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# The Galapagos group

An overview of Galapagos, its strategy and portfolio in the first nine months of 2022



### Letter from our CEO

When Galapagos was founded more than two decades ago, we set out to discover new medicines with novel modes of action. By applying our deep scientific expertise and disease pathway knowledge, we identified new targets and successfully brought a novel medicine to market. We are very proud of how far we have come and what we have achieved, demonstrated by the successful launch of our first medicine Jyseleca in Europe.

Guided by our purpose to bring transformational medicines to patients around the world to help them live longer and healthier lives, we are today announcing our *Forward, Faster* strategy to accelerate growth and value creation by reshaping the way we innovate and operate.



This new strategic direction is based on three key pillars. First, we will shift from novel target-based discovery to patient-centric medical need research and development with a focus on our key therapeutic areas of immunology and oncology. Second, we will build on our current capabilities and de-risk R&D through multiple drug modalities, including CAR-T and by focusing on best-in-disease validated targets in our strategic therapeutic areas with shorter time-to-patient potential. Third, we will increase our business development efforts to complement our pipeline and continue to work with our collaboration partner Gilead to bring more medicines to patients worldwide.

Our new fit-for-purpose organizational structure and operating model will focus on accelerating our pipelines in

immunology and oncology, supported by externally sourced opportunities. And we will discontinue our activities in fibrosis and kidney disease <sup>1</sup>.

As a result of our new strategic direction, we intend to reduce our workforce by approximately 200 positions across our sites in Europe to create room to reinvest in new capabilities and programs in our oncology franchise.

This is a difficult but necessary decision and we will follow all applicable processes with respect for our people.

We have a clear path forward for accelerated growth and value creation for all our stakeholders.

Respectfully,

Dr. Paul Stoffels <sup>2</sup>

CEO and Chairman of the Board of Directors

- <sup>1</sup> The study with '2737 in polycystic kidney disease is ongoing with topline results expected in the first half of 2023. If successful, we aim to purificense the program
- to outlicense the program

  Acting via Stoffels IMC BV



### Q3 2022 operational review

### Jyseleca commercial & regulatory progress

- Strong adoption across Europe with reimbursement for rheumatoid arthritis (RA) in 15 countries and for ulcerative colitis (UC) in 10 countries
- Marketing Authorization Application (MAA) submitted for the treatment of UC to Swissmedic, the regulatory authority in Switzerland
- Article 20 pharmacovigilance procedure ongoing by the European Medicines Agency (EMA)

### Pipeline update

 Preparations advanced to start Phase 2 of GLPG3667 (TYK2 inhibitor) in dermatomyositis, with the aim to recruit the first patients around year-end

### Corporate update

- Received various transparency notifications from FMR LLC, indicating that its shareholding in Galapagos changed, without crossing below the 5% threshold, to 5.65% of the current outstanding Galapagos shares
- Raised €6.7 million year-to-date through the exercise of subscription rights

### Post-period events

- On 27 October 2022, the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) concluded the safety review (Article 20 procedure) of all JAK inhibitors approved in the EU for the treatment of inflammatory diseases. On 28 October 2022, the PRAC recommended the harmonization of all labels and concluded that JAK inhibitors should remain indicated for the treatment of patients with RA who have responded inadequately to or who cannot tolerate disease modifying anti-rheumatic drugs (DMARDs) therapy, and for patients with UC who have responded inadequately to or who cannot tolerate conventional therapy or biologics. The PRAC also recommended to update all product labels to include a precautionary approach for use of JAK inhibitors in patients with identified risk factors only if no suitable treatment alternative is available (Section 4.4 Warning and Precautions). The PRAC recommendations will now be considered by the Committee for Medicinal Products for Human Use (CHMP) for an opinion
- Abstract accepted for poster presentation at the Annual Society of Hematology (ASH) conference taking place 10-13 December 2022 on the initial data from the ATALANTA-1 Phase 1/2 study in recurring/refractory Non-Hodgkin Lymphoma (rrNHL) evaluating the feasibility, safety and efficacy of the CD19 CAR-T candidate manufactured at point-of-care



### THE GALAPAGOS GROUP

- New *post hoc* analyses from SELECTION Phase 3 data set with filgotinib in UC patients presented at the United European Gastroenterology (UEG) Week
- Received positive CHMP opinion for Jyseleca European label update based on testicular function safety data from MANTA/RAy studies

### Near term outlook

# Immunology - an area in which we have built deep scientific know-how and expertise since our founding

We expect reimbursement decisions in most key European markets for Jyseleca in UC this year and anticipate that Sobi will further progress with reimbursement discussions in RA and UC in Eastern and Central Europe, Greece, and the Baltic countries. We also expect to report initial results from the FILOSOPHY Real-World Evidence Phase 4 trial in RA later this year, and topline results from the DIVERSITY Phase 3 study in Crohn's disease (CD) in the first quarter of 2023. Before the end of this year, we anticipate a CHMP opinion following the PRAC Article 20 recommendation issued on 28 October 2022.

We aim to recruit the first patients in a Phase 2 study of our TYK2 inhibitor product candidate, GLPG3667, in dermatomyositis around year-end, and we intend to start a Phase 2 study in patients with Systemic Lupus Erythematosus (SLE) in 2023. Finally, we continue to advance select compounds with optimized pharmacology and selectivity from our SIKi portfolio.

## Oncology - an area where we will continue to grow and invest

We will present the initial data from the ATALANTA-1 Phase 1/2 study of the CD19 CAR-T product candidate in patients with rrNHL at the annual ASH conference in December. The objectives of the ATALANTA-1 study are to evaluate the feasibility, safety and efficacy of the CD19 CAR-T candidate manufactured at point-of-care and will provide initial clinical validation of the CAR-T decentralized supply model.

The recruitment of the ongoing Phase 1/2 studies of the CD19 CAR-T candidate in patients with rrNHL (ATALANTA study) and recurring/refractory Chronic Lymphocytic Leukemia (rrCLL) (EUPLAGIA study) is progressing well, and we are on track to report topline results of the dose escalation cohorts in the first half of 2023, which will be followed by one or more dose expansion cohorts.



# Financial guidance and *Forward, Faster* strategy presentation

For the full year 2022, we reiterate our net cash burn of €480-€520 million, including the acceleration in oncology, and we further increase our net sales guidance for Jyseleca to €80-€90 million.

A detailed update of the strategy, portfolio and pipeline goals will be presented by Galapagos management and key opinion leaders at the company's R&D Day which will be held tomorrow, Friday, 4 November 2022, from 8:00 am to 10:30 am EDT (13:00 to 15:30 CET) in New York. The event will include a live video stream on the Investors section of the company's **website** and a replay will be available on the Galapagos website within 48 hours after the event. Presentations showcased during the event will be featured on the Presentations section of the company's **website**.



