

Galapagos reports third quarter 2023 results and releases new encouraging data from CAR-T studies for presentation at ASH 2023

- **First nine months 2023 key financials:**
 - Group revenues of €448.9 million
 - Jyseleca® net sales of €82.1 million
 - Cash and current financial investments of €3.8 billion at 30 September 2023
 - Full year 2023 net Jyseleca® sales guidance of €100-€120 million and cash burn guidance of €380-€420 million reiterated
- **Jyseleca® strategic evaluation completed: signed Letter of Intent to transfer the Jyseleca® (filgotinib) business to Alfasigma, including the European and UK Marketing Authorizations and development activities, and approximately 400 positions in 14 European countries**
- **Oncology pipeline:**
 - **New encouraging data from ongoing CAR-T Phase 1/2 studies in relapsed/refractory chronic lymphocytic leukemia (rrCLL) and non-Hodgkin lymphoma (rrNHL) will be presented at ASH:**
 - **GLPG5201 in rrCLL: On the higher dose level, 6 of 6 patients responded to treatment (Objective Response Rate, ORR, of 100%) and 5 of 6 patients achieved a Complete Response (CRR of 83%). Overall, 11 of 12 patients responded to treatment (ORR of 92%) and 9 of 12 patients achieved a CRR (75%). 5 of 7 patients with Richter's transformation (RT) achieved a CRR (71%). GLPG5201 shows an acceptable safety profile with no cytokine release syndrome (CRS) ≥ Grade 3 or any immune effector cell-associated neurotoxicity syndrome (ICANS) observed.**
 - **GLPG5101 in rrNHL: On the higher dose level, 5 of 6 patients achieved a CRR (83%). Overall, 11 of 13 patients responded to treatment (ORR of 85%) and 9 of 13 patients achieved a CRR (69%). GLPG5101 showed an acceptable safety profile with no CRS > Grade 3 or ICANS ≥ Grade 2 observed.**
 - **Manufacturing agreement with U.S.-based Landmark Bio marks important milestone in expanding CAR-T point-of-care network for the decentralized production in the Boston area**
- **Immunology pipeline:**
 - **Advanced novel, oral, selective tyrosine kinase inhibitor, GLPG3667, in patients with systemic lupus erythematosus**
 - **Further progress made in initiating Phase 1b study with CD19 CAR-T candidate, GLPG5101, in patients with refractory systemic lupus erythematosus**
- **Appointed Mr. Simon Sturge as Non-Executive Independent Director to the Board of Directors**

[Webcast presentation](#) tomorrow, 3 November 2023, at 13:00 CET / 8:00 am ET, www.glp.com

Mechelen, Belgium; 2 November 2023, 21:01 CET; regulated information – Galapagos NV (Euronext & NASDAQ: GLPG) today announced its financial results for the first nine months of 2023, a year-to-date business update and its outlook for the remainder of 2023.

“We continue to be very encouraged by the safety and efficacy results observed in the ongoing Phase 1/2 studies with our CD19 CAR-T programs, GLPG5201 and GLPG5101, with additional data to be presented at the upcoming ASH conference in December. The new data released today indicate that both CAR-T candidates have the potential to improve survival for patients with a broad range of B-cell malignancies such as rrCLL and rrNHL. Moreover, the data show that our platform for the decentralized production of fresh CAR-T products, close to patients, has the potential to reduce the median vein-to-vein time to only seven days. We look forward to further building our data package following the agreement with Boston-based Landmark Bio, which is a key milestone in the geographical expansion of this unique point-of-care

model and the start of clinical development of our CAR-T programs in the U.S.,” said Dr. Paul Stoffels¹, CEO and Chairman of Galapagos.

“We made good progress with our small molecules clinical pipeline in immunology and dosed the first patient in the Phase 2 study with our novel, oral, selective tyrosine kinase inhibitor, GLPG3667, in systemic lupus erythematosus. We also continue to prepare for the initiation of our Phase 1b study with CD 19 CAR-T candidate, GLPG5101, in patients with refractory systemic lupus erythematosus,” concluded Dr. Paul Stoffels, CEO and Chairman of Galapagos.

