Risk factors

Description of the risks
investors should be aware of

Forward with Purpose

Risks related to commercialization

The marketing and sale of filgotinib or future approved products may be unsuccessful or less successful than anticipated. We are heavily dependent on the success of filgotinib, which is approved for the treatment of RA and UC in Europe, and Japan.

The commercial success of filgotinib and of any future products, if approved, will depend upon the degree of market acceptance by physicians, healthcare payers, patients, and the medical community. Market acceptance will depend on a number of factors, many of which are beyond our control, but not limited to (i) the wording of the product label, (ii) changes in the standard of care for the targeted indications for any product and product candidate, (iii) acceptance by physicians, patients and healthcare payers of the product as safe, effective and cost-effective and (iv) sales, marketing and distribution support.

We have limited experience in the sale or marketing of pharmaceutical products and have build and continue to further develop a marketing and sales organization. We have established our own sales force in several European countries. We expect to continue to invest significant financial and management resources to continue to build these capabilities and to establish a European commercial infrastructure or to enter into collaboration arrangements with third parties to outsource the distribution or commercialization, such as SOBI, our distribution and commercialization partner in Eastern and Central Europe, Portugal, Greece, and the Baltic countries for filgotinib. Recruiting and training a sales force is expensive and costs of creating an independent sales and marketing organization and of marketing and promotion could be above those anticipated by us. To the extent any of our product candidates for which we maintain commercial rights is approved for marketing, if we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to market and sell any product effectively, or generate product revenues, which in turn would have a material adverse effect on our business, financial condition, and results of operation.

Further, to the extent that Gilead is commercializing filgotinib in one or more jurisdictions or a third party, such as Eisai, is commercializing filgotinib in one or more jurisdictions, we are significantly dependent on their successful accomplishment of commercialization efforts.

Coverage and reimbursement decisions by third-party payers may have an adverse effect on pricing and market acceptance. Legislative and regulatory activity, including enacted and future legislation, may exert downward pressure on potential pricing and reimbursement for any of our product candidates, if approved, that could materially affect the opportunity to commercialize.

Risks related to product development and regulatory approval

We operate adequate standard operating procedures to secure the integrity and protection of our research and development activities and results, and the optimum allocation of our R&D budgets. The progress of the most important research and development programs is continuously monitored by our Executive Committee; they are discussed with the Board of Directors at least once per quarter, and the members of our Board of Directors with expertise in clinical and scientific matters occasionally attend meetings with our scientific staff to discuss and assess such programs. Nevertheless, due to our limited resources and access to capital, we must and have in the past and during financial year 2022 decided to prioritize development of certain product candidates; these decisions may prove to have been wrong and may adversely affect our business.

We are heavily dependent on the success of filgotinib. We are also dependent on the success of our other product candidates, such as GLPG3667, GLPG5101, GLPG5201 and GLPG5301. During 2022, we shifted from novel target-based discovery to patient-focused medical need research and development with a focus on our key therapeutic areas of immunology and oncology. Filgotinib is approved for use in RA and UC in the European Union, Great Britain and Japan. In addition, we are heavily investing in our early-stage product candidate pipeline, including our SIK early-stage compounds, and these drug candidates must undergo rigorous preclinical and clinical testing, the results of which are uncertain and could substantially delay or prevent the drug candidates from reaching the market. Through the acquisitions of CellPoint and AboundBio, we gained access to innovative, scalable, decentralized and automated point-of-care cell therapy supply model as well as a fully human antibody-based therapeutics platform. We are heavily investing in building our therapeutic area of oncology, whereby cell therapies are novel, complex, and difficult to manufacture and require rigorous preclinical and clinical testing, the results of which are uncertain.

We cannot give any assurance that any product candidate will successfully complete clinical trials or receive regulatory approval, which is necessary before it can be commercialized.