### Financial highlights

### **Consolidated Key Figures**

(thousands of €, if not stated otherwise)	Third quarter of 2022	Third quarter of 2021	ended	30 September	Year ended 31 December 2021
Income statement					
Product net sales	25,135	5,691	60,491	6,147	14,753
Collaboration revenues	111,068	58,503	349,669	311,711	470,093
Cost of sales	(2,393)	(529)	(7,938)	(660)	(1,629)
R&D expenditure	(114,549)	(109,196)	(364,067)	(378,022)	(491,707)
S&M, G&A expenses	(68,677)	(45,448)	(202,686)	(151,267)	(210,855)
Other operating income	11,837	12,781	29,474	36,345	53,749
Operating loss	(37,578)	(78,199)	(135,056)	(175,747)	(165,596)
Net financial results	59,825	13,743	127,501	33,659	42,598
Taxes	(694)	(157)	(3,229)	316	(2,423)
Net profit/loss (-) from continuing operations	21,554	(64,613)	(10,784)	(141,772)	(125,422)
Net profit from discontinued operations, net of tax	-	-	-	22,191	22,191
Net profit/loss (-)	21,554	(64,613)	(10,784)	(119,581)	(103,231)

## **Galápa**gos

### THE GALAPAGOS GROUP

(thousands of €, if not stated otherwise)	Third quarter of 2022	Third quarter of 2021	ended	Nine months ended 30 September 2021	
Balance sheet					
Cash and cash equivalents	675,519	2,834,378	675,519	2,834,378	2,233,368
Current financial investments	3,686,557	2,039,787	3,686,557	2,039,787	2,469,809
R&D incentives receivables	153,460	149,271	153,460	149,271	144,013
Assets	4,972,070	5,331,987	4,972,070	5,331,987	5,193,160
Shareholders' equity	2,690,351	2,617,383	2,690,351	2,617,383	2,643,362
Deferred income	2,052,686	2,520,652	2,052,686	2,520,652	2,364,701
Other liabilities	229,033	193,952	229,033	193,952	185,097
Cash flow					
Operational cash burn	(125,979)	(153,546)	(343,081)	(376,743)	(564,840)
Cash flow used in operating activities	(116,942)	(136,925)	(320,682)	(340,056)	(503,827)
Cash flow generated from/used in (-) investing activities	(182,568)	311,138	(1,263,625)	993,191	541,238
Cash flow generated from/used in (-) financing activities	793	(964)	432	(2,438)	(3,876)
Increase/decrease (-) in cash and cash equivalents	(298,716)	173,249	(1,583,875)	650,697	33,535
Effect of currency exchange rate fluctuation on cash and cash equivalents	1,440	18,489	26,026	40,610	56,763
Cash and cash equivalents at the end of the period	675,519	2,834,378	675,519	2,834,378	2,233,368
Current financial investments at the end of the period	3,686,557	2,039,787	3,686,557	2,039,787	2,469,809
Total current financial investments and cash and cash equivalents at the end of the period	4,362,076	4,874,165	4,362,076	4,874,165	4,703,177

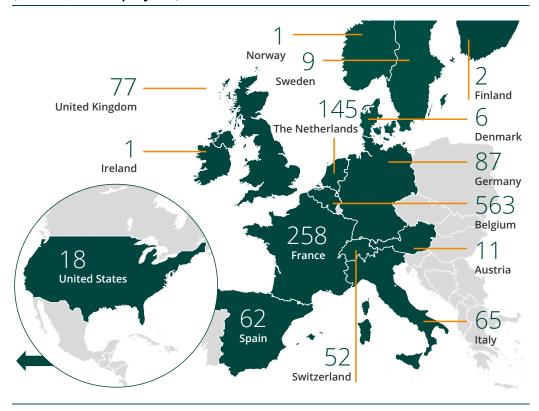
### **Galápa**gos

### THE GALAPAGOS GROUP

(thousands of €, if not stated otherwise)	Third quarter of 2022	quarter	ended	30 September	Year ended 31 December 2021
Financial ratios					
Number of shares issued at the end of the period	65,835,511	65,530,121	65,835,511	65,530,121	65,552,721
Basic and diluted income/loss (-) per share	0.33	(0.99)	(0.16)	(1.83)	(1.58)
Share price at the end of the period (in €)	43.92	45.16	43.92	45.16	49.22
Total group employees at the end of the period (number)	1,357	1,319	1,357	1,319	1,309

### Employees per site as of 30 September 2022

(total: 1,357 employees)





### Q3 2022 financial results

We reported product net sales of Jyseleca in Europe for the first nine months of 2022 amounting to €60.5 million (€6.1 million in the first nine months of 2021). Our counterparties for the sales of Jyseleca were mainly hospitals and wholesalers located across Europe.

Cost of sales related to Jyseleca net sales in the first nine months of 2022 amounted to €7.9 million.

Collaboration revenues amounted to €349.7 million for the first nine months of 2022, compared to €311.7 million for the first nine months of 2021.

Revenues recognized related to the collaboration agreement with Gilead for the filgotinib development were €166.8 million in the first nine months of 2022 compared to €136.4 million for the same period last year. This increase was due to a higher increase in the percentage of completion, as well as a higher revenue recognition of milestone payments strongly influenced by the milestone achieved related to the regulatory approval in Japan for UC in the first nine months of 2022.

The revenue recognition related to the exclusive access rights for Gilead to our drug discovery platform amounted to €172.6 million for the first nine months of 2022 (€173.3 million for the same period last year).

We have recognized royalty income from Gilead for Jyseleca for €8.2 million in the first nine months of 2022 (compared to €1.9 million in the same period last year) of which €3.6 million royalties on milestone income for UC approval in Japan.

Additionally, we recorded milestones of €2.0 million triggered by the first sales of Jyseleca in Czech Republic and Portugal by our distribution and commercialization partner Sobi, in the first nine months of 2022.

Our deferred income balance on 30 September 2022 includes €1.6 billion allocated to our drug discovery platform that is recognized linearly over the remaining period of our 10 year collaboration, and €0.5 billion allocated to filgotinib development that is recognized over time until the end of the development period.

Our R&D expenditure in the first nine months of 2022 amounted to €364.1 million, compared to €378.0 million for the first nine months of 2021. This decrease was primarily explained by a decrease in subcontracting costs from €189.1 million in the first nine months of 2021 to €158.5 million in the first nine months of 2022, primarily due to the winding down of the ziritaxestat (IPF) program and reduced spend on our SIKi and TYK2 programs. This was partly offset by cost increases for our filgotinib program, on a nine month basis compared to the same period in 2021. Personnel costs decreased from €134.3 million in the first nine months of 2021 to €130.0 million for the same period this year. Depreciation and impairment amounted to €35.6 million for the first nine months of 2022 (€14.1 million for the same period last year). This increase was primarily due to an impairment of €26.7 million of previously capitalized upfront fees related to our collaboration with Molecure on the dual chitinase inhibitor OATD-01 (GLPG4716), recorded in Q2 2022.



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Our S&M expenses were €105.3 million in the first nine months of 2022, compared to €46.6 million in the first nine months of 2021. This increase was primarily due to the termination of our 50/50 filgotinib co-commercialization cost sharing agreement with Gilead. The cost increase was also explained by an increase in personnel costs (€53.4 million for the first nine months of 2022 compared to €43.3 million for the same period last year) explained by an increase in the commercial work force from 234 average FTEs in the first nine months of 2021 to 304 average FTEs in the first nine months of 2022 driven by the commercial launch of filgotinib in Europe.

Our G&A expenses were €97.4 million in the first nine months of 2022, compared to €104.7 million in the first nine months of 2021. The cost decrease was primarily due to the impairment of €9.3 million on other tangible assets recorded in the first nine months of 2021 following our decision to reassess the construction project of our new future headquarter location in Mechelen (Belgium). Personnel costs amounted to €54.5 million for the first nine months of 2022 compared to €52.4 million for the same period last year.

Other operating income (€29.5 million for the first nine months of 2022, compared to €36.3 million for the first nine months of 2021) decreased by €6.9 million, mainly driven by lower grant and R&D incentive income.