“We ended the third quarter with a solid cash position of €3.8 billion and reiterate our cash burn guidance of €380-€420 million,” said Thad Huston, CFO and COO of Galapagos. “Earlier this week, we announced that we completed the strategic evaluation exercise for Jyseleca[®] and that we signed a letter of intent with Alfasigma for the transfer of the Jyseleca[®] business. This planned transaction is a major step in our transformation, allowing us to right-size our organization and focus our resources on building an R&D pipeline of transformational medicines, addressing high unmet patient needs.”

Third quarter 2023 performance and recent business update

Oncology portfolio

- **GLPG5201 (CD19 CAR-T) in relapsed/refractory chronic lymphocytic leukemia (CLL), with or without Richter’s transformation (RT)**
 - The Phase 1 dose-finding part of the EUPLAGIA-1 study has been completed and preparations to start the Phase 2 dose expansion are ongoing.
 - New preliminary data (data cut-off: 26 April 2023), for 12 patients enrolled in EUPLAGIA-1, will be presented at ASH (see ASH abstract and poster presentation details below). All 12 patients were diagnosed with rrCLL, 7 of 12 with RT. The results included in the abstract are summarized below:
 - GLPG5201 showed an acceptable safety profile with most treatment emergent adverse events (TEAEs) of Grade 1 or 2. CRS Grade 1 or 2 was observed in 50% of the patients, and no CRS Grade ≥ 3 or any ICANS were observed. No deaths were reported.
 - 11 of 12 patients responded to treatment (Objective Response Rate, ORR of 92%). 9 of 12 patients achieved a Complete Response (CRR of 75%). 5 of 7 patients with RT achieved a CRR (71%). On the higher dose level, 6 of 6 patients responded to treatment (ORR of 100%) and 5 of 6 patients achieved a CRR (83%).
 - Strong and consistent *in vivo* CAR-T expansion levels and a product consisting of early phenotype T cells were observed in all doses tested.
 - The data show that our point-of-care platform has the potential to deliver fresh product in a median vein-to-vein time of 7 days.
- **GLPG5101 (CD19 CAR-T) in relapsed/refractory non-Hodgkin lymphoma (rrNHL)**
 - We are in the final stages of the Phase 1 dose-finding part of the ongoing Phase 1/2 ATALANTA-1 study, which enrolled patients with diffuse large B cell lymphoma (DLBCL), mantle cell lymphoma and indolent lymphoma. The Phase 2 expansion cohorts for indolent lymphoma and mantle cell lymphoma are open and the first 10 patients have been dosed. Recruitment is ongoing.
 - New preliminary data (data cut-off: 2 May 2023) for 14 patients enrolled in ATALANTA-1 will be presented at ASH (see ASH abstract and poster presentation details below). 7 patients had diffuse large B-cell lymphoma, 3 had follicular lymphoma, 3 had mantle cell lymphoma and 1 had marginal zone lymphoma. The results included in the abstract are summarized below:

¹ Throughout this press release, ‘Dr. Paul Stoffels’ should be read as ‘Dr. Paul Stoffels, acting via Stoffels IMC BV’

