

First key steps in pipeline rebuild and strong commercial progress in H1 2022

- **First half-year 2022 financial results:**
 - **Jyseleca® net sales reached €35.4 million**
 - **Group revenues of €274.0 million**
 - **Operating loss of €97.5 million**
 - **Cash and current financial investments of €4.4 billion on 30 June 2022**
- **Increased 2022 guidance for Jyseleca from €65-75 million to €75-85 million**
- **Combined acquisitions of CellPoint and AboundBio in all-cash transactions positions company in CAR-T therapy space**

[Webcast presentation tomorrow, 5 August 2022, at 14.00 CET / 8 AM ET, \[www.glpq.com\]\(http://www.glpq.com\)](#)

Mechelen, Belgium; 4 August 2022, 22.01 CET; regulated information – Galapagos NV (Euronext & NASDAQ: GLPG) today announced its first half-year 2022 financial results, a year-to-date business update and its outlook for the remainder of 2022. The results are further detailed in the H1 2022 financial report available on the financial reports section of the [website](#).

“This quarter, we took a first key step in our strategic transformation by entering the field of oncology with the acquisitions of CellPoint and AboundBio. The combined transactions offer the potential for a paradigm shift in CAR-T¹ therapy through CellPoint’s breakthrough, decentralized point-of-care supply model, developed in a global strategic collaboration with Lonza, and AboundBio’s cutting-edge fully human antibody-based capabilities to design next-generation CAR-Ts. Patient enrolment in the ongoing Phase 1/2a trials in rrNHL and rrCLL² is progressing well, and we expect topline results in the first half of next year. Our near-term goal is to bring three additional differentiated, next-generation CAR-T candidates in the clinic over the next three years,” said Dr. Paul Stoffels³, CEO and chairman of the board of directors of Galapagos. “We strongly believe that we are taking the right steps in our transformation to accelerate value creation, and we look forward to presenting an in-depth update on our strategy later this year.”

“Our Jyseleca franchise is performing very well with robust sales momentum, supported by the regulatory approvals in ulcerative colitis (UC) in Great Britain and Japan earlier this year. The adoption of Jyseleca is strong across Europe with reimbursement for rheumatoid arthritis (RA) in 15 and for UC in 6 countries,” added Bart Filius, President, COO and CFO of Galapagos. “Following the acquisitions of CellPoint and AboundBio, we expect that second half operating expenses will increase by approximately €30 million. Therefore, we revised our cash burnⁱ guidance of €450-€490 million for the full year 2022 to €480-€520 million. As a result of the strong Jyseleca performance, we increase our full-year net sales guidance of €65-€75 million to €75-€85 million.”

¹ Chimeric antigen receptor T-cell

² rrNHL: relapsed/refractory non-Hodgkin Lymphoma, rrCLL: relapsed/refractory Chronic Lymphocytic Leukemia

³ Acting via Stoffels IMC BV

Year-to-date operational overview

Commercial & regulatory progress:

- Strong adoption across Europe with reimbursement for RA in 15 countries and for UC in 6 countries
- Sobi, our distribution and commercialization partner in Eastern and Central Europe, Portugal, Greece, and the Baltic countries, launched Jyseleca in RA in the Czech Republic and Portugal, resulting in €2 million milestone payments to Galapagos in H1
- Filed a type II variation for the label update for Jyseleca based on data from the MANTA and MANTA-RAY studies
- At the EULAR⁴ 2022 European Congress of Rheumatology, Galapagos hosted several expert sessions and presented 11 abstracts, further establishing us as a key player in RA
- Article 20 pharmacovigilance procedure ongoing by the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC), investigating the safety data of all JAK inhibitors for the treatment of certain chronic inflammatory disorders

Pipeline update:

- Decided to move forward with GLPG3667 (TYK2 inhibitor) in dermatomyositis with the aim to start a Phase 2 study before year-end
- Discontinued development of 4 early-stage programs as part of ongoing scientific and strategic exercise: GLPG3121, a local release formulation JAK1/TYK2 inhibitor with potential in inflammatory diseases; GLPG0555, a JAK1 inhibitor evaluated in osteoarthritis; GLPG4586, a compound with undisclosed mode of action directed toward fibrosis; and GLPG4716, a chitinase inhibitor directed toward idiopathic pulmonary fibrosis

Corporate update:

- Entered the field of oncology through the combined acquisitions of CellPoint and AboundBio in all-cash transactions
- Received a transparency notification from FMR LLC in Q2 indicating that its shareholding in Galapagos increased and crossed the 5% threshold, to 5.04% of the current outstanding Galapagos shares
- Raised €3.6 million through the exercise of subscription rights
- Created new subscription rights plans, offering all Galapagos employees the opportunity to participate
- All proposed resolutions regarding the extraordinary and annual shareholders' meetings were adopted by Galapagos' shareholders on 26 April 2022