We reported an operating loss amounting to €135.1 million for the first nine months of 2022, compared to an operating loss of €175.7 million for the same period last year.

Net financial income in the first nine months of 2022 amounted to  $\le$ 127.5 million (as compared to net financial income of  $\le$ 33.6 million in the same period last year). Net financial income in the first nine months of 2022 was primarily attributable to  $\le$ 102.1 million of unrealized currency exchange gain on our cash and cash equivalents and current financial investments at amortized cost in U.S. dollar (as compared to  $\le$ 54.9 million currency exchange gain on cash and cash equivalents and current financial investments in the first nine months of 2021) and  $\le$ 26.0 million positive changes in (fair) value of current financial investments ( $\le$ 7.2 million negative changes in the same period last year). The other financial expenses also contained the discounting effect of our long term deferred income of  $\le$ 5.7 million ( $\le$ 7.2 million in the same period last year). Net interest income amounted to  $\le$ 3.3 million in the first nine months of 2022 (compared to net interest cost of  $\ge$ 6.3 million in the same period last year), due to increasing interest rates. The fair value loss of financial assets held at fair value through profit or loss amounted to nil in the first nine months in 2022 (as compared to  $\ge$ 2.9 million in the same period last year).

We realized a net loss from continuing operations of €10.8 million for the first nine months of 2022, compared to a net loss of €141.8 million for the first nine months of 2021.

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

We reported a group net loss for the first nine months of 2022 of €10.8 million, compared to a group net loss of €119.6 million for the same period last year.



### Cash, cash equivalents and current financial investments

Cash and cash equivalents and current financial investments totaled €4,362.1 million on 30 September 2022 (€4,703.2 million on 31 December 2021).

A net decrease of €341.1 million in cash and cash equivalents and current financial investments was recorded during the first nine months of 2022, compared to a net decrease of €295.2 million during the first nine months of 2021. This net decrease was composed of (i) €343.1 million of operational cash burn, (ii) offset by €6.7 million of cash proceeds from capital and share premium increases from exercise of subscription rights in the first nine months of 2022, (iii) €26.0 million of positive changes in (fair) value of current financial investments and €105.6 million of mainly positive exchange rate differences, and (iv) €136.4 million cash out from the acquisitions of CellPoint and AboundBio, net of cash acquired.

The operational cash burn (or operational cash flow if this liquidity 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, the loans and advances given to third parties, if any, included in the net cash flows generated from/used in (–) investing activities

iii. the cash used for other liabilities related to the acquisition of businesses, if any, included in the net cash flows generated from/used in (–) operating activities.

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



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

Nine months ended
30 September

(thousands of €)	2022	2021
Increase/decrease (-) in cash and cash equivalents (excluding effect of exchange differences)	(1,583,875)	650,697
Less:		
Net proceeds from capital and share premium increases	(6,695)	(2,735)
Net purchase/sale (-) of current financial investments	1,111,139	(996,008)
Cash out from acquisition of subsidiaries, net of cash acquired	115,270	-
Cash advances and loans to third parties	10,000	-
Cash used for other liabilities related to the acquisition of subsidiaries	11,080	-
Cash in from disposals of subsidiaries, net of cash disposed of	-	(28,696)
Total operational cash burn	(343,081)	(376,743)

### The Galapagos share

### Performance of the Galapagos share on Euronext and Nasdaq





### Potential external impacts

### COVID-19

Whilst the beginning of 2022 was globally marked by steeply increasing infection rates mainly due to the spread of the highly infectious Omicron-variant, the situation improved significantly during the second and third quarter and the strict measures taken by local governments to help prevent the spread of the COVID-19 virus and protect the physical and mental health of our staff could gradually be loosened. We nevertheless continue to monitor COVID-19 infection rates at global and local levels, and have systems in place to react quicky where needed to guarantee business continuity. We report the following impacts:

#### ■ Staff

At Galapagos, we maintained the measures put in place by local governments to help prevent the spread of the COVID-19 virus and protect the physical and mental health of our staff, albeit that these measures were gradually loosened during 2022. The majority of our research staff continued to work from the office/labs. For teleworkable functions we continued the implementation of our hybrid working model launched in 2021, in locations where the ongoing COVID-19 situation and corresponding local governmental measures permitted us to do so. For those employees coming to the office, we maintained stringent cleaning and sanitation protocols. We further kept our global and site-specific business continuity plans up-to-date and continued to take appropriate recommended precautions.

### ■ Development portfolio

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 COVID-19 pandemic and the associated specific regulatory, institutional, government guidance and policies related to COVID-19. Within the boundaries of these guidelines and policies, and in consultation with our contract research organizations (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 the trials. These measures were implemented on a case-by-case basis, tailored to the specific study and country needs at any given time, with specific attention paid to vulnerable populations and the use of investigational medicines with immunosuppressive properties. The measures include, amongst 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 to mitigate its effect on the study where necessary and to facilitate the interpretation and reporting of results.



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■ 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 the relative competitiveness of our commercial operations due to travel restrictions, nor have the effects of COVID-19 impacted our ability to engage in market access discussions. Nevertheless, healthcare systems are under pressure across Europe, increasing the volatility in reimbursement procedures and cost containment measures, and potentially reducing the number of new therapy options initiated by healthcare providers.

### Conflict in Ukraine

The armed conflict between Russia and Ukraine could cause a material disruption in our operations. We currently have ongoing clinical studies for filgotinib with CROs located in Ukraine and Russia. If our CROs experience disruptions to their business due to the military conflict in Ukraine and the sanctions against Russia, it could result in delays in our clinical development activities, including delay of our clinical development plans and timelines, or could cause interruptions in operations of regulatory authorities. The impact on ongoing pivotal studies such as DIVERSITY 1 has remained limited. We continue to monitor the situation and are taking measures to mitigate the impact on our ability to conduct clinical development activities. Interruptions or delays in our and our CROs' ability to meet expected clinical development deadlines or to comply with contractual commitments with respect to the same, could lead to delays in our overall developmental and commercialization timelines, which would adversely impact our ability to conduct clinical development activities and complete them on a timely basis. Since 24 February 2022, we have extended the focus of the business continuity plan to closely monitor each program in context of the currently ongoing Ukraine-Russia conflict and the associated specific regulatory, institutional, and government guidance and policies.

### **Risk factors**

We refer to the **description of risk factors in our 2021 annual report**, pp. 57-69, 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. 6-50. In summary of the foregoing, the principal risks and uncertainties faced by us, relate to and include, but are not limited 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 pandemics 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 2021 annual report, pp. 250-254, which remains valid and unaltered.



### 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 as Jyseleca<sup>®</sup> for the treatment of rheumatoid arthritis (RA) and ulcerative colitis (UC) 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 English versions, the Dutch version shall prevail. Galapagos will use reasonable efforts to ensure the translation and conformity between the Dutch and English versions.