- GLPG5101 showed an acceptable safety profile with most TEAEs of Grade 1 or 2. No CRS Grade > 3 and no ICANS Grade \geq 2 were observed. In two patients, Grade 3-4 infections were observed, and three patients experienced Grade 4 neutropenia.
- One Grade 5 intra-abdominal hemorrhage occurred 12 days post infusion caused by Grade 4 disseminated intravascular coagulation. This event occurred in an elderly patient with very rapidly progressive, primary refractory, double hit DLBCL, severe comorbidities, including a medical history of pulmonary embolism pre-CAR-T treatment, complicated by a Grade 3 CRS and respiratory insufficiency. One patient developed Grade 5 sepsis at six months post infusion while the patient was in ongoing CR.
- 11 out of 13 evaluable patients responded to treatment (ORR of 85%) and 9 of 13 evaluable patients achieved a Complete Response (CRR of 69%). 5 of 6 patients treated with the higher dose achieved a CRR (83%). 7 of 13 patients reported an ongoing response at time of analysis, with a duration of up to 12 months (median follow-up of 4.5 months).
- Strong and consistent *in vivo* CAR-T expansion levels and a product consisting of early phenotype T cells were observed in all doses tested.
- The data show that our point-of-care platform has the potential to deliver fresh product in a median vein-to-vein time of 7 days.
- **Building a global CAR-T point-of-care network**
 - We signed an agreement with Boston-based Landmark Bio and started the technology transfer for the decentralized production of our CAR-T cell therapy candidates, a key milestone to expand our CAR-T programs beyond Europe and start clinical development in the U.S.

Immunology portfolio

- **Jyseleca® (filgotinib) (JAK1)**
 - Jyseleca® is reimbursed for rheumatoid arthritis (RA) and ulcerative colitis (UC) in 22 and 20 countries respectively. Sobi², our distribution and commercialization partner in Eastern and Central Europe, Portugal, Greece, and the Baltic countries, launched Jyseleca® in Slovenia in both RA and UC, and in Poland in RA.
- **Pipeline programs**
 - We dosed the first patients in the Phase 2 GALACELA study of our novel, oral, selective tyrosine kinase 2 (TYK2) inhibitor, GLPG3667, in patients with systemic lupus erythematosus (SLE). Recruitment in the Phase 2 study in dermatomyositis is also ongoing.
 - We are preparing to open the first clinical centers to begin screening of patients with refractory SLE (rSLE) in the Phase 1b GALALUCA study with our CD19 CAR-T candidate, GLPG5101.

Corporate update

- The Board of Directors appointed Mr. Simon Sturge as Non-Executive Independent Director by way of co-optation on 19 September 2023, replacing Dr. Mary Kerr who stepped down on 18 September 2023.
- On 30 October 2023, Galapagos announced that it signed a letter of intent to transfer the Jyseleca® business to Alfasigma, including the European and UK Marketing Authorizations and development activities, and approximately 400 positions in 14 European countries. Galapagos also announced that it intends to streamline its remaining operations and further build efficiencies, with an envisaged reduction of approximately 100 positions across the organization. Completion of the intended transaction is subject to customary conditions, including consultations with works councils.

² Swedish Orphan Biovitrum AB

Financial highlights for the first nine months of 2023 (unaudited)
(€ millions, except basic & diluted income/loss (-) per share)

	Nine months ended 30 September		Change
	2023	2022	
Product net sales	82.1	60.5	+36%
Collaboration revenues	366.8	349.7	+5%
Total net revenues	448.9	410.2	+9%
Cost of sales	(13.6)	(7.9)	+71%
R&D expenditure	(312.2)	(364.1)	-14%
G&A ⁱⁱ and S&M ⁱⁱⁱ expenses	(182.2)	(202.7)	-10%
Other operating income	40.1	29.5	+36%
Operating loss	(19.0)	(135.1)	
Fair value adjustments and net currency exchange differences	36.2	130.9	
Net other financial result	50.4	(3.4)	
Income taxes	(13.5)	(3.2)	
Net profit/loss (-) of the period	54.1	(10.8)	
Basic and diluted income/loss (-) per share (€)	0.82	(0.16)	
Current financial investments and cash and cash equivalents	3,811.7 (*)	4,362.1(**)	

(*) Starting from Q3 2023, our current financial investments and cash and cash equivalents include accrued interests (for a total of 21.7 million on 30 September 2023).

(**) Excluding €4.7 million of net accrued interest income.

