InflaRx N.V.

DUTCH STATUTORY BOARD REPORT AND FINANCIAL STATEMENTS

FOR THE FINANCIAL YEAR ENDED DECEMBER 31, 2024

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REPORT OF THE BOARD OF DIRECTORS

ITEM 1. INTRODUCTION

Preparation

In this report, the terms "we", "us", "our" and "the Company" refer to InflaRx N.V. and, where appropriate, its subsidiaries.

This report has been prepared by the Company's board of directors pursuant to Section 2:391 of the Dutch Civil Code ("DCC") and also contains (i) the Company's statutory annual accounts within the meaning of Section 2:361(1) DCC and (ii) to the extent applicable, the information to be added pursuant to Section 2:392 DCC. This report relates to the financial year ended December 31, 2024 and, unless explicitly stated otherwise, information presented in this report is as at December 31, 2024.

The statutory board (*bestuursverslag*) report as referred to in Section 2:391 DCC is formed by ITEM 1, 2 and ITEM 3. The consolidated financial statements enclosed with this report (the "Consolidated Financial Statements") have been prepared in accordance with IFRS Accounting Standards as issued by the International Accounting Standards Board (IASB) and adopted by the European Union (EU-IFRSs) and with Section 2:362(9) DCC. . The Company financial statements enclosed with this report (the "Company Financial Statements") have been prepared in accordance with the accounting principles promulgated by Title 9 of Book 2 DCC.

In this report, unless otherwise indicated, translations from U.S. dollars to Euros (and vice versa) relating to payments made on or before December 31, 2024 were made at the rate in effect at the time of the relevant payment.

The terms "$" or "dollar" refer to U.S. dollars, and the terms "€" or "Euro" refer to the currency introduced at the start of the third stage of European economic and monetary union pursuant to the treaty establishing the European Community, as amended.

Forward-looking statements

This Annual Report contains forward-looking statements that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “estimate,” “believe,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions intended to identify statements about the future. These statements speak only as of the date of this Annual Report and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements include, without limitation, statements about the following:

- our ability to successfully secure distribution channels and commercialize GOHIBIC (vilobelimab) as a treatment for COVID-19 patients and the receptiveness of our ability to positively influence treatment recommendations by U.S. and European hospitals, guideline bodies and other third-party organizations;

- our expectations regarding the size of the patient populations for, market opportunity for, coverage and reimbursement for, estimated returns and return accruals for, and clinical utility of GOHIBIC (vilobelimab) in its approved or authorized indication or for vilobelimab and any other product candidates, under the Emergency Use Authorization, or EUA, market authorization, or Market Authorization, and in the future if approved for commercial use in the United States, Europe or elsewhere;

- our ability to successfully implement The InflaRx Commitment Program, the success of our future clinical trials for vilobelimab’s treatment of other debilitating or life-threatening inflammatory indications, including acute respiratory distress syndrome, or ARDS, pyoderma gangrenosum, or PG, and any other product candidates, including INF904, and whether such clinical results will reflect results seen in previously conducted pre-clinical studies and clinical trials;

- the timing, progress and results of preclinical studies and clinical trials of vilobelimab, INF904 and any other product candidates, including for the development of vilobelimab in several indications, including to obtain full approval of GOHIBIC (vilobelimab) for COVID-19 and other virally induced ARDS, to treat PG, hidradenitis suppurativa, or HS, and chronic spontaneous urticaria, or CSU, and statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, the costs of such trials and our research and development programs generally;

- our interactions with and the receptiveness and approval by regulators regarding the results of clinical trials and potential regulatory approval or authorization pathways, including our biologics license application submission, or BLA, for GOHIBIC (vilobelimab);

- the timing and outcome of any discussions or submission of filings for regulatory approval or authorization of vilobelimab, INF904 or any other product candidate, and the timing of and our ability to obtain and maintain full regulatory approval, the EUA and/or Market Authorization of vilobelimab or GOHIBIC (vilobelimab) for any indication;

- our ability to leverage our proprietary anti-C5a and anti-C5aR technologies to discover and develop therapies to treat complement-mediated autoimmune and inflammatory diseases;

- our ability to protect, maintain and enforce our intellectual property protection for vilobelimab, INF904 and any other product candidates, and the scope of such protection;

- whether the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or EMA, or any comparable foreign regulatory authority will accept or agree with the number, design, size, conduct or implementation of our clinical trials, including any proposed primary or secondary endpoints for such trials;

- the success of our future clinical trials for vilobelimab, INF904 and any other product candidates and whether such clinical results will reflect results seen in previously conducted preclinical studies and clinical trials;

- our expectations regarding the size of the patient populations for, the market opportunity for, the medical need for and clinical utility of vilobelimab, INF904 or any other product candidates, if approved or authorized for commercial use;

- our manufacturing capabilities and strategy, including the scalability and cost of our manufacturing methods and processes and the optimization of our manufacturing methods and processes, and our ability to continue to rely on our existing third-party manufacturers and our ability to engage additional third-party manufacturers for our planned future clinical trials and for commercial supply of vilobelimab and for the finished product GOHIBIC (vilobelimab) in the U.S. and Europe;

- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;

- our expectations regarding the scope of any approved indication for vilobelimab;

- our ability to defend against liability claims resulting from the testing of our product candidates in the clinic or, if, approved or authorized, any commercial sales;

- if any of our product candidates obtain regulatory approval or authorization, our ability to comply with and satisfy ongoing drug regulatory obligations and continued regulatory overview;

- our ability to comply with enacted and future legislation in seeking marketing approval or authorization and commercialization;

- our future growth and ability to compete, which depends on our retaining key personnel and recruiting additional qualified personnel;

- our competitive position and the development of and projections relating to our competitors in the development of C5a and C5aR inhibitors and other therapeutic products being developed in similar

medical conditions in which vilobelimab, INF904 or any other of our product candidates is being developed or our industry; and

- other risk factors discussed herein under "Risk Factors" or incorporated herein by reference.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. You should refer to the "ITEM 1. INTRODUCTION: — C. Risk factors." section of this Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. You should, however, review the factors and risks and other information we describe in the reports we will file from time to time with the U.S. Securities and Exchange Commission, or the SEC, after the date of this Annual Report.

Risk factors

Summary of key risk factors

The principal risks and uncertainties which the Company faces include the risks and uncertainties summarized in this chapter 2.1. See chapter 2.2 of this report for additional detail and additional risks and uncertainties which the Company faces.

Risk Factor Summary

The following is a summary of the principal risks that could adversely affect our business, operations and financial results.

- Financial position and need for additional capital.
- Discovery, development, manufacturing and commercialization of our product candidates.
- Dependence on third parties
- Our intellectual property
- Employee matters and managing growth
- Risks related to ordinary shares and our status as a public company
- General Risk Factors

The summary describes the main risks to which InflaRx N.V. is exposed. These are not all risks but the core risks that the management considers important in connection with the business operations. To avoid repetition, we refer to chapter 2.2.and 2.3 for a more complete discussion of the risks and countermeasures.

Risk factors

You should carefully consider the risks and uncertainties described below and the other information in this Annual Report before making an investment in our ordinary shares. Our business, financial condition or results of operations could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our ordinary shares could decline, and you could lose all or part of your investment. This Annual Report also contains forward-looking statements that involve risks and uncertainties. See "Forward-Looking Statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors.

1. Risks related to our financial position and need for additional capital

We have a history of significant operating losses and expect to incur significant and increasing losses for the foreseeable future; we may never achieve or maintain profitability and investors may lose their entire investment

We incurred net losses of €46.1 million, €42.7 million and €29.5 million for the years ended December 31, 2024, 2023 and 2022, respectively. In addition, our accumulated deficit as of December 31, 2024 was €332.2 million.

We expect our net losses to increase as we advance vilobelimab and other product candidates into additional clinical trials, as well as larger and later-stage clinical trials. Further, we expect our net losses to increase as we advance the implementation of commercialization of GOHIBIC (vilobelimab) in the United States under the EUA and in the European Union under the marketing authorization while investing in start-up commercialization and marketing activities. To date, we have not commercialized any products other than for GOHIBIC (vilobelimab) for the treatment of severe COVID-19 or generated any meaningful revenues from the sale of products other than limited initial sales of GOHIBIC (vilobelimab) and absent the realization of sufficient revenues from product sales, we may never attain profitability. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies, clinical trials and manufacturing development. Our net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our shareholders' equity and working capital.

We anticipate that our expenses might increase if and as we:

continue to develop and conduct clinical trials with respect to our lead product candidate, vilobelimab;

continue research, preclinical and clinical development efforts for any future product candidates, including IFX002 and INF904;

actively seek to identify additional research programs and additional product candidates;

seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials, if any;

establish sales, marketing, distribution and other commercial infrastructure now and in the future to commercialize various products for which we may obtain marketing authorization or approval, if any;

require the scale-up and validation of the manufacturing process and the manufacturing of larger quantities of product candidates for clinical development and, potentially, commercialization;

collaborate with strategic partners to optimize the manufacturing process for vilobelimab, IFX002, INF904 and other pipeline products;

maintain, expand and protect our intellectual property portfolio;

hire and retain additional personnel, such as commercial, marketing, clinical, quality control and scientific personnel; and

add operational, financial and management information systems and personnel, including personnel to support our product development as well as commercialization and help us comply with our obligations as a public company.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue unless and until we are, or any future collaborator is, able to obtain marketing authorization or approval for, and successfully commercialize, one or more of our product candidates. Successful commercialization will require achievement of key milestones, including completing clinical trials of vilobelimab and any other product candidates, obtaining marketing authorization or approval for these product candidates, manufacturing, marketing and selling those products for which we, or any of our future collaborators, may obtain marketing authorization or approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately predict the timing and amount of revenues, and if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we do, or any future collaborators do, we may never generate revenue

that is large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. In order to succeed, we will need to transition from a company with a research and development focus to a company capable of undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays, and may not be successful in such a transition.

Our failure to become and remain profitable could depress the market price of our ordinary shares and could impair our ability to raise capital, pay dividends, expand our business, diversify our product offerings or continue our operations. If we continue to suffer losses as we have in the past, investors may not receive any return on their investment and may lose their entire investment.