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

### Galapagos NV

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

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

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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



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or phrases such as "believe," "anticipate," "expect," "intend," "plan," "seek," "upcoming," "future," "estimate," "may," "will," "could," "would," "potential," "forward," "goal," "next," "stand to," "continue," "should," "encouraging," "aim," "explore," "further" as well as similar expressions. Forward-looking statements contained in this report include, but are not limited to, statements made in the section captioned "Letter from our CEO" of this report, the information provided in the section captioned "Near term outlook" of this report, the guidance from management regarding the expected operational use of cash during the 2022 fiscal year, statements regarding our strategic and capital allocation priorities, statements regarding the acquisitions of CellPoint and AboundBio, including statements regarding anticipated benefits of the acquisitions and the integration of CellPoint and AboundBio into our portfolio and strategic plans, statements regarding our regulatory and R&D outlook, statements regarding expected financial results, statements regarding the amount and timing of potential future milestones, opt-in and/or royalty payments, our R&D strategy, including progress on our immunology or oncology portfolio or our SIKi platform, and potential changes in such strategy, statements regarding our pipeline and complementary technology platforms driving future growth, statements regarding the strategic re-evaluation, statements regarding our expectations on commercial sales of filgotinib, statements regarding the global R&D collaboration with Gilead and 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 RA, UC and Crohn's disease, (ii) with GLPG3667 in systemic lupus erythematosus and dermatomyositis, (iii) with compounds from our SIKi portfolio, (iv) with GLPG2737 in polycystic kidney disease, (v) with CD19 CAR-T in rrNHL and rrCLL, (vi) with the next-generation CAR-Ts and bispecific antibodies, including recruitment for trials and topline results for trials and studies in CAR-T, and (vii) with expected topline results from the DIVERSITY Phase 3 study in CD, statements related to the EMA's 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 interactions with regulatory authorities, the timing or likelihood of additional regulatory authorities' approval of marketing authorization for filgotinib for RA, UC or other indications for filgotinib in Europe, Great Britain, Japan, and the U.S., such additional regulatory authorities requiring additional studies, 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, statements related to the expected reimbursement for Jyseleca, statements regarding the effect of the conflict between Russia and Ukraine on our operations and ongoing studies (including the impact on our DIVERSITY 1 study), statements regarding the expected impact of COVID-19, and statements regarding our strategy (including our strategic transformation exercise), portfolio goals, business plans, focus, and plans for a sustainable future. We caution the reader that forward-looking statements are based on our management's current expectations and beliefs, and 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 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. Such risks include, but are not limited to, the risk that our beliefs, assumptions and expectations regarding our 2022 revenues and financial results or our 2022 operating expenses may be incorrect (including because one or more of our assumptions underlying our revenue or expense expectations may not be realized), the risk that ongoing and future clinical trials may not be completed in the currently envisaged timelines or at all, the inherent risks and uncertainties



### THE GALAPAGOS GROUP

associated with competitive developments, clinical trial, recruitment of patients for trials and product development activities and regulatory approval requirements (including, but not limited to, the risk that data from our ongoing and planned clinical research programs in RA, rrNHL, rrCLL, CD, UC, other immunologic indications or other indications or diseases, may not support registration or further development of our product candidates due to safety, or efficacy concerns, or other reasons), risks related to the acquisitions of CellPoint and AboundBio, including the risk that we may not achieve the anticipated benefits of the acquisitions of CellPoint and AboundBio, the inherent risks and uncertainties associated with target discovery and validation and drug discovery and development activities, risks related to our reliance on collaborations with third parties (including our collaboration partner for filgotinib, Gilead), 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, the risk that estimates regarding our filgotinib development program and the commercial potential of our product candidates and our expectations regarding the costs and revenues associated with the transfer of European commercialization rights to filgotinib may be incorrect, the risk that we will not be able to continue to execute on our currently contemplated business plan and/or will revise our business plan, including the risk that our plans with respect to CAR-T may not be achieved on the currently anticipated timeline or at all, the risk that our projections and expectations regarding the commercial potential of our product candidates or expectations regarding the costs and revenues associated with the commercialization rights may be inaccurate, the risks related to our strategic transformation exercise, including the risk that we may not achieve the anticipated benefits of such exercise on the currently envisaged timeline or at all, the risk that we will encounter challenges retaining or attracting talent, risks related to disruption in our operations or supply chain due to the conflict between Russia and Ukraine, the risks related to continued regulatory review of filgotinib following approval by relevant regulatory authorities and the EMA's safety review of IAK 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 market authorization for filgotinib in the EU be amended, the risk that the EMA may impose JAK class-based warnings, the risk that the EMA's safety review may negatively impact acceptance of filgotinib by patients, the medical community, and healthcare payors and the risks and uncertainties related 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 filings and reports with the Securities and Exchange Commission (SEC), 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 risks and uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. In addition, even if the result of our operations, financial condition and liquidity, or the industry in which we operate, are consistent with such forward-looking statements, they may not be predictive of results, performance or achievements in future periods. 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 2022



# Unaudited condensed consolidated interim financial statements for the first nine months of 2022

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

### (unaudited)

### **Consolidated income statement**

	Third quarter of		Nine months ended d quarter of 30 September	
(thousands of €, except per share data)	2022	2021	2022	2021
Product net sales	25,135	5,691	60,491	6,147
Collaboration revenues	111,068	58,503	349,669	311,711
Total net revenues	136,203	64,194	410,160	317,858
Cost of sales	(2,393)	(529)	(7,938)	(660)
Research and development expenditure	(114,549)	(109,196)	(364,067)	(378,022)
Sales and marketing expenses	(34,305)	(17,655)	(105,313)	(46,616)
General and administrative expenses	(34,372)	(27,793)	(97,373)	(104,651)
Other operating income	11,837	12,781	29,474	36,345
Operating loss	(37,578)	(78,199)	(135,056)	(175,747)
Fair value adjustments and net currency exchange differences	58,971	19,974	130,900	47,669
Other financial income	5,660	747	9,675	2,315
Other financial expenses	(4,806)	(6,978)	(13,074)	(16,325)
Profit/loss (-) before tax	22,247	(64,456)	(7,555)	(142,088)



### FINANCIAL STATEMENTS

	Third quarter of		Nine months ende 30 September	
(thousands of €, except per share data)	2022	2021	2022	2021
Income taxes	(694)	(157)	(3,229)	316
Net profit/loss (-) from continuing operations	21,554	(64,613)	(10,784)	(141,772)
Net profit from discontinued operations, net of tax	-	-	-	22,191
Net profit/loss (-)	21,554	(64,613)	(10,784)	(119,581)
Net profit/loss (-) attributable to:				
Owners of the parent	21,554	(64,613)	(10,784)	(119,581)
Basic and diluted income/loss (-) per share	0.33	(0.99)	(0.16)	(1.83)
Basic and diluted income/loss (-) per share from continuing operations	0.33	(0.99)	(0.16)	(2.16)

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



### Consolidated statement of comprehensive income/loss (-)

	Third quarter of					onths ended eptember	
(thousands of €)	2022	2021	2022	2021			
Net profit/loss (-)	21,554	(64,613)	(10,784)	(119,581)			
Items that may be reclassified subsequently to profit or loss:							
Translation differences, arisen from translating foreign activities	(100)	(32)	(7)	171			
Realization of translation differences upon sale of foreign operations	-	-	-	731			
Other comprehensive income/loss (-), net of income tax	(100)	(32)	(7)	902			
Total comprehensive income/loss (-) attributable to:							
Owners of the parent	21,454	(64,645)	(10,791)	(118,679)			
Total comprehensive income/loss (-) attributable to owners of the parent arises from:							
Continuing operations	21,454	(64,645)	(10,791)	(141,601)			
Discontinued operations	-	-	-	22,922			
Total comprehensive income/loss (-)	21,454	(64,645)	(10,791)	(118,679)			

