# 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 February 2022

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 [ X ] 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.

The information contained in this Report on Form 6-K, including Exhibit 99.1, except for the quotes of Mr. Onno van de Stolpe and Mr. 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).

On February 24, 2022, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

(c) Exhibit 99.1. Press release dated February 24, 2022

# **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: February 24, 2022

GALAPAGOS NV

(Registrant)

/s/ MARIE-THÉODORA VANDEWIELE

Marie-Théodora Vandewiele Company Secretary

# Galapagos 2021 results set stage for future growth

# Key 2021 and post period events:

- Appointment of Dr. Paul Stoffels<sup>1</sup> as new CEO, effective 1 April 2022, following planned retirement of CEO and cofounder Onno van de Stolpe
- Jyseleca sales booked by Galapagos in Europe were €14.8 million out of a total in-market performance of €25.7 million
- Jyseleca (filgotinib) approved for ulcerative colitis (UC) in Europe and Great Britain, reimbursement for rheumatoid arthritis (RA) secured in 14 countries
- Patient enrollment completed in the DIVERSITY Phase 3 program with filgotinib in Crohn's Disease (CD)
- Discontinuation of development of ziritaxestat, GLPG1690, in Phase 3 program in idiopathic pulmonary fibrosis (IPF)
- First patient results with salt inducible kinase (SIK) 2/3 inhibitor GLPG3970 support further work on this novel pharmacology
- Activity observed with selective tyrosine kinase (TYK) 2 inhibitor GLPG3667 in psoriasis (Pso) Phase 1b study

# Financial results in 2021:

- Group net revenues of €484.8 million as compared to €478.1 million in 2020
- Operating loss of €165.6 million as compared to €178.6 million in 2020
- Net loss of €103.2 million as compared to €305.4 million in 2020
- Cash and current financial investments of €4.7 billion on 31 December 2021
- Operational cash burn<sup>i</sup> of €564.8 million, within the guided range

Webcast presentation tomorrow, 25 February 2022, at 14.00 CET / 8 AM ET, www.glpg.com, +32 2 793 38 47, code 5438549

Mechelen, Belgium; 24 February 2022, 22.01 CET; regulated information – Galapagos NV (Euronext & NASDAQ: GLPG) presents financial results 2021, reviews key events for the company, and provides outlook for 2022.

"2021 was a year of reflection, resulting in refocused R&D activities and resized spend, as well as commercial roll-out, with a major effort to launch Jyseleca throughout Europe," said Onno van de Stolpe, CEO of Galapagos. "We made excellent progress with Jyseleca and successfully completed the process of becoming Marketing Authorization Holder (MAH) in Europe for our first medicine. Improving patients' lives is at the core of what we do, and completing our transition to a fully integrated, independent European biopharma is a major achievement to make that mission a reality for patients suffering from chronic debilitating conditions.

We received approval by the European Commission (EC), and most recently by the Medicines and Healthcare products Regulatory Agency (MHRA) in Great Britain, for a second indication for Jyseleca for patients suffering from UC, and we continue to roll out Jyseleca in RA and UC throughout Europe. Furthermore, following the completion of patient enrollment in the DIVERSITY Phase 3 program with filgotinib in CD, we anticipate topline results in the first half of 2023.

Also for filgotinib, we were pleased to report on the primary endpoint with the MANTA and MANTA-RAy studies investigating the effect on semen parameters, indicating that 8.3% patients on placebo and 6.7% patients on filgotinib had a 50% or more decline in sperm concentration at week 13.

In 2021, we also made important progress across our broader inflammation pipeline, most notably with our TYK2 and SIKi programs. We observed clinical activity with our TYK2 inhibitor GLPG3667 in a Phase 1b study in Pso, and we are currently finalizing a Phase 1 dose escalation study in healthy volunteers. We reported results from the first patient studies of our SIKi program with SIK2/3 inhibitor GLPG3970. The biological activity observed in the studies in Pso and UC highlights the pioneering role we are playing to unravel the role of SIKi in inflammation, and support further development of our SIKi portfolio. We are currently working on a set of follow-up SIKi compounds with improved pharmacology and selectivity profiles, and plan to select a preclinical candidate to move into a healthy volunteer study this year.

Beyond inflammation, we discontinued further development of ziritaxestat (GLPG1690) in IPF due to the unfavorable risk/benefit profile observed by an Independent Data Monitoring Committee (IDMC) in the Phase 3 trials. This not only was a major setback for Galapagos but most importantly for patients suffering from this debilitating disease for which current treatment options remain limited.

Finally, we completed the patient recruitment in our MANGROVE Phase 2 trial with our novel CFTR<sup>2</sup> inhibitor GLPG2737 in patients with ADPKD<sup>3</sup>, with results expected in the first half of 2023.