⁴ European Alliance of Associations for Rheumatology

First half-year 2022 financial highlights (unaudited)
(€ millions, except basic & diluted income/loss per share)

	30 June 2022 group total	30 June 2021 group total	Variance
Product net sales	35.4	0.5	34.9
Collaboration revenues	238.6	253.2	(14.6)
Total net revenues	274.0	253.7	20.3
Cost of sales	(5.5)	(0.1)	(5.4)
R&D expenditure	(249.5)	(268.8)	19.3
G&A ⁱⁱ and S&M ⁱⁱⁱ expenses	(134.0)	(105.8)	(28.2)
Other operating income	17.6	23.6	(5.9)
Operating loss	(97.5)	(97.6)	0.1
Net financial result	67.7	19.9	47.8
Income taxes	(2.5)	0.5	(3.0)
Net loss from continuing operations	(32.3)	(77.2)	44.9
Net profit from discontinued operations	-	22.2	(22.2)
Net loss of the period	(32.3)	(55.0)	22.7
Basic and diluted loss per share (€)	(0.49)	(0.84)	
Basic and diluted loss per share from continuing operations (€)	(0.49)	(1.18)	
Current financial investments and cash and cash equivalents	4,429.0	5,006.6	

H1 2022 financial results

We reported product net sales of Jyseleca in Europe for the first six months of 2022 amounting to €35.4 million (€0.5 million in the first six months of 2021). Our counterparties for the sales of Jyseleca were mainly hospitals and wholesalers located in Belgium, the Netherlands, France, Italy, Spain, Germany, Great Britain, Ireland, Austria, Norway, Sweden and Finland.

Cost of sales related to Jyseleca net sales in the first six months of 2022 amounted to €5.5 million.

Collaboration revenues amounted to €238.6 million for the first six months of 2022, compared to €253.2 million for the first six months of 2021.

Revenues recognized related to the collaboration agreement with Gilead for the filgotinib development were €115.3 million in the first six months of 2022 compared to €136.1 million for the same period last year. This decrease was due to a lower increase in the percentage of completion, partly offset by 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 half-year of 2022. The revenue recognition related to the exclusive access rights for Gilead to our drug discovery platform amounted to €114.9 million for the first six months of 2022 (€115.7 million for the same period last year).

We have recognized royalty income from Gilead for Jyseleca for €6.3 million in the first six months of 2022 (compared to €1.4 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 sale of Jyseleca in the Czech Republic and Portugal by our distribution and commercialization partner Sobi, in the first half-year of 2022.

Our deferred income balance on 30 June 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 the filgotinib development that is recognized over time until the end of the development period.

Our R&D expenditure in the first six months of 2022 amounted to €249.5 million, compared to €268.8 million for the first six months of 2021. This decrease was primarily explained by a decrease in subcontracting costs from €139.2 million in the first six months of 2021 to €104.1 million in the first six months of 2022, primarily due to the winding down of the ziritaxestat (IPF) program and reduced spend on our Toledo (SIKi) and TYK2 programs. This was partly offset by cost increases for our filgotinib program, on a six month basis compared to the same period in 2021. Personnel costs decreased from €94.2 million in the first half of 2021 to €86.0 million for the same period this year mainly due to a lower number of FTEs as well as lower costs for our subscription right plans. Depreciation and impairment amounted to €32.6 million for the first six months of 2022 (€8.1 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). As part of an ongoing strategic exercise to renew and accelerate our portfolio, we decided to return all rights to OATD-01 to Molecure.

Our G&A and S&M expenses amounted to €134.0 million in the first six months of 2022, compared to €105.8 million in the first six months of 2021. This increase was primarily due to the termination of our 50/50 filgotinib co-commercialization cost sharing agreement with Gilead for filgotinib in 2022. The cost increase was also explained by an increase in personnel costs for the first six months of 2022 compared to the same period last year explained by an increase in the commercial work force driven by the commercial launch of filgotinib in Europe.

Other operating income (€17.6 million vs €23.6 million for the same period last year) decreased, mainly driven by lower grant and R&D incentives income.

Net financial income in the first six months of 2022 amounted to €67.7 million, compared to net financial income of €19.9 million for the first six months of 2021. Net financial income in the first six months of 2022 was primarily attributable to €57.4 million of unrealized currency exchange gains on our cash and cash equivalents and current financial investments at amortized cost in U.S. dollars, and to €11.8 million of positive changes in (fair) value of current financial investments. The financial expenses also contained the effect of discounting our long term deferred income of €3.8 million.