Our business and future success is substantially dependent on our ability to develop successfully, obtain regulatory approval for, and then successfully commercialize our product filgotinib and our other product candidates. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA, the EMA, the MHRA, the MHLW or any other comparable regulatory authority, and we may never receive such regulatory approval for any of our product candidates. We cannot give any assurances that our clinical trials for filgotinib or our other product candidates, including our CD19 CAR-T product candidates, will be completed in a timely manner, or at all. If filgotinib or any other product candidate is not approved and commercialized in certain jurisdictions, we will not be able to generate any product revenues for that product candidate.

The regulatory approval processes of the FDA, the EMA, the MHRA, the MHLW and other comparable regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business, including its financial condition, will be substantially harmed.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Results of earlier studies and trials as well as data from any interim analysis of ongoing clinical trials may not be predictive of future trial results, and failure can occur at any time during the clinical trial process. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. If filgotinib or any of our product candidates are found to be unsafe or have a lack of efficacy, we will not be able to obtain or maintain regulatory approval for it and our business would be materially harmed.

The rates at which we complete our scientific studies and clinical trials depend on many factors, including, but not limited to, patient enrollment. Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors including competing clinical trials, clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies and the relatively limited number of patients. Any of these occurrences may harm our clinical trials and by extension, our business, financial condition and prospects.

Our product candidates may cause undesirable or unacceptable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the EMA, the MHRA, the MHLW or other comparable regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly and may adversely impact the viability of our other product candidates or preclinical programs.

In animal toxicology studies in the preclinical phase, filgotinib at an exposure dose above the approved dose in humans induced adverse effects on semen parameters. As a result, filgotinib may have a labeling statement warning for male patients. Adjacent to the filgotinib Phase 3 programs, we and Gilead were conducting dedicated male semen analysis studies in CD and UC patients (MANTA) and in RA, PsA, and AS, patients (MANTA-RAy). In March 2021, we reported on the primary endpoint with the MANTA and MANTA-RAY studies. Following submission of a type II variation application to the EMA and assessment of the data by the CHMP, a positive opinion has been issued in October 2022 by the CHMP to update the European label of filgotinib whereby the language in the

section of the Special Warnings and Precautions about the potential effect of filgotinib on sperm production and male fertility was removed from the Summary of Product Characteristics (SmPC). Such labeling statement warnings or changes of such labeling statement warnings may harm the commercialization of our product candidates and our business.

Even now when filgotinib has received regulatory approval or marketing authorization in previously mentioned jurisdictions, other regulatory authorities may impose dosing restrictions that differ from the approved dosing regimen in other jurisdictions.

Box warnings, labeling restrictions, dose limitations and similar restrictions on use could have a material adverse effect on our ability to commercialize filgotinib in those jurisdictions where such restrictions apply.

In February 2022, the European Medicines Agency's (EMA) announced that its Pharmacovigilance Risk Assessment Committee (PRAC) initiated an article 20 specific pharmacovigilance procedure to investigate whether certain serious risks associated with the JAK inhibitors Xeljanz (tofacitinib) and Olumiant (baricitinib) are associated with all JAK inhibitors authorized in the EU for the treatment of inflammatory disorders, including filgotinib. In November 2022, the EMA's Committee for Medicinal Products for Human Use, CHMP, adopted the recommendation of the PRAC to add measures to minimize risk of serious side effects with JAK inhibitors used for chronic inflammatory disorders, followed by the approval of the European Commission on 10 March 2023. If such safety review(s) result(s) in amendments to the marketing authorization for filgotinib, or other additional requirements that the EMA may put in place with respect to the development of JAK inhibitors generally, or other future actions by the EMA and other comparable regulatory authorities, then such delays or (perceived) adverse developments or results may harm our business, financial condition and prospects significantly.

