threonine. GLPG3667 is a reversible and selective TYK2 kinase domain inhibitor

Ulcerative colitis (UC)

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

Venous thrombotic events

When a blood clot breaks loose and travels in the blood, this is called a venous thromboembolism (VTE). The abbreviation DVT/PE refers to a VTE where a deep vein thrombosis (DVT) has moved to the lungs (PE or pulmonary embolism)

Ziritaxestat

Formerly known as GLPG1690. Ziritaxestat is a novel drug candidate targeting autotaxin; all development with ziritaxestat was discontinued in February 2021

Financial calendar

24 February 2022

Full year 2021 results

Colophon

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