Summary of risk factors

We are heavily dependent upon our global R&D collaboration with Gilead and the amendment of our arrangement with Gilead for the commercialization and development of filgotinib. There can be no assurance that these arrangements will deliver the benefits we expect, including but not limited to the payment of potential future milestones, opt-in and/or royalty payments by Gilead.

We have no historical profit from product sales and limited historical data on product revenues, which makes it difficult to assess our future prospects and financial results.

We have limited sales and distribution experience and we have built, and continue to develop a marketing and sales organization. We expect to continue to invest financial and management resources to continue to build these capabilities and to establish a European commercial infrastructure. 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 market and sell any product candidates effectively, or generate product revenues.

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 rheumatoid arthritis and ulcerative colitis in the European Union, Great Britain, and Japan and marketed under the brand name Jyseleca®.

We are also dependent on the success of our other clinical-stage product candidates, such as our immunology candidates/trials (such as filgotinib, GLPG3667 and GLPG5101) and our oncology candidates (such as GLPG5101, GLPG5201 and GLPG5301). 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.

Clinical development is a lengthy and expensive process with an uncertain outcome, and 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 or approved label for clinical use. Clinical failure can occur at any stage of clinical development.

Due to our limited resources and access to capital in the past, we have decided to prioritize development of certain product candidates and may have forgone the opportunity to capitalize on product candidates or indications that may ultimately have been more profitable or for which there was a greater likelihood of success.

We may not be successful in our efforts to progress and expand our immunology and oncology portfolio and to build a pipeline of product candidates.

The regulatory approval processes of the FDA, the EMA, the MHLW, and other comparable regulatory authorities are lengthy, time consuming and inherently unpredictable which may affect the commercial viability of our products in development. If we are unable to ultimately obtain regulatory approval for our product candidates, our business will be substantially harmed.

In connection with our global clinical trials, local regulatory authorities may have differing perspectives on clinical protocols and safety parameters, which impacts the manner in which we conduct these global clinical trials and could negatively impact our chances for obtaining regulatory approvals or marketing authorization in these jurisdictions, or for obtaining the requested label or dosage for our product candidates, if regulatory approvals or marketing authorizations are obtained.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Our future clinical trials or those of any of our collaborators may reveal significant adverse events not seen in our preclinical studies or earlier clinical trials and result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

Coverage and reimbursement decisions by third-party payers may have an adverse effect on pricing and market acceptance.

Legislative and regulatory activity 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.

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.

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

Our business, results of operations and future growth prospects could be materially and adversely affected by the COVID-19 pandemic and by the ongoing armed conflict between Russia and Ukraine.

The market price of the ADSs could be subject to wide fluctuations.

We may be at an increased risk of securities class action litigation.

PART I

Item 1 Identity of directors, senior management and advisers

Not applicable.

Item 2 Offer statistics and expected timetable

Not applicable.

Item 3 Key information

A. Reserved

B. Capitalization and indebtedness

Not applicable.

C. Reasons for the offer and use of proceeds

Not applicable.

D. Risk factors

Our business is subject to significant risks. You should carefully consider all of the information set forth in this annual report and in our other filings with the U.S. Securities and Exchange Commission, or the SEC, including the following risk factors which we face, and which are faced by our industry. Our business, financial condition, or results of operations could be materially adversely affected by any of these risks. This report also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements, as a result of certain factors including the risks described below and elsewhere in this annual report and our other SEC filings. See "Special Note Regarding Forward-Looking Statements" above.

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 rheumatoid arthritis and ulcerative colitis in the European Union (including Norway), Great Britain, and Japan.

We, and our collaboration partner, Gilead, began commercializing filgotinib in the European Union and Great Britain, and Gilead began commercializing filgotinib in Japan for the treatment of rheumatoid arthritis, or RA, following receipt in September 2020 of marketing approval from the European Medicines Agency, or the EMA, from the Medicines and Healthcare products Regulatory Agency, or the MHRA, and from the Japanese Ministry of Health, Labour and Welfare, or the MHLW. We received marketing approval from the EMA for the treatment of ulcerative colitis, or UC in November 2021, from the MHRA in January 2022, and from the MHLW in March 2022.

As of 2021, we assumed sole responsibility in Europe for the commercialization of filgotinib as well as for all future indications for filgotinib, including becoming the marketing authorization holder for Jyseleca for the treatment of RA and UC in twenty-seven European countries, Iceland, Norway and Liechtenstein (the European Economic Area or EEA), and Great Britain, with Gilead maintaining commercialization rights and remaining the marketing authorization holder for filgotinib and other future indications for filgotinib outside of Europe, including in Japan where Jyseleca is approved for the treatment of RA and UC and is co-marketed with Eisai. In October 2021, Galapagos signed a distribution agreement with Swedish Orphan Biovitrum AB (‘Sobi’). Sobi is our distribution and commercialization partner in Eastern and Central Europe, Portugal, Greece, and the Baltic countries. They launched Jyseleca in RA in the Czech Republic and Portugal. Although we have secured reimbursement for Jyseleca in fifteen European countries, including Germany, France, Spain, Italy and Great Britain, and our sales force commenced making sales of Jyseleca in the second half of 2021, we have limited experience as a commercial company, and there is limited information about our ability to overcome many of the risks and uncertainties encountered by companies commercializing products in the biopharmaceutical industry. To market and sell filgotinib, and any of our product candidates that may be approved for marketing in the future, we will need to successfully:

- establish and maintain, in the geographies where we hope to treat patients, relationships with qualified treatment centers who will treat the patients who receive filgotinib and any future products;
- continue to obtain adequate pricing and reimbursement for filgotinib and any future products in the jurisdictions in which we plan to commercialize approved products;
- obtain regulatory authorization for the development and commercialization of the product candidates in our pipeline;
- develop and maintain successful strategic alliances and collaborations; and
- manage our spending as costs and expenses are expected to increase due to clinical trials, marketing approvals, and commercialization, including any extension of marketing approval for filgotinib, and for any future products we may develop.

If we are not successful in accomplishing these objectives, we may not be able to develop product candidates, successfully commercialize filgotinib or any future products we may develop, raise capital, expand our business, or continue our operations. Further, to the extent that Gilead is commercializing filgotinib in one or more jurisdictions or a third party, such as Eisai or Sobi, is commercializing filgotinib in one or more jurisdictions, we are significantly dependent on their successful accomplishment of these objectives, which is largely out of our control.

The commercial success of filgotinib and of any future products will depend upon the degree of market acceptance by physicians, healthcare payers, patients, and the medical community.

The commercial success of filgotinib and of any future products we may develop will depend in part on acceptance by the medical community, patients, and third-party or governmental payers as medically useful, cost-effective, and safe. Filgotinib and any other products that we and our current and future partners may bring to the market may not gain market acceptance by physicians, patients, third-party payers and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of filgotinib and of any future products we may develop will depend on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of the product as well as the timing of entry of competitive products;
- the clinical indications for which the product is approved;
- acceptance by physicians, the medical community, and patients of the product as a safe and effective treatment;
- the convenience of prescribing and initiating patients on the product;
- the potential and perceived advantages of such product over alternative treatments;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payers and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects; and
- the effectiveness of sales and marketing efforts.

Even if a product displays a favorable efficacy and safety profile in preclinical and clinical studies and receives regulatory approval, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and third-party payers on the benefits of our products may require significant resources and may never be successful. Our efforts to educate the marketplace may require more resources than are required by the conventional methods marketed by our competitors. Any of these factors may cause filgotinib or any future products we may develop to be unsuccessful or less successful than anticipated.

We have limited sales and distribution experience. We expect to continue to invest financial and management resources to continue to build these capabilities further. To the extent that 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 products effectively, or generate product revenues as projected.

We have built, and continue to develop a marketing and sales organization for the marketing, sales, and distribution of pharmaceutical products. As of 2021, we assumed sole responsibility in Europe for the commercialization of filgotinib, approved in RA at that point, and as well as for all future indications for filgotinib, with Gilead maintaining commercialization rights and remaining the marketing authorization holder for filgotinib and other future indications for filgotinib outside of Europe. This assumption of responsibility by us has required us to, and will require us to continue to, develop robust marketing and sales capabilities, including a commercial infrastructure. We have limited experience as a commercial company and there is limited information about our ability to overcome many of the risks and uncertainties encountered by companies commercializing products in the biopharmaceutical industry. In order to

commercialize filgotinib independently in Europe and any product candidates that may receive marketing approval in the future and for which we maintain commercial rights, we will need to maintain and expand marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and these efforts may not achieve the desired results. Further, in the event of development of any other product candidates for which we maintain commercial rights, we may elect to build a targeted specialty sales force which will be expensive and time consuming. Any failure or delay in the development of our internal market access, sales, marketing and distribution capabilities would adversely impact the commercialization of these products. With respect to any proprietary product candidates we may have in the future, we may choose to partner with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems.

If we are unable to continue to develop and scale our own sales, marketing and distribution capabilities for filgotinib in Europe, or for any future products which we choose to commercialize ourselves, we will not be able to commercialize such products successfully without reliance on third parties and, in the case of filgotinib, we may be unable to realize all of the anticipated benefits of the transition of European rights to filgotinib from Gilead to us. Further, if we are unable to enter into collaborations with third parties for the commercialization of approved products, if any, on acceptable terms or at all, or if any such partner (such as Gilead and Eisai, in the case of filgotinib) does not devote sufficient resources to the commercialization of our product or otherwise fails in commercialization efforts, we may not be able achieve the commercial goal for any of our product candidates that may receive regulatory approval. If we are not able to commercialize our product candidates well, either on our own or through collaborations with one or more third parties, our future revenue will be materially and adversely impacted.

Coverage and reimbursement decisions by third-party payers may have an adverse effect on pricing and market acceptance.

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. To the extent that we retain commercial rights following clinical development, we may seek approval to market our product candidates in the United States, the European Union and other selected jurisdictions. Market acceptance and sales of our product candidates, if approved, in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party payers for any of our product candidates and may be affected by existing and future healthcare reform measures. Third-party payers, such as government authorities, private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. See section entitled “*Information on the Company – Pharmaceutical coverage, pricing and reimbursement*.”

We cannot be certain that coverage and adequate reimbursement will be available for any of our products or product candidates, if approved. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, any of our product candidates, if approved. If reimbursement is not available or is available on a limited basis for any of our products or product candidates, if approved, we may not be able to commercialize successfully any such product candidate.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payer is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payer. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement or to have pricing set at a satisfactory level. If reimbursement of our future products, if any, is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels such as may result where alternative or generic treatments are available, we may be unable to achieve or sustain profitability.

In certain countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our product candidates to other available therapies. In the United States, Medicare and Medicaid are significant third party payors. Medicare is administered by the Centers for Medicare & Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services (HHS) and Medicaid is administered jointly by CMS and the individual states. Obtaining adequate coverage and reimbursement under Medicare and Medicaid is important for new drug products. Additionally, private payors may adopt coverage policies or reimbursement methodologies similar to Medicare. Reimbursement by a third-party payer may depend upon a number of factors, including the third-party payor's

determination that use of a product is: a covered benefit under its health plan; safe, effective and medically necessary; appropriate for the specific patient; cost-effective; and neither experimental nor investigational. Novel and expensive cell therapies like CAR-T cell therapies have experienced and continue to experience coverage and reimbursement challenges. For example, Medicare only covers CAR-T cell therapies that meet specific criteria set forth in a national coverage decision. Other third party payors may impose coverage criteria more extensive than compliance with FDA labeling. If reimbursement of any of our products or product candidates, if approved, is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability of our products in such country.

The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we have or will obtain marketing approval.

Legislative and regulatory activity 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.

The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell any of our products or product candidates profitably, if approved. Among policy-makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. See section entitled "*Information on the Company – Patient Protection and Affordable Care Act and Healthcare Reform*." We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any of our product candidates, if approved;
- the ability to set a price that we believe is fair for any of our product candidates, if approved;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We expect that the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the ACA, as well as other healthcare reform measures that may be adopted in the future in any jurisdiction, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or successfully commercialize our products or product candidates.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical and biologic products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations or regulations, guidance or interpretations of other regulatory authorities will be changed, or what the impact of such changes on the marketing approvals of our products or product candidates, if any, may be. In addition, increased scrutiny by Congress of the

FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products or product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs in the United States or in other jursidictions may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or successfully commercialize our products.

Risks related to product development and regulatory approval

We are also dependent on the success of our other clinical-stage product candidates, such as our inflammation candidates (such as filgotinib, GLPG3667, and GLPG5101) and our oncology candidates (such as GLPG5101, GLPG5201, and GLPG5301). 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.

We anticipate to start Phase 3 trials with filgotinib in axial spondyloarthritis (AxSpA) in 2023. Our business and future success is substantially dependent on our ability to further commercialize filgotinib and to develop, obtain additional regulatory approval for, and then successfully commercialize filgotinib for additional indications. Our business and future success also depend on our ability to develop successfully, obtain regulatory approval for, and then successfully commercialize our other clinical-stage immunology and oncology product candidates, including GLPG3667, GLPG5101, GLPG5201 and GLPG5301.

Our product candidates will require additional clinical development, management of clinical and manufacturing activities, regulatory approval in multiple jurisdictions (if regulatory approval can be obtained at all), securing sources of commercial manufacturing supply, building of, or partnering with, a commercial organization, substantial investment and significant marketing, sales and distribution efforts before any revenues can be generated from product sales. 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, or any other comparable regulatory authority such as the MHLW, and we may never receive such regulatory approval for any of our product candidates. We cannot assure you that our clinical trials for filgotinib (in AxSpA), GLPG3667, GLPG5101, GLPG5201, GLPG5301 and other product candidates will be completed in a timely manner, or at all, or that we will be able to obtain approval from the FDA, the EMA, the MHRA, the MHLW, or any other comparable regulatory authority for any of these product candidates. We cannot be certain that we will advance any other product candidates into clinical trials. If any of filgotinib in AxSpA, GLPG3667, GLPG5101, GLPG5201, GLPG5301 or any future product candidate is not approved and commercialized, we will not be able to generate any product revenues for that product candidate. Moreover, any delay or setback in the development of any product candidate could adversely affect our business and cause the price of the American Depositary Shares, or ADSs, or our ordinary shares to fall.

Due to our limited resources and access to capital in the past, we have decided to prioritize development of certain product candidates and may have forgone the opportunity to capitalize on product candidates or indications that may ultimately have been more profitable or for which there was a greater likelihood of success.

Because we had limited resources in the past, we had to decide which product candidates to pursue and the resources to allocate to each. As of year-end 2022, we implemented a new innovation R&D model focusing on the therapeutic areas of immunology and oncology. Consequently, we are currently primarily focused on the commercialization of filgotinib in RA and UC, and the development of filgotinib in AxSpA, as well as on advancing our

clinical-stage pipeline, including filgotinib (for additional indications), GLPG3667, GLPG5101, GLPG5201 and GLPG5301. Our decisions concerning the allocation of research, collaboration, management, commercial and financial resources toward particular compounds, products or product candidates or therapeutic areas may not lead to the development of additional viable commercial products, we may forgo or delay the pursuit of opportunities with other product candidates, or for other indications that may prove to have greater commercial potential. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our products or product candidates or misread trends in the pharmaceutical industry, our business, financial condition and results of operations could be materially adversely affected.

