

Risk factors

Description of the risks of which
investors should be aware

we **raise** the bar.

Risks related to product development, regulatory approval and commercialization

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

We are heavily dependent on the success of our product candidate filgotinib. We are also dependent on the success of our other product candidates, such as GLPG1690, GLPG1205, GLPG1972, MOR106, and GLPG3312. We cannot give any assurance that any product candidate will successfully complete clinical trials or receive regulatory approval, which is necessary before it can be commercialized.

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

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

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Results of earlier studies and trials as well as data from any interim analysis of ongoing clinical trials may not be predictive of future trial results and failure can occur at any time during the clinical trial process. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. If filgotinib or any 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.

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

Our product candidates may cause undesirable 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 or other comparable regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Based on preclinical findings, we expect that filgotinib, if approved, may have a labeling statement warning female patients of child-bearing age to take precautionary measures of birth control to protect against pregnancy, similar to warnings included with other frequently used medications in RA, such as methotrexate.

In addition, there may be dose limitations imposed for male patients that are prescribed filgotinib, if approved. In connection with the DARWIN clinical program, we agreed with the FDA to exclude the 200 mg filgotinib daily dose for male subjects in the United States; males received a maximum daily dose of 100 mg in the U.S. sites in these trials. This limitation was not imposed by any other regulatory agency in any other jurisdiction in which the DARWIN clinical program is being conducted. We agreed to this limitation because in both rat and dog toxicology studies, filgotinib induced adverse effects on the male reproductive system and the FDA determined there was not a sufficient safety margin between the filgotinib exposure at the no-observed-adverse-effect-level, or NOAEL, observed in these studies and the anticipated human exposure at the 200 mg daily filgotinib dose. Accordingly, in connection with the DARWIN 3 clinical trial, in the United States, male subjects are dosed at a daily dose of 100 mg only. Male participants in this study and their partners are required to use highly effective contraceptive measures for the duration of the study and during a washout period thereafter. As an additional safety measure, we monitor clinical laboratory changes in hormone levels for subjects in the DARWIN 3 clinical trial.

More recently generated non-clinical data showed filgotinib did not induce any macroscopic or microscopic findings in the male reproductive system in animals with higher filgotinib exposure versus previous studies.

The Phase 3 FINCH program, led by our collaboration partner Gilead, is evaluating 100 mg and 200 mg filgotinib in both males and females in major RA patient populations world-wide. Men and women in both the Phase 2b/3 SELECTION and Phase 3 DIVERSITY trials in UC and CD, respectively, will be randomized to receive placebo, 100 mg or 200 mg filgotinib. In these SELECTION and DIVERSITY trials in the United States, males may receive 200 mg only if they failed conventional therapy, anti-TNF and vedolizumab. The filgotinib Phase 3 program also contains dedicated male patient testicular safety study called MANTA.

Even if filgotinib does receive regulatory approval or marketing authorization, the FDA or other regulatory authorities may impose dosing restrictions that differ from the approved dosing regimen in other jurisdictions.

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

If we are not able to maintain orphan product exclusivity for GLPG1690, or obtain such status for other or for future product candidates for which we seek this status, or if our competitors are able to obtain orphan product exclusivity before we do, we may not be able to obtain approval for our competing products for a significant period of time.

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, healthcare payers, patients and the medical community.

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.

As a result of the 2016 election in the United States, there is great political uncertainty concerning the fate of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or, collectively, the ACA, which became law in the United States in 2010, and other healthcare laws. The United States Congress is expected to draft legislation to repeal parts of the ACA, but it is uncertain when such legislation would be passed and whether Congress would replace the law and what any replacement law would encompass. We cannot predict any initiatives that may be adopted in the future.

Risks related to our financial position and need for additional capital

We are a clinical-stage biotechnology company and have not yet generated significant income. Our operations to date have been limited to developing our technology and undertaking preclinical studies and clinical trials of our product candidates.

Since our inception, we have incurred significant operating losses. 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 do not anticipate generating revenues from sales of products for the foreseeable future, if ever. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict the timing or amount of expenses and when we will be able to achieve or maintain profitability, if ever.

We will require substantial additional future capital which may not be available to us on acceptable terms, or at all, in order to complete clinical development and, if we are successful, to commercialize any of our current product candidates. In addition, raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our product candidates or technologies. The incurrence of additional indebtedness could result in increased fixed payment obligations and could also result in certain additional restrictive covenants that could adversely impact our ability to conduct our business. 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.