We realized a net loss from continuing operations of €32.3 million for the first six months of 2022, compared to a net loss of €77.2 million for the first six months of 2021.

The net profit from discontinued operations for the six months ended 30 June 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 six months of 2022 of €32.3 million, compared to a group net loss of €55.0 million for the first six months of 2021.

Cash position

Current financial investments and cash and cash equivalents totaled €4,429.0 million on 30 June 2022, as compared to €4,703.2 million on 31 December 2021.

Total net decrease in cash and cash equivalents and current financial investments amounted to €274.2 million during the first six months of 2022, compared to a net decrease of €162.7 million during the first six months of 2021. This net decrease was composed of (i) €217.1 million of operational cash burn, (ii) offset by €3.6 million of cash proceeds from capital and share premium increase from exercise of subscription rights in the first six months of 2022, (iii) €11.8 million positive changes in (fair) value of current financial investments and €60.4 million of mainly positive exchange rate differences, and (iv) the cash out from the acquisitions of CellPoint and AboundBio, net of cash acquired, of €132.9 million.

Acquisitions of CellPoint and AboundBio

The preliminary accounting of the acquisitions of CellPoint and AboundBio are included in our H1 2022 condensed consolidated financial statements. To date, we have performed a preliminary fair value analysis of the business combinations. 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.

Outlook 2022

Financial guidance:

Following the acquisitions of CellPoint and AboundBio, we revised our cash burn guidance for full year 2022 from €450-€490 million to €480-€520 million. Additionally, we increased our anticipated net sales guidance for Jyseleca from €65-€75 million to between €75 and €85 million.

Expected regulatory events:

We anticipate a Committee for Medicinal Products for Human Use (CHMP) opinion on the type II variation for the Jyseleca label, based on the data from the MANTA and MANTA-RAY studies around year-end. We also expect reimbursement decisions in most key European markets in UC and anticipate that Sobi will further progress with reimbursement discussions in RA and UC in Eastern and Central Europe, Greece, and the Baltic countries. As part of the ongoing article 20 pharmacovigilance procedure on all JAK inhibitors approved in Europe, we expect a CHMP opinion by the end of the year, followed by an adoption by the European Commission shortly afterwards.

Anticipated R&D milestones:

Patient enrolment in the Phase 1/2a trials in rrNHL and rrCLL is progressing well and we anticipate that additional clinical sites will be active by year-end. We are on track to report topline results of both trials in the first half of next year.

We plan to progress TYK2 inhibitor GLPG3667 into a Phase 2 program in dermatomyositis with first patients potentially recruited around year-end.

We continue to explore additional business development opportunities to further leverage our internal capabilities and renew our portfolio, and we look forward to presenting an in-depth update on our corporate strategy later this year.

First half-year 2022 financial report

Galapagos' financial report for the first six months ended 30 June 2022, including details of the unaudited consolidated results, is accessible on the financial reports section of our [website](#).

Conference call and webcast presentation

Management will host a conference call and webcast presentation followed by Q&A tomorrow 5 August 2022, at 14:00 CET / 8 AM ET. To participate in the conference call, please register in advance using [this link](#). Upon registration, the dial-in numbers will be provided. The conference call can be accessed 10 minutes prior to the start time by using the conference access information provided in the e-mail received at the point of registering, or by selecting the *call me* feature.

The live webcast can be accessed on the investors section of the Galapagos [website](#), and a replay will be made available shortly after the close of the call.

Financial calendar 2022

3 November 2022	Third quarter 2022 results	(webcast 4 November 2022)
23 February 2023	Full year 2022 results	(webcast 24 February 2023)

About Galapagos

Galapagos is a fully integrated biotechnology company focused on discovering, developing, and commercializing innovative medicines. We are committed to improving patients' lives worldwide by targeting diseases with high unmet needs. Our R&D capabilities cover multiple drug modalities, including small molecules and cell therapies. Our portfolio comprises discovery through to Phase 3 programs in inflammation, oncology, fibrosis, and other indications. Our first medicine for rheumatoid arthritis and ulcerative colitis is approved and available in the European Union (including Norway), Great Britain and Japan. For additional information, please visit www.glpq.com or follow us on [LinkedIn](#) or [Twitter](#).