We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or discontinue our product discovery and development programs or commercialization efforts

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. For example, for the years ended December 31, 2024 and December 31, 2023, we used €48.6 million and €37.8 million, respectively, in net cash for our operating activities, most of which were related to research and development activities. We expect our expenses to increase in connection with our ongoing activities, particularly as we initiate new clinical trials of, initiate new research and preclinical development efforts for, establish robust manufacturing processes for, establish comprehensive commercialization and marketing processes and seek marketing authorization or approval for, our current product candidates or any future product candidates, including those that we may acquire. In particular, we will incur significant expenses as we conduct our planned clinical trial program and initiate new research and preclinical development efforts. In addition, after obtaining the EUA and market authorization for GOHIBIC (vilobelimab) in the United States and Europe, respectively and if we obtain marketing approval for any of our product candidates, we may incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of a future collaborator. Furthermore, we expect to incur significant additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We plan to use our cash on hand primarily to fund our planned clinical trial programs, to initiate new research and preclinical development efforts, to establish commercial scale manufacturing processes and for working capital and other general corporate purposes. We will be required to expend significant funds in order to advance the development of vilobelimab in later stages of clinical development, as well as other product candidates we may seek to develop, including IFX002 and INF904. We are also evaluating vilobelimab for a number of additional indications. Any future development activities for our pipeline product candidates will depend heavily on the clinical as well as commercialization and marketing success of vilobelimab in any indication.

Our existing cash and cash equivalents will not be sufficient to fund all the efforts that we plan to undertake or to fund the completion of development of any of our product candidates. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, royalty-based financings, collaborations and licensing arrangements or other sources. Currently, we do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts and on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of vilobelimab or any of our other product candidates or potentially discontinue operations altogether. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategy.

We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements under our current business plan for at least the next 18 months. Changing circumstances, some of which may be beyond our control, could cause us to consume capital

significantly faster than we anticipate, and we may need to seek additional funds sooner than planned. Our future funding requirements, both short-term and long-term, will depend on many factors, including:

the scope, progress, timing, costs and results of clinical trials of, and research and preclinical development efforts for, our current and future product candidates, particularly for vilobelimab;

the number of future product candidates and indications that we pursue and their development requirements;

the outcome, timing and costs of seeking regulatory approvals;

the costs of preparation for and implementation of commercialization and commercialization activities for any of our product candidates that receive marketing authorization approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and commercial-scale manufacturing capabilities;

the effect of competing technological and market developments;

subject to receipt of marketing authorization or approval, revenue, if any, received from commercial sales of our current and future product candidates;

our ability to enter into, and the terms and timing of, any collaborations, licensing or other arrangements;

our headcount growth and associated costs as we expand our research, development, manufacturing, regulatory and commercial activities;

the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights including enforcing and defending intellectual property related claims; and

the costs of operating as a public company.

We have a limited operating history and history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability

We commenced operations in 2008. Our operations to date have been limited to establishing our Company, raising capital, developing our proprietary anti-C5a and anti-C5aR technologies, identifying and testing potential product candidates and conducting clinical trials of our lead product candidate, vilobelimab and establishing a commercial scale manufacturing process for vilobelimab. In April 2023, we received the EUA for GOHIBIC (vilobelimab) for the treatment of certain critically ill COVID-19 patients by the FDA. In January 2025, we received market authorization for GOHIBIC (vilobelimab) for use under exceptional circumstances by the European Commission following a positive opinion from the Committee for Medicinal Products for Human Use, or CHMP, recommending the marketing authorization. We have just started to arrange for third parties to manufacture and distribute our product at small commercial scale on our behalf. However, we have not yet demonstrated an ability to obtain full marketing approvals or conduct sales and marketing activities at large scale as necessary for successful product commercialization. Also, we are still in early stages of clinical development with our other product candidates. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially clinical-stage biopharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will eventually need to transition from a company with a predominant development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

We may be subject to risks in relation to financial grants received by the German federal government, which may result in the partial repayment of such grants

The research allowance act (Forschungszulagengesetz, or FZulG) in Germany is a law designed to promote research and development, or R&D, activities within companies by offering them tax incentives. Specifically, it allows businesses to claim a tax credit for eligible R&D expenditures. The tax authorities verify whether the company's R&D activities meet the criteria for the tax credit, and whether the expenses were appropriately documented. If the eligibility requirements are met, the determined research allowance (Forschungszulage) is offset against the tax liability of the eligible company or - if the research allowance exceeds this tax liability - paid out. The research allowance according to the research allowance act is funded by the German government, specifically through the Federal Ministry of Education and Research, or BMBF, and managed by the research allowance office (Forschungszulagenstelle) within the federal central tax office (Bundeszentralamt für Steuern, or BZSt).

In 2024 we have applied for the research allowance for the first time for the fiscal years 2020 to 2024. Specifically, we applied for a tax credit of €5.1 million for these past years. This claimed amount only covers activities that have not previously been subject to grants and subsidies by the German or European governments and all of their grant awarding agencies. The grant allowance period will end in 2027, and we might become subject to future audits by financial oversight authorities of the German federal government.

Outside of the research allowance under the FZulG, the clinical Phase 3 study of vilobelimab in critically ill COVID-19 patients and certain manufacturing development related activities of our product candidate vilobelimab were partly funded by the German federal government through a grant awarded to us in October 2021. The grant was structured as a reimbursement of 80% of certain pre-specified expenses related to the clinical development and manufacturing of vilobelimab. The grant period ended on June 30, 2023, as planned. In total, throughout the duration of the grant period and up to the date hereof, we received a total amount of €33.3 million. We might be subject to future audits by financial oversight authorities of the German federal government or European regulatory bodies and a failure to pass these audits in case the authorities identify non-adherence to all grant conditions could potentially lead to a retroactive revocation of parts of the funds awarded by the grant.

In addition, the German federal government has, in the case of a special public interest, a non-exclusive and transferable right to use intellectual property generated as part of the funded work. Contracts with third parties relating to the exploitation of the results of the funded work must be disclosed to the agency managing the grant on behalf of the German federal government and any such contracts with parties outside of the European Union require the prior consent of the German federal government to the extent they deviate from a commercial exploitation plan previously approved by the German federal government. Additionally, we may be required to grant third parties licenses to use such results under certain conditions. In certain scenarios, including if we come under the decisive influence of foreign investors, the funded results are exclusively or predominantly used outside Germany without the prior consent of the German federal government or if we are in breach of our obligations under the grant, the grant funding, including funding already received, can be revoked.

Exchange rate fluctuations may materially affect our results of operations and financial condition

Potential future expense and revenue may be incurred or derived from outside the European Union, particularly the United States. As a result, our business and our share price may be affected by fluctuations in foreign exchange rates between the euro and other currencies, particularly the U.S. dollar, which may also have a significant impact on our reported results of operations and cash flows from period to period. We currently do not have any exchange rate hedging arrangements in place.

We may face the risk of substantial write-downs of inventory due to the excess or obsolescence of our inventory relating to GOHIBIC (vilobelimab) due to expiration prior to sale or unsuitability for alternative use

Excess purchase of raw materials and production of products or the commitments to purchase or produce such items may result in high inventory levels that might not be commercially viable and could lead to the necessity to partially or fully write-down these items. Excess and obsolescence risks for our inventory could arise from factors such as shelf-life expiration, overstocking, or events like supply chain disruptions, manufacturing mistakes, raw material flaws which can result in errors, wastage, or delays and more. Whether

such obsolescence risks materialize, ultimately depends on market demand/penetration and medical need for our products, regulatory factors such as approvals or approval withdrawals by regulatory agencies in the territories in which we intend to commercialize our product, the competitive landscape of the markets in which we operate, including the development of comparable products by our competitors as well as our ability to command prices at which we can be competitive and our own plans regarding alternative use of unfinished or finished products in our inventory for alternative purposes, such as clinical trials in additional indications. Furthermore, changes in currency exchange rates can impact the cost of imported goods and affect inventory valuations. In valuing our inventory, we make assumptions regarding these factors and update these assumptions when applicable.

2. Risks related to the discovery, development, manufacturing and commercialization of our product candidates

We are at a clinical development stage in our development efforts, our approach of targeting C5a or C5aR inhibition is novel and we may not be able to successfully develop and commercialize any product candidates

Vilobelimab is a novel therapeutic antibody and its potential therapeutic benefit is unproven, and C5a or C5aR inhibition to treat complement-mediated autoimmune and inflammatory diseases has only been partly validated. We have not yet succeeded and may never succeed in demonstrating efficacy and safety for vilobelimab in pivotal clinical trials or in obtaining marketing approval thereafter for severe COVID-19 or any other indication. The aforementioned continues to be true, although GOHIBIC (vilobelimab) has been granted the EUA by the FDA for the treatment of coronavirus disease 19, or COVID-19, in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation, or IMV, or extracorporeal membrane oxygenation, or ECMO; and has been granted marketing authorization by the European Commission, or EC, under exceptional circumstances for GOHIBIC (vilobelimab) for the treatment of adult patients with SARS-CoV-2-induced ARDS, who are receiving systemic corticosteroids as part of standard of care and IMV (with or without ECMO). If we are unsuccessful in our development efforts, we may not be able to advance the development of our product candidates, commercialize products, raise capital, expand our business, or continue our operations.

We depend on the success of our product candidates, including our lead product candidate, vilobelimab, and if we are unable to obtain approval for and commercialize our product candidates for one or more indications in a timely manner, our business will be materially harmed

Our success depends on our ability to timely complete clinical trials and obtain marketing authorization or approval for, and then successfully commercialize, our product candidates, including our lead product candidate, vilobelimab, for one or more indications. Our product candidates will require additional clinical development, preclinical and manufacturing development activities, marketing approval from government regulators, commercial manufacturing, substantial investment, and significant marketing efforts before we generate any revenue from product sales. We are not permitted to market or promote any product candidates in a jurisdiction before receiving marketing authorization or approval from the relevant regulatory authority, including the FDA for marketing in the United States and EMA for marketing in Europe, and we may never receive such marketing approvals or marketing authorizations beyond the EUA and market authorization for GOHIBIC (vilobelimab) granted by the FDA in April 2023 and the EC in January 2025, respectively. The success of our product candidates will depend on numerous factors, including:

- raising additional funds, or entering into collaborations, necessary to complete the clinical development of and to commercialize of our product candidates;
- successful and timely completion of our ongoing clinical trials;
- initiation of successful patient enrollment and completion of additional clinical trials on a timely basis;
- efficacy, safety and tolerability profiles that are satisfactory to the FDA, EMA or any comparable foreign regulatory authority for marketing approval;
- timely receipt of marketing authorizations or approvals for our product candidates from applicable regulatory authorities;

- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- the maintenance of existing, or the establishment of new, supply arrangements with third-party drug product suppliers and manufacturers;
- the maintenance of existing, or the establishment of new, scaled production arrangements with third-party manufacturers to obtain finished products that are appropriately packaged for sale;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, in the United States and elsewhere;
- protection of our rights in our intellectual property portfolio, including our licensed intellectual property;
- successful launch of commercial sales following any marketing authorization or approval;
- a continued acceptable safety profile following any marketing authorization or approval;
- commercial acceptance by patients, the medical community and third-party payors;
- inclusion of approved or, such as GOHIBIC (vilobelimab), authorized products in guidelines by medical bodies, including but not limited to National Institute of Health, or NIH, guidelines;
- inclusion of approved or, such as GOHIBIC (vilobelimab), authorized products on hospitals formulary; and
- our ability to compete with other therapies.