Details of the financial results of the first nine months of 2023

Total net revenues for the nine months ended 30 September 2023 was €448.9 million, compared to €410.2 million for the nine months ended 30 September 2022, and consisted of:

- **Product net sales** of Jyseleca® in Europe for the first nine months of 2023 amounting to €82.1 million (€60.5 million in the first nine months of 2022).
- **Collaboration revenues** of €366.8 million for the first nine months of 2023, compared to €349.7 million for the first nine months of 2022.

Collaboration revenues increased mainly due to revenue recognition related to the collaboration agreement with Gilead for the filgotinib development amounting to €186.0 million in the first nine months of 2023 compared to €166.8 million for the same period last year. This increase is primarily driven by a positive catch-up of revenue explained by a decrease in the total estimated remaining costs to complete the filgotinib development. This was a consequence of the topline results from the Phase 3 DIVERSITY trial with filgotinib in CD and our decision not to submit a Marketing Authorization Application in Europe. Our deferred income balance on 30 September 2023 includes €1.4 billion allocated to our drug discovery platform that is recognized linearly over the remaining period of our 10-year collaboration, and €0.3 billion allocated to the filgotinib development that is recognized over time until the end of the development period.

Total operating loss for the nine months ended 30 September 2023 was €19.0 million, compared to total operating loss of €135.1 million for the first nine months ended 30 September 2022.

- **Cost of sales** related to Jyseleca® net sales in the first nine months of 2023 amounted to €13.6 million (€7.9 million in the first nine months of 2022).

- **R&D expenditure** in the first nine months of 2023 amounted to €312.2 million, compared to €364.1 million for the first nine months of 2022. This decrease was primarily explained by lower personnel costs due to lower bonuses and cost of subscription right plans, lower external outsourcing costs and lower depreciation costs. This decrease in depreciation costs was primarily due to an impairment recorded in the first nine months of 2022 of €26.7 million of previously capitalized upfront fees related to our collaboration with Molecure on the dual chitinase inhibitor OATD-01 (GLPG4716).
- **S&M and G&A expenses** amounted to €182.2 million in the first nine months of 2023, compared to €202.7 million in the first nine months of 2022. This decrease was primarily due to a decrease in personnel costs and agency deliverables.
- **Other operating income** amounted to €40.1 million in the first nine months of 2023, compared to €29.5 million for the same period last year, mainly due to higher grant income.

Net financial income in the first nine months of 2023 amounted to €86.6 million, compared to net financial income of €127.5 million for the first nine months of 2022.

- **Fair value adjustments and net currency exchange gains** in the first nine months of 2023 amounted to €36.2 million, compared to fair value adjustments and net currency exchange gains of €130.9 million for the first nine months of 2022, and were primarily attributable to €33.7 million of positive changes in fair value of current financial investments (compared to 26.0 million for the first nine months of 2022), and €3.5 million of unrealized currency exchange gains on our cash and cash equivalents and current financial investments at amortized cost in U.S. dollars (compared to €102.1 million for the first nine months of 2022).
- **Net other financial income** in the first nine months of 2023 amounted to €50.4 million, compared to net other financial expenses of €3.4 million for the first nine months of 2022, and was primarily attributable to €54.6 million of interest income, which increased significantly due to the increase in interest rates.

We reported a **group net profit** for the first nine months of 2023 of €54.1 million, compared to a group net loss of €10.8 million for the first nine months of 2022.

Cash position

Current financial investments and cash and cash equivalents totaled €3,811.7 million on 30 September 2023, as compared to €4,094.1 million on 31 December 2022 (excluding €9.9 million of net accrued interest income).

Total net decrease in cash and cash equivalents and current financial investments amounted to €282.4 million during the first nine months of 2023, compared to a net decrease of €341.1 million during the first nine months of 2022. This net decrease was composed of (i) €343.8 million of operational cash burn, offset by (ii) €3.5 million of positive exchange rate differences, (iii) €1.8 million of cash proceeds from capital and share premium increase from exercise of subscription rights in the first nine months of 2023, (iv) €24.5 million positive changes in fair value of current financial investments and (v) €20.2 million of accrued interest income on term deposits and €11.4 million accrued interest income on treasury bills.