If we lose orphan product exclusivity or are not able to obtain or maintain such status for future product candidates for which we seek this status, or if our competitors are able to obtain orphan product exclusivity before we do, we may not be able to obtain approval for our competing products for a significant period of time. Even if we are able to obtain orphan designation, we may not be the first to obtain marketing approval for such indication due to the uncertainties associated with developing pharmaceutical products. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

We must establish and maintain a pharmacovigilance system, including a qualified person responsible for oversight, submit safety reports to the regulators and comply with the good pharmacovigilance practice guidelines adopted by the relevant regulatory authorities. Failure to comply with these guidelines may harm our clinical trials or regulatory process and by extension, our business.

If the FDA, EMA, or any other comparable regulatory authority approves any of our product candidates, the manufacturing processes, distribution, adverse event reporting,

storage, advertising, and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements, which currently is applicable for filgotinib. These requirements include submissions of safety and other post-marketing information and reports, registration requirements and continued compliance with current good manufacturing practices, or cGMPs, and good clinical practices, or GCPs, for any clinical trials that we conduct post-approval. Failure to comply with the aforementioned practices may harm our clinical trials or regulatory process and by extension, our business, financial condition and prospects.

Risks related to our financial position and need for additional capital

We are an integrated biopharmaceutical company with a first and single commercial launch and have not yet generated significant income. We have only very recently commenced our transition from a clinical-stage to commercial-stage company. Until our first commercial launch, our operations have been limited to developing our technology and undertaking preclinical studies and clinical trials of our product candidates.

Since our inception, and with the exception of the year 2019, we have incurred significant operating losses. Our losses resulted principally from costs incurred in research and development, preclinical testing, clinical development of our product and our product candidates as well as costs incurred for research programs, (pre-)commercial activities and from general and administrative costs associated with our operations. We expect to continue incurring significant research, development and other expenses related to our ongoing operations, and to continue incurring operating losses for the foreseeable future. We cannot be sure we will generate future profits from the sales of filgotinib, our first product which was approved for commercialization in the European Union, Great Britain and Japan. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict the timing or amount of expenses and when we will be able to achieve or maintain profitability, if ever.

We may require substantial additional future capital which may not be available to us on acceptable terms, or at all, in order to complete clinical development and, if we are successful, to commercialize any of our current product candidates, if approved. Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. In addition, raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our product candidates or technologies. The incurrence of additional indebtedness could result in increased fixed payment obligations and could also result in certain additional restrictive covenants that could adversely impact our ability to conduct our business.

For further reference on financial risks in particular, see **note 34** of the notes to the consolidated financial statements.

Risks related to our reliance on third parties

We are heavily dependent upon our collaboration arrangements with Gilead and certain other third parties for the development and commercialization of our products and there can be no assurance that these arrangements will deliver the benefits we expect.

In July 2019, we entered into a 10-year global research and development collaboration with Gilead. In connection with our entry into the option, license and collaboration agreement, we received an upfront payment of $3.95 billion and a €960 million ($1.1 billion) equity investment from Gilead. Under the option, license and collaboration agreement, we will fund and lead all discovery and development autonomously until the end of the relevant Phase 2 clinical study. After the completion of the Phase 2 clinical study (or, in certain circumstances, the first Phase 3 study), Gilead will have the option to acquire an exclusive commercial license to that program in all countries outside of Europe. If the option is exercised, we and Gilead will co-develop the compound and share costs equally. In addition, we are heavily dependent on Gilead for the commercialization of filgotinib and the further development of filgotinib outside of Europe. Gilead may not devote sufficient resources or give sufficient priority to the programs in respect of which it acquires a commercial license pursuant to the option, license and collaboration agreement. Furthermore, Gilead may not be successful in the commercialization of filgotinib outside of Europe and further development and commercialization of filgotinib or other programs for which it acquires a commercial license, even when they do devote resources and prioritize their efforts for such programs. To the extent that Gilead is commercializing filgotinib in one or more jurisdictions via a third party, such as Eisai for certain Asian markets, we are significantly dependent on their successful accomplishment of commercialization efforts.