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 which may affect the commercial viability of our products or product candidates in development. If we are unable ultimately to obtain regulatory approval for our products or product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA, the EMA, the MHRA, the MHLW and other comparable regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Although we and Gilead have received regulatory approval for filgotinib in the European Union, Great Britain, and Japan for the treatment of RA and UC, it is possible that none of our other existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, the EMA, the MHRA, the MHLW or other comparable regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA, the MHRA, the MHLW or other comparable regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA, the MHRA, the MHLW or other comparable regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- filgotinib and many of our product candidates are developed to act against targets discovered by us, and because a number of our products and product candidates are novel mode of action compounds, they can carry an additional risk regarding the desired level of efficacy and safety profile;
- the FDA, the EMA, the MHRA, the MHLW or other comparable regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a new drug application, or NDA, supplemental NDA, biologics license application, or BLA, or other submission or to obtain regulatory approval in the United States, Europe or elsewhere;
- the FDA, the EMA, the MHRA, the MHLW or other comparable regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies, or such processes or facilities may not pass a pre-approval inspection; and
- the approval policies or regulations of the FDA, the EMA, the MHRA, the MHLW or other comparable regulatory authorities may change (in particular, the regulatory requirements and guidance with respect to cell

therapy products are still evolving) or differ from one another significantly in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our collaboration partners' failure to obtain regulatory approval to market filgotinib in AxSpA, GLPG3667, GLPG5101, GLPG5201, GLPG5301 and/or other product candidates, which would harm our business, results of operations and prospects significantly. In addition, even if we were to obtain additional approvals, regulatory authorities may approve any of our products or product candidates for fewer or more limited indications or patient populations than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product or product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. In certain jurisdictions, regulatory authorities may not approve the price we intend to charge for our products. Any of the foregoing scenarios could materially harm the commercial prospects for our products or product candidates.

We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even though we have successfully obtained regulatory approval for filgotinib in several jurisdictions and even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights or share in revenues from the exercise of such rights. If the markets for patient subsets that we are targeting (such as AxSpA) are not as significant as we estimate, we may not generate significant revenues from sales of such products or product candidates, if approved.

In connection with our global clinical trials, local regulatory authorities may have differing perspectives on clinical protocols and safety parameters, which impacts the manner in which we conduct these global clinical trials and could negatively impact our chances for obtaining regulatory approvals or marketing authorization in these jurisdictions, or for obtaining the requested label or dosage for our product candidates, if regulatory approvals or marketing authorizations are obtained.

In connection with our global clinical trials, we are obligated to comply with the requirements of local regulatory authorities in each jurisdiction where we execute and locate a clinical trial. Local regulatory authorities can request specific changes to the clinical protocol or specific safety measures that differ from the positions taken in other jurisdictions. For example, filgotinib received approval in RA and UC from the EMA in the European Union, the MHRA in Great Britain, and the MHLW in Japan, yet a complete response letter, or CRL, in RA from the FDA in the United States. The FDA, EMA, the MHRA, and MHLW will receive the full data from the MANTA and MANTA-RAy male semen parameter studies conducted in parallel to the FINCH Phase 3 program in RA. We cannot assure that the same view of the MANTA and MANTA-RAy results will be adopted by regulatory authorities at the marketing authorization stage, now that filgotinib received marketing authorization in the EEA, Great Britain, and Japan for RA and UC. The FDA or other regulatory authorities may approve different labels, including for whom the drug is indicated or require different warnings or precautions, or impose dosing restrictions that differ from the approved dosing regimen in other jurisdictions, and these differences could have a material adverse effect on our ability to commercialize our products in these jurisdictions. Regulatory authorities could also not approve our applications, which would adversely affect our business prospects and ability to achieve or sustain profitability.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product, and we may be required to include labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings.

If the FDA, EMA, the MHRA, the MHLW, or any other comparable regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. 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. Manufacturers and other parties involved in the drug supply chain for prescription drug and biological products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, untitled or warning letters or holds on clinical trials;
- imposition by the FDA, the EMA, the MHLW, or any other comparable regulatory authority of more restrictive labeling, including label updates and adjustments;
- refusal by the FDA, the EMA, the MHLW, or any other comparable regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals or licenses;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

For example, the MHRA has assigned a black triangle to filgotinib, indicating that it is on a list of medicines subject to additional monitoring. Additionally, in February 2022 the EMA announced that its Pharmacovigilance Risk Assessment Committee (PRAC), the EMA’s safety committee, started a safety review of JAK inhibitors used to treat certain chronic inflammatory disorders, including filgotinib. This safety study intended 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. Further, while we and Gilead elected in 2020 not to pursue approval and commercialization of filgotinib in the U.S., in 2021, the FDA announced that following completion of its review of a safety study of Xeljanz (tofacitinib), it would require revisions to the Boxed Warning, the FDA’s most prominent warning, for Xeljanz and certain other JAK inhibitors that are the subject of the EMA’s review to include information about the risks of serious heart-related events, cancer, blood clots and death.

In November 2022, the Committee for Medicinal Products for Human Use (CHMP), the EMA’s scientific committee, announced that it has endorsed PRAC’s recommendation to add measures to minimize risk of serious side effects with JAK inhibitors for chronic inflammatory disorders by updating the product labels of all JAK inhibitors to include a precautionary approach for patients aged 65 years or above, those at increased risk of major cardiovascular problems (such as heart attack or stroke), those who smoke or have done so for a long time in the past and those at increased risk of cancer. For those at-risk patients, the recommendation is that JAK inhibitors, including filgotinib, should be used only if no suitable treatment alternatives are available. The CHMP followed PRAC’s recommendation that JAK inhibitors should be used with caution in patients with risk factors for blood clots in the lungs and in deep veins (venous thromboembolism, VTE) other than those listed above.

Following the adoption by the CHMP, the European Commission approved this decision on 10 March, 2023.

The policies of the FDA, the EMA, the MHRA, the MHLW, and other comparable regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval

that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Filgotinib may be subject to box warnings, labeling restrictions or dose limitations in certain jurisdictions, which could have a material adverse impact on our ability to market filgotinib in these jurisdictions.

Based on preclinical findings, we expect that filgotinib, if approved in the U.S. or in other additional jurisdictions, may have a labeling statement warning female patients of childbearing age to take precautionary measures of birth control to protect against pregnancy. 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. We and Gilead conducted dedicated male semen analysis studies in CD and UC patients (MANTA) and in RA, psoriatic arthritis, or PsA, and ankylosing spondylitis, or AS, patients (MANTA-RAy).

We submitted a type II variation application to the EMA in June 2022, supported by interim data on the primary, secondary and exploratory endpoints at Week 13 and 26 for subjects who met a prespecified sperm decrease at these timepoints (up to Week 52) from the ongoing MANTA and MANTA-RAy studies, investigating the potential effect of filgotinib use on semen parameters and sex hormones in adult patients with IBD and various RC.

Following assessment of the interim data by the CHMP, it was concluded in the CHMP opinion that the data did not reveal a difference between treatment groups in the proportion of patients who had a 50% or more decrease from baseline in semen parameters at Week 13 (pooled primary endpoint: filgotinib 6.7%, placebo 8.3%) and at Week 26. Further, the CHMP concluded that the data did not show any relevant changes in sex hormone levels or change from baseline in semen parameters across treatment groups. Overall, CHMP concluded that these clinical data were not suggestive of filgotinib-related effects on testicular function. We received a positive CHMP opinion for the European label update of filgotinib based on testicular safety data from MANTA/RAy studies.

Following the positive CHMP opinion, the language in the section of the Special Warnings and Precautions about the potential effect of filgotinib on sperm production and male fertility will be removed from the Summary of Product Characteristics (SmPC).

In Japan and other jurisdictions where filgotinib has been approved for RA and UC, those regulatory authorities could impose new labeling or other requirements upon learning of new information related to filgotinib.

Even if filgotinib receives additional regulatory approval or marketing authorization, the FDA or other regulatory authorities may impose dosing restrictions that differ from the approved dosing regimens 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.

Clinical development is a lengthy and expensive process with an uncertain outcome, and 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 or an approved label for clinical use. Clinical failure can occur at any stage of clinical development.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Although product candidates may demonstrate promising results in early clinical (human) trials and preclinical (animal) studies, they may not prove to be effective in subsequent clinical trials. For example (without any limitation), testing on animals may occur under different conditions than testing in humans and therefore the results of animal studies may not accurately predict human experience. Likewise, early clinical studies may not be predictive of eventual safety or effectiveness results in larger-scale pivotal clinical trials. The results of preclinical studies and previous clinical trials as well as data from any interim analysis of ongoing clinical trials of our product candidates, as well as studies and trials of other products with similar mechanisms of action to our product candidates, may not be predictive of the results of ongoing or future clinical trials. For example (without any limitation), the positive results generated to date in preclinical studies and Phase 1, Phase 2 and Phase 3 clinical trials for filgotinib in RA and UC and in the Phase 2 clinical trials for CD do not ensure that later clinical trials, including any post-approval clinical trials for approved products, will continue to demonstrate similar results or observations. For our point-of-care cell therapy product candidates which are in Phase 1/2 of clinical development, dose escalation and dose expansion cohort data are required to establish the dose for pivotal trials, and durability of response can only be established based

on longer term follow up of patients who received therapy. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and earlier clinical trials. In addition to the safety and efficacy traits of any product candidate, clinical trial failures may result from a multitude of factors including flaws in trial design, dose selection, placebo effect and patient enrollment criteria. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and it is possible that we will as well. Based upon negative or inconclusive results, we or our collaboration partners may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval.

We may experience delays in our ongoing clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory authorization to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining Institutional Review Board, or IRB, or ethics committee approval at each site;
- obtaining regulatory concurrence on the design and parameters for the trial;
- obtaining approval for the designs of our clinical development programs for each country targeted for trial enrollment;
- recruiting suitable patients to participate in a trial, which may be impacted by the number of competing trials that are enrolling patients;
- having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites;
- for our point-of-care cell therapy product candidates, adding new manufacturing sites;
- manufacturing sufficient quantities of product candidate or obtaining sufficient quantities of comparator drug for use in clinical trials;
- the availability of adequate financing and other resources;
- the ongoing COVID-19 pandemic; or
- the ongoing armed conflict between Russia and Ukraine, and sanctions against Russia.

We could encounter delays if a clinical trial is suspended or terminated by us, our collaboration partners, by the IRBs or ethics committees of the institutions in which such trials are being conducted, or by the FDA, the EMA, the MHRA, MHLW, or other comparable regulatory authorities, or recommended for suspension or termination by the Data Monitoring Committee, or the DMC, for such trial. A suspension or termination, including in some cases a clinical hold, may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, the EMA, the MHRA, MHLW, or other comparable regulatory authorities, safety issues or adverse side effects, including those seen in the class to which our product candidates belong, failure to demonstrate a benefit from using a drug, changes in

governmental regulations or administrative actions, manufacturing issues or lack of adequate funding to continue the clinical trial. For example (without limitation), it is possible that safety issues or adverse side effects could be observed in trials for filgotinib in RA, UC, and CD; for GLPG3667 or GLPG5101 in immunology, and for GLPG5101, GLPG5201 or GLPG5301 in oncology, which could result in a delay, suspension or termination of the ongoing trials of filgotinib (in one or more indications), GLPG3667, GLPG5101, GLPG5201, and GLPG5301. If we experience delays in the completion of, or experience a 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 or prevented. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

If filgotinib in AxSpA, GLPG3667, GLPG5101, GLPG5201, or GLPG5301, or any other product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business would be materially harmed.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropouts among clinical trial participants. We do not know whether any Phase 2, Phase 3, or other clinical trials we or any of our collaboration partners may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If we are unable to bring any of our current or future product candidates to market, our ability to create long-term shareholder value will be limited.

We initiated our first clinical study in 2009, and for 15 of our compounds with novel modes of action, Phase 2 studies were initiated. Phase 3 studies in RA, UC, and CD were initiated by our collaboration partner Gilead for filgotinib.

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, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

Furthermore, our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials. In addition, any negative results we may report in clinical trials of our drug candidate may make it difficult or impossible to recruit and retain patients in other clinical trials of that same drug candidate. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We may not be successful in our efforts to use and expand our novel target discovery platform to build a pipeline of product candidates.

A key element of our strategy is to use and expand our novel target discovery platform to build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of a variety of diseases. Although our research and development efforts to date have resulted in a pipeline of product candidates directed at various diseases, we may not be able to develop product candidates that are safe and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be product candidates that will receive marketing approval and achieve market acceptance. If we do not continue to develop successfully and to commercialize products, we will face difficulty in

obtaining product revenues in future periods, which could result in significant harm to our financial position and adversely affect the price of the ADSs or our ordinary shares.

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. Our drug discovery and development efforts may target diseases and conditions that are already addressed by existing therapies or by product candidates that are being developed by our competitors, many of which have substantially greater resources, larger research and development staffs and facilities, more experience in completing preclinical testing and clinical trials, and more or better formulation, marketing and manufacturing capabilities than we do. As a result of these resources, our competitors may develop drug products that render our products and product candidates obsolete or noncompetitive by developing more effective drugs or by developing their products more efficiently. Our ability to develop competitive products would be limited if our competitors succeed in obtaining regulatory approvals for product candidates more rapidly than we are able to or in obtaining patent protection or other intellectual property rights that limit our drug development efforts. We depend upon our management team to develop and successfully implement strategies for us to obtain regulatory approvals for our selected product candidates more speedily than our competitors and to obtain and maintain patent protection and other intellectual property rights that protect our drug development efforts. Any drug products resulting from our research and development efforts, or from our joint efforts with collaboration partners or licensees, might not be able to compete successfully with our competitors' existing and future products, or obtain regulatory approval in the United States, European Union or elsewhere. Further, we may be subject to additional competition from alternative forms of treatment, including generic or over-the-counter drugs.

In the field of RA, therapies include conventional synthetic disease-modifying antirheumatic drugs (csDMARDs), such as methotrexate, which is considered the standard-of-care for the treatment of RA. In fact, both the European Alliance of Associations for Rheumatology (EULAR) recommendations and the American College of Rheumatology guidelines recommend inclusion of methotrexate in first-line therapies for patients with RA. Given that csDMARDs may be ineffective for some patients with RA or cause side effects, additional therapies for patients who do not respond adequately or who are intolerant to standard-of-care treatments are needed. Accordingly, in addition to csDMARDS, biological DMARDs, such as monoclonal antibodies targeting TNF, like AbbVie's Humira, or against IL-6 Receptor (IL-6R) like Roche's RoActemra in EU, and Actemra as marketed in the US, have been developed. These biologics which must be delivered via injection or infusion. In November 2012, Xeljanz, marketed by Pfizer, was approved by the FDA as an oral treatment of adult patients with RA who have had an inadequate response to, or who are intolerant to, MTX. Xeljanz was approved by the EMA in 2017. Olumiant, a once-daily JAK1/2 inhibitor, marketed by Eli Lilly, was approved by the EMA for RA with 2 dosages in 2017 and by the FDA in 2018. A JAK inhibitor called Rinvoq which received approval for use with 1 dosage in RA from FDA and EMA in 2019 and in UC from FDA and EMA in 2022 is marketed by AbbVie. Filgotinib (Jyseleca), developed by us in collaboration with Gilead, is a preferential JAK1 inhibitor approved in 2020 for use in RA with 2 dosages and in 2022 in UC in European Union, Great Britain and Japan. We expect that Jyseleca is competing with all of these advanced therapies now that it is marketed. If generic or biosimilar versions of these therapies are approved, we would also expect Jyseleca to compete against these versions of the therapies.