Additionally, we cannot be sure that we can obtain necessary regulatory authorizations or approvals on a timely basis, if at all, for any of the products we are developing or manufacturing or that we can maintain necessary regulatory authorizations or approvals for our existing products, and all of the following could have a material adverse effect on our business:

- significant delays in obtaining or failing to obtain required authorizations approvals;
- loss of, or changes to, previously obtained authorizations or approvals;
- failure to comply with existing or future regulatory requirements; and
- changes to manufacturing processes or manufacturing process standards following authorization or approval, or changing interpretations of these factors.

Many of such factors remain outside of our control, and if we are unable to achieve one or more of the objectives set forth above, our business will be materially harmed.

GOHIBIC (vilobelimab) for which we received the EUA is subject to continuing regulatory oversight, which might lead to a withdrawal or revocation of the granted EUA, if the FDA considers the underlying requirements or conditions for the EUA not to be given anymore. We may incur significant losses including loss of reputation, if the EUA for GOHIBIC (vilobelimab) is withdrawn or revoked by the FDA

GOHIBIC (vilobelimab) for which we received the EUA for the treatment of COVID-19 in certain hospitalized adult patients, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) is subject to continuing regulatory oversight, including the determination and verification of underlying requirements such as a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. The granted EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act. If the conditions or requirements for granting the EUA cease to be apparent in the future, or if reported drug safety events lead to a new situation in determining the overall pharmacovigilance of vilobelimab, the FDA may suspend, withdraw or revoke the granted EUA. Any of

these events could have a material adverse effect on our business, financial condition, results of operations and prospects.

Clinical failure may occur at any stage of clinical development, and the results of our clinical trials may not support our proposed indications for our product candidates

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. Moreover, success in clinical trials in a particular indication does not ensure that a product candidate will be successful in other indications, even for the same underlying disease. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, even after promising results in earlier preclinical studies or clinical trials or successful later-stage trials in other related indications, including in the context of controlling complement activation through C5 and C5a or C5aR inhibition. For example, while others in our industry have attempted to develop C5a-specific antibodies, there is no approved therapy inhibiting C5a. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events as well as lack of efficacy and patient benefit as reported by clinical trial investigators. In particular, development of antibodies that target C5a rather than C5 to control complement activation is comparatively novel, and there is no approved therapy specifically targeting C5a. As a result, inhibition of C5a rather than C5, which blocks signaling to the two receptors C5aR and C5L2, may have unforeseen consequences or negative results that may lead to clinical failure or withdrawal in later stages of our product candidate development. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and initial clinical trials for a variety of reasons, including differences in patient populations, changes in trial protocols and complexities of larger, multi-center trials among others. We may fail to complete clinical trials and/or to meet predetermined endpoints in the clinical trials, which may cause us to abandon a product candidate or an indication and may delay development of any other product candidates. Any delay in, or termination of, our clinical trials will delay the submission of the Biologics License Application, or BLA, the New Drug Application, or NDA to the FDA, the Marketing Authorization Application, or MAA to the EMA or other similar applications with other relevant foreign regulatory authorities and, ultimately, our ability to commercialize any of our product candidates and generate revenue.

Failure to maintain compliance with FDA requirements and/or remain in alignment with FDA feedback may prevent or delay the development, marketing or manufacturing of vilobelimab for the treatment of critically ill COVID-19 patients or patients with SARS-CoV-2-induced ARDS and, potentially, of vilobelimab in ulcerative PG

Our manufacturing and laboratory facilities are periodically subject to inspection by the FDA and other governmental agencies to ensure they meet production and quality requirements. Operations at these facilities could be interrupted or halted if the FDA or another governmental agency deems the findings of such inspections unsatisfactory. Further, failure to comply with FDA or other regulatory requirements regarding the development, marketing, promotion, manufacturing and distribution of vilobelimab could result in fines, unanticipated compliance expenditures, recall or seizures of our products, total or partial suspension of production or distribution, restrictions on labeling and promotion, termination of ongoing research, disqualification of data for submission to regulatory authorities, enforcement actions, injunctions and criminal prosecution. If we do not meet applicable regulatory or quality standards, our products may be subject to recall, and under certain circumstances, we may be required to notify applicable regulatory authorities about a recall.

GOHIBIC (vilobelimab) and any other product candidates for which we receive approval or the EUA are subject to continuing regulatory oversight, and we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. We may be subject to penalties if we fail to comply with regulatory requirements

GOHIBIC (vilobelimab) and any other product candidates for which we received or might receive approval or the EUA are subject to continuing regulatory oversight, including the review of promotional materials and additional safety information, and the applicable regulatory authority may still impose significant restrictions on the indicated uses or marketing of our product or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. In other countries, advertising and promotional material may be subject to similar rules. If we fail to comply with

applicable regulatory requirements following authorization or approval of any of our product candidates, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw the granted EUA or regulatory approval or revoke a license;
- suspend any ongoing clinical studies;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any authorized or approved products and generate revenues.

Any of these events could prevent us from achieving or maintaining market acceptance of any products we may identify and develop and could have a material adverse effect on our business, financial condition, results of operations and prospects.

If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy to the FDA and other regulators, we, or any future collaborators, may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of these product candidates

We, and any future collaborators, are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval or an EUA from the FDA. Foreign regulatory authorities, such as the EMA, impose similar requirements in their respective markets as well. We, and any future collaborators, must complete extensive preclinical development and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals.

The clinical development of our product candidates is susceptible to the risk of failure inherent at any stage of product development. It is possible that even if one or more of our product candidates has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. In addition, many of our product candidates are in early stages of development or clinical testing. As a result, it may be years before any of our product candidates receives regulatory approval, if at all, and additional clinical trials may fail to demonstrate safety, efficacy or tolerability for our targeted indications.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or any future collaborators and impair our ability to generate revenue from product sales, regulatory and commercialization milestones and royalties. Moreover, if we or any future collaborators are required to conduct additional clinical trials or other testing of our product candidates beyond the trials and testing that we or they contemplate, if we or they are unable to successfully complete clinical trials of our product candidates or other testing or the results of these trials or tests are unfavorable, uncertain or are only modestly favorable, or there are unacceptable safety concerns associated with our product candidates, we or any future collaborators may:

- incur additional unplanned costs, including costs relating to additional required clinical trials or preclinical testing;
- be delayed in obtaining marketing approval for vilobelimab or any of our other product candidates;
- not obtain marketing approval at all or the withdrawal or revocation of the EUA by the FDA or the European marketing authorization by responsible European regulatory authorities;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;

- be subject to additional post-marketing testing or other requirements; or
- be required to remove the product from the market after obtaining marketing approval or the EUA.

Our failure to successfully complete clinical trials of our product candidates and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any of our product candidates would significantly harm our business.

Our product candidates may cause or be perceived to 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, denial or withdrawal of regulatory approval by the FDA or comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. In addition, many of the patients that we enrolled in our clinical trials of vilobelimab suffer from serious pre-existing disorders. While such disorders may lead to serious adverse events, or SAEs, during trial periods that may be found to be unrelated to vilobelimab, such events may create a negative safety perception and adversely impact market acceptance of vilobelimab following any approval.

If unacceptable side effects arise in the development of our product candidates, we, the FDA or comparable foreign regulatory authorities, the Institutional Review Boards, or IRBs, or independent ethics committees at the institutions in which our studies are conducted or elsewhere, or the Data Safety Monitoring Board, or DSMB, could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Side effects, whether treatment-related or not, could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Moreover, clinical trials of our product candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any future collaborator, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, we, or others, discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

- regulatory authorities may withdraw their authorization or approval of the product or seize the product;
- we, or any future collaborators, may need to recall the product, or be required to change the way the product is administered or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we, or any future collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we, or any future collaborators, may be required to implement a REMS that imposes distribution and use restrictions or to conduct post-market studies or clinical trials;
- we, or any future collaborators, could be sued and held liable for harm caused to patients;

- the product may become less competitive; and
- our reputation may suffer.

Any of these events could harm our business and operations and could negatively impact our share price.

Our most advanced product candidates are either chimeric or humanized antibody proteins that could cause an immune response in patients, resulting in the creation of harmful or neutralizing antibodies against these therapeutic proteins

In addition to the safety, efficacy, manufacturing and regulatory hurdles faced by our product candidates, the administration of proteins such as monoclonal antibodies that are chimeric or humanized, including our product candidates vilobelimab and IFX002, respectively, can cause an immune response, resulting in the creation of antibodies against the therapeutic protein. These anti-drug antibodies, or ADAs, can have no effect or can neutralize the effectiveness of the protein or require that higher doses be used to obtain a therapeutic effect. Whether ADAs will be created and how they react can often not be predicted from preclinical or even clinical studies, and their detection or appearance is often delayed. As a result, neutralizing antibodies may be detected at a later date or upon longer exposure of patients with our product candidates, such as following more chronic administration in longer lasting clinical trials. In some cases, detection of such neutralizing antibodies can even occur after pivotal clinical trials have been completed. Therefore, there can be no assurance that neutralizing antibodies will not be detected in future clinical trials or at a later date upon longer exposure (including after commercialization). If ADAs reduce or neutralize the effectiveness of our product candidates, the continued clinical development or receipt of marketing approval for any of our product candidates could be delayed or prevented and, even if any of our product candidates is approved, their commercial success could be limited, any of which would impair our ability to generate revenue and continue operations. Low levels of ADAs were detected in previously completed clinical studies.

Even if we complete the necessary preclinical studies and clinical trials for vilobelimab and any other product candidates, the marketing approval process including the EUA and European marketing authorization process is expensive, time consuming and uncertain and may prevent us or any future collaborators from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we, or any future collaborators, will obtain marketing authorization or approval to commercialize a product candidate

The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of products are subject to extensive regulation by the FDA and comparable foreign regulatory authorities. We, and any future collaborators, are not permitted to market our product candidates in the United States or in other countries until we, or they, receive approval of a BLA or the EUA from the FDA or marketing approval from applicable regulatory authorities in other countries. Our product candidates are in various stages of development and are subject to the risks of failure inherent in drug development. We have not submitted an application for or received marketing approval for any product candidate in the United States or in any other jurisdiction. We have limited experience in conducting and managing the clinical trials necessary to obtain marketing approvals, including FDA approval of a BLA or EUA. Further, there is no prior history of regulatory approval for product candidates targeting C5a inhibition.