In addition, the terms of the collaboration with Gilead and any collaboration or other arrangement that we may establish may not ultimately prove to be favorable to us or may not be perceived as favorable, which may negatively impact the trading price of the ADSs or our ordinary shares. In addition, pursuant to the collaboration with Gilead, we are entitled to certain option payments and tiered royalties, and milestone payments on certain products. There can be no assurance that such payments will be sufficient to cover the cost of development of the relevant product candidates.

We are subject to a number of additional risks associated with our dependence on our collaborations with third parties, the occurrence of which could cause our collaboration arrangements to fail. In particular, the collaboration we entered into in July 2019 is managed by a set of joint committees comprised of equal numbers of representatives from each of us and Gilead. Conflicts may arise between us and Gilead, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration, and there can be no assurance that the joint committees will be able to resolve any such conflicts. If any such conflicts arise, Gilead could act in a manner

adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of product candidates subject to the collaboration arrangements, and in turn prevent us from generating sufficient revenues to achieve or maintain profitability:

- reductions or delays in the payment of milestone payments, royalties or other payments we believe are due;
- actions taken by Gilead inside or outside our collaboration which could negatively impact our rights or benefits under our collaboration including termination of the collaboration for convenience; or
- unwillingness on the part of Gilead to keep us informed regarding the progress of its development and commercialization activities or regulatory approval or to permit public disclosure of the results of those activities.

In addition to our collaboration with Gilead, we may also enter into future collaborations which will give rise to similar risks, although our ability to enter into such collaborations may be limited given the scale of our collaboration with Gilead.

If our global research and development collaboration with Gilead or other collaborations on research and development candidates do not result in the successful development and commercialization of products or if Gilead or another one of our collaboration partners terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product candidates could be delayed and we may need additional resources to develop product candidates.

We may not be successful in establishing future development and commercialization collaborations, particularly given the scale of our collaborations with Gilead, and this could adversely affect, and potentially prohibit, our ability to develop our product candidates.

Developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive. Accordingly, we have sought and may in the future seek to enter into collaborations with companies that have more resources and experience. In the future, however, our ability to do so may be limited given the scale of the 10-year global research and development collaboration that we entered into with Gilead in July 2019. If Gilead declines to exercise its option and we are otherwise unable to obtain a collaboration partner for our product candidates, we may be unable to advance the development of our product candidates through late-stage clinical development and seek approval in any market. In situations where we enter into a development and commercial collaboration arrangement for a product candidate, we may also seek to establish additional collaborations for development and commercialization in territories outside of those addressed by the first collaboration arrangement for such product candidate. If any of our product candidates receives marketing approval, we may enter into sales and marketing arrangements with third parties with respect to otherwise unlicensed

or unaddressed territories. Furthermore, there are a limited number of potential collaboration partners, and we expect to face competition in seeking appropriate collaboration partners. If we are unable to enter into any development and commercial collaborations and/or sales and marketing arrangements on acceptable terms, or at all, we may be unable to successfully develop and seek regulatory approval for our product candidates and/or effectively market and sell approved products, if any.

In October 2021, we signed an agreement (as amended from time to time) with Sobi regarding the distribution of Jyseleca®. Sobi acts as our distribution and commercialization partner of filgotinib and will distribute the medicine in Central and Eastern Europe, Greece, Portugal, and the Baltic countries. Launches and first sales of filgotinib in the aforementioned countries trigger milestone payments by Sobi to us. We are significantly dependent on Sobi's successful accomplishment of commercialization efforts, and if, for any reason, the collaboration terminated, we may be unable to timely or successfully find another distribution and commercialization partner, which may interrupt or delay our commercialization efforts.