For further reference on financial risks in particular, see [note 31](#) of the notes to the consolidated financial statements.

Risks related to our reliance on third parties

We may not be successful in maintaining development and commercialization collaborations, and a collaboration partner may not devote sufficient resources to the development or commercialization of our product candidates. In particular, we are heavily dependent on Gilead for its further development of our product candidate filgotinib. Gilead may not devote sufficient resources or give sufficient priority to the filgotinib program. Our collaborators may not elect to advance the product candidates on which we collaborate. Gilead may not be successful in the further development and commercialization of filgotinib, even when they do devote resources and prioritize their efforts for filgotinib.

The collaboration arrangements that we have established, and any collaboration arrangements that we may enter into in the future, may ultimately not be successful, which could have a negative impact on our business, results of operations, financial condition and growth prospects. It is possible that a collaboration partner may not devote sufficient resources to the development or commercialization of our product candidate or may otherwise fail in development or commercialization efforts, in which event the development and commercialization of such product candidate could be delayed or terminated and our business could be substantially harmed.

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

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

We have relied on and plan to continue to rely on contract research organizations, or CROs, to monitor and manage data for our preclinical and clinical programs. We and our CROs also rely on clinical sites and investigators for the performance of our clinical trials in accordance with the applicable protocols and applicable legal, regulatory and scientific standards. If CROs do not successfully carry out their contractual duties or obligations or meet quality standards, regulatory requirements or expectations, 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. We do retain responsibility for all our studies and are required to and have put in place measures to manage, oversee, and control our studies, including the CRO selection process, audits, strong focus on deliverables, timelines, roles & responsibilities, and oversight of conduct of the studies.

We rely on clinical data and results obtained by third parties that could ultimately prove to be inaccurate or unreliable.

As part of our strategy to mitigate development risk, we seek to develop product candidates with validated mechanisms of action and we utilize biomarkers to assess potential clinical efficacy early in the development process. This strategy necessarily relies on clinical data and other results obtained by third parties. If the third-party data and the results that we rely on prove to be inaccurate, unreliable or not applicable to our product candidates, we could make inaccurate assumptions and conclusions about our product candidates and our research and development efforts could be materially adversely affected.

Risks related to our competitive position

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

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

Risks related to our intellectual property

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

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

Our commercial success depends on obtaining and maintaining proprietary rights to our product 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. If we fail to maintain to protect or to enforce our intellectual property rights successfully, our competitive position could suffer, which could harm our results of operations.

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

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

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

Filing, prosecuting and defending patents on our product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries could be less extensive than those in the United States and Europe. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries, or from selling or importing products made using our inventions.

Risks related to our organization, structure and operation

Our future success depends on our ability to retain the members of our executive committee and to attract, retain and motivate qualified personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. Attractive development and training programs, adequate remuneration and incentive schemes and a safe and healthy work environment mitigate this risk.

We expect that if 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 and expand our internal organization, systems, controls and facilities to accommodate additional anticipated growth. If we are unable to manage our growth effectively, our business could be harmed and our ability to execute our business strategy could suffer.

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

Our information technology systems could face serious disruptions that could adversely affect our business. Continuing an uninterrupted performance of our IT system is critical to the success of our business strategy and operations. A recovery plan for data has been implemented, as well as a system for interception of power failures. Fire walls and virus scanners provide an additional and adequate protection. Our personnel should adhere to continuity plans and procedures regarding access rights and installation of different programs. Business interruptions could delay us in the process of developing our product candidates. This risk has a high potential impact, but is mitigated by policies and procedures such as surveillance of the buildings, annual appraisals and bonuses, and monthly management meetings.

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

Despite our efforts to monitor social media and comply with applicable rules, there is a risk that the use of social media by us or our employees to communicate about our drug candidates or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets, or result in public exposure of sensitive information. Furthermore, negative posts or comments in social media could seriously damage our reputation, brand image, and goodwill.

Our collaboration arrangements with our strategic partners may make us an attractive target for potential acquisitions under certain circumstances. Under certain circumstances, due to the structure of our collaboration arrangements with our strategic partners, our strategic partners may prefer to acquire us rather than paying the milestone payments or royalties under the collaboration arrangements, which may bring additional uncertainties to our business development and prospects.