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



# Consolidated statements of financial position (unaudited)

	30 September	31 December
(thousands of €)	2022	2021
Assets		
Goodwill	174,994	-
Intangible assets other than goodwill	38,493	60,103
Property, plant and equipment	150,394	137,512
Deferred tax assets	4,091	4,032
Non-current R&D incentives receivables	133,869	127,186
Other non-current assets	7,833	2,473
Non-current assets	509,673	331,306
Inventories	25,510	20,569
Trade and other receivables	34,783	111,337
Current R&D incentives receivables	19,591	16,827
Current financial investments	3,686,557	2,469,809
Cash and cash equivalents	675,519	2,233,368
Other current assets	20,436	9,945
Current assets	4,462,397	4,861,854
Total assets	4,972,070	5,193,160



### FINANCIAL STATEMENTS

	30 September	31 December
(thousands of €)	2022	2021
Equity and liabilities		
Share capital	293,605	292,075
Share premium account	2,735,557	2,730,391
Other reserves	(10,860)	(10,177)
Translation differences	(1,046)	(1,722)
Accumulated losses	(326,905)	(367,205)
Total equity	2,690,351	2,643,362
Retirement benefit liabilities	12,521	11,699
Non-current lease liabilities	15,759	19,655
Other non-current liabilities	38,209	7,135
Non-current deferred income	1,683,023	1,944,836
Non-current liabilities	1,749,512	1,983,325
Current lease liabilities	6,926	7,204
Trade and other liabilities	154,745	137,622
Current tax payable	873	1,782
Current deferred income	369,663	419,866
Current liabilities	532,207	566,474
Total liabilities	2,281,719	2,549,798
Total equity and liabilities	4,972,070	5,193,160

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



# Consolidated cash flow statements (unaudited)

### Nine months ended 30 September

	September		
(thousands of €)	2022	2021	
Net loss of the period	(10,784)	(119,581)	
Adjustment for non-cash transactions	(25,707)	59,050	
Adjustment for items to disclose separately under operating cash flow	1,599	6,013	
Adjustment for items to disclose under investing and financing cash flows	(1,700)	(28,845)	
Change in working capital other than deferred income	57,472	46,642	
Cash used for other liabilities related to the acquisition of subsidiaries	(11,080)	-	
Decrease in deferred income	(318,167)	(295,651)	
Cash used in operations	(308,367)	(332,372)	
Interest paid	(10,940)	(9,436)	
Interest received	2,262	2,049	
Corporate taxes paid	(3,637)	(297)	
Net cash flows used in operating activities	(320,682)	(340,056)	



### Nine months ended 30 September

	Septen	ilbei
(thousands of €)	2022	2021
Purchase of property, plant and equipment	(19,808)	(33,907)
Purchase of and expenditure in intangible fixed assets	(9,308)	(1,661)
Proceeds from disposal of property, plant and equipment	719	-
Purchase of current financial investments	(2,505,688)	(905,124)
Interest received related to current financial investments	1,181	10
Sale of current financial investments	1,394,549	1,901,132
Cash in from disposals of subsidiaries, net of cash disposed of	-	28,696
Cash out from acquisition of subsidiaries, net of cash acquired	(115,270)	-
Cash advances and loans to third parties	(10,000)	-
Proceeds from sale of financial assets held at fair value through profit or loss	-	4,045
Net cash flows generated from/used in (-) investing activities	(1,263,625)	993,191
Payment of lease liabilities	(6,263)	(5,174)
Proceeds from capital and share premium increases from exercise of subscription rights	6,695	2,735
Net cash flows generated from/used in (-) financing activities	432	(2,438)
Increase/decrease (-) in cash and cash equivalents	(1,583,875)	650,697



### Nine months ended 30 September

(thousands of €)	2022	2021		
Cash and cash equivalents at beginning of year	2,233,368	2,143,071		
Increase/decrease (-) in cash and cash equivalents	(1,583,875)	650,697		
Effect of exchange rate differences on cash and cash equivalents	26,026	40,610		
Cash and cash equivalents at end of the period	675,519	2,834,378		

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

### 30 September

(thousands of €)	2022	2021
Current financial investments	3,686,557	2,039,787
Cash and cash equivalents	675,519	2,834,378
Current financial investments and cash and cash equivalents	4,362,076	4,874,165

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



# Consolidated statements of changes in equity (unaudited)

(thousands of €)	Share capital	•	Translation differences	Other reserves	Accumul. losses	Total
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	1				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
On 1 January 2022	292,075	2,730,391	(1,722)	(10,177)	(367,205)	2,643,362
Net loss					(10,784)	(10,784)
Other comprehensive income/loss (-)			676	(683)		(7)
Total comprehensive income/loss (-)			676	(683)	(10,784)	(10,791)
Share-based compensation	1				51,085	51,085
Exercise of subscription rights	1,530	5,165				6,695
On 30 September 2022	293,605	2,735,557	(1,046)	(10,860)	(326,905)	2,690,351

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 2022

### **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 2021**.

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

### 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 2021.

New standards and interpretations applicable for the annual period beginning on 1 January 2022 did not have any material 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

### **Business combinations**

Business combinations are accounted for using the acquisition method. In the statement of financial position, the acquiree's identifiable assets, liabilities and contingent liabilities are initially recognized at their fair value at the acquisition date. The results of acquired operations are included in our consolidated income statement from the date on which control is obtained. Any contingent consideration to be transferred by us will be recognized at fair value at the acquisition date. Subsequent changes to the fair value of the contingent consideration, which is deemed to be an asset or liability, will be recognized in profit or loss. The excess of the fair value of the total purchase consideration transferred over the fair value of the acquired assets and assumed liabilities is recognized as goodwill. The valuations in support of fair value determinations are



based on information available at the acquisition date. Acquisition related costs are expensed as incurred.

### Key sources of estimation uncertainty

### **Acquisition of CellPoint**

We determine and allocate the purchase price relating to the acquisition of CellPoint to the assets acquired and liabilities assumed as of the acquisition date, being 21 June 2022. The purchase price determination process requires us to use significant estimates and assumptions that determine the present fair value of the contingent consideration included in the transaction. These estimates depend on development, regulatory and sales-based milestones that are adjusted by our best estimate of their probability of success and discounted. We also anticipate to use significant estimates and assumptions in the finalization of the purchase price accounting process.



# Details of the unaudited condensed consolidated interim results

### Product net sales

We reported net sales of Jyseleca for the first nine months of 2022 amounting to €60.5 million (€6.1 million in the first nine months of 2021).

Related costs of sales in the first nine months of 2022 amounted to €7.9 million.

### **Collaboration revenues**

The following table summarizes our collaboration revenues for the nine months ended 30 September 2022 and 2021:

		Third quarter of		Third quarter of		ths ended ember
		Point in				
(thousands of €)	Over time	time	2022	2021	2022	2021
Recognition of non- refundable upfront						
payments and license fees			101,325	58,928	305,626	291,370
Gilead collaboration agreement for filgotinib	✓		43,633	1,277	133,018	118,021
Gilead collaboration agreement for drug discovery platform	<b>√</b>		57,692	57,651	172,608	173,348
	•					
Milestone payments			7,821	(978)	35,759	18,391
Gilead collaboration agreement for filgotinib	✓		7,821	(978)	33,759	18,391
Sobi distribution agreement for Jyseleca		✓		-	2,000	-
Royalties			1,923	553	8,285	1,950
Gilead royalties on Jyseleca		✓	1,923	557	8,240	1,907
Other royalties		✓	-	(4)	44	43
Total collaboration revenues			111,068	58,503	349,669	311,711



The rollforward of the outstanding balance of the current and non-current deferred income between 1 January 2022 and 30 September 2022 can be summarized as follows:

			Gilead	
		Gilead	collaboration	
		collaboration	agreement for	Other deferred
(thousands of €)	Total	agreement for filgotinib	platform <sup>(1)</sup>	Other deferred income
On 1 January 2022	2,364,701	604,875	1,759,828	-
Milestones achieved	18,238	18,238		
Significant financing				
component <sup>(2)</sup>	5,673	5,673		
Revenue recognition of upfront	(305,626)	(133,018)	(172,608)	
	(303,020)	(133,010)	(172,000)	
Revenue recognition of				
milestones	(33,759)	(33,759)		
Other movements	3,457			3,457
On 20 Contombox 2022	2.052.696	462.000	1 507 330	2 457
On 30 September 2022	2,052,686	462,009	1,587,220	3,457

<sup>(1)</sup> The upfront received and the outstanding balance at 1 January 2022 and at 30 September 2022 comprise the issuance liabilities for the warrants and the upfront payment allocated to the drug discovery platform.