Through the acquisitions of CellPoint and AboundBio, we gained access to an innovative, scalable, decentralized and automated point-of-care cell therapy supply model as well as fully human antibody-based therapeutics platform and research capabilities for novel, differentiated CAR-T constructs. To address important limitations of current CAR-T treatments, CellPoint has developed, in a strategic collaboration with Lonza, a Swiss manufacturing company for the pharmaceutical, biotechnology and nutrition sectors, a novel decentralized delivery model designed to manufacture non-frozen CAR-T therapies at the point-of-care. The platform consists of CellPoint's end-to-end xCellit workflow management and monitoring software and Lonza's Cocoon®, a functionally closed, automated manufacturing platform for cell therapies. Clinical studies with this decentralized supply model have been approved by regulatory authorities in Belgium, Spain, and the Netherlands. If, for any reason, the collaboration is terminated or is otherwise materially changed and we are no longer entitled to use such technology platform, then we may be unable to secure alternatives to such technology and, our research, development or other efforts may be interrupted or delayed, and our financial condition and results of operation may be materially adversely affected.

We rely on third party suppliers for which a reliable supply of materials is required in order to avoid delays in the drug discovery and development process and commercial supplies of any approved product. Most goods and services are provided by several different suppliers, which mitigates the risk of loss of key suppliers.

Expanding the suppliers' network can be time consuming as all source suppliers are subject to rigorous ethical and quality control standards. Our suppliers are required to adhere to contractual terms that include anti-bribery and anti-corruption provisions. Our general terms and conditions of purchase also contain a specific clause on anti-bribery and anti-corruption. They can be found on our **website**.

We have relied on and plan to continue to rely on contract research organizations, or CROs, to monitor and manage data for our preclinical and clinical programs. We and our CROs also rely on clinical sites and investigators for the performance of our clinical

trials in accordance with the applicable protocols and applicable legal, regulatory and scientific standards, including Good Clinical Practices (GCPs). Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, investigators and clinical sites. If CROs do not successfully carry out their contractual duties or obligations or meet quality standards, regulatory requirements or expectations, such as the applicable GCPs, our clinical trials may be extended, delayed or terminated, the clinical data generated in our clinical trials may be deemed unreliable and regulatory authorities may require us to perform additional clinical trials before approving our marketing applications and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. We do retain responsibility for all our studies and are required to and have put in place measures to manage, oversee, and control our studies, including the CRO selection process, audits, strong focus on deliverables, timelines, roles & responsibilities, and oversight of conduct of the studies. In addition to GCPs, our clinical trials must be conducted with products produced under current Good Manufacturing Practice (cGMP) regulations.

We rely on clinical data and results obtained by third parties that could ultimately prove to be inaccurate or unreliable. If the third-party data and the results that we rely on prove to be inaccurate, unreliable or not applicable to our product candidates, we could make inaccurate assumptions and conclusions about our product candidates and our research and development efforts could be materially adversely affected.

Risks related to our competitive position

We face significant competition for our drug discovery and development efforts, and if we do not compete effectively, our commercial opportunities will be reduced or eliminated.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change and innovation. Our competitors may now or in the future develop drug products that render our products obsolete or non-competitive by developing more effective drugs or by developing their products more efficiently. In addition, our ability to develop competitive products would be limited if our competitors succeeded in obtaining regulatory approvals for drug candidates more rapidly than we were able to or in obtaining patent protection or other intellectual property rights that limited our drug development efforts.

These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the development of our product and product candidates. If we, our product and product candidates or our technology platforms do not compete effectively, it is likely to have a material adverse effect on our business, financial condition and results of operation.

Risks related to our intellectual property

Our ability to compete may decline if we do not adequately protect our proprietary rights.

We endeavor to protect our proprietary technologies and know-how by entering into confidentiality and proprietary information agreements with our employees and partners, and by setting up special procedures (e.g. with respect to the handling of the laboratory books).

Our commercial success depends on obtaining and maintaining proprietary rights to our product and product candidates, as well as successfully defending these rights against third party challenges. We will only be able to protect our product and product candidates, and their uses from unauthorized use by third parties to the extent that valid and enforceable patents, or effectively protected trade secrets, cover them. If we fail to maintain to protect or to enforce our intellectual property rights successfully, our competitive position could suffer, which could harm our results of operations.

