Risk factors

Description of the risks of which investors should be aware

> Galapagos is an innovator that discovers and develops novel treatments for patients suffering from diseases with high unmet medical needs.
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> CSO of Galapagos

Risks related to Galapagos' financial position and need for additional capital

Galapagos is a clinical-stage biotechnology company and has not yet generated significant income. Galapagos' operations to date have been limited to developing its technology and undertaking pre-clinical studies and clinical trials of its product candidates.

Galapagos has incurred significant operating losses since its inception. Galapagos expects to continue incurring significant research, development and other expenses related to its ongoing operations, and to continue incurring losses for the foreseeable future. Galapagos does 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, Galapagos is unable to predict the timing or amount of expenses and when it will be able to achieve or maintain profitability, if ever.

Galapagos will require substantial additional future capital which may not be available to it on acceptable terms, or at all, in order to complete clinical development and, if Galapagos is successful, to commercialize any of its current product candidates. In addition, raising additional capital may cause dilution to Galapagos' existing shareholders, restrict Galapagos' operations or require Galapagos to relinquish rights to its 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 Galapagos' ability to conduct its business. In the event that Galapagos enters into collaborations and/or licensing arrangements in order to raise capital, it may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms its rights to technologies or product candidates.

For further reference on financial risks in particular, see note 38 of the notes to the consolidated financial statements.

Risks related to product development, regulatory approval and commercialization

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

Galapagos is heavily dependent on the success of its product candidate filgotinib and its other product candidates. Galapagos may not be successful in its efforts to use and expand its novel, proprietary target discovery platform to build a pipeline of product candidates.

Galapagos' business and future success is substantially dependent on its ability to develop successfully, obtain regulatory approval for, and then successfully commercialize its product candidate filgotinib and its other product candidates. Galapagos is not permitted to market or promote any of its product candidates before it receives regulatory approval from the FDA, the EMA or any other comparable regulatory authority, and Galapagos may never receive such regulatory approval for any of its product candidates. Galapagos cannot give any assurances that its clinical trials for filgotinib or its other product candidates will be completed in a timely manner, or at all. Galapagos has never completed a Phase 3 trial or submitted an NDA. If filgotinib or any future product candidate is not approved and commercialized, Galapagos 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 Galapagos is ultimately unable to obtain regulatory approval for its product candidates, its 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 Galapagos experiences delays in the completion of, or termination of, any clinical trial of its product candidates, the commercial prospects of its product candidates will be harmed, and its 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, Galapagos will not be able to obtain regulatory approval for it and its business would be materially harmed.

The rates at which Galapagos completes its scientific studies and clinical trials depend on many factors, including, but are 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 Galapagos' clinical trials and by extension, its business, financial condition and prospects.

Galapagos' 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 Galapagos' product candidates could cause Galapagos 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 Galapagos' business, financial condition and prospects significantly.

Risks related to Galapagos' reliance on third parties

Galapagos may not be successful in maintaining development and commercialization collaborations, and any partner may not devote sufficient resources to the development or commercialization of Galapagos' product candidates.

The collaboration arrangements that Galapagos has established, and any collaboration arrangements that it may enter into in the future may not ultimately be successful, which could have a negative impact on its business, results of operations, financial condition and growth prospects. It is possible that a partner may not devote sufficient resources to the development or commercialization of Galapagos' 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 Galapagos' business could be substantially harmed.

Galapagos relies 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. The suppliers should perform as contractually required or expected.

Galapagos relies on third parties to conduct its pre-clinical studies and clinical trials.

Galapagos has relied upon and plans to continue to rely upon contract research organizations ("CROs") to monitor and manage data for its pre-clinical and clinical programs. Galapagos and its CROs also rely upon clinical sites and investigators for the performance of its 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 expected, Galapagos' clinical trials may be extended, delayed or terminated and Galapagos may not be able to obtain regulatory approval for or successfully commercialize its product candidates.

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

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

Risks related to Galapagos' competitive position

Galapagos faces significant competition for its drug discovery and development efforts, and if it does not compete effectively, its commercial opportunities will be reduced or eliminated.

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

Risks related to Galapagos' intellectual property

Galapagos' ability to compete may decline if Galapagos does not adequately protect its proprietary rights.