In the field of AxSpA, Axial spondyloarthritis (AxSpA) is an umbrella term that includes different inflammatory diseases primarily targeting the sacro-iliac joints and the spine. The most notable diseases of the AxSpA group are radiographic AxSpA (r-AxSpA; also known as ankylosing spondylitis, AS) and non-radiographic AxSpA (nr-AxSpA). The latter was introduced by the Assessment in SpondyloArthritis International Society (ASAS) to classify a group of patients who did not meet criteria for radiographic sacroiliitis but still experienced a burden of disease comparable to patients with well-defined AS. The disease usually arises in the third decade of life and is characterised by a chronic course, flares and high permanent invalidity rates. Next to physiotherapy, pharmacological therapy to treat signs and symptoms of the disease is based on the use of NSAIDs. In patients who do not respond or cannot tolerate first line treatments, biologic anti-rheumatic disease modifying (bDMARDs) drugs such as anti-TNF and IL-17 can be used. These include AbbVie's Humira (AS only in US), UCB's Cimzia (severe only in EU), Novartis' Cosentyx and Lilly's Taltz. Bimzelix (bimekizumab) from UCB is currently under regulatory review for AS and nr-AxSpA and Netakimab (BCD-085) from Biocad is in Phase 3 for AS. Inhibition of the JAK pathway with tsDMARDs has recently shown to be a good additional strategy to effectively manage AxSpA. Both tofacitinib and upadacitinib have been approved in the European Union (EU) for the treatment of adult patients with active AS who have responded inadequately to

conventional therapy. Furthermore, upadacitinib has been approved in the EU for the treatment of active non-radiographic axial spondyloarthritis (nrAxSpA) in adult patients with objective signs of inflammation, as indicated by elevated C-reactive protein (CRP) and/or MRI, who have responded inadequately to NSAIDs.

In the field of UC, first line therapies are oral (or local) treatments with several low-cost generic compounds such as mesalamine. Steroids such as budesonide are also used in UC. For more advanced therapy, monoclonal antibodies with various targets such as TNF and more recently, integrins such as vedolizumab (Entyvio, marketed by Takeda) are approved. We are also aware of other biologics currently approved or in clinical development for these indications, such as ustekinumab (Stelara), developed by Johnson & Johnson, which is approved for UC, and binutuzumab (Skyrizi), developed by AbbVie and under development for UC. Celgene/BMS has a new oral therapy, ozanimod (Zeposia), approved in UC. Pfizer's Xeljanz was approved by the FDA for UC in 2018. Filgotinib (Jyseleca) is approved in the European Union, Great Britain and Japan for UC. Abbvie's Rinvoq is approved for UC. The number of treatments for UC presents a substantial level of competition for any new treatment entering the IBD market. We expect that Jyseleca competes with all of these therapies now marketed for UC. If generic or biosimilar versions of these therapies are approved, we would also expect Jyseleca to compete against these versions of the therapies.

In the field of dermatomyositis (DM), DM is commonly treated with physical therapy, exercise and medication including corticosteroids, immunosuppressants or recently immunoglobulin treatment. Treatment of this disease has relied for many years on off-label medication and in 2021 the FDA approved immunoglobulin treatment Octagam, based on the Phase 3 ProDerm trial of Octapharma.

In the field of SLE, corticosteroids, antimalarials and immunosuppressants are commonly used to control lupus disease activity. Only two products are approved to treat SLE, both as add-on therapy: Belimumab (Benlysta) (anti-BAFF) from GSK and recently anifrolumab (Saphnelo) (anti-IFN) from Astra Zeneca. There are currently 8 product at Phase 3 for SLE, only two of which are oral – deucravacitinib (Sotyktu) (TYK2) from BMS and cenerimod (S1P1) from Idorsia. .

In the field of hematologic malignancies, such as Non-Hodgkin's Lymphoma (NHL), Chronic Lymphocytic Leukemia (CLL) and Multiple Myeloma (MM), there are many approved therapies or therapies in development (chemotherapy, BTKi, antibodies, bispecific antibodies, antibody drug conjugates, CAR-Ts, cytokines, NK and T-cell engagers, etc.) and many different types of cell therapy in development (allogeneic / autologous, T / NK / CAR-NK, TIL, TCR-T, dendritic, etc.) which creates a highly competitive environment. New technologies and therapies such as in vivo modification of immune cells may further disrupt this market in the long-term. Six CAR T treatments have been approved for hematological cancers: Novartis' Kymriah (CD19 CAR T), Gilead/Kite's Yescarta (CD19 CAR T), Tecartus (CD19 CAR T), J&J's Carvykti (BCMA CAR T) BMS' Breyanzi (CD19 CAR T) and Abecma (BCMA CAR T).

Many of our competitors have significantly greater financial, technical, and human resources than we have. Mergers and acquisitions in the pharmaceutical, medical device and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity could be reduced or eliminated if our competitors develop or market products or other novel therapies that are more effective, safer, or less costly than our current or future product candidates, or obtain regulatory approval for their products more rapidly than we may obtain approval for our product candidates. Our success will be based in part on our ability to identify, develop, and manage a portfolio of product candidates that are safer and more effective than competing products.

Our product candidates may cause undesirable 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. Results of our trials could reveal a high and unacceptable severity and prevalence of certain side effects. In such an event, our trials could be suspended or terminated and the FDA, the EMA, the MHRA, the MHLW, or comparable regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. 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.

For example (without any limitation), the ISABELA Phase 3 program in IPF was discontinued in February 2021, prior to recruitment completion. The decision was based on the recommendations of the Independent Data Monitoring Committee (IDMC) which, following a regular review of unblinded data, concluded that ziritaxestat's benefit-risk profile no longer supported continuing these studies.

If one or more of our products or product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label or impose updates to the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product or product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Our future clinical trials or those of any of our collaborators may reveal significant adverse events not seen in our preclinical studies or earlier clinical trials and result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

If significant adverse events or other side effects are observed in any of our clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, we may be required to pause, delay, or abandon the trials or our development efforts of one or more product candidates altogether, we may be required to have more restrictive labeling, including updates and adjustments of product labels, or we may experience the delay or denial of regulatory approval by the FDA, EMA, MHRA, the MHLW, or other applicable regulatory authorities. We, the FDA, or other applicable regulatory authorities, or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects or patients in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause adverse events or other side effects that prevented their further development. Even if any such adverse events or other side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies.

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 June 2022, we acquired CellPoint and AboundBio with the aim to enter the space of oncology. Through the acquisitions of CellPoint and AboundBio, respectively, 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. CellPoint has developed, in a strategic collaboration with Lonza, a novel point-of-care supply model, which offers the potential for efficient, 7-day delivery of CAR-T therapies and avoids complex logistics, thereby addressing important limitations of current CAR-T treatments. The platform that we use consists of end-to-end xCellit workflow management and monitoring software and Lonza's Cocoon® platform, a functionally closed, automated manufacturing platform for cell and gene therapies.

The manufacturing processes that we use to produce our product candidates for human therapeutics are complex, novel, have not been validated for commercial use and are subject to multiple risks. Several factors could cause production interruptions, including equipment malfunctions, facility contamination, raw material shortages or contamination, natural disasters, disruption in utility services, human error, or disruptions in the operations of our suppliers. Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic often cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product will perform in the intended manner. Accordingly, it is necessary to employ multiple steps to control our manufacturing process to assure that the product candidate is made strictly and consistently in compliance with the process. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims, or insufficient inventory.

In addition, the manufacture of our point-of-care cell therapy product candidates involves complex processes, such as harvesting and transporting cells from every patient to Lonza's Cocoon® system, engineering the cells *ex vivo* to express a specific biologic receptor for a specific target, and finally transporting the point-of-care cell therapy product candidates from Lonza's Cocoon® system back to the patient for infusion into the patient. As a result of the complexities, the manufacturing process for our point-of-care cell therapy product candidates is more variable and difficult to reproduce than traditional small molecule chemical compounds or biologics. Our manufacturing process may be susceptible to product loss or failure due to logistical issues associated with the collection of patients' cells and the infusion of the patient with our point-of-care cell therapy product candidates. Product loss or failure may also be caused by a number of factors, including manufacturing issues associated with the variability in patient material, interruptions in the manufacturing process, contamination, equipment failure, assay failures, improper installation or operation of Lonza's Cocoon® system, vendor or operator error, inconsistency in cell growth, and variability in product characteristics.

If for any reason a patient's starting material is lost, or if any point-of-care cell therapy product candidate does not meet the preset specifications, the manufacturing process for that patient will need to be restarted, sometimes including the re-collection of cells from the patient, and the resulting delay may adversely affect that patient's outcome. It may even happen that failed product candidate manufacture may prevent a patient from receiving our point-of-care cell therapy product candidates. If microbial, environmental or other contaminations are discovered in our point-of-care cell therapy product candidates or in the third-party facilities in which our point-of-care cell therapy product candidates are manufactured through Lonza's Cocoon® system, delays can occur and such facilities can be closed. If such contaminations or other product quality issues are not discovered and if as a result thereof patients are exposed to a health risk, we may be held liable. Our insurance may not cover those cases, or the financial coverage may not be sufficient. Because our point-of-care cell therapy product candidates are manufactured specifically for each individual patient, vendors and operators will be required to maintain a chain of identity with respect to the patient's cellular material as it moves from the patient through the Cocoon® point-of-care manufacturing process, and back to the patient for infusion. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product, or regulatory action including clinical hold or other suspension or termination of our clinical trials or withdrawal of our point-of-care cell therapy products from the market, if approved.

Further, as product candidates are developed through preclinical to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as point-of-care manufacturing methods, are altered along the way to optimize processes and results. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our point-of-care cell therapy product candidates or our manufacturing process to perform differently and affect the results of planned clinical trials or other future clinical trials or otherwise necessitate the conduct of additional studies, which can be costly and time-consuming. We and our vendors may not successfully establish a robust point-of-care production process, including quality release and monitoring process, that fulfills the requirements of the FDA, the EMA and comparable regulatory authorities. There can be no assurance that Lonza's Cocoon® system for our point-of-care cell therapy product candidates is viable and can be effectively scaled up or transferred to third party vendors and operators for commercialization. We are dependent on a third party for the end-to-end xCellit workflow management and monitoring software and if there are any issues with this software, we may be unable to obtain regulatory approval for our product candidates.

Any failure to follow regulatory requirements or any delay, interruption or other issues that arise in the manufacture or storage of our product candidates as a result of a failure of our facilities or the facilities and operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our point-of-care cell therapy product candidates. Point-of-care cell

therapy product candidates that have been produced and stored for later use may degrade, become contaminated or suffer other quality defects, which may cause the affected point-of-care cell therapy product candidates to no longer be suitable for their intended use. Furthermore, if our vendors or operators fail to deliver the required commercial quantities or supply of our point-of-care cell therapy product candidates on a timely basis and at reasonable costs, we would likely be unable to meet demand for our point-of-care cell therapy product candidates, and we would lose potential revenues.

In addition, the manufacturing process and facilities used to produce our point-of-care cell therapy product candidates through our Cocoon® system are subject to FDA, the EMA and comparable regulatory authority approval processes and compliance with applicable Good Manufacturing Practices, and we and our vendors and operators will need to meet all applicable regulatory authority requirements on an ongoing basis, including requirements pertaining to quality control, quality assurance, and the maintenance of records and documentation. The FDA, the EMA and comparable regulatory authorities enforce these requirements through facility inspections. In the EU, the national competent authorities are responsible for manufacturing facility inspections, but the EMA plays a coordinating role in ensuring that standards are enforced consistently throughout the EU. Facilities using our point-of-care manufacturing process, including Lonza's Cocoon® system, must be approved by the FDA, national competent authorities in the EU or comparable regulatory authorities. Vendors and operators are also subject to continuing FDA, EMA and comparable regulatory authority compliance.

Our own or third parties' facilities where Lonza's Cocoon® system is in use may be unable to comply with these regulatory requirements. Poor control of production processes can lead to the introduction of contaminants, or to inadvertent changes in the properties or stability of our point-of-care cell therapy product candidates that may not be detectable in final product testing. If we or our vendors and operators are unable to reliably produce product candidates to specifications acceptable to the FDA, the EMA or comparable regulatory authorities, or in accordance with the strict regulatory requirements, we may not obtain or maintain the approvals we need to commercialize our point-of-care cell therapy product candidates. Even if we obtain regulatory approval for any of our point-of-care cell therapy product candidates, there can be no assurance that either we or our third party vendors or operators will be able to manufacture the approved product to specifications acceptable to the FDA, the EMA or comparable regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Deviations from manufacturing requirements may further require remedial measures that may be costly and/or time-consuming for us or a third party to implement and may include the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

Even to the extent we use vendors or operators for Lonza's Cocoon® system, we are ultimately responsible for the manufacturing of our point-of-care cell therapy product candidates. A failure to comply with regulatory requirements may result in regulatory enforcement actions against our vendors or operators or us, including fines and civil and criminal penalties.

Patients receiving T cell-based immunotherapies may experience serious adverse events, including neurotoxicity and cytokine release syndrome. Serious adverse events or undesirable side effects associated with our CAR T product candidates may result in delays, clinical holds, or terminations of our preclinical or clinical trials, impact our ability to obtain regulatory or marketing approval, and impact the commercial potential of such product candidates, which will significantly harm our business, financial condition and prospects.

We are currently developing CAR-T product candidates, including (1) GLPG5101, a CD19 CAR-T product candidate manufactured at point-of-care for which we aim to start clinical development in rSLE in 2023; (2) GLPG5101 and GLPG5201, CD19 CAR-T product candidates manufactured at point-of-care, currently in Phase 1/2 in rrNHL and rrCLL, respectively; and (3) GLPG5301, a BCMA CAR-T product candidate manufactured at point-of-care, for which we plan to start clinical development in rrMM. In previous and ongoing clinical studies, including our current studies, involving CAR-T products and product candidates, patients experienced side effects such as neurotoxicity and cytokine release syndrome. There have been life-threatening events related to severe neurotoxicity and cytokine release syndrome, requiring intense medical intervention such as intubation or vasopressor support, and in several cases, resulted in death. Severe neurotoxicity is a condition that is currently defined clinically by cerebral edema, confusion, drowsiness, speech impairment, tremors, seizures, or other central nervous system side effects, when such side effects are serious enough to lead to intensive care. In some cases, severe neurotoxicity was thought to be associated with the use of certain lymphodepletion regimens used prior to the administration of the CAR-T products. Cytokine release syndrome is a condition that is currently defined clinically by certain symptoms related to the release of cytokines, which

can include fever, chills, low blood pressure, when such side effects are serious enough to lead to intensive care with mechanical ventilation or significant vasopressor support. The exact cause or causes of cytokine release syndrome and severe neurotoxicity in connection with treatment of CAR-T products is not fully understood at this time. In addition, patients have experienced other adverse events in these studies, such as a reduction in the number of blood cells (in the form of neutropenia, thrombocytopenia, anemia or other cytopenias), febrile neutropenia, chemical laboratory abnormalities (including elevated liver enzymes), and renal failure.

Undesirable side effects caused by any of our CAR-T product candidates targeting rrNHL, rrCLL, or BCMA, could cause us or regulatory authorities to interrupt, delay or halt preclinical or clinical studies and could result in restrictions on the labeling, distribution, or marketing of any approved products or a requirement to conduct potentially costly post-approval studies or the delay or denial of marketing approval by the FDA or other comparable foreign regulatory authorities. Side effects and toxicities associated with any of or product candidates, if approved, as well as the warnings, precautions, and requirements listed in the prescribing information, could affect the willingness of physicians to prescribe, and patients to use, such product candidates, if approved, and negatively affect market acceptance and commercial sales. In some cases, side effects such as neurotoxicity or cytokine release syndrome have resulted in clinical holds of ongoing clinical trials and/or discontinuation of the development of the product candidate. Results of our studies could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the studies or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from engineered cell therapies are not normally encountered in the general patient population and by medical personnel. Medical personnel may need additional training regarding engineered cell therapies to understand their side effects. Complexity of the potential side effects of engineered cell therapies , associated with the potential presence of comorbidities, could result in deaths. Any of these occurrences may harm our business, financial condition and prospects significantly.