Outlook 2023

Financial outlook

- We reiterate our full year 2023 net sales guidance for Jyseleca® of €100-€120 million and full year 2023 cash burn guidance in the range of €380-€420 million.

R&D outlook

- **Oncology pipeline**
 - We expect to include the first patient in the PAPILIO-1 Phase 1/2 study evaluating the feasibility, safety, and efficacy of our point-of-care manufactured BCMA CAR-T candidate,

GLPG5301, in relapsed/refractory multiple myeloma (rrMM) in the coming weeks. The study will be conducted in centers across Europe.

- Three abstracts on our CAR-T portfolio in hemato-oncology have been selected for poster presentations at the 65th Society of Hematology (ASH) Annual Meeting and exposition conference taking place on 9-12 December in San Diego, California (see details below). The two presentations on EUPLAGIA-1 and ATALANTA-1 will include more recent data updates and additional data not found in the ASH abstracts. One presentation will outline the clinical study design of the PAPILIO-1 Phase 1/2 study.
- Following the point-of-care manufacturing agreement with Boston-based Landmark Bio, we expect to submit an Investigational New Drug Application in the U.S. to start clinical development with our CD19 CAR-T programs in the first half of 2024.
- **Immunology portfolio**
 - Pending approval of the Clinical Trial Application submitted in the European Union for our CD19 CAR-T candidate, GLPG5101, in patients with rSLE, we expect to open the first clinical centers and begin screening patients with rSLE in early 2024.

Business development

- We will continue to extensively evaluate various product candidates and business development opportunities to further leverage our internal capabilities and accelerate and expand our product portfolio.

Conference call and webcast presentation

We will host a conference call and webcast presentation tomorrow 3 November 2023, at 13:00 CET / 8:00 am ET. To participate in the conference call, please register in advance using this [link](#), after which the dial-in numbers will be provided. The conference call can be accessed 10 minutes prior to the start by using the conference access information provided in the email after registration, or by selecting the “call me” feature. The live webcast is available on glpg.com or via the following [link](#). The archived webcast will be available for replay shortly after the close of the call on the investor section of the [website](#).

ASH presentation details

Abstract Title	Authors	Presentation details
Seven-day Vein-to-Vein Point-of-Care Manufactured CD19 CAR T Cells (GLPG5201) in Relapsed/Refractory CLL/SLL including Richter’s Transformation: Results from the Phase 1 Euplagia-1 Trial	Natalia Tovar, Valentin Ortiz-Maldonado, Nuria Martinez-Cibrian, Sergi Betriu, Daniel Esteban, Ana Triguero, Nadia Verbruggen, Anna D.D. van Muyden, Maike Spoon, Margot J. Pont	Abstract Poster Number: 2112 Date: 9 Dec 2023, 5:30–7:30 pm Session: Cellular Immunotherapies: Early Phase and Investigational Therapies: Poster I
Seven-day Vein-to-Vein Point-of-Care Manufactured CD19 CAR T Cells (GLPG5101) in Relapsed/Refractory NHL: Results from the Phase 1 Atalanta-1 Trial	Marie José Kersten, Kirsten Saevels, Sophie Servais, Yves Beguin, Joost Vermaat, Nadia Verbruggen, Anna DD Van Muyden, Margot J Pont, Maria T Kuipers, Sébastien Anguille	Abstract Poster Number: 2113 Date: 9 Dec 2023, 5:30–7:30 pm Session: Cellular Immunotherapies: Early Phase and Investigational Therapies: Poster I
Rationale for and Design of Papilio-1: a Phase 1/2, Multicenter, Open-Label Study to Evaluate the Feasibility, Safety, and Efficacy of Point-of-Care–Manufactured Anti–B-Cell Maturation Antigen Chimeric Antigen	Niels van der Donk, Sebastien Anguille, Jo Caers, Marte C. Liefwaard, Christian Jacques, Anna D.D. van Muyden	Abstract Poster Number: 4859 Date: 11 Dec 2023, 6:00–8:00 pm