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

Galapagos' commercial success depends on obtaining and maintaining proprietary rights to its product candidates, as well as successfully defending these rights against third party challenges. Galapagos will only be able to protect its 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 Galapagos fails to maintain to protect or to enforce its intellectual property rights successfully, its competitive position could suffer, which could harm Galapagos' results of operations.

Pharmaceutical patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to Galapagos, could negatively impact its 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, the European Patent Office, and other foreign counterparts are sometimes uncertain and could change in the future. If Galapagos fails to obtain and maintain patent protection and trade secret protection of its product candidates, it could lose its competitive advantage and competition Galapagos faces would increase, reducing any potential revenues and adversely affecting its ability to attain or maintain profitability.

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

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

Risks related to Galapagos' organization, structure and operation

Galapagos' future success depends on its ability to retain the members of its Executive Committee and to attract, retain and motivate qualified personnel. If Galapagos is not successful in attracting and retaining highly qualified personnel, it may not be able to successfully implement its business strategy. Adequate remuneration and incentive schemes and the sharing of Galapagos' knowledge amongst key employees mitigate this risk. In the recent past, Galapagos has continued to be successful in attracting and retaining qualified employees.

Risks from the improper conduct of employees, agents, contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition. 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. Galapagos' 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.

Galapagos could be subject to liabilities under environmental, health and safety laws or regulations, or fines, penalties or other sanctions, if it fails to comply with such laws or regulations or otherwise incurs costs that could have a material adverse effect on the success of the business. The very limited use of hazardous materials, the existence of stringent health and safety operation procedures, and regular inspections and safety days significantly decrease the potential impact as well as the estimated likelihood of the risk. Furthermore, the Group employs quality & environmental health and safety managers who closely monitor laboratory safety and continuously seek to improve quality and safety conditions.

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.

Galapagos may undertake strategic acquisitions in the future and any difficulties from integrating such acquisitions could adversely affect Galapagos' share price, operating results and results of operations. Galapagos may acquire companies, businesses and products that complement or augment its existing business. Galapagos 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 Galapagos predicts. As part of its efforts to acquire companies, business or product candidates or to enter into other significant transactions, Galapagos conducts business, legal and financial due diligence with the goal of identifying and evaluating material risks involved in the transaction. Despite its efforts, Galapagos 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 Galapagos is unable to use tax loss carryforwards to reduce future taxable income or benefit from favorable tax legislation, Galapagos' business, results of operations and financial condition may be adversely affected. Galapagos 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 the Group's activities, financial situation and results. Such potential changes and their impact are monitored carefully by management and its advisors.

As a company active in research and development in Belgium and France, Galapagos has 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, Galapagos' results of operations could be adversely affected. Galapagos also expects to benefit in the future from the "patent income deduction" initiative in Belgium. If, however, there are unexpected adverse changes to the Belgian "patent income deduction" initiative, or Galapagos is unable to qualify for such advantageous tax legislation, its business, results of operations and financial condition may be adversely affected.

Galapagos has 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 Galapagos fails to comply with its contractual obligations under the applicable technological innovation grant agreements, Galapagos could be forced to repay all or part of the grants received. Such repayment could adversely affect Galapagos' ability to finance its research and development projects.

Galapagos annually establishes a detailed budget that is submitted to the Board of Directors for review and approval. The Group's performance compared to the budget is continuously monitored by the Executive Committee and is discussed with the Board at least once per quarter. For the establishment of its financial information, the Group has processes and methods in place that enable the preparation of consolidated financial statements for its annual and mid-year reporting, and more often if required. The Group's management reporting systems – which include an advanced integrated ERP system – secure the generation of consistent financial and operational information, allowing management to follow-up the Group's performance on a daily basis.

Market risks relating to the Galapagos shares

Galapagos has 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 Galapagos or its suppliers or customers may impact the ability or willingness of others to trade with Galapagos

- **Dilution through exercise of warrant plans**
  The exercise of existing warrants can significantly increase the number of outstanding Galapagos shares

- **Inability to distribute dividends**
  The Group has 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' stock

- **Reputational damage**
  High ethical standards are maintained throughout the entire organization at all levels. Laws and guidelines are complied with

- **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 Galapagos 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 Group risks

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