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

The United Kingdom held a referendum on 23 June 2016 in which a majority voted for the United Kingdom's withdrawal from the European Union (referred to as "Brexit"). While the United Kingdom's withdrawal from the European Union is expected to take effect shortly after the date of publication of this report, significant uncertainty remains regarding the future relationship between the United Kingdom and the European Union, in particular if the United Kingdom and the European Union fail to reach agreement on the terms of such withdrawal (referred to as a "No-Deal Brexit"). The effects of Brexit have been and are expected to continue to be far-reaching. Brexit and the perceptions as to its impact may adversely affect business activity and economic conditions in Europe and globally and could continue to contribute to instability in global financial and foreign exchange markets. Brexit could also have the effect of disrupting the free movement of goods, services and people between the United Kingdom and the European Union. In the event of a No-Deal Brexit, we anticipate incurring additional costs for customs duties and declarations, and handling and storage of supplies. In addition, we expect that Brexit could lead to legal uncertainty and potentially divergent national laws and regulations. If the United Kingdom significantly alters its regulations affecting the pharmaceutical industry, we could face significant new costs and altered regulations could also add time and expense to the process by which our product candidates receive regulatory approval in the United Kingdom and European Union. Given these possibilities and others we may not anticipate, as well as the lack of comparable precedent, the full extent to which our business, results of operations and financial condition could be adversely affected by Brexit is uncertain.

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

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

As a company active in research and development in Belgium, we also expect to benefit from the “innovation income deduction” in Belgium. The innovation income deduction regime allows net profits attributable to revenue from among others patented products (or products for which the patent application is pending) to be taxed at a lower rate than other revenues, i.e., 4.4%, and 3.75% as of 1 January 2020.

When taken in combination with tax losses carried forward and research and development incentives mentioned above, we expect that this will result in a long-term low rate of corporation tax for us. It should be noted however that the Belgian corporate income tax reform introduced as of assessment year 2019 a *de facto* minimum taxable base, whereby the existing tax attributes have to be allocated into 2 so-called “baskets”: a first basket which contains the tax deductions that can be applied without any restrictions and a second basket which contains the tax deductions that are subject to restrictions. The first basket contains (in order of deduction) the non-taxable items (such as deductible gifts), current year dividends received deduction (DRD), grandfathered patent income deduction (PID), current year innovation income deduction (IID) and investment deduction. The second basket contains (in order of deduction and subject to the restrictions as mentioned hereunder) the current year notional income deduction (NID), DRD carry-forward, IID carry-forward, tax loss carry-forward, unlimited NID carry-forward and NID carry-forward subject to the 7-year limitation. The taxable base can be reduced without any limitation with the deductions contained in the first basket. Any remaining taxable basis below €1 million can be fully compensated with deductions contained in the second basket. If the remaining taxable basis exceeds €1 million, the excess above €1 million can only be compensated with deductions of the second basket up to 70%. Such minimum taxable basis may have an impact on our future cash flows. At the end of 2018 we had €195.4 million of carryforward innovation income deduction in Belgium.

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

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

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

Market risks relating to the Galapagos shares

We have identified the following major market risks:

■ **Possible volatility of share price**

The market price of the shares might be affected by a variety of factors outside management control, such as the global economic situation, the business development of competitors, sector mergers and acquisitions; it is difficult to mitigate this risk.

■ **Economic risk due to failure in confidence**

General public confidence about future economic conditions or performance of us or our suppliers or customers may impact the ability or willingness of others to trade with us.

■ **Dilution through capital increases**

Raising additional capital may cause dilution to our existing shareholders. By raising additional capital through capital increases with cancellation of the preferential subscription rights of our existing shareholders, these shareholders will be diluted.

■ **Dilution through exercise of warrant plans**

The exercise of existing warrants can significantly increase the number of outstanding Galapagos shares.

■ **Inability to distribute dividends**

We have a limited operating history and future profitability cannot be guaranteed. Galapagos NV has significant losses carried-forward and will thus not be able to distribute dividends in the near future. This can cause people to refrain from investing in Galapagos shares.

■ **Reputational damage**

High ethical standards are maintained throughout the entire organization at all levels. Laws and guidelines are complied with. Our suppliers are required to adhere to contractual terms which include anti-bribery and anti-corruption provisions. In addition, our external consultants are required to comply with our Code of Business Conduct and Ethics and U.S. Foreign Corrupt Practices Act Policy.

■ **Belgian law provisions**

There are several provisions of Belgian company 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 shares at a premium (which is typically offered in the framework of a takeover bid).

General statement about Galapagos' risks

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