<sup>(2)</sup> 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



### Operating costs and other operating income

### **Operating costs**

### Research and development expenditure

The following table summarizes our research and development expenditure for the nine months ended 30 September 2022 and 2021:

	Third quarter of		Nine mont 30 Sept	
(thousands of €)	2022	2021	2022	2021
Personnel costs	(44,044)	(40,102)	(130,001)	(134,256)
Subcontracting	(54,412)	(49,907)	(158,472)	(189,100)
Disposables and lab fees and premises costs	(5,286)	(5,401)	(15,596)	(17,688)
Depreciation and impairment	(3,091)	(5,998)	(35,646)	(14,097)
Professional fees	(3,317)	(3,747)	(10,719)	(10,788)
Other operating expenses	(4,399)	(4,040)	(13,633)	(12,092)
Total research and development expenditure	(114,549)	(109,196)	(364,067)	(378,022)

The increase in depreciation and impairment for the first nine months of 2022 is primarily due to an impairment of €26.7 million of previously capitalized upfront fees related to our collaboration with Molecure on the dual chitinase inhibitor OATD-01.

The table below summarizes our R&D expenditure for the nine months ended 30 September 2022 and 2021, broken down by program.

	Third quarter of		Nine mont 30 Sept	
(thousands of €)	2022	2021	2022	2021
Filgotinib program	(62,255)	(40,656)	(178,402)	(128,496)
SIKi program	(9,692)	(19,625)	(35,789)	(71,860)
TYK2 program on GLPG3667	(5,931)	(5,482)	(15,009)	(19,456)
Ziritaxestat program	(114)	(4,001)	(752)	(23,420)
Other programs	(36,557)	(39,432)	(134,115)	(134,790)
Total research and development expenditure	(114,549)	(109,196)	(364,067)	(378,022)



### Sales and marketing expenses

The following table summarizes our sales and marketing expenses for the nine months ended 30 September 2022 and 2021:

	Third quarter of		Nine mont 30 Sept	
(thousands of €)	2022	2021	2022	2021
Personnel costs	(17,726)	(16,403)	(53,449)	(43,274)
Depreciation	(660)	(153)	(1,782)	(321)
External outsourcing costs	(12,226)	(15,190)	(37,897)	(40,149)
Sales and marketing expenses recharged to Gilead	-	15,680	31	41,207
Professional fees	(744)	(143)	(2,278)	(323)
Other operating expenses	(2,949)	(1,445)	(9,938)	(3,755)
Total sales and marketing expenses	(34,305)	(17,655)	(105,313)	(46,616)

The termination of our 50/50 filgotinib co-commercialization cost sharing agreement with Gilead explains a significant part of the increase in sales & marketing expenses.

### **General and administrative expenses**

The following table summarizes our general and administrative expenses for the nine months ended 30 September 2022 and 2021:

	Third quarter of		Nine months ended 30 September	
(thousands of €)	2022	2021	2022	2021
Personnel costs	(18,875)	(14,851)	(54,504)	(52,419)
Depreciation and impairment	(2,129)	(1,901)	(6,426)	(14,631)
Legal and professional fees	(5,935)	(4,161)	(16,752)	(17,629)
Other operating expenses	(7,434)	(6,881)	(19,692)	(19,972)
Total general and administrative expenses	(34,372)	(27,793)	(97,373)	(104,651)



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### Other operating income

The following table summarizes our other operating income for the nine months ended 30 September 2022 and 2021:

	Third quarter of		Nine mon	
(thousands of €)	2022	2021	2022	2021
Grant income	486	1,878	1,495	5,665
R&D incentives	7,216	10,152	23,119	29,653
Other	4,135	752	4,860	1,027
Total other operating income	11,837	12,781	29,474	36,345



## Financial income/expenses

The following table summarizes our financial income/expenses (-) for the nine months ended 30 September 2022 and 2021:

	Third quarter of		Nine months ended 30 September	
(thousands of €)	2022	2021	2022	2021
Fair value adjustments and net currency exchange differences				
Net currency exchange gain	44,647	21,149	104,815	54,762
Fair value re-measurement of warrants	129	198	80	3,025
Fair value loss on financial assets held at fair value through profit or loss	-	-	-	(2,913)
Fair value gain/loss (-) on current financial investments	14,195	(1,373)	26,005	(7,206)
Total fair value adjustments and net currency exchange differences	58,971	19,974	130,900	47,669
Other financial income:				
Interest income	5,622	714	9,240	2,156
Discounting effect of non-current R&D incentives receivables	23	23	69	69
Other finance income	15	10	366	90
Total other financial income	5,660	747	9,675	2,315
Other financial expenses:				
Interest expenses	(1,721)	(4,049)	(5,927)	(8,474)
Discounting effect of non-current deferred income	(1,874)	(2,400)	(5,673)	(7,170)
Discounting effect of other non-current liabilities	(812)	-	(812)	-
Other finance charges	(398)	(529)	(662)	(681)
Total other financial expenses	(4,806)	(6,978)	(13,074)	(16,325)
Total net financial result	59,825	13,743	127,501	33,659



## **Cash position**

Cash and cash equivalents and current financial investments totaled €4,362.1 million on 30 September 2022 (€4,703.2 million on 31 December 2021).

Cash and cash equivalents and current financial investments comprised cash at banks, term deposits, treasury bills and money market funds. 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 €235.3 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 and current accounts. Our credit risk is mitigated by selecting a panel of highly rated financial institutions for our deposits.

Current financial investments comprised €1,625.7 million of term deposits which all had an original maturity longer than three months and which are not available on demand within three months. Our current financial investments also comprised money market funds and treasury bills. 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.

	30 September	31 December
(thousands of €)	2022	2021
Money market funds	1,310,203	1,317,460
Treasury bills	750,696	877,349
Term deposits	1,625,657	275,000
Total current financial investments	3,686,557	2,469,809
Cash at banks	440,261	1,225,860
Term deposits	235,259	1,007,508
Total cash and cash equivalents	675,519	2,233,368
Total current financial investments and cash and cash		
equivalents	4,362,076	4,703,177

On 30 September 2022, our cash and cash equivalents and current financial investments included \$951.6 million held in U.S. dollars (\$942.5 million on 31 December 2021) 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



#### FINANCIAL STATEMENTS

exchange loss (–)/gain in case of a 10% change in the EUR/U.S. dollar exchange rate amounts to €97.1 million.

## **Capital increase**

On 30 September 2022, Galapagos NV's share capital was represented by 65,835,511 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 2022.