I am very proud of our committed teams for working tirelessly to bring novel mode of action medicines to patients, and now that my tenure at the helm of this company is drawing to an end, I could not be more honored to hand over the baton to Paul. As a cofounder and board member in the early years, Paul has a keen understanding of our roots as well as who we are today. I strongly

believe that Paul's strategic and inspirational leadership, along with his deep knowledge of both the industry and Galapagos, make him the right next CEO to deliver tremendous value to all stakeholders."

Bart Filius, President, COO and CFO of Galapagos, added: "We ended 2021 with a very strong balance sheet, providing us with the foundations for future growth. One year after receiving approval for Jyseleca in RA in Europe and Great Britain, we secured reimbursement in 14 countries, covering the major markets of Germany, France, Spain, Italy, and Great Britain. We reported €14.8 million of Jyseleca sales in Europe out of a total in-market performance of €25.7 million.

Following a strategic operational review in March 2021, we implemented a cost savings program of €150 million on a full year basis, which will take full effect in the course of 2022. Our operational cash burn<sup>i</sup> in 2021 was €564.8 million, within our reduced guidance. For 2022 we anticipate a further significant reduction of our cash burn and expect to land between €450 and €490 million. This includes sales for Jyseleca that we anticipate between €65 and €75 million."

# Key figures 2021 (consolidated) (€ millions, except basic & diluted loss per share)

	31 December	31 December
	2021 group total	2020 group total
Product net sales	14.8	-
Collaboration revenues	470.1	478.1
Total net revenues	484.8	478.1
Cost of sales	(1.6)	-
R&D expenditure	(491.7)	(523.7)
G&A <sup>ii</sup> and S&M <sup>iii</sup> expenses	(210.9)	(185.2)
Other operating income	53.7	52.2
Operating loss	(165.6)	(178.6)
Fair value re-measurement of financial	3.0	3.0
instruments	5.0	5.0
Net other financial result	39.6	(134.2)
Income taxes		
	(2.4)	(1.2)
Net loss from continuing operations	(125.4)	(311.0)
Net profit from discontinued operations	22.2	5.6
Net loss of the period	(103.2)	(305.4)
Basic and diluted loss per share (€)	(1.58)	(4.69)
Current financial investments and cash and cash equivalents	4,703.2	5,169.3

### **Details of the financial results**

After the sale of our fee-for-service business (Fidelta) to Selvita on 4 January 2021, we only have one remaining reporting segment. The results of Fidelta, including the impact of the 2021 sale, are presented as "Net profit from discontinued operations" in our consolidated income statements for the years 2021 and 2020.

### **Revenues from continuing operations**

Our net revenues from continuing operations in 2021 amounted to €484.8 million compared to €478.1 million in 2020.

We reported net sales of Jyseleca in 2021 amounting to €14.8 million, which reflects the sales booked by Galapagos after the country-by-country transition from Gilead.

Collaboration revenues amounted to €470.1 million in 2021, compared to €478.1 million last year. The revenue recognition linked to the upfront consideration and milestone payments in the scope of the collaboration with Gilead for filgotinib, amounted to €235.7 million in 2021 (€228.1 million in 2020). The revenue recognition related to the exclusive access rights for Gilead to our drug discovery platform amounted to €230.6 million in 2021 (€229.6 million last year). Additionally we have recognized royalty income from Gilead for Jyseleca for €3.8 million in 2021 (compared to €16.2 million in 2020, which was mainly from income related to upfront payments from a distribution agreement for the commercial launch of filgotinib in Japan).

Our deferred income balance at 31 December 2021 includes  $\leq$ 1.8 billion allocated to our drug discovery platform that is recognized linearly over 10 years, and  $\leq$ 0.6 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 €125.4 million in 2021, compared to a net loss of €311.0 million in 2020.

We reported an operating loss amounting to €165.6 million in 2021, compared to an operating loss of €178.6 million in 2020.

Cost of sales related to Jyseleca net sales in 2021 amounted to €1.6 million.

Our R&D expenditure in 2021 amounted to €491.7 million, compared to €523.7 million in 2020. This decrease was primarily due to the winding down of the programs with ziritaxestat (IPF), MOR106 (atopic dermatitis), and GLPG1972 (OA), and reduced spend on our other programs. This was partly offset by cost increases for our filgotinib and Toledo (SIKi) programs, on a yearly comparison basis.

Our S&M and G&A expenses were respectively €70.0 million and €140.9 million in 2021, compared to respectively €66.5 million and €118.8 million in 2020. This increase was primarily due to an increase in personnel costs resulting from an increase in headcount and other operating expenses mainly driven by the commercial launch of filgotinib in Europe. This increase was partly offset by higher cost recharges from us to Gilead in the scope of our commercial cost sharing for filgotinib in Europe.