The process of obtaining marketing authorizations or approvals, both in the United States and elsewhere is lengthy, expensive and uncertain. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval, including the EUA, requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval, including the EUA, also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate's clinical development and may vary among jurisdictions. Any marketing approval, including the EUA, we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. For example, the EUA for the GOHIBIC (vilobelimab) has been granted for the treatment

of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV or ECMO. In addition, the EC has granted marketing authorization under exceptional circumstances for GOHIBIC (vilobelimab) for the treatment of adult patients with SARS-CoV-2-induced ARDS who are receiving systemic corticosteroids as part of standard of care and receiving IMV (with or without ECMO). The FDA, EMA or any comparable foreign regulatory authorities may delay, limit or deny approval of vilobelimab for many reasons, including:

- we may not be able to demonstrate that vilobelimab is safe and effective as a treatment for our targeted indications, excluding GOHIBIC (vilobelimab) in certain applications for the treatment of COVID-19 in hospitalized adults, to the satisfaction of the FDA, the EMA or certain comparable foreign regulatory agencies;

- the FDA, EMA or comparable foreign regulatory authorities may require additional activities, clinical trials or non-clinical studies of vilobelimab in addition to those already performed or planned, either before approval or as a post-approval commitment, which would increase our costs and prolong our development time for vilobelimab;

- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA, EMA or comparable foreign regulatory authorities to obtain marketing approval;

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials, including designated clinical endpoints;

- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;

- the contract research organizations, or CROs, that we retain to conduct clinical trials may take actions outside of our control that materially adversely impact our clinical trials;

- the FDA, EMA or comparable foreign regulatory authorities may not find the data from preclinical studies and clinical trials sufficient to demonstrate that the clinical and other benefits of vilobelimab and any other product candidates outweigh its safety risks;

- the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies and clinical trials;

- the FDA, EMA or comparable foreign regulatory authorities may not accept data generated at clinical trial sites, including for non-compliance with cGCP;

- if our BLA, when submitted, is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;

- the FDA, EMA or comparable foreign regulatory authorities may require development of a risk evaluation and mitigation strategy, or REMS, as a condition of approval;

- the FDA, EMA or comparable foreign regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers, including non-compliance with current Good Manufacturing Practices, or cGMP; or

- the FDA, EMA or comparable foreign regulatory authorities may change their respective approval policies or adopt new regulations.

Of the large number of drugs in development in the biopharmaceutical industry, only a small percentage result in the submission of a BLA to the FDA and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market vilobelimab, any such approval may be subject to limitations on the indicated uses or patient populations for which we may market the product. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we cannot assure you that vilobelimab and/or any other product candidates will be successfully developed or commercialized.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authorities. The FDA or other regulatory authorities may conclude that a principal investigator, potentially including because of a financial relationship with us, has a conflict of interest that has affected interpretation of the study. The FDA or other regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or other regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing authorization or approval of one or more of our product candidates.

Any delay in obtaining or failure to obtain required approvals could negatively impact our ability or that of any future collaborators to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our share price.

We depend on enrollment of patients in our clinical studies for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected

We will also be required to identify and enroll a sufficient number of patients with PG, and potentially other indications, for our planned or ongoing clinical trial of vilobelimab in these indications. Some of these are rare disease indications or indication with a relatively small patient population. Trial participant enrollment could be limited in future trials given that many potential participants may be ineligible because they are already undergoing treatment with approved medications or are participating in other clinical trials.

Patient enrollment is affected by other factors, including:

- severity of the disease under investigation;
- design of the clinical trial protocol;
- size and nature of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under trial;
- perceived safety and tolerability of the product candidate;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including standard-of-care and any new drugs that may be approved for the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- our ability to monitor patients adequately during and after treatment.

Further, there are only a limited number of specialist physicians who treat patients with these diseases and major clinical centers are concentrated in a few geographic regions. We also may encounter difficulties in identifying and enrolling such patients with a stage of disease appropriate for our ongoing or future clinical trials. In addition, the process of finding and diagnosing patients may prove costly. Our inability to enroll a sufficient number of patients for any of our clinical trials, if any, would result in significant delays or may require us to abandon one or more clinical trials.

Previously, we experienced slower recruitment than anticipated in the clinical trials of vilobelimab in severe COVID 19, PG and cSCC, because of other compounds in clinical development for the same patient population, low disease prevalence, difficulties in diagnosis or due to restrictions at clinical trial sites in light of the COVID-

19 pandemic. Further delays in the completion of any clinical trials will increase our costs, slow down our product candidate development and delay or potentially jeopardize our ability to commence marketing and generate revenue. In addition, we may not be able to initiate or continue clinical trials required by the FDA, EMA or other foreign regulatory agencies for vilobelimab or any of our other product candidates that we pursue if we are unable to locate and enroll a sufficient number of eligible patients to participate in these clinical trials.

Even if one of our product candidates receives marketing approval, including the EUA, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable

Even if our other product candidates are approved by the appropriate regulatory authorities for marketing and sale or receives the EUA, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. As a general proposition, physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to existing therapies and do not want to switch therapies unless their physicians recommend doing so or they are required to do so due to lack of reimbursement for existing therapies. Further, we may face a lack of acceptance by the physician community of the efficacy of targeting C5a to inhibit terminal complement activation compared to targeting C5, which is well established in clinical practice (such as eculizumab). In addition, vilobelimab may not be accepted by physicians or patients if we cannot demonstrate, or if vilobelimab is perceived as not having, strong duration of effect, including compared to existing treatments. The duration of effect of vilobelimab has only been studied prospectively for durations less than the expected duration of any pivotal Phase 3 clinical trials. It is possible that the effects seen in shorter term clinical trials will not be replicated at later time points or in larger clinical trials. Further, even if we are able to demonstrate our product candidates' safety and efficacy to the FDA and other regulators, safety concerns in the medical community may hinder market acceptance.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, including management time and financial resources, and may not be successful. If any of our product candidates is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to competitive therapies, notwithstanding success in meeting or exceeding clinical trial endpoints;
- the prevalence and severity of any side effects;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions contained in the product's approved labeling;
- the strength of sales, marketing and distribution support;
- changes in the standard of care for the targeted indications for the product; and
- availability and amount of coverage and reimbursement from government payors, managed care plans and other third-party payors.

The failure of any of our product candidates, if authorized or approved, to find market acceptance would harm our business and could require us to seek additional financing.

Even if we, or any future collaborators, are able to commercialize any product candidate that we, or they, develop, the product may become subject to unfavorable pricing regulations or third-party payor coverage and reimbursement policies, any of which could harm our business

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Therefore, our ability, and the ability of any future collaborators, to commercialize any of our product candidates will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from third-party payors including government health administration authorities and public or private health coverage insurers. Third-party payors decide which medications they will cover and establish reimbursement levels. We cannot be certain that reimbursement will be available for vilobelimab or any of our product candidates. Also, we cannot be certain that less fulsome reimbursement policies will not reduce the demand for, or the price we can charge for, our products, if approved. The insurance coverage and reimbursement status of newly approved products for orphan diseases is particularly uncertain and failure to obtain or maintain adequate coverage and reimbursement for vilobelimab or any other product candidates could limit our ability to generate revenue.

If coverage and reimbursement are not available, or reimbursement is available only to limited levels, we, or any future collaborators, may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, or any future collaborators, to establish or maintain pricing sufficient to realize a sufficient return on our or their investments. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. Marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sales price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we, or any future collaborators, might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability or the ability of any future collaborators to recoup our or their investment in one or more product candidates, even if our product candidates obtain marketing approval.

The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability or that of any future collaborators to sell our product candidates profitably. These payors may not view our products, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or those of any future collaborators, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost-control initiatives or other policy measures by government authorities could cause us, or any future collaborators, to decrease the price we, or they, might establish for products, which could result in lower than anticipated product revenues. If the prices for our products, if any, decrease or if governmental and other third-party payors do not provide coverage or adequate reimbursement, our prospects for revenue and profitability will suffer.

There may also be delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is authorized or approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services.

In addition, increasingly, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. We cannot be sure that

reimbursement coverage will be available for any product candidate that we, or any future collaborator, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of our product candidates for which we, or any future collaborator, obtain marketing authorization or approval could significantly harm our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates

We have limited marketing, sales or distribution capabilities and experience within our organization. If any of our product candidates is authorized or approved, we either have to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize any such candidate, or to outsource this function to a third party. These activities were initiated in 2023 regarding the FDA's EUA for GOHIBIC (vilobelimab) in the United States. Either of these options would be expensive and time consuming. Some or all of these costs may be incurred in advance of any approval of our product candidates, including our lead candidate vilobelimab. In addition, we may not be able to hire a sales force in the United States, Europe or other target market that is sufficient in size or has adequate expertise in the medical markets that we intend to target. To address these challenges with GOHIBIC (vilobelimab) in Europe, we are pursuing options with regard to product distribution through a commercial partner. These risks may be particularly pronounced due to our focus on severe COVID-19, as well as additional focus on PG, each of which are disease areas with relatively small patient populations. Any failure or delay in the development of our or third parties' internal sales, marketing and distribution capabilities would adversely impact the commercialization of vilobelimab and other future product candidates.

With respect to our existing and future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems (such as we are planning with GOHIBIC (vilobelimab) in the European Union), either to augment or to serve as an alternative to our own sales force and distribution systems. Our product revenue may be lower than if we directly marketed or sold any approved products. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any authorized or approved products. If we are not successful in commercializing any authorized or approved products, our future product revenue will suffer and we may incur significant additional losses.

We may be subject to risks in relation to shelf-life expiration of drug product for GOHIBIC (vilobelimab), including but not limited to substantial write-offs in the balance sheet

Our finished drug product for GOHIBIC (vilobelimab) for use of commercial purposes and/or clinical trials is subject to limited shelf-life periods. If we fail to use such finished drug product for the intended use prior to its shelf-life expiration, such drug product will have to be destroyed accordingly, which might cause additional and substantial costs and expense as well as which might lead to substantial write-offs of destroyed drug product.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success

We have limited financial and managerial resources, and therefore we intend to focus on developing product candidates for specific indications that we identify as most likely to succeed, in terms of both their potential for marketing authorization, approval and commercialization. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that may prove to have greater commercial potential.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty

arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate.