(thousands of €, except share data)	Number of shares	Share capital	Share premium	Share capital and share premium	•	Closing share price on date of capital increase (in €/share)
On 1 January 2022	65,552,721	292,075	2,730,391	3,022,467		
18 March 2022: exercise of						
subscription rights	95,500	517	1,643	2,160	22.61	57.38
20 June 2022: exercise of						
subscription rights	80,290	434	1,025	1,460	18.18	53.52
27 September 2022: exercise of subscription						
rights	107,000	579	2,497	3,076	28.75	44.49
On 30 September 2022	65,835,511	293,605	2,735,557	3,029,162		



## Note to the cash flow statement

#### Nine months ended 30 September

	September		
(thousands of €)	2022	2021	
Adjustment for non-cash transactions			
Depreciation and impairment	43,854	29,050	
Share-based compensation expenses	51,085	62,971	
Increase in retirement benefit obligations and provisions	405	285	
Unrealized exchange gains and non-cash other financial result	(102,163)	(47,975)	
Discounting effect of non-current deferred income	5,673	7,170	
Discounting effect of other non-current liabilities	812	-	
Fair value re-measurement of warrants	(80)	(3,025)	
Net change in (fair) value of current financial investments	(26,004)	7,206	
Fair value adjustment financial assets held at fair value through profit or loss	-	2,913	
Other non-cash expenses	712	455	
Total adjustment for non-cash transactions	(25,707)	59,050	
Adjustment for items to disclose separately under operating cash flow			
Interest expense	5,927	8,474	
Interest income	(7,557)	(2,146)	
Tax expense	3,229	(316)	
Total adjustment for items to disclose separately under operating cash flow	1,599	6,013	



#### Nine months ended 30 September

	эсрес	
(thousands of €)	2022	2021
Adjustment for items to disclose under investing and financing cash flows		
Gain on sale of subsidiaries	-	(22,191)
Gain (-)/loss on sale of fixed assets	(17)	1
Realized exchange gain on sale of current financial investments	-	(6,645)
Interest income on current financial assets	(1,683)	(10)
Total adjustment for items to disclose separately under investing and financing cash flow	(1,700)	(28,845)
Change in working capital other than deferred income		
Increase in inventories	(5,667)	(2,060)
Decrease in receivables	63,502	82,008
Decrease in liabilities	(363)	(33,306)
Total change in working capital other than deferred income	57,472	46,642

#### **Business combinations**

On 21 June 2022 we acquired, in an all-cash transaction, 100% of the shares and voting interests of CellPoint for a total agreed payment at completion of  $\leq$ 125 million, including consideration for other liabilities associated with the transaction amounting to  $\leq$ 10.3 million. Additional contingent consideration up to  $\leq$ 100.0 million is due when certain development ( $\leq$ 20.0 million), regulatory ( $\leq$ 30.0 million) and sales-based ( $\leq$ 50.0 million) milestones would be achieved. Total fair value at acquisition date of these milestones amounted to  $\leq$ 22.9 million. This fair value is measured with most significant inputs being the probability of success of reaching these milestones, expected timing and the discount rate. During the third quarter of 2022 no changes were made to the assumptions used in the valuation. The discounting impact, amounting to  $\leq$ 0.8 million, is recognized in financial results.

On the same date we acquired all of the outstanding capital of AboundBio, for a total agreed price of \$14 million, including consideration for other liabilities associated with the transaction.

The main reason for these acquisitions is to position ourselves in next-generation cancer therapy market and to significantly broaden our portfolio and capabilities. As a result of these acquisitions, we gain access to an innovative, scalable, decentralized and automated point-of-care cell therapy supply model as well as a next-generation fully human antibody-based therapeutics platform. Combined and supported by us as a fully integrated biopharma, they have the potential to disrupt the CAR-T treatment paradigm. The goal is to expand the current



#### FINANCIAL STATEMENTS

market for CAR-T therapies and have an important impact on patients in need of additional and improved treatment options.

Details of the preliminary fair value of identifiable assets and liabilities acquired in both transactions, the preliminary purchase consideration and provisional goodwill at the acquisition date are as follows:

21	lune	2022
	,	

	•		
(thousands of €)	CellPoint	AboundBio	Total
Property, plant and equipment	1,289	965	
Other non-current assets	81	4	
Trade and other receivables	162	-	
Cash and cash equivalents	3,179	4,279	
Other current assets	1,254	536	
Trade and other liabilities	(32,789)	(587)	
Current deferred income	-	(474)	
Net assets acquired	(26,824)	4,723	
Consideration paid in cash	107,750	14,976	
Fair value re-measurement of previously held equity investment	-	342	
Deferred consideration	6,088	-	
Fair value of contingent consideration	22,865	-	
Fair value of total consideration	136,703	15,318	
Goodwill	163,526	10,595	
Exchange differences on goodwill	-	872	
Goodwill in the balance sheet	163,526	11,467	174,994



#### Net cash outflow arising on acquisition

(thousands of €)	CellPoint	AboundBio	Total
Consideration paid in cash	107,750	14,976	
Less: cash and cash equivalents balances acquired	(3,179)	(4,279)	
Cash out from acquisition of subsidiaries, net of cash acquired	104,571	10,698	115,270
Cash used in operating activities for other liabilities related to the acquisition of subsidiaries	11,080		11,080

The preliminary fair value of the identifiable assets and liabilities are included in our condensed consolidated interim financial statements as per 30 September 2022. To date we have performed a preliminary fair value analysis of the business combinations, with corresponding adjustments to the trade and other liabilities. We expect the provisional amount of goodwill to change significantly upon the completion of the purchase price allocation, resulting from the valuation of the different assets and liabilities acquired, including the valuation of in-process R&D.

## **Contingencies and commitments**

## Contractual obligations and commitments

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

On 30 September 2022, we had outstanding obligations for purchase commitments, which become due as follows:

		Less than			More than
(thousands of €)	Total	1 year	1 - 3 years	3 - 5 years	5 years
Purchase commitments	439,317	269,994	137,127	32,041	155

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 €276.1 million at 30 September 2022 for which we have direct purchase commitments of €230.7 million at 30 September 2022 reflected in the table above.

## Contingent liabilities and assets

We refer to our **Annual Report 2021** for a description of our contingent liabilities and assets.



## Related party transactions

On 6 May 2022, certain members of the Executive Committee were offered new subscription rights under Subscription Right Plan 2022 BE. The final number of accepted subscription rights under Subscription Right Plan 2022 BE was enacted by notary deed on 7 July 2022 and on 2 September 2022. 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 €57.46 (*i.e.* 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 2022 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 2026.

The table below sets forth the number of subscription rights accepted by each member of the Executive Committee under Subscription Right Plan 2022 (B) and Subscription Right Plan 2022 BE, respectively, during the first nine months of 2022:

Name	Title	Number of 2022 subscription rights accepted
Stoffels IMC BV <sup>(1)</sup>	CEO	1,000,000
Bart Filius	President, COO & CFO	68,000
Walid Abi-Saab	СМО	32,000
Michele Manto	CCO	24,000

<sup>(1)</sup> Stoffels IMC BV (permanently presented by Dr. Paul Stoffels).

During the first nine months of 2022, other than as disclosed in the paragraph above or in our half-year 2022 financial report, there were no changes to related party transactions disclosed in the 2021 annual report that potentially had a material impact on the financials of Galapagos of the first nine months of 2022.

## Events after the end of the reporting period

In this Q3 report 2022, we announced our new strategic direction for which the actual financial impact cannot be reliably estimated at this time and will be included in future reporting periods.