Pharmaceutical patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position. Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. We cannot guarantee that our business, product, product candidates and methods do not or will not infringe the patents or other intellectual property rights of third parties. There is significant litigation activity in the pharmaceutical industry regarding patent and other intellectual property rights. Such litigation could result in substantial costs and be a distraction to management and other employees.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. The interpretation and breadth of claims allowed in some patents covering pharmaceutical compositions may be uncertain and difficult to determine, and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. The standards of the United States Patent and Trademark Office, the European Patent Office, and other foreign counterparts are sometimes uncertain and could change in the future. If we fail to obtain and maintain patent protection and trade secret protection of our product and product candidates, we could lose our competitive advantage and the competition we face would increase, reducing any potential revenues and adversely affecting our ability to attain or maintain profitability.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on our product and product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and

our intellectual property rights in some countries could be less extensive than those in the United States and Europe. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries, or from selling or importing products made using our inventions.

Risks related to our organization, structure and operation

Our future success depends on our ability to retain the members of our Executive Committee, and to attract, retain and motivate qualified personnel to develop our business if we expand into the fields that will require additional skills and expertise, including oncology. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to achieve our objectives and successfully implement our business strategy, which could have a material adverse effect on our business and prospects. Attractive development and training programs, adequate remuneration and incentive schemes, and a safe and healthy work environment mitigate this risk as they, among others, induce valuable qualified personnel to continue their employment or services with our business.

We expect that if we continue to build our development, medical and commercial organizations, including in the field of oncology, we will require significant additional investment in personnel, management and resources. Our ability to achieve our research, development and commercialization objectives depends on our ability to respond effectively to these demands, expand our internal organization, systems, controls and facilities to accommodate additional anticipated growth, and upon our management developing and implementing strategies for our business to realize these objectives. If we are unable to manage our growth effectively, our business could be harmed and our ability to execute our business strategy could suffer.

We have limited experience in the field of oncology, and continue to build our therapeutic area of oncology. We expect to invest significant financial and management resources to continue to build these capabilities and to establish such therapeutic area within our business. In June 2022, we acquired CellPoint and AboundBio with the aim to enter the space of oncology. Through such acquisitions, we believe we reinforced our portfolio by gaining access to an innovative, scalable, decentralized and automated point-of-care cell therapy supply model as well as fully human antibody-based therapeutics platform. Cell therapies are novel, complex, and difficult to manufacture, and we may not be successful in our efforts to develop and commercialize such therapies, in which case our financial condition and results of operation may be materially adversely affected. The manufacturing processes that we use to produce product and our product candidates for human therapeutics are complex, novel and have not been validated for commercial use. Several factors could cause production interruptions, including (without limitation) equipment malfunctions and facility contamination. Problems with the manufacturing process, even minor deviations from

the normal process, could result in product defects or manufacturing failures that can result in lot failure or product liability claims.

We remain building our marketing and sales organization. To the extent any of our product candidates for which we maintain commercial rights is approved for marketing, if we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to effectively market and sell any product candidates, or generate product revenues.

We must have a robust quality management system and team in place to ensure (continued) compliance with current good laboratory practices, current good manufacturing practices and current good clinical practices. If we are unable to comply with these practices, this may harm our clinical trials or regulatory process and by extension, our business.

Our information technology systems could face serious disruptions that could adversely affect our business. Continuing an uninterrupted performance of our IT system is critical to the success of our business strategy and operations. A recovery plan for data has been implemented, as well as a system for interception of power failures. Fire walls and virus scanners provide an additional and adequate protection. Our personnel should adhere to continuity plans and procedures regarding access rights and installation of different programs. Business interruptions could delay us in the process of developing our product candidates. This risk has a high potential impact, and thus we have a process to identify and mitigate threats by policies and procedures such as surveillance of the buildings, annual appraisals and bonuses, and monthly management meetings. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely, and there can be no assurance that any measures we take will prevent cyber-attacks (including phishing attempts or e-mail fraud to cause payments or information to be transmitted on an unintended recipient), security breaches or similar attacks or breaches that could adversely affect our business.