If we or others identify undesirable side effects caused by our product candidates, a number of potentially significant negative consequences could result, including:

- regulatory authorities may not approve our CAR-T product candidates, or, if such product candidates are approved, may limit or withdraw such approval;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication, if our product candidates are approved;
- if our product candidates were approved, regulatory authorities may require a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- our reputation may suffer.

Negative public opinion and increased regulatory scrutiny of cell therapies and cellular research may damage public perception of our CAR-T product candidates, and any future products or adversely affect our ability to conduct our business or obtain and maintain marketing approvals for our CAR-T product candidates.

Public perception may be influenced by claims that cell therapy, including cell editing technologies, is unsafe or unethical, and research activities and adverse events in the field, even if not ultimately attributable to us or our CAR-T product candidates, could result in increased governmental regulation, unfavorable public perception, challenges in recruiting patients to participate in our clinical studies, potential regulatory delays in the testing or approval of our CAR-T product candidates, labeling restrictions for any future approved CAR-T products, and a decrease in demand for any such product. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our CAR-T product candidates or demand for any approved products.

Delays in obtaining regulatory approval of manufacturing processes and facilities or disruptions in manufacturing processes may delay or disrupt our commercialization efforts.

Before we can begin to commercially manufacture our product candidates for human therapeutics, the FDA must review for the applicable manufacturing process and facilities as part of its review of our marketing application. This will likely require the manufacturing facilities to pass a pre-approval inspection by the FDA. A manufacturing authorization must also be obtained from the appropriate European Union regulatory authorities or other comparable regulatory authorities.

In order to obtain FDA approval, we will need to ensure that all of the processes, methods, and equipment are compliant with cGMP and perform extensive audits of vendors, contract laboratories, and suppliers. If any of our vendors, contract laboratories or suppliers is found to be out of compliance with cGMP, we may experience delays or disruptions in manufacturing while we work with these third parties to remedy the violation(s) or while we work to identify suitable replacement vendors. The cGMP requirements govern, among other things, quality control of the manufacturing process, raw materials, containers/closures, buildings and facilities, equipment, storage and shipment, labeling, laboratory activities, data integrity, documentation policies and procedures, and returns. In complying with cGMP, we will be obligated to expend time, resources, and efforts in production, record keeping, and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we would be subject to possible regulatory action that could adversely affect our business, results of operations, financial condition, and cash flows, including the inability to sell any products that we may develop.

Risks related to our financial position and need for additional capital

We have no historical profit from product sales and limited historical data on product revenues, which makes it difficult to assess our future prospects and financial results.

Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of uncertainty. Our operations to date have been generally limited to developing our technology and undertaking preclinical studies and clinical trials of our immunology and oncology product candidates, currently including filgotinib (in AxSpA), GLPG3667, GLPG5101, GLPG5201 or GLPG5301. We may not have the ability to overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical area. We have only recently commenced our transition from clinical-stage to a commercial-stage company and continue to build a marketing and sales organization for the marketing, sales, and distribution of pharmaceutical products. We have limited experience as a commercial company, have no historical profit from product sales and limited historical data on product revenues. Consequently, the ability to predict our future operating results or business prospects is more limited than if we had a longer operating history or approved products on the market.

With the exception of the year ended December 31, 2019, we have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

With the exception of the year ended December 31, 2019, we have incurred significant operating losses since our inception in 1999. We reported net losses of €305.4 million for the year ended December 31, 2020, net losses of €103.2 million for the year ended December 31, 2021, and net losses of €218.0 million for the year ended December 31, 2022. 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, commercial activities (as of 2020) and from general and administrative costs associated with our operations. In the future we intend to continue the aforementioned activities. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our shareholders' equity and working capital. 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 that we will generate significant revenues from sales of products for the foreseeable future. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if any of our products or product candidates, if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

Even with one approved product, filgotinib, and if one or more of our product candidates is approved for commercial sale and we retain commercial rights, we anticipate incurring significant costs associated with commercializing any such approved product candidate. Additionally, we may not achieve significant revenues from sales of products. Therefore, even if we are able to generate revenues from the sale of any approved product, we may not become or sustain profitable.

We may require substantial additional funding, which may not be available to us on acceptable terms, or at all.

Our operations have consumed substantial amounts of cash since inception. We are currently conducting clinical trials for filgotinib in AxSpA, GLPG3667, GLPG5101, GLPG5201, GLPG5301, and other immunology and oncology product candidates. Developing pharmaceutical product candidates, including conducting clinical trials, is expensive. We will require substantial additional future capital in order to complete clinical development and, if we are successful, to commercialize any of our current product candidates. If the FDA, or any other comparable regulatory agency, such as the EMA, requires that we perform studies or trials in addition to those that we currently anticipate with respect to the development of our product candidates, or repeat studies or trials, our expenses would further increase beyond what we currently expect, and any delay resulting from such further or repeat studies or trials could also result in the need for additional financing and other resources.

Our existing current financial investments and cash and cash equivalents may not be sufficient for us to complete advanced clinical development of our product candidates or, if applicable, to commercialize product candidates that would be approved. Accordingly, we may continue to require substantial additional capital to continue our clinical development activities and potentially engage in commercialization activities. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds and resources we will require to complete research and development and commercialize our product candidates. The amount and timing of our future funding requirements will depend on many factors, including but not limited to:

- the progress, costs, results of and timing of our ongoing and planned clinical trials;
- our ability to reach milestones under our existing collaboration arrangements and enter into additional collaborative agreements for the development and commercialization of our product candidates;
- the willingness of the FDA, EMA, the MHRA, the MHLW, and other comparable regulatory authorities to accept our clinical trials and preclinical studies and other work as the basis for review and approval of product candidates;
- the outcome, costs and timing of seeking and obtaining regulatory approvals from the FDA, EMA, the MHRA, the MHLW, and other comparable regulatory authorities;
- whether our collaboration partners continue to collaborate with us on the development and commercialization of our product candidates;
- the number of product candidates and indications that we pursue, whether developed internally or in-licensed;
- the timing and costs associated with manufacturing our product candidates for clinical trials and other studies and, if approved, for commercial sale;
- our need to expand our development activities and, potentially, our research activities;
- the timing and costs associated with establishing sales and marketing capabilities;
- the costs associated with our existing and future product sales, marketing, commercial manufacturing, and distribution activities;
- the costs associated with adding new manufacturing sites for our point-of-care cell therapy product candidates;

- market acceptance of any approved product candidates;
- the costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the extent to which we may be required to pay milestone or other payments under our in-license agreements and the timing of such payments;
- our need and ability to hire additional management, development and scientific personnel; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

Some of these factors are outside of our control. Based upon our current expected level of operating expenditures and our existing current financial investments and cash and cash equivalents, we believe that we will be able to fund our operating expenses and capital expenditure requirements for the coming years. This period could be shortened, but not below a period of 12 months, if there are any significant increases beyond our expectations in spending on development programs or more rapid progress of development programs than anticipated. Accordingly, we expect that we could need to raise additional funds in the future. Additional funding may not be available to us on acceptable terms, or at all. If we are unable to obtain funding from equity offerings or debt financings, including on a timely basis, we may be required to:

- seek additional collaboration partners for one or more of any future proprietary product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms our rights to technologies or any future proprietary product candidates that we otherwise would seek to develop or commercialize ourselves;
- significantly curtail one or more of our research or development programs;
- curtail our product sales, marketing, commercial manufacturing, and
- cease operations altogether.

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.

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and/or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of the ADSs or our ordinary shares. The incurrence of indebtedness and/or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt and/or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of the ADSs or our ordinary shares to decline. In the event that we enter into collaborations and/or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect the Company's current and projected business operations and its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. In addition, on March 13, 2023, The Bank of England announced that, in consultation with the Prudential Regulation Authority (PRA), HM Treasury (HMT) and the Financial Conduct Authority (FCA), has taken the decision to sell Silicon Valley Bank UK Limited (SVBUK), the UK subsidiary of the US bank, to HSBC UK Bank Plc (HSBC). The Bank of England stated that all depositors' money with SVBUK is safe and secure as a result of this transaction. The Bank of England further stated that SVBUK's business will continue to be operated normally by SVBUK and that all services will continue to operate as normal and customers should not notice any changes.

Although we are not a borrower or party to any such instruments with SVB, SVBUK, Signature or any other financial institution currently in receivership or a similar proceeding, if any of our lenders or counterparties to any such instruments were to be placed into receivership or a similar proceeding, we may be unable to access such funds. In addition, if any of our customers, suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to SVB or SVBUK credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and the sale of SVBUK to HSBC, and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the Company, the financial institutions with which the Company has credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which the Company has financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- delayed or lost access to, or reductions in borrowings available under revolving existing credit facilities or other working capital sources and/or delays, inability or reductions in the company's ability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- potential or actual breach of contractual obligations that require the Company to maintain letters of credit or other credit support arrangements;
- potential or actual breach of financial covenants in our credit agreements or credit arrangements;
- potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements; or
- termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our customers or suppliers, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a customer may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a customer or supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts to us, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any customer or supplier bankruptcy or insolvency, or the failure of any customer to make payments when due, or any breach or default by a customer or supplier, or the loss of any significant supplier relationships, could result in material losses to us and may have a material adverse impact on our business.

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 a qualifying Phase 2 clinical study (or in certain circumstances, the first Phase 3 clinical 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.

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 milestones 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 and commercialize our product candidates.

Developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities, commercializing, and marketing approved products is 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.

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates, and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon CROs to monitor and manage data for our preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and we control only certain aspects of their activities. We and our CROs also rely upon clinical sites and investigators for the performance of our clinical trials in accordance with the applicable protocols and applicable legal and regulatory requirements and scientific standards. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol and applicable legal and regulatory requirements and scientific standards, and our reliance on CROs as well as clinical sites and investigators does not relieve us of our regulatory responsibilities. We are required to, and do, have mechanisms in place to adequately manage, oversee and control our clinical trials, including selection of CROs, auditing activities, strong focus on set-up (during which deliverables, timelines and roles and responsibilities are defined), and strong oversight during the conduct of clinical trials. We, our CROs, as well as the clinical sites and investigators are required to comply with current Good Clinical Practices (GCPs), which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, investigators and clinical sites. If we, any of our CROs or any of the clinical sites or investigators fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA, the MHRA, MHLW, or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. We also cannot assure you that our CROs, as well as the clinical sites and investigators, will perform our clinical trials in accordance with the applicable protocols as well as applicable legal and regulatory requirements and scientific standards, or report the results obtained in a timely and accurate manner. In addition to GCPs, our clinical trials must be conducted with products produced under current Good Manufacturing Practice (cGMP) regulations. While we have agreements governing activities of our CROs, we have limited influence over the actual performance of our CROs as well as the performance of clinical sites and investigators. In addition, significant portions of the clinical trials for our product candidates are and will continue to be conducted outside of Belgium, which will make it more difficult for us to monitor CROs as well as clinical sites and investigators and perform visits of our clinical sites, and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials in accordance with the applicable protocols and compliance with applicable regulations, including GCPs, and scientific standards. Failure to comply with applicable protocols and regulations in the conduct of the clinical trials for our product candidates may require us to repeat clinical trials, which would delay the regulatory approval process. Additionally, the performance of our CROs may also be delayed or disrupted by the ongoing COVID-19 pandemic, availabilities of staff, exposure of CRO staff to COVID-19 or re-prioritization of CRO resources as a result of the pandemic, or by the ongoing armed conflict between Russia and Ukraine, and sanctions against Russia.

Some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, or as a result of data integrity compromise, or if there is reasonable belief that good clinical practice or applicable laws or regulations will be materially violated, or if we make a general assignment for the benefit of our creditors, or if we are liquidated.

If any of our relationships with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our preclinical and clinical programs. If CROs do not carry out their contractual duties or obligations successfully or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure (including by clinical sites or investigators) to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or

terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenues could be delayed significantly.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely completely on third parties to manufacture our preclinical and clinical drug supplies and to produce commercial supplies of any approved product.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our drug supply for our approved products or preclinical and clinical drug supplies. This reliance on third parties increases the risk of shortages of our drugs or drug candidates and of the availability of such drugs or drug candidates at an acceptable cost or quality. This could potentially delay, prevent or impair our development and commercialization efforts.

If, for any reason, we were to experience an unexpected loss in the supply of any of our approved products, our product candidates or placebo or comparator drug used in certain of our clinical trials, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials or commercial distribution of our approved products could be negatively affected. The facilities used by our contract manufacturers or other third-party manufacturers to manufacture our approved products and our product candidates are subject to the FDA's, EMA's, MHRA's, MHLW's and other comparable regulatory authorities' pre-approval inspections that can be conducted after we submit the required approval applications to any relevant regulatory authority, such as, for example, an NDA or BLA to the FDA. We monitor, but do not control, the implementation of the manufacturing process of, but are dependent on, our contract manufacturers or other third-party manufacturers for compliance with cGMP regulatory requirements for manufacture of any drug products. If our contract manufacturers or other third-party manufacturers do not successfully manufacture material that conforms to applicable specifications and the strict regulatory requirements of the FDA, EMA, MHRA, MHLW or others or if such authority finds deficiencies at a contract manufacturer's facility or is unable to conduct an inspection necessary to evaluate such facility due to delays or disruptions caused by the COVID-19 pandemic, we will not be able to secure and/or maintain regulatory approvals for our products manufactured at these facilities. This could significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials and our approved products. There are a limited number of suppliers for raw materials that we use to manufacture our drugs and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials and our approved products. We do not have any control over the process or timing of the acquisition of raw materials by our manufacturers, and delays may result for reasons beyond our control, including the COVID-19 pandemic or the ongoing armed conflict between Russia and Ukraine.

Moreover, although we have established agreements for commercial production of filgotinib as certain manufacturing obligations are transferred back to us from Gilead, we currently do not have any agreements for the commercial production of the underlying raw materials. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our products would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our products. Additionally, if we receive regulatory approval for our product candidates, we may experience unforeseen difficulties or challenges in the manufacture of our products on a commercial scale compared to the manufacture for clinical purposes.

We expect to continue to depend on contract manufacturers or other third-party manufacturers for the foreseeable future. We recently entered into long-term agreements with some of our historical contract manufacturers and currently

obtain our supplies of finished drug product through individual purchase orders which cannot guarantee adequate supplies of finished products. In addition, although we intend to do so in the coming months, we have not yet entered into agreements with any alternate fill/finish suppliers.

Via the acquisition of CellPoint on June 21, 2022, we gained access to a decentralized and automated point-of-care cell therapy supply model, which CellPoint B.V. had developed in a strategic collaboration with a third party, Lonza. The proprietary platform consists of the end-to-end xCellit workflow management and monitoring software and Lonza's Cocoon® platform, a functionally closed, automated manufacturing platform for cell and gene 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 terminates 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 clinical data and results obtained by third parties that could ultimately prove to be inaccurate or unreliable.