Clinical development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of vilobelimab or any other product candidate we may develop

The risk of failure for vilobelimab and any other product candidates we may develop such as INF904 is high. It is impossible to predict when or if vilobelimab will prove to be effective and safe in humans or will receive full regulatory approval for the treatment of severe COVID-19 in the U.S., for a PG indication, or other indications. Additionally, before regulatory authorities grant marketing approval or an EUA for vilobelimab, for any future indications, or any future product candidate that we seek to develop, we will be required to complete our ongoing extensive clinical trials to demonstrate safety and efficacy in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

We may experience numerous unforeseen events during or as a result of the regulatory authorization and/or approval process that could delay or prevent our ability to receive marketing approval or an EUA from regulators or commercialize vilobelimab or any future product candidate, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- clinical trials of our product candidates may produce negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, ethics committees or institutional review boards to suspend or terminate the trials;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators, ethics committees or institutional review boards may require that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks; and
- regulators or institutional review boards my not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site.

We could also encounter delays if a clinical trial is suspended or terminated by us, by an overseeing ethics committee, by the institutional review boards of the institutions in which such trials are being conducted, by the data safety monitoring board for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination 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 or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. 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 drug revenues from any of these product candidates will be delayed. 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 drug 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.

Our product development costs will further increase if we experience delays in testing or marketing approvals. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring drugs to market before we do and impair our ability to successfully commercialize our product candidates. We are evaluating applications for orphan drug or breakthrough therapy designation for vilobelimab in various indications, but we may be unable to obtain any such designation or to maintain the benefits associated with orphan drug status, including market exclusivity, even if that designation is granted

We are evaluating applications for orphan drug or breakthrough therapy designation for vilobelimab in some indications, and we may seek orphan drug designation for other preclinical product candidates in our pipeline or that we may develop. In the United States and other countries, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA or other foreign regulatory agency grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the FDA review and approval process. Breakthrough therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint. Breakthrough therapy designation may make us eligible for intensive guidance by the FDA on an efficient drug development program and organizational commitment involving senior FDA managers, among others. Although we are evaluating applications for orphan drug or breakthrough therapy designation in some indications, there can be no assurance that we will obtain such designations. Moreover, obtaining orphan drug or breakthrough therapy designation for one indication does not mean we will be able to obtain such designation for another indication.

If a product that has orphan drug designation from the FDA subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same drug for the same indication for seven years, except in limited circumstances such as if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Similarly, the FDA can subsequently approve a drug with the same active moiety for the same condition during the exclusivity period if the FDA concludes that the later drug is clinically superior, meaning the later drug is safer, more effective, or makes a major contribution to patient care. Even if we were to obtain orphan drug designation for vilobelimab from the FDA, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products, and thus approval of vilobelimab could be blocked for seven years if another company obtains approval and orphan drug exclusivity for the same drug and same condition before us. If we do obtain exclusive marketing rights in the United States, they may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of the relevant patients. Further, exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition, the same drugs can be approved for different indications and might then be used off-label in our approved indication, and different drugs for the same condition may already be approved and commercially available.

Even if we obtain FDA approval or as we have received market authorization in Europe for vilobelimab or any of our other product candidates, we may never obtain authorization or approval to commercialize our products outside of the United States

In order to market any approved products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding clinical trial design, safety and efficacy. If approved by the relevant governmental authorities, we expect to market vilobelimab for the treatment of COVID-19 and other indications in Europe and jurisdictions outside the United States, in part due to the relatively larger patient population that exists in Europe as compared to that in the United States. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials, which would be

costly and time consuming and could delay or prevent introduction of vilobelimab or any of our other product candidates in those countries.

In addition, we expect to be subject to a variety of risks related to operating in other countries if we obtain the necessary approvals, including:

- differing regulatory requirements in countries outside the United States;
- the potential for so-called parallel importing (i.e., when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally);
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- foreign reimbursement, pricing and insurance regimes;
- compliance with tax, employment, immigration and labor laws for employees living or traveling outside the United States;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in countries that do not protect intellectual property rights to the same extent as in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities as well as supply chain disruptions outside the United States; and
- business interruptions, including as a result of geopolitical uncertainty and instability (including related to the Russia-Ukraine conflict, Hamas-Israel conflict and tensions between China and Taiwan).

If we or our partners fail to comply with regulatory requirements or to obtain and maintain required approvals, our target market will be reduced, including if we are unable to market vilobelimab in Europe or elsewhere, and our ability to realize the full market potential of our product candidates will be harmed.

We are subject to extensive government regulation and the failure to comply with these regulations may have a material adverse effect on our operations and business

Both before and after approval of any product, we and our suppliers, contract manufacturers and clinical investigators are subject to extensive regulation by governmental authorities in the United States and other countries, covering, among other things, testing, manufacturing, quality control, clinical trials, post-marketing studies, labeling, advertising, promotion, distribution, import and export, governmental pricing, price reporting and rebate requirements. Failure to comply with applicable requirements could result in one or more of the following actions: warning letters; unanticipated expenditures; delays in approval or refusal to approve a product candidate; product recall or seizure; interruption of manufacturing or clinical trials; operating or marketing restrictions; injunctions; criminal prosecution and civil or criminal penalties including fines and other monetary penalties; adverse publicity; and disruptions to our business. Further, government investigations into potential violations of these laws would require us to expend considerable resources and face adverse publicity and the potential disruption of our business even if we are ultimately found not to have committed a violation.

Obtaining FDA, EMA or other regulatory agency authorization or approval of our product candidates requires substantial time, effort and financial resources and may be subject to both expected and unforeseen delays, and there can be no assurance that any approval will be granted on any of our product candidates on a timely basis, if at all. The FDA, EMA or other regulatory agencies may decide that our data are insufficient for authorization or approval of our product candidates and require additional preclinical, clinical or other studies or additional work related to chemistry, manufacturing and controls, or CMC. If we are required to conduct additional trials or to conduct other testing of our product candidates beyond that which we contemplate for regulatory approval, if we are unable to complete successfully our clinical trials or other testing or if the results of these and other trials or tests fail to demonstrate efficacy or raise safety concerns, we may face substantial additional expenses, be delayed in obtaining marketing approval for our product candidates or may never obtain marketing approval.

We are also required to comply with extensive governmental regulatory requirements after a product has received marketing authorization or approval. Governing regulatory authorities may require post-marketing studies that may negatively impact the commercial viability of a product. Once on the market, a product may become associated with previously undetected adverse effects and/or may develop manufacturing difficulties. As a result of any of these or other problems, a product's regulatory approval could be withdrawn, which could harm our business and operating results.

Our current and future relationships with third-party payors, health care professionals and customers in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to significant penalties

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with health care professionals, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including the federal Anti-Kickback Statute and the federal civil False Claims Act, that may constrain the business or financial arrangements and relationships through which we conduct clinical research, sell, market and distribute any drugs for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation in the United States and other jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. Further, several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- federal civil and criminal false claims laws, including the federal civil False Claims Act (that can be enforced through civil whistleblower or qui tam actions), and the civil monetary penalties law, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the Physician Payments Sunshine Act, created under Section 6002 of Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the Affordable Care Act, and its implementing regulations, which requires specified manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other "transfers of value" made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals and applicable manufacturers to report annually to CMS ownership and investment interests held by physicians and their immediate family members by the 90th day of each calendar year. All such reported information is publicly available; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom may recommend, purchase or prescribe vilobelimab, if approved, may not comply with current or future statutes, regulations 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 these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including damages, fines, disgorgement, individual imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing authorization or approval of and commercialize vilobelimab and affect the prices we may obtain

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of vilobelimab, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing authorization or approval.

Among policy makers and payors 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. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives such as the Affordable Care Act in 2010, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of

healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our drug candidate.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year effective April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025, unless additional congressional action is taken. The American Taxpayer Relief Act of 2012, further reduced, among other things, Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and, accordingly, our financial operations.

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 commercialize our drugs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of vilobelimab, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent drug labeling and post-marketing testing and other requirements.

Even if we, or any future collaborators, obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products, which could impair our ability to generate revenue

Once marketing approval or an EUA has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulations. We, and any future collaborators, must therefore comply with requirements concerning advertising and promotion for any of our product candidates for which we or they obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we and any future collaborators will not be able to promote any products we develop for indications or uses for which they are not approved.

In addition, manufacturers of authorized and approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, assuming we, or any future collaborators, receive marketing approval for one or more of our product candidates, we, and any future collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

The manufacturing and distribution of GOHIBIC (vilobelimab) is subject to a number of risks that could harm our reputation, business, financial condition and operating results.

The manufacturing processes of GOHIBIC (vilobelimab) is complex. We may encounter manufacturing difficulties, including difficulties related to product storage and shelf-life. Such difficulties could result from the complexities of manufacturing product batches at a larger scale, equipment failure, availability of excipients and other product components/ingredients (including related to choice and quality of raw materials), analytical testing technology and product instability. Specifically, insufficient product stability or shelf-life of GOHIBIC (vilobelimab) or its components could materially limit or delay our or our collaborators' ability to distribute and commercialize GOHIBIC (vilobelimab) at the current price or at all. Further, if GOHIBIC (vilobelimab)

becomes subject to a product recall, including as the result of manufacturing errors, design/labeling defects or other deficiencies, our reputation would be adversely affected.

GOHIBIC (vilobelimab) is a "cold-chain product" that must be shipped and stored at cold temperatures. We could lose supply of GOHIBIC (vilobelimab) due to distribution difficulties, including generally related supply chain management (e.g., shelf-life expiration) and specifically related to shipping and storing GOHBIC (vilobelimab) at cold temperatures. If so, we could incur additional manufacturing costs in order to supply required quantities to U.S. hospitals under the EUA.

Any such manufacturing and distribution difficulties may harm our reputation, business, financial condition and operating results.

Governments, including those outside the United States, tend to impose strict price controls, which may adversely affect our revenues, if any

In many countries, such as countries of the European Union, the pricing of prescription pharmaceuticals is subject to varying price control mechanisms, often as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we, or any future collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed. Additional price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates, and we believe the increasing emphasis on cost-containment initiatives in the European Union has and will continue to put pressure on the pricing and usage of our product candidates. As a result, given the relatively smaller target markets for severe COVID-19 and PG, any reduced reimbursement for such product candidates may be insufficient for us to generate commercially reasonable revenue and profits and would adversely affect our financial condition and results of operations.