We have to comply with applicable data privacy laws, including the European General Data Protection Regulation (GDPR), which, among others, imposes strict obligations and restrictions on the collection and use of personal data. In the ordinary course of our business, we collect and store sensitive data. Many third-party vendors that support our business processes also have access to and process personal data. Although we have taken preventative measures and set up procedures regarding data processing, data breaches, loss of data and unauthorized access could still occur. These could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, including the GDPR, and significant regulatory penalties, disrupt our operations and damage our reputation. Any of the foregoing could materially harm our business, prospects, financial condition, and results of operation.

Despite our efforts to monitor social media and comply with applicable rules, there is a risk that the use of social media by us or our employees to communicate about our drug candidates or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual

requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of sensitive information. Furthermore, negative posts or comments in social media could seriously damage our reputation, brand image, and goodwill.

We may undertake strategic acquisitions in the future and any difficulties from integrating such acquisitions could adversely affect our share price, operating results and results of operations. We may acquire companies, businesses and products that complement or augment our existing business. As our programs may require the use of property rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, license-in or use these proprietary rights. We may be unable to acquire or in-license any third-party proprietary rights that we identify necessary for our drug candidates, for whatsoever reason. We may not be able to integrate any acquired business successfully or operate any acquired business profitably. Integrating any newly acquired business could be expensive and time-consuming. Integration efforts often take a significant amount of time, place a significant strain on managerial, operational and financial resources, result in loss of key personnel and could prove to be more difficult or expensive than we predict. As part of our efforts to acquire companies, business or product candidates or to enter into other significant transactions, we conduct business, legal and financial due diligence with the goal of identifying and evaluating material risks involved in the transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, might not realize the intended advantages of the transaction.

If we are unable to use tax loss carryforwards to reduce future taxable income or benefit from favorable tax legislation, our business, results of operations and financial condition may be adversely affected. We may incur unexpected tax charges, including penalties, due to the failure of tax planning or due to the challenge by tax authorities on the basis of transfer pricing. Any changes to Belgian and international taxation legislation or the interpretation of such legislation by tax authorities may adversely affect our activities, financial situation and results. Such potential changes and their impact are monitored carefully by our management and advisors.

Being active in research and development in Belgium, France and the Netherlands, we have benefited from certain research and development incentives. If the Belgian, the French or the Dutch governments decide to eliminate, or reduce the scope or the rate of, the research and development incentive benefits, either of which they could decide to do at any time, our results of operations could be adversely affected.

As a company active in research and development in Belgium, we also expect to benefit from the “innovation income deduction” in Belgium. The innovation income deduction regime allows net profits attributable to revenue from among others patented products (or products for which the patent application is pending) to be taxed at a lower effective rate than other revenues. The effective tax rate can thus be reduced down to 3.75%. At 31 December 2022 we had €346.2 million of carry-forward innovation income deduction in Belgium.

Our inability to qualify for the abovementioned advantageous tax regimes, as well as the introduction of the minimum taxable base and any other future adverse changes of Belgian tax legislation, may adversely affect our business, results of operations and financial condition.

We have received several technological innovation grants to date from an agency of the Flemish government to support various research programs and technological innovation in Flanders. If we fail to comply with our contractual obligations under the applicable technological innovation grant agreements, we could be forced to repay all or part of the grants received, which could adversely affect our ability to finance our research and development projects.