Other operating income (€53.7 million in 2021 vs €52.2 million last year) slightly 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 in 2021 (€3.0 million in 2020), mainly due to the decreased implied volatility of the Galapagos share price and its evolution between 31 December 2020 and 31 December 2021.

Net other financial income in 2021 amounted to €39.6 million, compared to net other financial loss of €134.2 million in 2020. Net other financial income in 2021 was primarily attributable to €57.2 million of currency exchange gains on our cash and cash equivalents in U.S. dollars, and to €8.8 million of net interest expenses. The other financial expenses also contained the effect of discounting our long term deferred income of €9.3 million.

# **Results from discontinued operations**

The net profit from discontinued operations in 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 in 2021 of €103.2 million, compared to a group net loss of €305.4 million in 2020.

# **Cash position**

Current financial investments and cash and cash equivalents totaled €4,703.2 million on 31 December 2021, as compared to €5,169.3 million on 31 December 2020 (including the cash and cash equivalents included in the assets as classified as held for sale).

Total net decrease in cash and cash equivalents and current financial investments amounted to €466.1 million in 2021, compared to a net decrease of €611.5 million in 2020. This net decrease was composed of (i) €564.8 million of operational cash burn, offset by (ii) €6.8 million positive changes in (fair) value of current financial investments and €59.9 million of mainly positive exchange rate differences, (iii) €3.3 million of cash proceeds from capital and share premium increase from exercise of subscription rights in 2021, and (iv) €28.7 million cash in from disposal of subsidiaries.

Our balance sheet on 31 December 2021 included R&D incentives receivables from the French government (Crédit d'Impôt Recherche<sup>iv</sup>) and from the Belgian government, for a total of €144.0 million.

### Outlook 2022

Early in 2022, we announced the appointment of Dr. Paul Stoffels as successor to our co-founder and current CEO Onno van de Stolpe, effective 1 April 2022. Paul is widely recognized as an inspirational industry leader with exceptional R&D and global executive experience, with an outstanding track record of accelerated product development in biotech and pharma through insightful acquisitions and strategic partnerships.

In 2022, we expect reimbursement decisions in most key European markets for Jyseleca in UC. In Japan, collaboration partner Gilead expects a decision on the potential approval for Jyseleca in UC in the first half of 2022, which potentially could add a second indication for Jyseleca in this market.

Early this year, the EMA announced that its Pharmacovigilance Risk Assessment Committee (PRAC) started an Article 20 specific pharmacovigilance procedure to investigate the safety data for all JAK inhibitors following recent results from the ORAL Surveillance study with tofacitinib<sup>4</sup> as well as the data from an observational study with baricitinib<sup>5</sup>. Following initiation of this procedure, all JAKi MAHs will be invited to submit evidence and we will continue to work with the EMA. The European Commission has asked the EMA to give its opinion by 30 September 2022.

Within our broader inflammation portfolio, we expect the read out from a Phase 1b trial with JAK1 inhibitor GLPG0555 in osteoarthritis and from multiple Phase 1 trials in healthy volunteers. We aim to progress our TYK2 inhibitor GLPG3667 into a Phase 2 program, following the dose escalation Phase 1 study currently being finalized, also taking into account the current regulatory and competitive landscape for TYK2 as a class. We aim to advance selected compounds with optimized pharmacology

and selectivity from our SIKi portfolio into the clinic. Within our fibrosis portfolio, we anticipate starting a Phase 2 trial with chitinase inhibitor GLPG4716 in IPF.

For 2022 we anticipate a further significant reduction of our cash burn and expect to land between €450 and €490 million. This includes sales for Jyseleca that we anticipate between €65 and €75 million.

We believe our strong cash balance affords us the opportunity to develop our pipeline through internal as well as externally sourced assets. We expect our scientific expertise, strong leadership, and growing commercial Jyseleca franchise to propel us forward as we rebuild a differentiated pipeline of novel mode of action drug candidates to help patients in need of new treatment options.

# **Annual report 2021**

Galapagos is currently finalizing its financial statements for the year ended 31 December 2021. Our independent auditor has confirmed that its audit procedures, which are substantially completed, have not revealed any material corrections required to be made to the financial information included in this press release. Should any material changes arise during the audit finalization, an additional press release will be issued. Galapagos expects to be able to publish its fully audited annual report for the full year 2021 on or around 24 March 2022.