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

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

Contact

Investors:

Sofie Van Gijsel
Head of Investor Relations
+1 781 296 1143

Sandra Cauwenberghs
Director Investor Relations
+32 495 58 46 63
ir@glpg.com

Media:

Marieke Vermeersch
Head of Corporate Communication
+32 479 490 603
media@glpg.com

Forward-looking statements

This press release includes forward-looking statements. These statements are often, but are not always, made through the use of words or phrases such as "believe," "anticipate," "expect," "intend," "plan," "seek," "estimate," "may," "will," "could," "would," "potential," "forward," "goal," "next," "stand to," "continue," "should," "encouraging," "aim," "explore," "further," as well as similar expressions. These statements include, but are not limited to, the information provide in the sections "Year-to-date operation overview" and "outlook 2022"; the 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 amount and timing of potential future milestones, opt-in and/or royalty payments, our R&D strategy, including progress on our fibrosis, inflammation, CAR-T portfolio, kidney disease and SIK platform, and potential changes of such ambitions, statements regarding our pipeline and complementary technology platforms driving future growth, the guidance from management (including guidance regarding the expected financial results, expected operational use of cash during financial year 2022 and our strategic and capital allocation priorities), statements regarding the acquisition of CellPoint and AboundBio (including statements regarding anticipated benefits of the acquisition and integration of CellPoint and AboundBio into our portfolio and strategic plans), statements regarding the expected timing, design and readouts of ongoing and planned clinical trials (or the discontinuation thereof), including recruitment for trials and topline results for our trials and studies in our portfolio, statements regarding the strategic re-evaluation, 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 any other indication 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, statements and expectations regarding commercial sales for filgotinib, and statements regarding our strategy, business plans and focus. We caution the reader that forward-looking statements are based on our management's current beliefs and expectations and are not guarantees of future performance. Forward-looking statements involve known and unknown risks, uncertainties and other factors which might cause our actual results, financial condition and liquidity, performance or achievements of , or industry results, to be materially different from any historic or future results, financial conditions and liquidity, performance or achievements expressed or implied by such forward-looking statements, including, but not limited to, the risk that our expectations regarding our 2022 revenues and financial results and our 2022 operating expenses may be incorrect (including because one or more of its assumptions underlying its expense expectations may not be realized), our expectations regarding its development programs may be incorrect, the inherent risks and uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including the risk that data from our ongoing and planned clinical research programs in RA, rrNHL, rrCLL, Crohn's disease, UC, IPF , other inflammatory indications, dermatomyositis, and kidney disease or any other indication or disease, may not support registration or further development of its product candidates due to safety or efficacy concerns or other reasons), risks related to the acquisition of CellPoint and AboundBio, including the risk that we may not achieve the anticipated benefits of the acquisition of CellPoint and AboundBio, the inherent risks and uncertainties associated with target discovery and validation and drug discovery and development activities, our reliance on collaborations with third parties (including our collaboration partner Gilead), the timing of and the risks related to the implementation of the transition of the European commercialization responsibility of filgotinib from Gilead to us, the risk that the transition will not be completed on the currently contemplated timeline or at all, including the transfer of the supply chain, and the risk that the transition will not have the currently expected results for our business and results of operations, estimating the commercial potential of our product candidates and 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 costs and revenues with the commercialization rights may be inaccurate, the risk that we will be unable to successfully achieve the anticipated benefits from our leadership transition plan, the risk that we will encounter challenges retaining or attracting talent, risks related to disruption in our operations and ongoing studies (including our DIVERSITY 1 study) 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 JAK inhibitors used to treat certain inflammatory disorders, including the risk that the EMA and/or other regulatory authorities determine that additional non-clinical or clinical studies are required with respect to filgotinib, the risk that the EMA may require that the 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 Securities and Exchange Commission (SEC) filings and reports, including in our most recent annual report on Form 20-F filed with the SEC and other filings and reports filed by us with the SEC. Given these risks and uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. In addition, even if our results, performance, financial condition and liquidity, and the development of the industry in which we operate, are consistent with such forward-looking statements, they may not be predictive of results, 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.

ⁱ The operational cash burn (or operational cash flow if this liquidity measure is positive) is equal to the increase or decrease in our cash and cash equivalents (excluding the effect of exchange rate differences on cash and cash equivalents), minus:

- the net proceeds, if any, from share capital and share premium increases included in the net cash flows generated from/used in (-) financing activities
- the net proceeds or cash used, if any, related to the acquisitions or disposals of businesses; the movement in restricted cash and movement in current financial investments, if any, the cash advances and loans given to third parties, if any, included in the net cash flows generated from/used in (-) investing activities
- 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 operational cash burn for the six months ended 30 June 2022 amounted to €217.1 million and can be reconciled to our cash flow statement by considering the decrease in cash and cash equivalents of €1,285.2 million, adjusted by (i) the cash proceeds from capital and share premium increase from the exercise of subscription rights by employees for €3.6 million, (ii) the net purchase of current financial investments amounting to €938.7 million, (iii) the cash out from acquisition of subsidiaries, net of cash acquired, of €132.9 million

ⁱⁱ General and administrative

ⁱⁱⁱ Sales and marketing