Any of our product candidates for which we, or any future collaborators, have obtained an EUA, marketing authorization or intend to obtain market approval in the future could be subject to post-marketing restrictions or withdrawal from the market and we, or any future collaborators, may be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our products following approval or the EUA

Any of our product candidates for which we, or any future collaborators, obtain marketing approval or the EUA, as well as the manufacturing processes, post-approval studies and measures, labeling, advertising and promotional activities for such product, among other things, will be subject to ongoing requirements of and review by the FDA, the EMA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval or the EUA of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a REMS.

The FDA, the EMA and other regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the authorized or approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we, or any future collaborators, do not market any of our product candidates for which we, or they, receive marketing approval for only their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing. Violation of the FDCA and other statutes relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws, including the False Claims Act.

In addition, later discovery of previously unknown adverse events or other problems with our products or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on the manufacturing of such products;
- restrictions on the labeling or marketing of such products;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- restrictions on coverage by third-party payors;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals, including the EUA;
- refusal to permit the import or export of products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Our ability to successfully commercialize and generate revenue from sales of GOHIBIC (vilobelimab) is subject to a number of risks that could harm our business, financial condition and operating results

Our ability to successfully commercialize GOHIBIC (vilobelimab) is subject to a number of risks that could impact our business, financial condition and operating results. Specifically, our ability to generate revenue from sales of GOHIBIC (vilobelimab) is uncertain, including due to the market opportunity for, and interest and perception in, GOHIBIC (vilobelimab). In particular, given fluctuations in the number of patients developing severe symptoms from COVID-19 infections, the size of the addressable patient population and, thus, the market opportunity for GOHIBIC (vilobelimab) is uncertain and may shrink over time. In addition, since GOHIBIC (vilobelimab) has been granted an EUA by the FDA, but not a full FDA approval, sales of GOHIBIC (vilobelimab) depend on whether healthcare providers at U.S. hospitals are interested in and receptive to providing GOHIBIC (vilobelimab) as a treatment for COVID-19. Specifically, if GOHIBIC (vilobelimab) is not included in the treatment guidelines issued by medical institutions and other third-party medical/healthcare organizations, such as the NIH or others, or if such institutions and organizations do not recommend GOHIBIC (vilobelimab), hospitals may not be willing to make GOHIBIC (vilobelimab) available for treatment of patients. Ultimately, if we are unable to successfully commercialize and generate revenue from sales of GOHIBIC (vilobelimab), our business, financial condition and operating results could be adversely affected.

3. Risks related to our dependence on third parties

We rely on third parties to conduct our clinical trials. If they do not perform satisfactorily, our business could be harmed

We do not independently conduct clinical trials of any of our product candidates. We rely on third parties, such as CROs, clinical data management organizations, third-party consultants, medical institutions and clinical investigators, to conduct these clinical trials and expect to rely on these third-parties to conduct clinical trials of any other product candidate that we develop. Any of these third parties may terminate their engagements with us under certain circumstances. We may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, there is a natural transition period when a new CRO begins work.

As a result, delays would likely occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects.

Further, although our reliance on these third parties for clinical development activities limits our control over these activities, we remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. For example, notwithstanding the obligations of a CRO for a trial of one of our product candidates, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA, the EMA and potentially other regulatory agencies of different countries require us to comply with requirements, commonly referred to as current Good Clinical Practices, or cGCP, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA and regulatory agencies inside the European Union and other regulatory agencies enforce these cGCP regulations through periodic inspections of trial sponsors, principal investigators, clinical trial sites and IRBs. If we or our third-party contractors fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory agencies may require us to perform additional clinical trials before approving our product candidates, which would delay the marketing approval process. We cannot be certain that, upon inspection, the FDA or other regulatory agencies will determine that any of our clinical trials comply with cGCP. We are also required to register clinical trials and post the results of completed clinical trials on a government-sponsored database, such as ClinicalTrials.gov in the United States, within certain timeframes. The same requirement applies to clinical trials outside the United States, such as EudraCT.ema.europa.eu in Europe. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties, including clinical investigators, do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

Our reliance on foreign third-party manufacturers and suppliers increases our risk of obtaining adequate, timely and cost-effective product candidates and products

Foreign manufacturing is subject to a number of risks, including political and economic disruptions, the imposition of tariffs, quotas and other import or export controls, changes in governmental policies and geopolitical uncertainty and instability, which have created market volatility. In particular, we rely on third-party manufacturer located in China and elsewhere for supply of vilobelimab. We outsource all manufacturing of our product candidates and products to third parties while conducting certain quality control tests in-house. The supply chain and manufacturing in China may, also as a result of the global political situation, significantly impact our operations.

We engage a third-party manufacturer located in China for the clinical and commercial supply of the final drug product formulation of vilobelimab. There is no assurance that we would be able to timely secure needed alternative supply arrangements on satisfactory terms, or at all, if needed. Our reliance on our manufacturer and our failure to secure alternative supply arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or, to commercialize them, if approved. There may be difficulties in scaling up to commercial quantities or optimization of processes and formulation of vilobelimab and the costs of manufacturing could be prohibitive.

Even if we were able to establish and maintain arrangements with other third-party manufacturers, reliance on third-party manufacturers generally entails additional risks beyond our control, including:

- reliance on third parties for manufacturing process development, regulatory compliance and quality assurance;
- reliance on third parties for storage and safeguarding of substantially all inventory;
- costs and validation of new equipment and facilities required for additional scale-up or optimization of processes;
- failure to comply with cGMP and similar foreign standards;
- limitations on supply availability resulting from capacity and scheduling constraints of third parties;
- lack of qualified backup suppliers for those components that are purchased from a sole or single source supplier;
- closures and restrictions on critical facilities resulting from public health crises;
- the ability to freely import clinical trial and marketing material manufactured at our third-party manufacturer in China into the countries in which the clinical trials are being conducted or product potentially to be sold;
- the possible breach of manufacturing agreements by third parties because of factors beyond our control; and
- the possible termination or non-renewal of the manufacturing agreements by the third party, at a time that is costly or inconvenient to us, and our ability to obtain alternative supply.

If we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our products. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other foreign regulatory authorities. In addition, a change of the manufacturing facility contains inherent risks and is generally viewed as a major change in the manufacturing process such that comparability studies have to be conducted to assure comparability between the before established manufacturing process and the newly established manufacturing process potentially causing delays in the drug product supply or, in case of a non-comparability of the manufactured drug product, warrant further additional pre-clinical and or clinical studies with such non-comparable drug product which may also be imposed by any regulatory agency upon review of the comparability data. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

The process of manufacturing biologics, such as vilobelimab, is extremely susceptible to product loss

The process of manufacturing our products is complex, highly regulated and subject to several other risks. The process of manufacturing biologics, such as vilobelimab, is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Further, our product candidates that have been produced and are stored for later use may degrade, become contaminated or suffer other quality defects, which may cause the affected product candidates to no longer be suitable for their intended use in clinical trials or other development activities. If the defective product candidates cannot be replaced in a timely fashion, we may incur significant delays in our development programs that could adversely affect the value of such product candidates and, thus, adversely affect our business, financial condition, results of operations and prospects.

Our manufacturing process is subject to quality control risks and related regulatory requirements

We participate in the manufacturing process with crucial quality control testing within our own laboratories, and we hold the manufacturer license for, and therefore oversee, the overall manufacturing process, and we are

responsible for ensuring that this part of our business also operates according to cGMP standards. Additionally, we hold an importing license. We therefore employ key personnel within the manufacturing process, such as a head of quality assurance, a head of manufacturing and a qualified person.

Thus, our laboratories and our quality control system and related documentation and personnel, are also subject to frequent governmental inspections to assure adherence to cGMP guidelines and to maintain our manufacturing and importing license. Related to these activities, there are risks which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects, including:

- a loss of key personnel within the manufacturing activities could result in significant delays in the manufacturing and release testing of our drug candidate and replacement of such personnel could be time consuming and be associated with additional costs for us;

- mistakes or misconduct within the release testing could result in false results which could result in both, the wrongfully rejection of a manufactured drug product from being released or the wrongfully acceptance of a dysfunctional drug product, causing data and trial results achieved with such drug product being false and potentially wrongly interpreted; and

- an inadequate cGMP compliance could result in a potential temporary or permanent loss of the manufacturing or importing license resulting from an inspection of regulatory agencies.

Our third-party manufacturers, or we, may not be able to comply with the cGMP regulatory requirements applicable to vilobelimab and biologics, including applicable provisions of the FDA's drug cGMP regulations, device cGMP requirements embodied in the Quality System Regulation, or QSR, or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. In addition, our third-party manufacturers and suppliers and we are subject to FDA and other local regulatory authority inspection from time to time. Failure by our third-party manufacturers and suppliers or us to pass such inspections and otherwise satisfactorily complete the FDA approval regimen with respect to our product candidate may result in regulatory actions such as the issuance of FDA Form 483 notices of observations, warning letters or injunctions or the loss of operating licenses.

In addition, we and our third-party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of the regulatory action, our clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could have a material adverse effect on our business, including our clinical research activities and our ability to develop our product candidates and market our products following approval, if any.

If any third-party manufacturer of our product candidates is unable to increase the scale of its production of our product candidates, and/or increase the product yield of its manufacturing, then our costs to manufacture the product may increase and commercialization may be delayed

In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of vilobelimab or any of our other product candidates in our pipeline or that we may develop, our third-party manufacturers will be required to increase their production and optimize their manufacturing processes while maintaining the quality of the product. The transition to larger scale production could prove difficult or costly. Further, any claims in our manufacturing process as a result of scaling up or optimization of the manufacturing, supply and fill process may result in the need to obtain regulatory approvals. If our third-party manufacturers are not able to optimize manufacturing process to increase the product yield for our product candidates or are unable to produce increased amounts of our product candidates while maintaining the quality of the product, then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits. Difficulty in achieving commercial scale-up production or production optimization or the need for additional regulatory approvals as a result could have a material adverse impact on our business and results of operations.

We expect to seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans

We expect to seek one or more collaborators for the development and commercialization of one or more of our product candidates. Likely collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. In addition, if we obtain marketing authorization or approval for product candidates from foreign regulatory authorities, we may enter into strategic relationships with international biotechnology or pharmaceutical companies for the commercialization of such product candidates outside of the United States.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the potential differentiation of our product candidate from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA, the EMA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Collaborations are complex and time-consuming to negotiate and document. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that may have resulted in a reduced number of potential future collaborators. Any collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations or to otherwise develop specified product candidates. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all.