If the third-party data and results we rely upon 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 intellectual property

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

Our commercial success depends on obtaining and maintaining proprietary rights to filgotinib, any future product, and our current and any future product candidates, as well as successfully defending these rights against third-party challenges. We will only be able to protect our 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. Our ability to obtain patent protection for our product candidates is uncertain due to a number of factors, including:

- we may not have been the first to make the inventions covered by pending patent applications or issued patents;
- we may not have been the first to file patent applications for our product candidates or the compositions we developed or for their uses;
- others may independently develop identical, similar or alternative products or compositions and uses thereof;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our pending patent applications may not result in issued patents;
- we may not seek or obtain patent protection in countries that may eventually provide us a significant business opportunity;
- any patents issued to us may not provide a basis for commercially viable products, may not provide any competitive advantages, or may be successfully challenged by third parties;
- our compositions and methods may not be patentable;
- others may design around our patent claims to produce competitive products which fall outside of the scope of our patents; or
- others may identify prior art or other bases which could invalidate our patents.

Even if we have or obtain patents covering our product candidates or compositions, we may still be barred from making, using and selling our product candidates or technologies because of the patent rights of others. Others may have filed, and in the future may file, patent applications covering compositions or products that are similar or identical to ours. If a patent owned by a third party covers one of our product candidates or its use, this could materially affect our ability to develop the product candidate or sell the resulting product if approved. Because patent applications are not published until 18 months from their priority date, there may be currently pending applications unknown to us that may later result in issued patents that our product candidates or compositions may infringe. Additionally, because the scope of claims in pending patent applications can change, there may be pending applications whose claims do not currently cover any of our product candidates but may be altered such that one or more of our product candidates are covered when the resulting patent issues. These patent applications may have priority over patent applications filed by us.

Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. For example (without any limitation), others may be able to develop a product that is similar to, or better than, ours in a way that is not covered by the claims of our patents.

Obtaining and maintaining a patent portfolio entails significant expense and resources. Part of the expense includes periodic maintenance fees, renewal fees, annuity fees, various other governmental fees on patents and/or applications due in several stages over the lifetime of patents and/or applications, as well as the cost associated with complying with numerous procedural provisions during the patent application process. We may or may not choose to pursue or maintain protection for particular inventions. In addition, there are situations in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we choose to forgo patent protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer. Moreover, in some circumstances, we do not have the right to control the preparation, filing or prosecution of patent applications, or to maintain the patents, covering technology subject to our collaboration or license agreements with third parties. For example, under our collaboration agreement with Gilead, Gilead controls litigation on our patents for filgotinib in jurisdictions outside the European region and for any optioned programs. Therefore, these patents and patent applications may not be prosecuted or enforced in a manner consistent with the best interests of our business.

Legal actions to enforce our patent rights can be expensive and may involve the diversion of significant management time. In addition, these legal actions could be unsuccessful and could also result in the invalidation of our patents or a finding that they are unenforceable. We may or may not choose to pursue litigation or other actions against those that have infringed on our patents, or used them without authorization, due to the associated expense and time commitment of monitoring these activities. If we fail 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.

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, or USPTO, the European Patent Office, and other foreign counterparts are sometimes uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Certain U.S. patents and patent applications may also be subject to interference proceedings, and U.S. patents may be subject to reexamination proceedings, post-grant review and/or inter partes review in the USPTO. European patents and other foreign patents may be subject also to opposition or comparable proceedings in the corresponding foreign patent office, which could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, reexamination, post-grant review, inter partes review and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

In addition, changes in or different interpretations of patent laws in the United States, Europe, and other jurisdictions may permit others to use our discoveries or to develop and commercialize our technology and products

without providing any compensation to us, or may limit the number of patents or claims we can obtain. The laws of some countries do not protect intellectual property rights to the same extent as U.S. and European laws and those countries may lack adequate rules and procedures for defending our intellectual property rights.

If we fail to obtain and maintain patent protection and trade secret protection of our product candidates, we could lose our competitive advantage and competition we face would increase, reducing any potential revenues and adversely affecting our ability to attain or maintain profitability.

Developments in patent law could have a negative impact on our business.

From time to time, courts and other governmental authorities in the United States, Europe, Japan, and other jurisdictions may change the standards of patentability and any such changes could have a negative impact on our business.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patent protection, because we operate in the highly technical field of development of therapies, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. It is our policy to enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keeps confidential and does not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example (without any limitation), in the case of misappropriation of a trade secret by an employee or a third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets, with protection varying across Europe and in other countries. Trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

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 current and future 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, assuming that rights are obtained in the United States and Europe. Furthermore, even if patents are granted based on our European patent applications, we may not choose to perfect or maintain our rights in all available European countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws 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. The statutory deadlines for pursuing patent protection in individual foreign jurisdictions are based on the priority dates of each of our patent applications.

Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent

protection, but enforcement is not as strong as that in the United States and Europe. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to pharmaceuticals or biotechnologies. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors.

In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, changes in the law and legal decisions by courts in the United States, Europe and other jurisdictions may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected.

Our inability to protect our intellectual property or failure to maintain the confidentiality and integrity of data or other sensitive company information, by cyber-attack or other event, could have a material adverse effect on our business.

Our success and competitive position are dependent in part upon our proprietary intellectual property. We rely on a combination of patents and trade secrets to protect our proprietary intellectual property, and we expect to continue to do so. Although we seek to protect our proprietary rights through a variety of means, we cannot guarantee that the protective steps we have taken are adequate to protect these rights. Patents issued to or licensed by us in the past or in the future may be challenged and held invalid. In addition, as our patents expire, we may be unsuccessful in extending their protection through patent term extensions or supplementary protection certificates. The expiration of, or the failure to maintain or extend our patents, could have a material adverse effect on us.

We also rely on confidentiality agreements with certain employees, consultants, and other third parties to protect, in part, trade secrets and other proprietary information. These agreements could be breached, and we may not have adequate remedies for such a breach. In addition, others could independently develop substantially equivalent proprietary information or gain access to our trade secrets or proprietary information.

Our intellectual property, other proprietary technology, and other sensitive company information is dependent on sophisticated information technology systems and is potentially vulnerable to cyber-attack, loss, damage, destruction from system malfunction, computer viruses, loss of data privacy, or misappropriation or misuse of it by those with

permitted access, and other events. While we have invested to protect our intellectual property and other information, and continue to upgrade and enhance our systems to keep pace with continuing changes in information processing technology, there can be no assurance that our precautionary measures will prevent breakdowns, breaches, cyber-attacks, or other events. Such events could have a material adverse effect on our reputation, financial condition, or results of operations.

Risks related to intellectual property litigation

We may be subject to claims by third parties asserting ownership or commercial rights to inventions we develop or obligations to make compensatory payments to employees.

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. We have written agreements with collaboration partners that provide for the ownership of intellectual property arising from our collaborations. Some of these agreements provide that we must negotiate certain commercial rights with collaboration partners with respect to joint inventions or inventions made by our collaboration partners that arise from the results of the collaboration. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise from a collaboration. If we cannot successfully negotiate sufficient ownership and commercial rights to the inventions that result from the collaboration with a third-party collaboration partner, or if disputes otherwise arise with respect to the intellectual property developed in the framework of the collaboration, we may be limited in our ability to capitalize on the market potential of these inventions. In addition, we may face claims by third parties that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business.

While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing or obtaining such an agreement with each party who, in fact, develops intellectual property that we regard as our own. In addition, such agreements may be breached or may not be self-executing, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who were previously employed at universities, pharmaceutical companies or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business.

Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. We cannot assure you that our business, products, commercialization activities, and methods do not or will not infringe the patents, trademarks, or other intellectual property rights of third parties.

There is significant litigation in the pharmaceutical industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such

threatened litigation, we may be exposed to future litigation by third parties based on claims that our products or our product candidates, technologies or activities infringe the intellectual property rights of others. If our development activities are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented drugs or compositions. We may need to resort to litigation to enforce a patent issued to us, to protect our trade secrets, or to determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel or consultants formerly employed by other companies involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of prior affiliations. Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our products. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. Any adverse ruling or perception of an adverse ruling in defending ourselves against these claims could have a material adverse impact on our cash position and the price of the ADSs or our ordinary shares. Any legal action against us or our collaboration partners could lead to:

- payment of substantial damages for past use of the asserted intellectual property and potentially treble damages, if we are found to have willfully infringed a party's patent rights;

- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell our product candidates; or

- us or our collaboration partners having to enter into license arrangements that may not be available on commercially acceptable terms, if at all, all of which could have a material adverse impact on our cash position and business and financial condition. As a result, we could be prevented from commercializing current or future product candidates.

Any of these risks coming to fruition could have a material adverse effect on our business, results of operations, financial condition and prospects.

Issued patents covering our approved product and product candidates could be found to be invalid or unenforceable if challenged in court

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering our approved product or one of our product candidates, the defendant could counterclaim that the patent covering our approved product or one of our product candidates is invalid and/or unenforceable. In patent litigation, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements in most jurisdictions, including lack of novelty, obviousness or non-enablement. In the United States, grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions, e.g., opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our approved product or product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our approved product and/or our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Risks related to our employee matters

Our future success depends on our ability to retain the members of our Executive Commitee and to attract, retain and motivate qualified scientists, development, medical and commercial staff, consultants and advisors. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our industry has experienced a high rate of turnover of management and other personnel in recent years. Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel, many of whom have been instrumental for us and have substantial experience with our therapies and related technologies. We are highly dependent on our management, scientific and medical personnel, especially our Executive Committee, which at the date of this annual report is comprised of: (i) Stoffels IMC BV (permanently represented by Dr. Paul Stoffels), our Chief Executive Officer; (ii) Bart Filius, our President, Chief Operating Officer, and Chief Financial Officer; (iii) Michele Manto, our Chief Commercial Officer; (iv) Annelies Missotten, our Chief Human Resources Officer; and (v) Valeria Cnossen, our General Counsel, each of whose services are critical to the successful implementation of our product candidates' acquisition, development and regulatory strategies. To our best knowledge, we are not aware of any present intention of any of these individuals to leave our company. In order to induce valuable employees to continue their employment with us, we have granted subscription rights and restricted stock units (RSUs) that vest over time. The value to employees of subscription rights that vest over time is significantly affected by movements in our share price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

Despite our efforts to retain valuable employees, members of our management, scientific, development, medical and commercial teams may terminate their employment with us at any time, with or without notice. The loss of the services of any of the members of our Executive Committee or other key employees and senior scienists could delay our research, development and other activities, and our inability to find suitable replacements could harm our business, financial condition and prospects. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers, as well as junior, mid-level and senior scientific and medical personnel.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we have to offer. Therefore, we might not be able to attract or retain these key personnel on conditions that are economically acceptable. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize products products or product candidates could be adversely affected.

Furthermore, we will need to recruit new managers and qualified scientific, commercial, regulatory and financial personnel to develop our business as we expand into the fields that will require additional skills and expertise, including oncology. Our inability to attract and retain these key personnel could prevent us from achieving our objectives and implementing our business strategy, which could have a material adverse effect on our business and prospects.

Risks from the improper conduct of employees, agents, contractors, CROs, consultants, vendors, or collaboration partners could adversely affect our reputation and our business, prospects, operating results, and financial condition.

We cannot ensure that our compliance controls, policies and procedures will in every instance protect us from acts committed by our employees, agents, contractors, CROs, consultants, vendors, or collaboration partners that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, healthcare, employment, securities, manufacturing standards, data manipulation, scientific fraud, foreign corrupt practices, environmental, competition, and patient privacy and other privacy and data protection laws and regulations. Such improper actions could subject us to civil or criminal investigations and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results and reputation.

In particular, our business activities may be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give, anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise, and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are governmental entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the SEC and U.S. Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. There is no certainty that all of our employees, agents, contractors, CROs, onsultants, vendors, or collaboration partners, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws and regulations. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person could allege such misconduct, even if none occurred. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

We could be subject to liabilities under human rights, corruption, environmental, health and safety laws or regulations, or fines, penalties or other sanctions, if we fail to comply with such laws or regulations or otherwise incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous human rights, corruption, environmental, health and safety laws, regulations, and permitting requirements, including those governing laboratory procedures, decontamination activities and the handling, transportation, use, remediation, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous, biological, and flammable materials, including chemicals, radioactive isotopes and biological materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials or wastes either at our sites or at third-party disposal sites. In the event of such contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs and reputational loss associated with civil or criminal fines and penalties. Although we maintain workers’ compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws, regulations or permitting requirements, in which case our research, development or other efforts may be interrupted or delayed, and our financial condition and results of operation may be materially adversely affected. These current or future laws, regulations and permitting requirements may impair our research, development or production efforts. Failure to comply with these laws, regulations and permitting requirements also may result in substantial fines, penalties or other sanctions. As an example, climate change and more specifically the related current and future regulatory requirements, as well as the accelerated transition to a low carbon economy globally, might adversely impact Galapagos’ compliance status and value chain, if not addressed adequately.

Risks related to our business operations and growth

If we fail to manage our growth effectively, our ability to develop and commercialize products could suffer.

We expect that if our drug discovery efforts continue to generate product candidates, our clinical product candidates continue to progress in development, and we continue to build our development, medical and commercial organizations, 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 to expand our internal organization, systems, controls and facilities to accommodate additional anticipated growth and upon our management developing and implementing strategies for us 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.

As a result of our limited financial, manufacturing and management recourses, we may forgo or delay pursuit of opportunities with potential product candidates that later prove to have greater market potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

We must maintain effective internal control over financial reporting, and if we are unable to do so, the accuracy and timeliness of our financial reporting may be adversely affected, which could have a material adverse effect on our business, investor confidence and market price.

We must maintain effective internal control over financial reporting in order to accurately and timely report our results of operations and financial condition. We often use estimates and assumptions concerning the future. We make reference to section “Critical accounting judgments and key sources of estimation uncertainty” for more information. In addition, because we are a U.S. public company, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requires, among other things, that we assess the effectiveness of our disclosure controls and procedures annually, and the effectiveness of our internal control over financial reporting at the end of each fiscal year.

Section 404 of the Sarbanes-Oxley Act, or Section 404, requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on, and our independent registered public accounting firm to attest to, the effectiveness of our internal control over financial reporting. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weakness, or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. The rules governing the standards that must be met for our management to assess our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act are complex and require significant documentation, testing and possible remediation. These stringent standards require that our Audit Committee be advised and regularly updated on management’s review of internal control over financial reporting. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of the ADSs or our ordinary shares could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources. Furthermore, investor perceptions of our company may suffer if deficiencies are found, and this could cause a decline in the market price of the ADSs or our ordinary shares. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our stated operating results and harm our reputation. If we are unable to implement these requirements effectively or efficiently, it could harm our operations, financial reporting or financial results, and could result in an adverse opinion on our internal control over financial reporting from our independent registered public accounting firm.

Galapagos’ management notes that the material weakness that has been identified in our internal control over financial reporting as of December 31, 2021 relating to the review of the filgotinib collaboration revenue recognition, has been fully remediated as of December 31, 2022. Notwithstanding the material weakness in the prior period, management has concluded that our audited financial statements included in this Annual Report on Form 20-F are fairly stated in all material respects in accordance with IFRS for each of the periods presented herein. See the section of this annual report titled “Item 15— Controls and Procedures.”

Our information technology systems could face serious disruptions that could adversely affect our business.

Our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines and connection to the internet, face the risk of system failure that could disrupt our operations. A significant disruption in the availability of our information technology and other internal infrastructure systems could cause

interruptions in our collaborations with our partners, and delays in our research, development work and other work. The loss of product development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our product candidates could be delayed.