Receptor T Cells (GLPG5301) in Relapsed/Refractory Multiple Myeloma		Session: Cellular Immunotherapies: Early Phase and Investigational Therapies: Poster III
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Financial calendar 2024

22 February 2024	Full year 2023 results	(webcast 23 February 2024)
28 March 2024	Annual report 2023	
30 April 2024	Annual Shareholders' Meeting	
2 May 2024	First quarter 2024 results	(webcast 3 May 2024)
1 August 2024	Half-year 2024 results	(webcast 2 August 2024)
30 October 2024	Third quarter 2024 results	(webcast 31 October 2024)

About Galapagos

We are a global biotechnology company with operations in Europe and the US dedicated to developing transformational medicines for more years of life and quality of life. Focusing on high unmet medical needs, we synergize the most compelling science, technology, and collaborative approaches to create a deep pipeline of best-in-class small molecules, CAR-T therapies, and biologics in oncology and immunology. With capabilities from lab to patient, including a decentralized, point-of-care CAR-T manufacturing network, we are committed to challenging the status quo and delivering results for our patients, employees and shareholders. For additional information, please visit www.glp.com or follow us on [LinkedIn](#) or [X \(formerly Twitter\)](#).

Jyseleca® is a trademark of Galapagos NV and Gilead Sciences, Inc. or its related companies. Except for filgotinib's approval as Jyseleca® for the treatment of moderate to severe active RA and UC by the relevant regulatory authorities in the European Union, Great Britain, and Japan, our drug candidates are investigational; their efficacy and safety have not been fully evaluated by any regulatory authority.

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Forward-looking statements

This release may contain forward-looking statements, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "anticipate," "on track," "expect," "encouraging," "expand," "advance," "plan," "estimate," "will," "continue," "aim," "intend," "future," "guidance," "outlook," "indicate," "forward," as well as similar expressions. Forward-looking statements contained in this release include, but are not limited to, statements made in the sections captioned "Third quarter 2023 performance and recent business update" and "Outlook 2023", the guidance from management regarding our expected operational use of cash and estimated peak sales for Jyseleca® during the financial year 2023, statements related to the contemplated transaction between Galapagos and Alfasigma and the planned reduction in force, statements regarding our strategic and capital allocation priorities, including progress on our immunology or oncology portfolio, our CAR-T-portfolio and our SIKi-portfolio, and potential changes of such plans, statements regarding our pipeline and complementary technology platforms facilitating future growth, statements regarding our regulatory and R&D outlook, statements regarding the expected timing, design and readouts of ongoing and planned clinical trials, including but not limited to (i) filgotinib in juvenile arthritis, (ii) GLPG5101 in rrNHL and rSLE, (iii) GLPG5201 in rrCLL, and (iv) GLPG5301 in rrMM, statements regarding our commercialization efforts for filgotinib, our product candidates, and any of our future approved products, if any, statements regarding our expectations on commercial sales of filgotinib and any of our product candidates (if approved), statements related to the timing for submission of an Investigational New