If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

If we enter into collaborations with third parties for the development and commercialization of our product candidates, our prospects with respect to those product candidates will depend in significant part on the success of those collaborations

We expect to maintain existing collaborations and enter into additional collaborations for the development and commercialization of certain of our product candidates and in certain geographies. We may have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, any future collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms.

Collaborations involving our product candidates pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs, based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;

- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;

- disagreements with collaborators, including disagreements over proprietary rights, including trade secrets and other intellectual property, contract interpretation, or the preferred course of research and development might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly prosecute, maintain, defend or enforce our intellectual property rights or may use our proprietary information or other intellectual property in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or expose us to potential litigation;

- collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability;

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and

- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours is involved in a business combination, it could decide to delay, diminish or terminate the development or commercialization of any product candidate licensed to it by us.

Changes in funding or disruptions at the FDA and other governmental agencies caused by funding shortages or global health concerns could hinder their ability to perform normal business functions on which the operation of our business may rely, which could negatively impact our business

The ability of the FDA to review and clear or approve new product candidates and products can be affected by a variety of factors, including:

- government budget and funding levels, and statutory, regulatory and policy changes;

- the FDA's ability to hire and retain key personnel and accept the payment of user fees; and

- federal government shutdowns and other events that may otherwise affect the FDA's ability to perform routine functions.

Average review times at the agency have fluctuated in recent years as a result.

Further, if a prolonged government shutdown occurs, or if global health concerns continue to prevent or delay the FDA or other regulatory authorities from conducting, at all or in a timely manner, their regular inspections, reviews or other regulatory activities, the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions could be significantly impacted, which could have a material adverse effect on our business.

4. Risks related to our intellectual property

Our success depends on our ability to obtain, maintain, protect, defend and enforce patent, trade secret and other intellectual property protection

Our success depends on our ability to obtain, maintain, protect, defend and enforce patent, trade secret and other intellectual property protection in the United States and other countries with respect to vilobelimab and other proprietary product candidates. If we do not adequately protect, maintain, defend and enforce our intellectual property rights, competitors may be able to erode, negate or preempt any competitive advantage

we may have, which could adversely affect our business and ability to achieve profitability. To seek to protect our proprietary position, we file patent applications in the United States and in certain other countries related to our novel product candidates and their potential use in different medical indications that are important to our business. The patent application and approval process is expensive and time-consuming and we may not be able to file and prosecute all necessary or desirable patent applications and obtain and maintain issued patents at a reasonable cost or in a timely manner.

If the scope of the patent protection we obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the market may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, contractors, prospective business collaborators, clinical investigators and other third parties, any of these parties could breach the agreements and disclose such output before a patent application is filed, which could jeopardize our ability to seek and obtain patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights may be uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. For example, there can be no assurance that our issued patents contain and pending patent applications will contain, when granted, claims of sufficient breadth to cover all antibodies alleged to be a biosimilar of our product candidates. Furthermore, there can be no assurance that our issued patents will not be challenged at the United States Patent and Trademark Office, or USPTO, or foreign patent offices or in court proceedings, and if any such challenge were successful, the scope of our issued patent claims could be limited so as to not cover antibodies alleged to be a biosimilar of our product candidates. In addition, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of other countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including significant commercial markets, such as Europe, restrict the patentability of methods of treatment of the human body more than patent laws in the United States.

Some of our future patents and patent applications and other intellectual property may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications or other intellectual property, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we would need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Furthermore, we, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our patents covering our proprietary anti-C5a and anti C5aR technologies may be subject to challenge, narrowing, circumvention and invalidation by third parties

Any of our patents may be challenged, narrowed, circumvented, or invalidated by third parties. The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the United States and elsewhere. We may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, revocation,

reexamination, post-grant and inter partes review, or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, enforceability or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

In addition, our competitors and other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to vilobelimab or other product candidates but that uses a technology that falls outside the scope of our patent protection. Our competitors may also seek approval to market generic versions of any approved products and in connection with seeking such approval may claim that our patents are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We cannot be sure that we were the first to make the anti-C5a and anti-C5aR technologies claimed in our patents or patent applications or that we were the first to file for patent protection

Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, we cannot be certain that parties from whom we may license or purchase patent rights were the first to make relevant claimed inventions, or were the first to file for patent protection for them. If third parties have filed patent applications on inventions claimed in our patents or applications on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine who was the first to invent the subject matter covered our patent applications. If third parties have filed such applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs.

The patent application process is subject to numerous risks and there can be no assurance that we will be successful in obtaining patents for which we have applied

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until such patent is issued. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance 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. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;

- the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance;

- patent applications may not result in any patents being issued;

- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, narrowed, found to be unenforceable or otherwise may not provide any competitive advantage;

- our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our potential product candidates;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations and prospects.

It is difficult and costly to protect our intellectual property and our proprietary anti-C5a and anti-C5aR technologies, and we may not be able to ensure their protection

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for the composition, use and structure of our product candidates, the methods used to manufacture them, the related therapeutic targets and associated methods of treatment as well as on successfully defending these patents against potential third-party challenges. Our ability to protect our product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The ultimate determination by the USPTO or by a court or other trier of fact in the United States, or any corresponding foreign patent offices or courts or other triers of fact, on whether a claim meets all requirements of patentability cannot be assured. Although our C5a and C5aR inhibitor portfolio consists of six families of patents and patent applications that we own directed to C5a and C5aR inhibitors and related methods of use, we cannot predict the breadth of claims that may be allowed or enforced in our patents or patent applications, in our future licensed patents or patent applications or in third-party patents.

We cannot provide assurances that any of our patent applications will be found to be patentable, including over our own prior art patents, publications or other disclosures. Furthermore, given the differences in patent laws in the United States, Europe and other foreign countries, for example, the availability of grace periods for filing patent applications and what can be considered as prior art, we cannot make any assurances as to the scope of any claims that may issue from our pending and future patent applications in the United States or in other jurisdictions. Similarly, we cannot make any assurances as to the scope of any claims that may survive a proceeding initiated by a third party challenging the patentability, validity or enforceability of our patents and patent applications in the United States or in other jurisdictions. Any such challenge, if successful, could limit patent protection for our product candidates and/or materially harm our business.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we may not be able to generate sufficient data to support patent applications that protect the entire breadth of developments in one or more of our programs;

- it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent(s) will be insufficient to protect our technology or products, provide us with a basis for commercially viable products or provide us with any competitive advantages;

- if our pending patent applications issue as patents, they may be challenged by third parties as not infringed, invalid or unenforceable under United States or foreign laws; or

- if issued, the patents under which we hold rights may not be valid or enforceable.

In addition, to the extent that we are unable to obtain and maintain patent protection for one of our product candidates or in the event that such patent protection expires, it may no longer be cost-effective to extend our portfolio by pursuing additional development of a product or product candidate for follow-on indications. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Obtaining and maintaining patent protection of our anti-C5a and anti-C5aR technologies depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. We may enter into certain license agreements where we will not have the ability to maintain or prosecute patents in the portfolio and must therefore rely on third parties to take such actions and comply with certain requirements. Failure by us or our future or any existing licensors to maintain protection of our patent portfolio could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, it is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced, eliminated, invalid and/or unenforceable. If any of our present or future partners, collaborators, licensees, or licensors, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time and if we do not obtain protection under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Amendments, and similar non-U.S. legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available, however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar to our product candidates.

Depending upon the timing, duration and conditions of the FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments and similar legislation in the EU and other jurisdictions. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method

for manufacturing it may be extended. In Europe, a maximum of five and a half years of supplementary protection can be achieved for an active ingredient or combinations of active ingredients of a medicinal product protected by a basic patent, if a valid marketing authorization exists (which must be the first authorization to place the product on the market as a medicinal product) and if the product has not already been the subject of supplementary protection. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business, financial condition, results of operations and prospects.

Others may claim an ownership interest in our intellectual property and proprietary anti-C5a and anti-C5aR technologies which could expose us to litigation and have a significant adverse effect on our prospects

A third party may claim an ownership interest in one or more of our, or our future or any existing licensors', patents or other proprietary or other intellectual property rights. A third party could bring legal actions against us and seek monetary damages and/or enjoin clinical testing, manufacturing and marketing of the affected product or products. While we are presently unaware of any material claims or assertions by third parties with respect to our patents or other intellectual property, we cannot guarantee that a third party will not assert a claim or an interest in any of such patents or other intellectual property. If we become involved in any litigation, it could consume a substantial portion of our resources, and could cause a significant diversion of effort by our technical and management personnel. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product, in which case we may be required, for example, to pay substantial royalties or grant cross-licenses to our patents. We cannot, however, assure you that any such license will be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations as a result of claims of patent infringement or other violations of other intellectual property rights. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are sued for infringing, misappropriating, or otherwise violating intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing, misappropriating, or otherwise violating the proprietary or any other intellectual property rights of third parties. Third parties may have U.S. and non-U.S. issued patents and pending patent applications relating to compounds, methods of manufacturing compounds and/or methods of use for the treatment of the disease indications for which we are developing our product candidates that may cover our product candidates or approach to complement inhibition. If any third-party patents or patent applications are found to cover our product candidates or their methods of use or manufacture, or our approach to complement inhibition, we may not be free to manufacture or market our product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms or at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates, including interference and post-grant proceedings before the USPTO. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the composition, use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be pending patent applications which may later result in issued patents that our product candidates may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Accordingly, third parties may assert infringement claims against us based on intellectual property rights that exist now or arise in the future. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants,

including us, which patents cover various types of products or methods of use or manufacture. The scope of protection afforded by a patent is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe, misappropriate, or otherwise violate a third party's intellectual property right, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or commercializing the infringing product candidate or product. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us; alternatively or additionally, it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the trade secrets or other confidential information of any third parties could have a similar negative impact on our business. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property and proprietary anti-C5a and anti-C5aR technologies

Many of our current and former employees and our licensors' current and former employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including some which may be competitors or potential competitors. Although we try to ensure that our employees 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 these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who are involved in the development of intellectual property for us within the scope of such employees', consultants' and contractors' employment or other engagement by us to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, or such agreements may be breached or alleged to be ineffective, which may result in claims by or against us related to the ownership of such 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. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may lose exclusivity to certain of our intellectual property rights to the German federal government

We hold all of our intellectual property through our wholly owned subsidiary InflaRx GmbH in Germany. In the event of a national epidemic or pandemic, the German federal government, and the Federal Ministry of Health and other authorities have the right to order the use of our owned and in-licensed patents in the interest of the public welfare or the security of the Federal Republic of Germany. The German federal government may

issue such an order with respect to our owned and in-licensed patents and we may lose exclusivity with respect to the technologies covered by such patents.