# Conference call and webcast presentation

Galapagos will conduct a conference call open to the public tomorrow, 25 February 2022, at 14:00 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: 5438549**

 Standard
 +44 2071 928338

 International:
 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.glpg.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 March 2022	Publication Annual Report 2021 and 20-F 2021	
26 April 2022	Annual Shareholders' meeting	
5 May 2022	First quarter 2022 results	(webcast 6 May 2022)
4 August 2022	Half Year 2022 results	(webcast 5 August 2022)
3 November 2022	Third quarter 2022 results	(webcast 4 November 2022)
23 February 2023	Full year 2022 results	(webcast 24 February 2023)

#### **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.glpg.com.

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

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

# Contact Investors:

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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' R&D plans and strategy, including progress on our fibrosis portfolio, oral therapeutics and SIK platform, and potential changes in such ambitions, statements regarding Galapagos' commercialization efforts for filgotinib and any future approved products, guidance from management regarding our financial results (including guidance regarding the expected operational use of cash during financial year 2022), statements regarding the expected timing and design of our ongoing and planned preclinical studies and clinical trials, including for (i) filgotinib in RA, UC and CD, including the MANTA/MANTA-RAy trials, (ii) GLPG3667 in Pso and UC, (iii) GLPG3970 in UC and Pso, (iv) GLPG2737 in ADPKD, (v) GLPG0555 in OA and (vi) GLPG4716 in IPF, including expected timing for subject recruitment and enrollment and timing of results, statements relating to interactions with regulatory authorities, statements related to the EMA's planned safety review of JAK inhibitors used to treat certain inflammatory disorders, including filgotinib, initiated at the request of the European Commission (EC) under Article 20 of Regulation (EC) No 726/2004, statements relating to the timing or likelihood of additional regulatory authorities' approval of marketing authorization for filgotinib for RA, UC or any other indication, including UC for filgotinib in Japan, and the U.S. and IBD in Europe, Great Britain, Japan, and the U.S., statements regarding planned changes in our leadership and expected resulting benefits, the timing or likelihood of pricing and reimbursement interactions for filgotinib, statements relating to the build-up of our commercial organization, including in Europe and Great Britain, and statements and expectations regarding commercial sales for filgotinib and rollout in Europe. Galapagos cautions the reader that forward-looking statements are not quarantees of future performance. Forward-looking statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and other important factors that may cause actual events, financial condition and liquidity, performance, or results to differ materially from any historic or future results, financial conditions and liquidity, performance or achievements expressed or implied by such forward-looking statements. When used in this press release, the words "anticipate", "believe", "could", "expect", "intend", "will", "plan", "potential", "should", and similar expressions are intented to identify 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 one or more assumptions, beliefs or expectations underlying management's guidance regarding our 2022 revenues, operating expenses and financial results may be incorrect (including one or more of its assumptions underlying its expense expectations), 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), risks related to our reliance on collaborations with third parties (including, but not limited to, our collaboration partner Gilead), the risks related to the timing and 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, the risk that the transition will be more expensive to us than expected, the risk that the transition will not have the currently expected results for our business and results of operations, the risk that our projections and expectations regarding the commercial potential of filgotinib and any other product candidates may be inaccurate, the risk that our planned leadership transition may be disruptive to our business operations, the risk that we will be unable to successfully achieve the anticipated benefits from our planned leadership transition, the risk that we will encounter challenges retaining or attracting talent; risks related to continued regulatory review of filgotinib following approval by relevant regulatory authorities and the EMA's planned safety review of JAK inhibitors used to treat certain inflammatory disorders, including the risk that the EMA and/or other regulatory authorities determine that additional non-clinical or clinical studies are required with respect to filgotinib, the risk that the EMA may require that the marketing authorization for filgotinib in the EU be amended, the risk that the EMA may impose JAK class-based warnings, and the risk that the EMA's planned safety review may negatively impact acceptance of filgotinib by patients, the medical community, and healthcare payors, the risk that regulatory authorities may require additional post-approval trials of filgotinib or any other product candidates that are approved in the future, and risks related to the ongoing COVID-19 pandemic. For a discussion of other risks and uncertainties and other important factors any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (SEC), as supplemented and/or modified by any other filings and reports that we have made or will make with the SEC in the future.

All information in this press release is as of the date of the release, and Galapagos undertakes no duty to update this information unless required by law or regulation.

- <sup>1</sup> Acting via Stoffels IMC BV
- <sup>2</sup> Cystic Fibrosis Transmembrane Conductance Regulator
- <sup>3</sup> Autosomal Dominant Polycystic Kidney Disease
- <sup>4</sup> Xeljanz<sup>®</sup>, Pfizer
- <sup>5</sup> Olumiant<sup>®</sup>, Eli Lilly

<sup>i</sup> 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 in 2021 amounted to €564.8 million and can be reconciled to our cash flow statement by considering the increase in cash and cash equivalents of €33.5 million, adjusted by (i) the cash proceeds from capital and share premium increase from the exercise of subscription rights by employees for €3.3 million, (ii) the net sale of current financial investments amounting to €566.4 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

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