## Approval of interim financial statements

The interim financial statements were approved by the Board of Directors on 31 October 2022.



#### REPORT OF THE STATUTORY AUDITOR

# Report on the review of the condensed consolidated interim financial statements for the nine-month period ended 30 September 2022

The original text of this report is in Dutch.

In the context of our appointment as the company's statutory auditor, we report to you on the condensed consolidated interim financial information. These condensed consolidated interim financial statements comprise the consolidated statements of financial position as at 30 September 2022, the consolidated income statements and comprehensive income/loss (–), the consolidated statement of changes in equity and the consolidated cash flow statements for the period of nine months then ended, as well as selective notes.

# Report on the condensed consolidated interim financial statements

We have reviewed the condensed consolidated interim financial statements of Galapagos NV ("the company") and its subsidiaries (jointly "the group"), prepared in accordance with International Accounting Standard (IAS) 34, "Interim Financial Reporting" as adopted by the European Union.

The consolidated statement of financial position shows total assets of 4 972 070 (000) EUR and the consolidated income statement shows a consolidated loss (group share) for the period then ended of 10 784 (000) EUR.

The Board of Directors of the company is responsible for the preparation and fair presentation of the condensed consolidated interim financial statements in accordance with IAS 34, "Interim Financial Reporting" as adopted by the European Union. Our responsibility is to express a conclusion on these condensed consolidated interim financial statements based on our review.

## Scope of review

We conducted our review of the condensed consolidated interim financial statements in accordance with International Standard on Review Engagements (ISRE) 2410, "Review of interim financial information performed by the independent auditor of the entity". A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit performed in accordance with the International Standards on Auditing (ISA) and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion on the condensed consolidated interim financial statements.



## REPORT OF THE STATUTORY AUDITOR

#### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the condensed consolidated interim financial statements of Galapagos NV have not been prepared, in all material respects, in accordance with IAS 34, "Interim Financial Reporting" as adopted by the European Union.

Signed at Zaventem, 3 November 2022. The statutory auditor

Deloitte Bedrijfsrevisoren/Réviseurs d'Entreprises BV/SRL Represented by Nico Houthaeve



# **Glossary**

## 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

#### **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

## **Antibody**

A blood protein produced in response to and counteracting a specific antigen. Antibodies combine chemically with substances which the body recognizes as alien, such as bacteria, viruses, and foreign substances



## **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

## Bispecific antibody

An antibody that binds to two different antigens

#### **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

#### **CAR-T**

Chimeric antigen receptor T cells (also known as CART cells) are T cells that have been genetically engineered to produce an artificial T cell receptor for use in immunotherapy

#### **CD19**

CD19 is a protein found on the surface of B-cells, a type of white blood cell. Since CD19 is a hallmark of B-cells, the protein has been used to diagnose cancers that arise from this type of cell - notably B-cell lymphomas



#### **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

Chitotriosidase (CHIT1) is a protein coding gene, and AMCase is an inactive acidic mamalian 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

#### **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

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

#### **CRP**

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

## **Cash position**

Current financial investments and cash and cash equivalents

#### 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



## Chronic Lymphocytic Leukemia (CLL)

Chronic lymphocytic leukemia is the most common leukemia in adults. It is a type of cancer that starts in cells that become certain white blood cells (called lymphocytes) in the bone marrow. The cancer (leukemia) cells originate in the bone marrow and migrate to the bloodstream

## 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 send 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 on a contract basis

#### **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

## 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

#### **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

## 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

## Dermatomyositis

Dermatomyositis is a rare inflammatory disease. Common symptoms include distinctive skin rash, and inflammatory myopathy, or inflamed muscles, causing muscle weakness

## 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



#### OTHER INFORMATION

## **Disease-modifying**

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

## Dose-range finding study

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

#### Double-blind

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

#### EC

**European Commission** 

#### **EMA**

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

## **Efficacy**

Effectiveness for intended use

#### End-to-end

A process that takes a system or service from beginning to end and delivers a complete functional solution, usually without strong reliance on third parties

## Endoscopy

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

#### **FDA**

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

#### 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

#### **FILOSOPHY**

Phase 4 program evaluating filgotinib in RA

#### **FINCH**

Phase 3 program evaluating filgotinib in RA



#### **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

#### **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

#### Fee-for-service

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

## **Filgotinib**

Formerly known as GLPG0634, commercial name is Jyseleca. Small molecule preferential JAK1 inhibitor, approved in RA and UC in European Union, Great Britain, and Japan. Filgotinib is partnered with Gilead. Filgotinib currently is in Phase 3 trials in CD, and in a Phase 4 trial 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

## **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



#### **GLIDER**

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

#### **GLPG0555**

A JAK1 inhibitor in Phase 1b. Development was stopped in July 2022

#### **GLPG0634**

Molecule number currently known as filgotinib and Jyseleca

#### **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 in Phase 1 targeting JAK1/TYK2 directed toward inflammation (IBD). Development was stopped in July 2022

#### **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 in multiple Phase 2 Proof of Concept studies. Topline results from the studies in UC, psoriasis and RA were reported in July 2021. The compound was discontinued in March 2022

#### **GLPG4399**

A SIK3 inhibitor currently in Phase 1 directed toward inflammation

#### **GLPG4586**

A compound with undisclosed mode of action in preclinical phase directed toward fibrosis and inlicensed from Fibrocor. The development was stopped in July 2022

#### **GLPG4605**

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

#### **GLPG4716**

A chitinase inhibitor inlicensed from Molecure (previously OncoArendi). The rights to the molecule have been returned to Molecure in July 2022



#### Genome

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

#### **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

#### **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

#### 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

## 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



## 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

## **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

#### 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

#### **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

#### **MTX**

Methotrexate; a first-line therapy for inflammatory diseases

## **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

#### 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

#### **NDA**

New Drug Application



#### **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

## 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

## Non-Hodgkin Lymphoma (NHL)

Non-Hodgkin lymphoma is a type of cancer that begins in the lymphatic system, which is part of the body's germ-fighting immune system. In non-Hodgkin lymphoma, white blood cells called lymphocytes grow abnormally and form tumors throughout the body

## 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

#### **PRAC**

Pharmacovigilance Risk Assessment Committee of the European Medicines Agency, responsible for assessing all aspects of risk management of human medicines



#### **PROTAC**

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

## 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 and access to the market

## 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

#### Point-of-care

Drug treatment is provided close to or near the patient



#### **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

## 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

## Refractory

"Refractory" refers to a patient with cancer that is/has become resistant to, or does not respond to, treatment

## Relapsed

"Relapsed" refers to a patient with cancer that develops cancer again after a period of improvement



## 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

## **S&M** expenses

Sales and marketing expenses

#### 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)

#### SIK

Salt-inducible kinase

## 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

## **Short interfering RNA**

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

## 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

## 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

#### **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

#### **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

## **Target**

Proteïn 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

## Technology access fee

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

## **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 synthetized from mRNA



## **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)



## Financial calendar

## 23 February 2023

Full year 2022 results

## 23 March 2023

Annual report 2022

## 25 April 2023

Annual Shareholders' meeting

## 4 May 2023

First quarter 2023 results

## 3 August 2023

Half year 2023 results

## 2 November 2023

Third quarter 2023 results



# Colophon

#### Concept, design and online programming

nexxar GmbH, Vienna – Online annual reports and online sustainability reports www.nexxar.com

#### Photography

Frank van Delft

Copy deadline: 3 November 2022

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

# **Galáp**agos

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