We annually establish a detailed budget that is submitted to the Board of Directors for review and approval. Our performance compared to the budget is continuously monitored by our Executive Committee, and is discussed with the Board of Directors at least once per quarter. For the establishment of our financial information, we have processes and methods in place that enable the preparation of non-consolidated and consolidated financial statements for our annual and quarterly reporting. Our management reporting systems – which include an advanced integrated Enterprise Resource Planning (ERP system) – secure the generation of consistent financial and operational information, allowing management to follow-up our performance on a daily basis.

Our business may be adversely affected as a result of information technology or computer system failures. We may suffer data leaks, security incidents or become the target of cyber-attacks, as a result of which our financial assets, confidential information and/or intellectual property may be materially negatively impacted. We may not be able to successfully protect our information technology or computer systems against unauthorized access by third parties.

The occurrence of unforeseen or catastrophic events, including extreme weather events and other acts of god or natural disasters, man-made disasters, electricity or telecommunication interruption, geopolitical an and other economic and political events or conditions (such as the armed conflict between Russia and Ukraine), or the emergence of epidemics or diseases, depending on their scale, may cause different degrees of damage to the national and local economies, and could cause a disruption in our operations and have a material adverse effect on our financial condition and results of operations. Man-made disasters, epidemics or diseases, and other events connected with the regions in which we operate could have similar effects. For example, the impact of COVID-19 on our business, operations and financial performance cannot be precisely determined or quantified, and will depend on future developments, but governmental measures in order to control the spread of the virus may disrupt our operations and the operations of our agents, contractors, consultants or collaborators, which could negatively impact our business, results of operations and financial condition. Further, continuing uncertainty around these and related issues could lead to adverse effects on the economy of the United States and other economies, which could impact our ability to develop and commercialize our products and raise capital going forward.

The armed conflict between Russia and Ukraine could cause a disruption in our operations, including clinical development activities and clinical trials. We currently have no clinical studies that are enrolling patients in Ukraine and Russia. If our CROs experience significant or extended 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 pivotal studies such as DIVERSITY 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 CROs' and our 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. This 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.

Market risks relating to the Galapagos shares

We have identified the following major market risks:

- Possible volatility of share price
  The market price of the shares might be affected by a variety of factors outside management's control, such as, without limitation, the global economic situation, the business development of competitors, and sector mergers and acquisitions; it is difficult to mitigate these risk.
- Economic risk due to failure in confidence
  General public confidence about future economic conditions or performance of us, our business, or our suppliers or customers may impact the ability or willingness of others to trade with us.
- Dilution through capital increases
  Raising additional capital may cause dilution to our existing shareholders. By raising additional capital through capital increases with cancellation of the preferential subscription rights of our existing shareholders, these shareholders would be diluted.
- Dilution through exercise of subscription right plans
  The exercise of existing subscription rights can significantly increase the number of outstanding Galapagos shares.

- Inability to distribute dividends
  We have a limited operating history, and future profitability cannot be guaranteed. Galapagos NV has significant losses carried-forward, and will thus not be able to distribute dividends in the near future. This can cause people to refrain from investing in Galapagos' shares.
- Reputational damage
  High ethical standards are maintained throughout the entire organization at all levels. Laws and guidelines are complied with. Our suppliers are required to adhere to contractual terms which include anti-bribery and anti-corruption provisions. In addition, our external consultants are required to comply with our Code of Conduct and our Anti-Bribery and Anti-Corruption Policy.
- Belgian law provisions
  There are several provisions of Belgian company law and certain other provisions of Belgian law, such as, without limitation, the obligation to disclose important shareholdings and merger control, that may apply to us, and which may make an unfriendly tender offer, merger, change in management or other change in control, more difficult. These provisions could discourage potential takeover attempts that third parties may consider, and thus deprive the shareholders of the opportunity to sell their shares at a premium (which is typically offered in the framework of a takeover bid).

General statement about Galapagos' risks

According to our current assessment and knowledge, we consider the major risks to be manageable, and our going concern not to be endangered at the time of the current report. Assuming no further deterioration of the global business, financial, and regulatory environment, we consider ourselves prepared to meet future challenges.