Drug application and the clinical development of our CAR-T program in the United States, and statements related to our portfolio goals and business plans. Any forward-looking statements in this release are based on management's current expectations and beliefs 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 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. Such risks include, but are not limited to, the risk that our expectations regarding our 2023 revenues, operating expenses, cash burn and other financial estimates may be incorrect (including because one or more of our assumptions underlying our revenue and 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 associated with competitive developments, clinical trials, recruitment of patients, product development activities and regulatory approval requirements (including the risk that data from our ongoing and planned clinical research programs in RA, UC, DM, SLE, AxSpA, refractory/relapsed NHL, rrCLL, rrSLL, rrMM and other immunologic indications or any 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, the risk that the preliminary and topline data from the OLINGUITO, ATALANTA-1, EUPLAGIA-1, GALARISSO, TORTUGA, PAPILIO-1, GALALUCA and GALACELA-studies may not be reflective of the final data, risks related to our reliance on collaborations with third parties (including, but not limited to, our collaboration partners Gilead and Lonza), risks related to the implementation of the transition of the European commercialization responsibility of filgotinib from Gilead to us, 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, 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 estimates of the commercial potential of our product candidates or expectations regarding the costs and revenues associated with the commercialization rights may be inaccurate, 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, the risks related to our strategic transformation, 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 potential disruptions in our operations, the risk that the EMA may impose JAK class-based warnings, and the risk that the EMA's safety review may negatively impact acceptance of filgotinib by patients, the medical community, and healthcare payors, the risk that regulatory authorities may require additional post-approval trials of filgotinib or any other product candidates that are approved in the future. A further discussion 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 other filings and reports filed 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 or developments in future periods. These forward-looking statements speak only as of the date of publication of this release. We expressly disclaim any obligation to update any such forward-looking statements in this release unless 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, in 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 nine months ended 30 September 2023 amounted to €343.8 million and can be reconciled to our cash flow statement by considering the decrease in cash and cash equivalents of €348.1 million, adjusted by (i) the cash proceeds from capital and share premium increase from the exercise of subscription rights by employees for €1.8 million, and (ii) the net purchase of current financial investments amounting to €6.1 million.

ⁱⁱ General and administrative

ⁱⁱⁱ Sales and marketing

Addendum

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

Consolidated income statement

(thousands of €, except per share data)	Nine months ended 30 September	
	2023	2022
Product net sales	82,075	60,491
Collaboration revenues	366,773	349,669
Total net revenues	448,848	410,160
Cost of sales	(13,540)	(7,938)
Research and development expenditure	(312,180)	(364,067)
Sales and marketing expenses	(88,147)	(105,313)
General and administrative expenses	(94,022)	(97,373)
Other operating income	40,086	29,474
Operating loss	(18,954)	(135,056)
Fair value adjustments and net currency exchange differences	36,247	130,900
Other financial income	55,122	9,675
Other financial expenses	(4,767)	(13,074)
Profit/loss (-) before tax	67,648	(7,555)
Income taxes	(13,510)	(3,229)
Net profit/loss (-)	54,138	(10,784)
Net profit/loss (-) attributable to:		
Owners of the parent	54,138	(10,784)
Basic and diluted income/loss (-) per share	0.82	(0.16)

Consolidated statement of comprehensive income/loss (-)

(thousands of €)	Nine months ended 30 September	
	2023	2022
Net profit/loss (-)	54,138	(10,784)
Items that may be reclassified subsequently to profit or loss:		
Translation differences, arisen from translating foreign activities	318	(7)
Other comprehensive income/loss (-), net of income tax	318	(7)
Total comprehensive income/loss (-) attributable to:		
Owners of the parent	54,456	(10,791)

Consolidated statements of financial position (unaudited)