We could be required to expend significant amounts of money and other resources to respond to these threats or breaches and to repair or replace information systems or networks, and could suffer reputational loss, financial loss or the loss of valuable confidential information, which could include patient data, customer data and other personal data. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome implemented security measures become increasingly sophisticated. 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 payment or information to be transmitted on an unintended recipient), security breaches or similar attacks or breaches that could adversely affect our business.

Many third-party vendors support our business processes and require access to sensitive or confidential information in the course of their work supporting our operations. Despite clear guidance, supporting processes and requirements and assessments and audits of our third party vendors, the risk that such vendors could be susceptible to cybersecurity or security breaches, including personal data breaches, continues to be present. Any such breach could result in the accidental or unlawful destruction, loss, alteration, unauthorized access, disclosure, or other loss of proprietary, personal or other confidential information, or other disruption to our business and operations.

Any system failure, accident or security breach that causes interruptions in our own or in third party service vendors' operations could result in a material disruption of our product development programs. For example (without any limitation), the loss of clinical trial data from completed or future clinical trials could result in delays in our or our partners' regulatory approval efforts and significantly increase our costs in order to recover or reproduce the lost data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability, our product development programs and competitive position may be adversely affected and the further development of our product candidates may be delayed. If the integrity of our cybersecurity systems is breached, we may incur significant effects such as remediation expenses, lost revenues, litigation costs, and increased insurance premiums and may also experience reputational damage and the erosion of shareholder value. Furthermore, we may incur additional costs to remedy the damage caused by these disruptions or security breaches. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing, business email compromise attacks, or other cyber-attacks. Whereas none of these instances had a material impact so far, the number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our third party service providers occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged.

Although Galapagos has invested time and resources in the protection of its information technology and other internal infrastructure systems, a single event has occurred in respect of which Galapagos has taken appropriate measures. We have not encountered any material impact so far in relation to such event.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our approved product and any future approved products.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and an even greater risk in connection with our commercialization of our current and future drugs (if approved). For example (without any limitation), we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing, commercialization, use, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the

product, negligence, strict liability and a breach of warranties. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our products. Any claims against us, regardless of their merit, could be difficult and costly to defend, and could materially adversely affect the market for our products and product candidates, or any prospects for commercialization or our products and product candidates. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to stop development or, if approved, limit commercialization of our products and product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- delay or termination of clinical trials;
- injury to our reputation;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- decreased demand for our approved product, any future products, or our product candidates;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues from product sales; and
- the inability to commercialize our approved product or any of our product candidates, if approved.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the development or commercialization of our products and product candidates. We currently carry clinical trial liability insurance and product liability insurance at levels which we believe are appropriate for our clinical trials and our commercialization activities for filgotinib as presently conducted. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital or other assets to pay such amounts and our business operations could be impaired. We may not be able to maintain insurance coverage at a reasonable cost or to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

Our relationships with customers and third-party payers may be subject, directly or indirectly, to applicable anti-kickback laws, fraud and abuse laws, false claims laws, health information privacy and security laws and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

We are subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians and third-party payers play a primary role in the recommendation and prescription of any of our approved products and product candidates for which we obtain marketing approval. Our current and future arrangements with third-party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships with third-parties through which we market, sell and distribute any products for which we obtain marketing approval. In addition, we may be subject to privacy, data

protection and security regulation of the European Union, the United States and other jurisdictions in which we conduct our business. See section entitled "*Information on the Company – Other healthcare laws and compliance requirements*."

The scope and enforcement of each of laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, (including, but not limited to, reputational harm), fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and time consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any legislative and/or regulatory initiatives and changes would lead to increased restriction on the marketing of our approved products and product candidates, or lead to limiting the funds available for healthcare in any relevant jurisdiction which may reduce reimbursement levels and is likely to affect the prices we may set, we would be negatively impacted in our ability to successfully and profitably market our approved products and product candidates. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

We may fail to comply with evolving privacy and data protection laws and requirements in effect in the European Union and other jurisdictions.

In the European Union, or "EU", we may face particular privacy, data security and data protection risks in connection with requirements of the Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, or the "GDPR", and implementing laws and regulations. The GDPR applies inter alia to the processing of personal data in the context of the activities of an establishment of a controller in the EU. The GDPR has enhanced data protection obligations for controllers of personal data, including, for example, expanded disclosures about how personal data is to be used, limitations on retention of data, enhanced requirements for securing personal data, mandatory data breach notification requirements, restrictions on transferring such personal data outside the European Economic Area, or the "EEA", including to the United States, appointing data protection officers, conducting data protection impact assessments, and has created onerous liabilities on controllers or processors. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including possible fines of up to €20,000,000 or up to 4% of our total worldwide annual turnover of the preceding year for the most serious infringements. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm in connection with our activities. A similar legislative framework, including similar obligations and penalties, applies in Switzerland and the UK, where similar efforts are needed.

If we are investigated by a data protection authority, we may face fines and other penalties. Any such investigation or charges by data protection authorities could have a negative effect on our existing business and our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to continue to use our products due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection

authorities in interpretation of current law, including the GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

We are also subject to evolving European privacy laws on electronic marketing and cookies. The EU is in the process of replacing the e-Privacy Directive (2002/58/EC) with a new set of rules taking the form of a regulation. While the e-Privacy Regulation was originally intended to be adopted on May 25, 2018 (alongside the GDPR), it is still going through the European legislative process. In February 2021, the EU Member States reached agreement on the European Council's negotiating mandate for the European Parliament. While the final draft of the e-Privacy Regulation is closer to being finalized, it is unlikely that the new ePrivacy Regulation will come into effect before 2023. Preparing for and complying with the ePrivacy Regulation (if and when it becomes effective) has required, and will continue to require, us to incur substantial operational costs and may require us to change our business practices.

Despite our efforts to bring practices into compliance with the GDPR and before the effective date of the ePrivacy Regulation, we may not be successful either due to internal or external factors such as resource allocation limitations. Non-compliance could result in proceedings against us by governmental entities, customers, data subjects, consumer associations or others, as well as in penalties issued by data protection authorities as is also stated above.

Although Galapagos has invested time and resources in the protection of its personal data and information technology and monitors its systems on an ongoing basis, some immaterial incidents have occurred in respect of which Galapagos has taken appropriate measures. To date, no material risk has been identified, and Galapagos' business or operations have not been materially impacted by such incidents.

Business interruptions could delay us in the process of developing our product candidates.

Loss of our laboratory, warehouse or other real estate facilities through fire or other causes could have an adverse effect on our ability to continue to conduct our business. We currently have insurance coverage to compensate us for such business interruptions; however, such coverage may prove insufficient to compensate us fully for the damage to our business resulting from any significant property or casualty loss to our facilities.

We may undertake strategic acquisitions in the future and any difficulties from integrating such acquisitions could adversely affect our share price, and results of operations.

We may acquire companies, businesses and products that complement or augment our existing business. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license any compositions, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The acquisition and licensing of third-party intellectual property rights is a competitive area, and other companies having a competitive advantage over us due to their size, cash resources or otherwise, may pursue strategies to in-license or acquire third-party intellectual property rights that we may consider attractive. We may not be able to integrate any acquired companies, business or products successfully, or operate any acquired company, business or product profitably. Integrating any newly acquired companies, business or products could be expensive and timeconsuming. Integration efforts often take a significant amount of time, place a significant strain on managerial, operational and financial resources, could result in loss of key personnel and could prove to be more difficult or expensive than we predict. The diversion of our management's attention and any delay or difficulties encountered in connection with any future acquisitions or in-licensing we may consummate could result in the disruption of our ongoing business or inconsistencies in standards and controls that could negatively affect our ability to maintain third-party relationships. Moreover, we may need to raise additional funds through public or private debt or equity financing, or issue additional shares, to acquire any businesses or products, which may result in dilution for shareholders or the incurrence of indebtedness.

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 fail to realize the expected benefits from acquisitions we may consummate in the future or have consummated in the past, whether as a result of

unidentified risks or liabilities, integration difficulties, regulatory setbacks, litigation with current or former employees and other events, our business, results of operations and financial condition could be adversely affected. If we acquire product candidates, we will also need to make certain assumptions about, among other things, development costs, the likelihood of receiving regulatory approval, and the market for such product candidates. Our assumptions may prove to be incorrect, which could cause us to fail to realize the anticipated benefits of these transactions.

In addition, we will likely experience significant charges to earnings in connection with our efforts, if any, to consummate acquisitions. For transactions that are ultimately not consummated, these charges may include fees and expenses for investment bankers, attorneys, accountants and other advisors in connection with our efforts. Even if our efforts are successful, we may incur, as part of a transaction, substantial charges for closure costs associated with elimination of duplicate operations and facilities and acquired in-process research and development charges. In either case, the incurrence of these charges could adversely affect our results of operations for particular periods.

Actions of activist shareholders could cause us to incur substantial costs, divert our management's and our directors' attention and resources, and have an adverse effect on our business and trading price.

From time to time, we may be subject to proposals by shareholders urging us to take certain corporate actions or to nominate certain individuals to our Board of Directors. If activist shareholder activities by shareholders ensue, our business could be adversely affected, as responding to actions by activist shareholders can be costly and time-consuming, disrupt our operations and divert the attention of management and directors. For example (without any limitation), we may be required to retain the services of various professionals to advise us on activist shareholders' matters, including legal, financial, and communications advisors, the costs of which may negatively impact our future financial results. In addition, perceived uncertainties as to our future direction, strategy or leadership created as a consequence of activist shareholders' initiatives may result in the loss of potential business opportunities, harm our ability to attract new investors, customers, and employees, and cause the price of our ADSs or ordinary shares to experience periods of volatility or stagnation.

Our international operations subject us to various risks, and our failure to manage these risks could adversely affect our results of operations.

We could face significant operational risks as a result of doing business internationally, which could have a material adverse effect on our business, financial condition and results of operations, such as (without any limitation):

- fluctuations in foreign currency exchange rates;
- potentially adverse and/or unexpected tax consequences, including penalties due to the failure of tax planning or due to the challenge by tax authorities on the basis of transfer pricing and liabilities imposed from inconsistent enforcement;
- potential changes to the accounting standards, which may influence our financial situation and results;
- becoming subject to the different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- reduced protection of, or significant difficulties in enforcing, intellectual property rights in certain countries;
- difficulties in attracting and retaining qualified personnel;
- restrictions imposed by local labor practices and laws on our business and operations, including unilateral cancellation or modification of contracts;
- rapid changes in global government, economic and political policies and conditions, political or civil unrest or instability, terrorism or epidemics and other similar outbreaks or events, and potential failure in confidence of our suppliers or customers due to such changes or events; and

- tariffs, trade protection measures, import or export licensing requirements, trade embargoes, economic sanctions, and other trade barriers.

Unforeseen or catastrophic events, including extreme weather events and other natural disasters, man-made disasters or the emergence of epidemics, could cause a disruption in our operations or other consequences that could have a material adverse effect on our financial condition and results of operations.

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 and other economic or political conditions or events (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. Russia invaded Ukraine in February 2022 which has resulted in significant uncertainty and may cause the market price and demand for our ADSs or ordinary shares to fluctuate substantially. Man-made disasters, epidemics or disease, and other events connected with the regions in which we operate could have similar effects. If a natural or man-made disaster, electricity or telecommunication interruption or other event occurred that prevented us from using all or a significant portion of our facilities, that damaged critical infrastructure, such as clinical trial sites or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business.

The ongoing military conflict between Russia and Ukraine and other macroeconomic factors could adversely impact our business, including our commercial operations, clinical development activities and clinical trials.

We currently have no clinical studies that are enrolling patients in Russia or Ukraine. 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. This conflict could cause extended periods of time in which trials are suspended, sustained difficulties enrolling patients in clinical trials and/or disruptions to ongoing trials based on the attrition of patients, facility closures or limitations on the use of hospitals as clinical trial sites and governmental restrictions on “non-essential” procedures and activities, any of which may further delay our clinical development plans and timelines and also may impact the integrity of our clinical trial data for ongoing trials. This conflict may also include interruptions in FDA operations or the operations of comparable foreign regulatory agencies, which may in turn impact our timelines for receiving regulatory approvals and feedback.

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 and our CROs’ ability to meet expected clinical development deadlines or to comply with contractual commitments with respect to the same, including timelines around preclinical studies and planned clinical trials, could lead to delays in our overall developmental and commercialization timelines, which would adversely impact our ability to conduct clinical development activities and complete them on a timely basis. Since February 24, 2022, we have extended the focus of the business continuity plan to closely monitor each program in context of the currently ongoing Ukraine-Russia crisis and the associated specific regulatory, institutional, and government guidance and policies.

Our business, results of operations and future growth prospects could be materially and adversely affected by the ongoing COVID-19 pandemic.

At the fourteenth meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic held on Friday 27 January 2023, the Committee stated that the event continues to constitute a public health emergency of international concern (PHEIC), yet is probably at a transition point. The Committee advised to navigate this transition carefully and mitigate the potential negative consequences.

Due to this continued evolution and uncertain global impacts of the COVID-19 pandemic, we cannot precisely determine or quantify the impact this pandemic will have on our business, operations and financial performance. The extent to which COVID-19 may impact our preclinical studies, clinical trial operations, business, results of operations and future growth prospects will depend on a variety of factors and future developments, which remain uncertain and

cannot be predicted with confidence, such as the duration, scope and severity of the pandemic, the duration and extent of travel restrictions and social distancing restrictions, business closures or business disruptions and the effectiveness of other governmental actions taken to contain and treat COVID-19.

The continued spread of COVID-19 globally, and public health actions being undertaken in response thereto, have presented operational challenges for our business. For ongoing and planned clinical trials, delays or disruptions due to the COVID-19 pandemic, including limited or reduced patient access to trial investigators, hospitals and trial sites, delayed initiation of new clinical trial sites and limited on-site personnel support at various trial sites, which could adversely impact our development plans, including the initiation of planned clinical trials, the rate of enrollment and our ability to conduct ongoing clinical trials may still occur. There may also be local orders affecting one or more trial sites, which may trigger mandated changes to our clinical trial protocols or temporary suspensions in the affected trial sites. The COVID-19 pandemic, and measures undertaken to control the spread of the virus, could impair our ability to initiate clinical trial sites and to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography or due to prioritization of hospital resources toward the outbreak and restrictions in travel. Furthermore, some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. COVID-19 may also affect employees of third-party contract research organizations located in affected geographies that we rely upon to carry out our clinical trials. Additionally, the spread of COVID-19 may also negatively affect the operations of our third-party manufacturers, which could result in delays or disruptions in the supply of our current product candidates and any future product candidates. Any negative impact COVID-19 has on patient enrollment or treatment or the execution of our planned and ongoing preclinical studies and clinical trials, on our manufacturers and suppliers, and on our business plans generally could cause costly delays, which could adversely affect our ability to commercialize filgotinib and to obtain regulatory approval for and commercialize any future approved products, and our current and any future product candidates, increase our operating expenses, and could have a material adverse effect on our financial results.

In addition, we may take temporary precautionary measures intended to help minimize the risk of the virus to the physical health and mental health of our employees, including temporarily requiring all employees to work remotely, suspending all non-essential travel worldwide for our employees, and discouraging employee attendance at industry events and in-person work-related meetings, which could negatively affect our business. The COVID-19 pandemic may also cause delays in regulatory approvals.

Continuing uncertainty around the ongoing pandemic 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 increasing use of social media platforms presents risks and challenges.

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally. Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our products and product candidates, operations, or business may cause us to be found in violation of applicable legal or contractual 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 personal information of our employees, clinical trial patients, collaboration partners, and others, and which could have an adverse effect on our business, financial conditions and results of operations. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image and goodwill.

Risks related to tax and other financial matters

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.

As of December 31, 2022, we had cumulative carry forward tax losses of €769.9 million in Belgium, €64.3 million in France, and €52.2 million related to the other entities of our group. These are available to carry forward and offset against possible future taxable income for an indefinite period in Belgium and France, but €2.7 million of these tax

loss carryforwards in the United States will expire between 2028 and 2034. If we are unable to use tax loss carryforwards to reduce possible future taxable income or in case of changes in tax regulatons affecting the use of tax loss carryforwards, our business, results of operations and financial condition may be adversely affected.

As a company active in research and development in Belgium and France, we have benefited from certain research and development incentives including, for example, but not limited to, the Belgian research and development tax credit and the French research tax credit (*crédit d'impôt recherche*). These tax credits can be offset against Belgian and French corporate income tax due, respectively. The excess portion may be refunded as from the end of a five-year fiscal period for the Belgian research and development incentive, and at the end of a three-year fiscal period for the French research and development incentive. The research and development incentives are both calculated based on the amount of eligible research and development expenditure. The Belgian tax credit represented €21.7 million for the year ended December 31, 2020, and €20.9 million for the year ended December 31, 2021, and €17.3 million for the year ended December 31, 2022. The French tax credit amounted to €12.4 million for the year ended December 31, 2020, and €12.4 million for the year ended December 31, 2021, and €11.4 million for the year ended December 31, 2022. The Belgian and/or French tax authorities may audit each research and development program in respect of which a tax credit has been claimed and assess whether it qualifies for the tax credit regime. The tax authorities may challenge our eligibility for, or our calculation of, certain tax reductions and/or deductions in respect of our research and development activities and, should the Belgian and/or French tax authorities be successful, we may be liable for additional corporate income tax, and penalties and interest related thereto, which could have a significant impact on our results of operations and future cash flows. Furthermore, if the Belgian or French 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, or IID, 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 tax rate than other revenues. The effective tax rate can thus be reduced down to 3.75%. At the end of 2022, we had €346.2 million of carry-forward IID in Belgium.

On December 14, 2022, the Council of the EU formally adopted the Council Directive on ensuring a global minimum level of taxation for multinational groups in the Union, laying down rules for ensuring a minimum level of effective corporate taxation of large multinational groups and large-scale purely domestic groups operating in the Single Market. The Directive is largely aligned with the OECD Model Rules agreed by the Inclusive Framework and published on December 20, 2021 (the so-called "Pillar II"). The aim of the directive is to realize a 15% global minimum effective tax rate at country-per-country level. At this stage, no carve-out for patent box regimes or R&D incentives is included in the directive. This directive could have an impact on the company's future effective tax rate and/or tax attributes. Member States will now have to transpose said directive into their national laws before December 31, 2023.

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.

Our shareholders residing in countries other than Belgium may be subject to double withholding taxation with respect to dividends or other distributions made by us.

Any dividends or other distributions we make to shareholders will, in principle, be subject to withholding tax in Belgium at a rate of 30%, except for shareholders which qualify for an exemption of withholding tax such as, among others, qualifying pension funds or a company qualifying as a parent company in the sense of the Council Directive (90/435/EEC) of July 23, 1990, or the Parent-Subsidiary Directive, as amended, or that qualify for a lower withholding tax rate or an exemption by virtue of a tax treaty. Various conditions may apply and shareholders residing in countries other than Belgium are advised to consult their advisers regarding the tax consequences of dividends or other distributions made by us. Our shareholders residing in countries other than Belgium may not be able to credit the amount of such withholding tax to any tax due on such dividends or other distributions in any other country than Belgium. As a result, such shareholders may be subject to double taxation in respect of such dividends or other distributions. Belgium and the United States have concluded a double tax treaty concerning the avoidance of double taxation, or the U.S.-Belgium Tax Treaty. The U.S.-Belgium Tax Treaty reduces the applicability of Belgian withholding tax to 15%, 5% or 0% for U.S. taxpayers that are the beneficial owner of the dividend income concerned, provided that the U.S. taxpayer

meets the limitation on benefits conditions imposed by the U.S.-Belgium Tax Treaty. The Belgian withholding tax is generally reduced to 15% under the U.S.-Belgium Tax Treaty. The 5% withholding tax applies in case where the U.S. shareholder, beneficial owner of the income, is a company which holds at least 10% of the shares in the company. A 0% Belgian withholding tax applies when the shareholder, beneficial owner of the income, is a U.S. company which has held directly at least 10% of the shares in the company for at least 12 months on the date the dividend is declared, or is, subject to certain conditions, a U.S. pension fund. The U.S. shareholders are encouraged to consult their own tax advisers to determine whether they can invoke the benefits and meet the limitation on benefits conditions as imposed by the U.S.-Belgium Tax Treaty.

Changes in tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local and non-U.S. taxation are constantly under review by persons involved in the legislative process, the Internal Revenue Service, the U.S. Treasury Department and other taxing authorities. Changes to tax laws or tax rulings, or changes in interpretations of existing laws (which changes may have retroactive application), could adversely affect us or holders of our ADSs. These changes could subject us to additional income-based taxes and non-income taxes (such as payroll, sales, use, value-added, digital tax, net worth, property, and goods and services taxes), which in turn could materially affect our financial position and results of operations. Additionally, new, changed, modified, or newly interpreted or applied tax laws could increase our customers' and our compliance, operating and other costs, as well as the costs of our products. In recent years, many such changes have been made, and changes are likely to continue to occur in the future. As we expand the scale of our business activities, any changes in the U.S. and non-U.S. taxation of such activities may increase our effective tax rate and harm our business, financial condition, and results of operations.

We believe that we were a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for the 2022 taxable year, but this conclusion is a factual determination that is made annually and thus may be subject to change. Because we were a PFIC for our 2022 taxable year, this could result in adverse U.S. tax consequences to certain U.S. holders.

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest, and gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. Our status as a PFIC depends on the composition of our income and the composition and value of our assets (for which purpose the total value of our assets may be determined in part by reference to the market value of the ADSs and our ordinary shares, which are subject to change) from time to time. Because we were a PFIC for the 2022 taxable year, certain U.S. holders of the ADSs may suffer adverse tax consequences, including, but not limited to, having gains realized on the sale of the ADSs treated as ordinary income, rather than capital gain, losing the preferential rate applicable to dividends received on the ADSs by individuals who are U.S. holders, and having interest charges apply to distributions by us and the proceeds of sales of the ADSs. See "Item 10.E.—Taxation—Certain Material U.S. Federal Income Tax Considerations to U.S. Holders—Passive Foreign Investment Company Considerations."

Based upon the value of our assets, including any goodwill, and the composition of our income and assets, we believe that we were a PFIC for our 2022 taxable year. However, our status as a PFIC is a fact-intensive determination made on an annual basis, and we cannot provide any assurances regarding our PFIC status for the current, prior or future taxable years. Because we were a PFIC for the 2022 taxable year, we will provide information necessary for our U.S. holders to make a "qualified electing fund," or QEF, election with respect to us for the 2022 taxable year and expect to provide such information for any subsequent year if we believe we are a PFIC. We will provide such information on our website.

We believe that we were not a controlled foreign corporation, or CFC, for U.S. federal income tax purposes for the 2022 taxable year. If we were to qualify as a CFC, this could result in adverse U.S. federal income tax consequences to certain U.S. holders.

Each "Ten Percent Shareholder" (as defined below) in a non-U.S. corporation that is classified as a "controlled foreign corporation," or a CFC, for U.S. federal income tax purposes generally is required to include in income for U.S.

federal tax purposes such Ten Percent Shareholder's pro rata share of the CFC's "Subpart F income" and investment of earnings in U.S. property, even if the CFC has made no distributions to its shareholders. Subpart F income generally includes dividends, interest, rents and royalties, gains from the sale of securities, and income from certain transactions with related parties. For tax years beginning after December 31, 2017, each Ten Percent Shareholder of a CFC is also required to include in income such Ten Percent Shareholder's share of "global intangible low-taxed income" with respect to such CFC. In addition, a Ten Percent Shareholder that realizes gain from the sale or exchange of shares in a CFC may be required to classify a portion of such gain as dividend income rather than capital gain. A non-U.S. corporation generally will be classified as a CFC for United States federal income tax purposes if Ten Percent Shareholders own, directly or indirectly, more than 50% of either the total combined voting power of all classes of stock of such corporation entitled to vote or of the total value of the stock of such corporation. A "Ten Percent Shareholder" is a United States person (as defined by the U.S. Internal Revenue Code of 1986, as amended (the "Code")) who owns or is considered to own 10% or of either (1) the total combined voting power of all classes of stock entitled to vote of such corporation or (2) the total value of all classes of stock of such corporation. The determination of CFC status is complex and includes attribution rules, the application of which is not entirely certain. In addition, recent changes pursuant to U.S. tax reform to the attribution rules relating to the determination of CFC status may make it difficult to determine our CFC status for any taxable year.

To our best knowledge, we do not believe that we were a CFC for the taxable year ended December 31, 2022. Furthermore, it is possible that our non-United States subsidiaries will be CFCs for the taxable year ended December 31, 2022 (or future taxable years) even if we are not a CFC for such taxable year(s). However, we cannot provide any assurances regarding our status or the status of our subsidiaries as a CFC for the 2022 taxable year or any future taxable years. U.S. holders should consult their own tax advisors with respect to the potential adverse U.S. tax consequences of becoming a Ten Percent Shareholder in a CFC. If we are classified as both a CFC and a PFIC, we generally will not be treated as a PFIC with respect to those U.S. holders that meet the definition of a Ten Percent Shareholder during the period in which we are a CFC.

We may be forced to repay the technological innovation grants if we fail to comply with our contractual obligations under the applicable grant agreements.

We have received several technological innovation grants to date, totaling €35.9 million as of December 31, 2022, from an agency of the Flemish government to support various research programs and technological innovation in Flanders. These grants carry clauses which require us to maintain a presence in the Flemish region for a number of years and invest according to pre-agreed budgets. 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. Such repayment could adversely affect our ability to finance our research and development projects. In addition, we cannot ensure that we will then have the additional financial resources needed, the time or the ability to replace these financial resources with others.

We may be exposed to significant foreign exchange risk.

We hold portions of our cash and cash equivalents and current financial investments in currencies other than the euro, in particular, the U.S. dollar. We also incur portions of our expenses and derive revenues, in currencies other than the euro, in particular, the U.S. dollar. As a result, we are exposed to foreign currency exchange risk as our reporting currency is the euro. We currently do not engage in exchange rate hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the euro. Therefore, for example (without any limitation), an increase in the value of the euro against the U.S. dollar could be expected to have a negative impact on our revenue and earnings growth as U.S. dollar revenue and earnings, if any, would be translated into euros at a reduced value. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our business, financial condition, results of operations and cash flows.

The requirements of being a U.S. public company may strain our resources and divert management's attention.

We are required to comply with various corporate governance and financial reporting requirements under the Sarbanes-Oxley Act of 2002, the Exchange Act, and the rules and regulations adopted by the SEC and the U.S. Public Corporation Accounting Oversight Board, or PCAOB, and other applicable securties rules and regulations imposing various requirements on non-U.S. public companies. Further, compliance with various regulatory reporting requires significant commitments of time from our management and our directors, which reduces the time available for the

performance of their other responsibilities. Our failure to track and comply with the various rules may materially adversely affect our reputation, ability to obtain the necessary certifications to financial statements, lead to additional regulatory enforcement actions, and could adversely affect the value of the ADSs or our ordinary shares. However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Risks related to ownership of our ordinary shares and ADSs

The market price of the ADSs could be subject to wide fluctuations.

The market price of the ADSs could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including (without any limitation):

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations, or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities or industry analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us; share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key management or scientific personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- changes to coverage policies or reimbursement levels by commercial third-party payers and government payers and any announcements relating to coverage policies or reimbursement levels;
- announcement or expectation of additional debt or equity financing efforts;
- public concern relating to the commercial value or safety of any of our products or product candidates;
- changes in government regulations;
- positive or negative results of testing and clinical trials by us, strategic partners or competitors;
- outcome of regulatory review of our product candidates;
- sales of the ADSs by us, our insiders or our other shareholders; and
- general economic and market conditions.

In addition, although the ADSs are listed on the Nasdaq Global Select Market stock exchange, we cannot assure that a trading market for those securities will be maintained.

These and other market and industry factors may cause the market price and demand for the ADSs to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their ADSs and may otherwise negatively affect the liquidity of our capital shares. In addition, the stock market in general, and biotechnology and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

We may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant share price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Share ownership is concentrated in the hands of our principal shareholders and management, which may have the effect of delaying or preventing a change of control of our company.

As of the date of this annual report on FORM 20-F, our executive officers, directors, current 5% or greater shareholders and their affiliated entities, including Gilead Sciences, Inc. and its affiliates, together beneficially own approximately 43.52% of our ordinary shares, including shares in the form of ADSs. This concentration of ownership might have the effect of delaying or preventing a change of control of our company that other shareholders may view as beneficial, and might therefore negatively affect the market price of the ADSs.

Fluctuations in the exchange rate between the U.S. dollar and the euro may increase the risk of holding the ADSs.

Our ordinary shares currently trade on Euronext Brussels and Euronext Amsterdam in euros, while the ADSs trade on Nasdaq in U.S. dollars. Fluctuations in the exchange rate between the U.S. dollar and the euro may result in temporary differences between the value of the ADSs and the value of our ordinary shares, which may result in heavy trading by investors seeking to exploit such differences.

In addition, as a result of fluctuations in the exchange rate between the U.S. dollar and the euro, the U.S. dollar equivalent of the proceeds that a holder of the ADSs would receive upon the sale on Euronext Brussels or Euronext Amsterdam of any ordinary shares withdrawn from the depositary and the U.S. dollar equivalent of any cash dividends paid in euros on our shares represented by the ADSs could also decline.

If securities or industry analysts do not publish research or publish inaccurate research or unfavorable research about our business, the price of the ordinary shares and ADSs and trading volume could decline.

The trading market for the ordinary shares and ADSs depends in part on the research and reports that securities or industry analysts publish about us or our business. If no or few securities or industry analysts cover our company, the trading price for the ordinary shares and ADSs would be negatively impacted. If one or more of the analysts who covers us downgrades the ordinary shares and ADSs or publishes incorrect or unfavorable research about our business, the price of the ordinary shares and ADSs would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, or downgrades the ordinary shares and ADSs, demand for the ordinary shares and ADSs could decrease, which could cause the price of the ordinary shares and ADSs or trading volume to decline.

We have no present intention to pay dividends on our ordinary shares in the foreseeable future and, consequently, your only opportunity to achieve a return on your investment during that time is if the price of the ADSs appreciates.

We have no present intention to pay dividends in the foreseeable future. Even if future operations lead to significant levels of distributable profits, we currently intend that any and all earnings will be reinvested in our business. Any proposal by our Board of Directors to pay dividends will depend on many factors, including our financial condition (including losses carried-forward), results of operations, legal requirements, business prospects, cash requirements, new product development, and other factors. Furthermore, pursuant to Belgian law, the calculation of amounts available for distribution to shareholders, as dividends or otherwise, must be determined on the basis of our non-consolidated

statutory accounts prepared in accordance with Belgian accounting rules and Belgian generally accepted accounting principles as used by us in the preparation of these accounts. In addition, in accordance with Belgian law and our Articles of Association, we must allocate each year an amount of at least 5% of our annual net profit under our non-consolidated statutory accounts to a legal reserve until such legal reserve equals 10% of our share capital. Therefore, we are unlikely to pay dividends or other distributions in the foreseeable future. If the price of the ADSs declines before we pay dividends, you will incur a loss on your investment, without the likelihood that this loss will be offset in part or at all by potential future cash dividends. Accordingly, investors cannot rely on cash dividend income from ADSs and any returns on an investment in the ADSs will likely depend entirely upon any future appreciation in the price of the ADSs.