	30 September	31 December
(thousands of €)	2023	2022
Assets		
Goodwill	69,863	69,813
Intangible assets other than goodwill	132,313	146,354
Property, plant and equipment	136,803	154,252
Deferred tax assets	1,232	1,363
Non-current R&D incentives receivables	138,121	119,941
Other non-current assets	16,911	5,778
Non-current assets	495,244	497,501
Inventories	55,605	52,925
Trade and other receivables	46,918	40,429
Current R&D incentives receivables	26,126	26,126
Current financial investments	3,652,333	3,585,945
Cash and cash equivalents	159,375	508,117
Other current assets	15,735	23,307
Current assets	3,956,092	4,236,850
Total assets	4,451,336	4,734,351
Equity and liabilities		
Share capital	293,937	293,604
Share premium account	2,736,993	2,735,557
Other reserves	(4,932)	(4,853)
Translation differences	(1,196)	(1,593)
Accumulated losses	(403,242)	(496,689)
Total equity	2,621,560	2,526,026
Retirement benefit liabilities	2,408	5,540
Deferred tax liabilities	25,325	20,148
Non-current lease liabilities	8,469	14,692
Other non-current liabilities	31,449	21,808
Non-current deferred income	1,318,090	1,623,599
Non-current liabilities	1,385,741	1,685,787
Current lease liabilities	5,678	7,209
Trade and other liabilities	121,129	148,675
Current tax payable	1,764	1,022
Current deferred income	315,465	365,631
Current liabilities	444,036	522,538
Total liabilities	1,829,776	2,208,325
Total equity and liabilities	4,451,336	4,734,351

Consolidated cash flow statements (unaudited)

(thousands of €)	Nine months ended 30 September	
	2023	2022
Net profit/loss (-) of the period	54,138	(10,784)
Adjustment for non-cash transactions	44,344	(25,707)
Adjustment for items to disclose separately under operating cash flow	(40,165)	1,599
Adjustment for items to disclose under investing and financing cash flows	(11,809)	(1,700)
Change in working capital other than deferred income	(50,329)	57,472
Cash used for other liabilities related to the acquisition of subsidiaries	-	(11,080)
Decrease in deferred income	(359,259)	(318,167)
Cash used in operations	(363,081)	(308,367)
Interest paid	(3,729)	(10,940)
Interest received	35,063	2,262
Corporate taxes paid	(7,357)	(3,637)
Net cash flows used in operating activities	(339,104)	(320,682)
Purchase of property, plant and equipment	(11,073)	(19,808)
Purchase of and expenditure in intangible fixed assets	(222)	(9,308)
Proceeds from disposal of property, plant and equipment	2,304	719
Purchase of current financial investments	(2,615,112)	(2,505,688)
Investment income received related to current financial investments	9,857	1,181
Sale of current financial investments	2,609,023	1,394,549
Cash out from acquisition of subsidiaries, net of cash acquired	-	(115,270)
Cash advances and loans to third parties	-	(10,000)
Net cash flows used in investing activities	(5,222)	(1,263,625)
Payment of lease liabilities	(5,580)	(6,263)
Proceeds from capital and share premium increases from exercise of subscription rights	1,770	6,695
Net cash flows generated from/used in (-) financing activities	(3,810)	432
Decrease in cash and cash equivalents	(348,136)	(1,583,875)
Cash and cash equivalents at beginning of year	508,117	2,233,368
Decrease in cash and cash equivalents	(348,136)	(1,583,875)
Effect of exchange rate differences on cash and cash equivalents	(607)	26,026
Cash and cash equivalents at end of the period	159,375	675,519

(thousands of €)	30 September	
	2023	2022
Current financial investments	3,652,333	3,686,557
Cash and cash equivalents	159,375	675,519
Current financial investments and cash and cash equivalents	3,811,708	4,362,076

Consolidated statements of changes in equity (unaudited)

(thousands of €)	Share capital	Share premium account	Translation differences	Other reserves	Accumulated losses	Total
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					51,085	51,085
Exercise of subscription rights	1,530	5,165				6,695
On 30 September 2022	293,604	2,735,557	(1,046)	(10,860)	(326,905)	2,690,351
On 1 January 2023	293,604	2,735,557	(1,593)	(4,853)	(496,689)	2,526,026
Net profit					54,138	54,138
Other comprehensive income/loss (-)			397	(79)		318
Total comprehensive income/loss (-)			397	(79)	54,138	54,456
Share-based compensation					39,308	39,308
Exercise of subscription rights	333	1,437				1,770
On 30 September 2023	293,937	2,736,993	(1,196)	(4,932)	(403,242)	2,621,560