Future sales of ordinary shares or ADSs by existing shareholders could depress the market price of the ordinary shares and ADSs.

If our existing shareholders sell, or indicate an intent to sell, substantial amounts of ordinary shares or ADSs in the public market, the trading price of the ADSs could decline significantly. As of March 15, 2023, 48,845,244 shares were eligible for sale in the public market, 33,934 of which shares were held by directors, executive officers and other affiliates and are subject to volume limitations under Rule 144 under the Securities Act. In addition, the ordinary shares subject to outstanding subscription rights will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. We have filed registration statements on Form S-8 with the SEC covering ordinary shares available for future issuance under our subscription rights plans. Sales of a large number of the shares issued under these plans in the public market could have an adverse effect on the market price of the ADSs and ordinary shares, and could also dilute shareholders. We are also unable to predict the effect that such sales may have on the prevailing market price of ADSs and ordinary shares.

We are a Belgian public limited liability company, and shareholders of our company may have different and in some cases more limited shareholder rights than shareholders of a U.S. listed corporation.

We are a public limited liability company incorporated under the laws of Belgium. Our corporate affairs are governed by Belgian corporate law and our Articles of Association. The rights provided to our shareholders under Belgian corporate law and our articles of association may differ in certain respects from the rights that you would typically enjoy as a shareholder of a U.S. corporation under applicable U.S. federal and state laws.

Under Belgian corporate law, other than certain limited information that we must make public and except in certain limited circumstances, our shareholders may not ask for an inspection of our corporate records, while under Delaware corporate law any shareholder, irrespective of the size of its shareholdings, may do so. Shareholders of a Belgian corporation are also unable to initiate a derivative action, a remedy typically available to shareholders of U.S. companies, in order to enforce a right of our company, in case we fail to enforce such right ourselves, other than in certain cases of director liability under limited circumstances. In addition, a majority of our shareholders present or represented at our Shareholders' Meeting may release a member of our Board of Diectors from any claim of liability we may have, including if he or she has acted in bad faith or has breached his or her duty of loyalty, provided, in some cases, that the relevant acts were specifically mentioned in the convening notice to the Shareholders' meeting of shareholders deliberating on the discharge. In contrast, most U.S. federal and state laws prohibit a company from releasing a director from liability altogether if he or she has acted in bad faith or has breached his or her duty of loyalty to the company. Finally, Belgian corporate law does not provide any form of appraisal rights in the case of a business combination. Please see the section of this annual report titled "Item 10.B.—Memorandum and Articles of Association."

The responsibilities of members of our Board of Directors may be different from these in companies governed by U.S. laws. In the performance of its duties, our Board of Directors is required by Belgian law to consider the interests of our company, in all cases with due observation of the principles of reasonableness and fairness. It is possible that some of these parties will have interests that are different from, or in addition to, your interests as a shareholder.

As a result of these differences between Belgian corporate law and our Articles of Association, on the one hand, and the U.S. federal and state laws, on the other hand, in certain instances, you could receive less protection as an ADS holder of our company than you would as a shareholder of a listed U.S. company.

Takeover provisions in Belgian law may make a takeover difficult.

Public takeover bids on our ordinary shares and other voting securities, such as subscription rights or convertible bonds, if any, are subject to the Belgian Act of April 1, 2007, as amended, and to the supervision by the Belgian Financial Services and Markets Authority, or FSMA. Public takeover bids must be made for all of our voting securities, as well as for all other securities that entitle the holders thereof to the subscription to, the acquisition of or the conversion into voting securities. Prior to making a bid, a bidder must issue and disseminate a prospectus, which must be approved by the Belgian FSMA. The bidder must also obtain approval of the relevant competition authorities, where such approval is legally required for the acquisition of our company.

The Belgian Act of April 1, 2007, as amended, provides that a mandatory bid will be triggered if a person, as a result of its own acquisition or the acquisition by persons acting in concert with it or by persons acting on their account, directly or indirectly holds more than 30% of the voting securities in a company that has its registered office in Belgium and of which at least part of the voting securities are traded on a regulated market or on a multilateral trading facility designated by the Royal Decree of April 27, 2007, as amended, on public takeover bids. The mere fact of exceeding the relevant threshold through the acquisition of one or more shares will give rise to a mandatory bid, irrespective of whether or not the price paid in the relevant transaction exceeds the current market price.

There are several provisions of Belgian corporate law and certain other provisions of Belgian law, such as 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 ordinary shares at a premium (which is typically offered in the framework of a takeover bid). These provisions may also have the effect of depriving ADS holders of the opportunity to sell their ADSs at potential a premium.

Holders of the ADSs are not treated as shareholders of our company, do not have the same voting rights as the holders of our ordinary shares and may not receive voting materials in time to be able to exercise your right to vote.

Holders of the ADSs are not treated as shareholders of our company, unless they withdraw our ordinary shares underlying the ADSs in accordance with the deposit agreement and applicable laws and regulations. The depositary, or its nominee, is the holder of the ordinary shares underlying the ADSs. Holders of ADSs therefore do not have any rights as shareholders of our company, other than the rights that they have pursuant to the deposit agreement.

Holders of ADSs may exercise voting rights attached to the ordinary shares represented by the ADSs only in accordance with the provisions of the deposit agreement. The deposit agreement provides that, upon receipt of notice of any meeting of holders of our ordinary shares, the depositary will fix a record date for the determination of ADS holders who shall be entitled to give instructions for the exercise of voting rights. Upon timely receipt of notice from us, if we so request, the depositary shall distribute to the holders as of the record date (1) the notice of the meeting or solicitation of consent or proxy sent by us and (2) a statement as to the manner in which instructions may be given by the holders.

Holders of ADSs may instruct the depositary of their ADSs to vote the ordinary shares underlying their ADSs. Otherwise, ADS holders will not be able to exercise their right to vote, unless they withdraw the ordinary shares underlying the ADSs they hold. However, ADS holders may not know about the meeting far enough in advance to withdraw those ordinary shares. We cannot guarantee ADS holders that they will receive the voting materials in time to ensure that they can instruct the depositary to vote their ordinary shares or to withdraw their ordinary shares so that they can vote them themselves. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that ADS holders may not be able to exercise their right to vote, and there may be nothing they can do if the ordinary shares underlying their ADSs are not voted as they requested.

We may not be able to complete equity offerings without cancellation or limitation of the preferential subscription rights of our existing shareholders, which may as a practical matter preclude us from timely completion of offerings.

In accordance with the Belgian Companies Code, our Articles of Association provide for preferential subscription rights to be granted to our existing shareholders to subscribe on a pro rata basis and in exchange for contributions in cash, for any issue of new shares, convertible bonds or subscription rights that, unless such rights are cancelled or

limited either by resolution of our Shareholders' Meeting or by our Board of Directors in the framework of the authorized capital, as described below. The Extraordinary Shareholders' Meeting authorized the Board of Directors to increase the share capital of Galapagos NV, in one or several times, and under certain conditions set forth in extenso in our articles of association. We refer to this authority for our Board of Directors to increase our share capital as our authorized capital. This authorization consists of two parts. A general authorization for capital increases up to 20% of the share capital at the time of convening the Shareholders' Meeting of October 22, 2019 (i.e. €67,022,402.04) was renewed and is valid for a period of five years from the date of publication of this renewal in the Annexes to the Belgian State Gazette, i.e. November 13, 2019, so until November 12, 2024. A specific authorization for capital increases of more than 20% and up to 33% of the share capital at the time of the convening the shareholders' meeting of April 25, 2017 (i.e. €82,561,764.93), was renewed and was valid for a period of five years from the date of publication of this renewal in the Annexes to the Belgian State Gazette, i.e. May 31, 2017, so until May 30, 2022. This specific part of the authorized capital can, however, only be used in a number of specific circumstances and upon a resolution of the Board of Directors that all its independent members within the meaning of article 7:87 of the Belgian Companies Code) approve. This specific authorization was not renewed in 2022. As of the date of this annual report, our Board of Directors may decide to issue up to 4,600,607.06 ordinary shares pursuant to the general authorization. Please see the section of this annual report titled "Item 10.B.—Memorandum and Articles of Association." Absent renewal by our shareholders of this authorization of the Board of Directors or absent cancellation or limitation by our shareholders of the preferential subscription rights of our existing shareholders, the requirement to offer our existing shareholders the preferential right to subscribe, pro rata, for new shares being offered may as a practical matter preclude us from timely raising capital on commercially acceptable terms or at all.

Shareholders may not be able to participate in equity offerings we may conduct from time to time.

If we conduct equity offerings in the future, certain shareholders, including those in the United States, may, even in the case where preferential subscription rights have not been cancelled or limited, not be entitled to exercise such rights, unless the offering is registered or the shares are qualified for sale under the relevant regulatory framework. As a result, there is the risk that investors may suffer dilution of their shareholdings should they not be permitted to participate in preference right equity or other offerings that we may conduct in the future.

Holders of ADSs may be subject to limitations on the transfer of their ADSs and the withdrawal of the underlying ordinary shares.

ADSs are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason, subject to the right of ADS holders to cancel their ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of your ADSs and withdrawal of the underlying ordinary shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on our ordinary shares. In addition, ADS holders may not be able to cancel their ADSs and withdraw the underlying ordinary shares when they owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities.

As a foreign private issuer, we are exempt from a number of rules under the U.S. securities laws and are permitted to file less information with the SEC than a U.S. company. This may limit the information available to holders of ADSs or our ordinary shares.

We are a "foreign private issuer," as defined in the SEC's rules and regulations and, consequently, we are not subject to all of the disclosure requirements applicable to public companies organized within the United States. For example (without any limitation), we are exempt from certain rules under the Securities Exchange Act 1937, as amended, (the Exchange Act) that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act, including the U.S. proxy rules under Section 14 of the Exchange Act. In addition, our officers and directors are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, while we currently make annual and semi-annual filings with respect to

our listing on Euronext Brussels and Euronext Amsterdam and voluntarily report our results of operations on a quarterly basis, we will not be required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. domestic issuers and will not be required to file quarterly reports on Form 10-Q or current reports on Form 8-K under the Exchange Act. Accordingly, there is and will continue to be less publicly available information concerning our company than there would be if we were not a foreign private issuer.

As a foreign private issuer, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq corporate governance listing standards. These practices may afford less protection to shareholders than they would enjoy if we complied fully with corporate governance listing standards.

As a foreign private issuer listed on the Nasdaq Global Select Market, we are subject to corporate governance listing standards. However, rules permit a foreign private issuer like us to follow the corporate governance practices of its home country. Certain corporate governance practices in Belgium, which is our home country, may differ significantly from corporate governance listing standards applicable to U.S. domestic issuers. For example (without any limitation), neither the corporate laws of Belgium nor our Articles of Association require a majority of the members of our Board of Directors to be independent, and we could include non-independent board members as members of our Nomination Committee and Remuneration Committee, and our independent board members would not necessarily hold regularly scheduled meetings at which only independent Board members are present. Currently, we intend to follow home country practice to the maximum extent possible. Therefore, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers. See the sections of this annual report titled “Item 6—Directors, Senior Management and Employees” and “Item 16G —Corporate Governance.”

We may lose our foreign private issuer status in the future, which could result in significant additional cost and expense.

While we currently qualify as a foreign private issuer, and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers, the determination of foreign private issuer status is made annually on the last business day of an issuer’s most recently completed second fiscal quarter and, accordingly, the next determination will be made with respect to us on June 30, 2023.

In the future, we would lose our foreign private issuer status if we to fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. In order to maintain our current status as a foreign private issuer, either (a) a majority of our ordinary shares must be either directly or indirectly owned of record by non-residents of the United States or (b) (i) a majority of our executive officers or directors may not be U.S. citizens or residents, (ii) more than 50% of our assets cannot be located in the United States and (iii) our business must be administered principally outside the United States. As of March 15, 2023, a majority of our executive officers and directors are not U.S. citizens or residents.

The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly more than costs we incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects than the forms available to a foreign private issuer. We would be required under current SEC rules to prepare our financial statements in accordance with U.S. GAAP, rather than IFRS, in U.S. dollars rather than euros and modify certain of our policies to comply with corporate governance practices associated with U.S. domestic issuers. Such conversion of our financial statements to U.S. GAAP will involve significant time and cost. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers such as the ones described above and exemptions from procedural requirements related to the solicitation of proxies.

It may be difficult for investors outside Belgium to serve process on, or enforce foreign judgments against, us or our directors and senior management.

We are a Belgian public limited liability company. Less than a majority of the members of our Board of Directors and members of our Executive Committee are residents of the United States. All or a substantial portion of the assets of such non-resident persons and most of our assets are located outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or on us or to enforce against them or us a judgment obtained in U.S. courts. Original actions or actions for the enforcement of judgments of U.S. courts relating to the civil liability provisions of the federal or state securities laws of the United States (as amended from time to time) are not directly enforceable in Belgium. The United States and Belgium do not currently have a multilateral or bilateral treaty providing for reciprocal recognition and enforcement of judgments, other than arbitral awards, in civil and commercial matters. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in Belgium. This will depend on the applicable Belgian national rules.

In order for a final and conclusive judgment rendered by U.S. courts based on civil liability to produce any effect on Belgian soil, it is accordingly required that this judgment be recognized or be declared enforceable by a Belgian court in accordance with Articles 22 to 25 of the 2004 Belgian Code of Private International Law, as amended. Recognition or enforcement does not imply a review of the merits of the case and is irrespective of any reciprocity requirement. A U.S. judgment will, however, not be recognized or declared enforceable in Belgium if it infringes upon one or more of the grounds for refusal that are exhaustively listed in Article 25 of the Belgian Code of Private International Law, as amended. Actions for the enforcement of judgments of U.S. courts might be successful only if the Belgian court confirms the substantive correctness of the judgment of the U.S. court and if it is satisfied that:

- the effect of the enforcement judgment is not manifestly incompatible with Belgian public policy;
- the judgment did not violate the rights of the defendant;
- the judgment was not rendered in a matter where the parties transferred rights subject to transfer restrictions with the sole purpose of avoiding the application of the law applicable according to Belgian international private law;
- the judgment is not subject to further recourse under U.S. law;
- the judgment is not compatible with a judgment rendered in Belgium or with a subsequent judgment rendered abroad that might be enforced in Belgium;
- a claim was not filed outside Belgium after the same claim was filed in Belgium, while the claim filed in Belgium is still pending;
- the Belgian courts did not have exclusive jurisdiction to rule on the matter;
- the U.S. court did not accept its jurisdiction solely on the basis of either the nationality of the defendant or the location of the disputed goods; and
- the judgment submitted to the Belgian court is authentic.

Under the Belgian Code of Private International law, in addition to recognition or enforcement and before a Belgian court, a judgment by a federal or state court in the United States against us may also serve as evidence in a similar action in a Belgian court if it meets the conditions required for the authenticity of judgments according to the law of the state where it was rendered. The findings of a federal or state court in the United States will not, however, be taken into account to the extent they appear incompatible with Belgium’s (international) public policy.

U.S. judgments ordering to pay a certain amount that are declared enforceable in Belgium are subject to the applicable registration tax in the same way as Belgian judgments. As such, a registration tax at the rate of 3% of the