Additionally, the research resulting in certain of our patents and technology, including patents and technology relating to our clinical development in severe COVID-19, was funded in part by the German federal government. Results of such government funded research projects must, subject to certain conditions, be made available free of charge for academic research and teaching in Germany and must be published in bi-annual interim reports and a final report following completion of the funded work. Information relating to intellectual property generated, commercial expectations, scientific chances of success, next steps and certain additional information must be disclosed to the German government and to third parties for academic research and teaching upon request under a written confidentiality agreement. The German federal government additionally has, in the case of a special public interest, a non-exclusive and transferable right to use intellectual property generated as part of the funded work.

Certain of our employees and directors are subject to German law, including as it relates to the ownership of, and compensation for, inventions

A number of our personnel, including some of our directors, work in Germany and may be subject to German employment law. Inventions that may be the subject of a patent or of protection as a utility model as well as technical improvement proposals for other technical innovations that may not be the subject of a patent or of protection as a utility model made by such employees are subject to the provisions of the German Act on Employees' Inventions (Gesetz über Arbeitnehmererfindungen), which regulates the ownership of, and compensation for, inventions made by employees. We face the risk that disputes may occur between us and our current or past employees pertaining to the sufficiency of compensation paid by us, allocation of rights to inventions under the German Act on Employee's Inventions or alleged non-adherence to the provisions of this act, any of which may be costly to resolve and take up our management's time and efforts whether we prevail or fail in such dispute. In addition, under the German Act on Employees' Inventions, certain employees retain rights to patents they invented or co-invented and disclosed to us prior to October 1, 2009. While we believe that all of our current and past German employee inventors have subsequently assigned to us their interest in patents and inventions they invented or co-invented, there can be no assurance that all such assignments are fully effective. Even if we lawfully own all inventions of our employee inventors who are subject to the German Act on Employees' Inventions, we are required under German law to reasonably compensate such employees for the use of the patents.

If any of our current or past employees obtain or retain ownership of any inventions or other intellectual property rights that we believe we own, we may lose valuable intellectual property rights and may be required to obtain and maintain licenses from such employees to such inventions or intellectual property rights, which may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain a license to any such employee's interest in such inventions or intellectual property rights, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. In addition, any loss of exclusivity of our intellectual property rights could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not be able to enforce our intellectual property rights throughout the world

Filing, prosecuting, maintaining, enforcing and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our product candidates.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in the United States and foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection 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, including India, China and other countries, do not favor the enforcement of patents and other

intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation or other violations of our other intellectual property rights. For example, many countries outside the United States have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and market their own products and, further, may export otherwise infringing products to jurisdictions where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. 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.

Agreements under which we may be granted a license to any patent rights may not give us sufficient rights to permit us to pursue enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents (or control of enforcement or defense) of such patent rights in all relevant jurisdictions as requirements may vary.

Proceedings to enforce our patent rights in the United States or foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Moreover, such proceedings could put our patents at risk of being invalidated or interpreted narrowly and 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. Furthermore, while we intend to seek to protect our intellectual property rights in major markets for our product candidates, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful

Our competitors and others may infringe, misappropriate or otherwise violate our patents or other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement or other claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel.

Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving one or more of our patents could limit our ability to assert those patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from developing, making and selling similar or competitive products. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of our ordinary shares. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Any such litigation could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Our 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 or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections that we are unable to overcome, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

If we fail to comply with our obligations under any future or other intellectual property licenses with third parties, we could lose license rights that are important to our business

We may be reliant upon licenses to certain patent rights and proprietary anti-C5a and anti-C5aR technologies and other intellectual property from third parties that are important or necessary to the development of our product candidates and the manufacture and other commercialization of our products. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop, manufacture or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing, manufacturing and commercializing competitive products in territories included in all of our licenses. Our licensors may have sublicensed patents and other intellectual property owned by a third party, or relied on third-party consultants or collaborators or funds from third parties that have an ownership or other right, title or interest in or to such in-licensed intellectual property, such that our licensors are not the sole and exclusive owners of the patents and other intellectual property we in-license. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In addition, agreements under which we may license patent rights may not give us control over patent filings prosecution or maintenance, so that we may not be able to control which claims or arguments are presented and may not be able to secure, maintain, or successfully enforce and defend necessary or desirable patent protection from those patent rights. We cannot be certain that patent filing prosecution and maintenance activities by our licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. Even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our future or any existing licensors, and cannot guarantee that we would receive it and on what terms. We cannot be certain that our future licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in any licensed patents. If we cannot obtain patent protection or enforce existing or future patents against third parties, it could have a material adverse effect on our business, financial condition, results of operations and prospects.

Further, agreements under which we may license technology or any other intellectual property to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant technology or any other intellectual property, or increase what we believe to be our financial or other obligations under the relevant agreement. Moreover, if disputes over technology or other intellectual property that we may license prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop manufacture and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights that may be granted under license agreements and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property rights of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under current and any future collaborative development relationships;

- our diligence obligations under any license agreement and what activities satisfy such obligations;
- the inventorship and ownership of inventions and know-how and other intellectual property resulting from the joint creation or use of intellectual property by our license counterparties and us and our partners; and
- the priority of invention of patented technology.

In spite of our best efforts, our license counterparties might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, which may remove our ability to develop manufacture- and commercialize the product candidates and technology covered by these license agreements. If any in-licenses are terminated, competitors may be able to seek regulatory approval of, and to market, products identical to ours. It is possible that we may be unable to obtain any additional licenses that we require at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our product candidates, technology, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop, manufacture or commercialize the affected product candidates, which could harm our competitive position, business, financial conditions, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be negatively impacted and our business would be harmed

In addition to the protection afforded by patents, we also rely on trade secret protection for certain aspects of our intellectual property. However, trade secrets are difficult to protect. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, advisors, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants and independent contractors. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed or otherwise obtained by a competitor or other third party, it could have a material adverse effect on our business, financial condition, results of operations and prospects.

5. Risks related to employee matters and managing growth

We only have a limited number of employees to manage and operate our business

As of December 31, 2024, we had 74 full-time or part-time employees (2023: 66) .Our focus on the development and commercialization of vilobelimab requires us to optimize cash utilization and to manage and operate our business with limited personnel. We cannot assure you that we will be able to hire additional employees and/or retain adequate staffing levels to develop and commercialize vilobelimab or run our operations or to accomplish all the objectives that we otherwise would seek to accomplish.

We depend heavily on our executive officers and directors, and the loss of their services would materially harm our business

Our success depends, and will likely continue to depend, upon our ability to hire and retain the services of our current executive officers, directors, principal consultants and others. We are highly dependent on the management, development, clinical, financial and business development expertise of Niels Riedemann, our Chief Executive Officer, Renfeng Guo, our Chief Scientific Officer, Thomas Taapken, our Chief Financial Officer, and, Camilla Chong, our Chief Medical Officer. Our ability to compete in the biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel.

Our industry has experienced a high rate of turnover of management personnel in recent years. Any of our personnel may terminate their employment at will. If we lose one or more of our executive officers or other key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain marketing approval of and commercialize products successfully.

Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

We rely on consultants and advisors, including scientific, strategic, regulatory and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize our product candidates will be limited.

We expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations

We expect to expand scope of our operations, particularly in the areas of clinical development and regulatory affairs. To manage such growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of its attention to managing these growth activities. Moreover, our expected growth could require us to relocate to a different geographic area of the country. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion or relocation of our operations, retain key employees, or identify, recruit, attract and train retain human capital. Competition for qualified, motivated, and highly-skilled executives, professionals and other key personnel in biotechnology and pharmaceuticals industries is significant. Our inability to manage the expansion or relocation of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful development and commercialization of our product candidates.

Our employees, independent contractors, consultants, collaborators and CROs may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation

We are exposed to the risk that our employees, independent contractors, consultants, collaborators and CROs may engage in fraudulent conduct or other illegal activity. Misconduct by those parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (ii) manufacturing and clinical trial conduct standards, (iii) federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities, and (iv) laws that require the reporting of financial information or data accurately. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, 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 be in compliance with such laws, standards or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and

future earnings, and curtailment of our operations, any of which could have a material adverse effect on our ability to operate our business and our results of operations.

6. Risks related to our ordinary shares and our status as a public company

The trading price of our ordinary shares has been and may in the future be highly volatile, which could result in substantial losses for holders of our ordinary shares, and a decline in our share price and invite securities litigation against our company or our management

Our share price has been and is likely to be highly volatile in the future. The stock market in general and the market for smaller pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. You should consider an investment in our ordinary shares as risky and invest only if you can withstand a significant loss and wide fluctuations in the market value of your investment. The market price for our ordinary shares may be influenced by many factors, including:

- the timing, enrollment and results of clinical trials of vilobelimab and any other product candidates;
- regulatory actions with respect to vilobelimab, our other product candidates or our competitors' products and product candidates;
- the success of the commercialization of GOHIBIC (vilobelimab);
- the success of existing or new competitive products or technologies;
- any delay in our development or regulatory filings for vilobelimab or any future product candidate and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including the FDA's issuance of a "refusal to file" letter or a request for additional information;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- commencement or termination of collaborations for our development programs;
- failure or discontinuation of any of our development programs;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results or development timelines;
- announcement or expectation of additional financing efforts;
- sales of our ordinary shares by us, our insiders or other shareholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our shares;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology industries;

- general economic, industry, market and political conditions; and
- the other factors described in this 'ITEM 3. KEY INFORMATION — D. Risk factors' section.

In the past, securities class action litigation has often been brought against a company and its management following a decline in the market price of its securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years. Such litigation, if instituted against us, could cause us or members of our management to incur substantial costs and divert management's attention and resources from our business.

Future sales, or the possibility of future sales, of a substantial number of our ordinary shares could adversely affect the price of the shares and dilute shareholders

Future sales of a substantial number of our ordinary shares, or the perception that such sales will occur, could cause a decline in the market price of our ordinary shares. Pursuant to our at-the-market program subject to the Sales Agreement with Leerink Partners LLC, or Leerink Partners, dated June 28, 2024, for the sale of ordinary shares for an aggregate offering price of up to $75,000,000 from time to time through Leerink Partners acting as our agent, and potentially other offerings, we plan to continue to raise money to fund our operations through the issuance of our equity securities. If we or our existing shareholders sell substantial amounts of ordinary shares in the public market, or the market perceives that such sales may occur, the market price of our ordinary shares and our ability to raise capital through an issue of equity securities in the future could be adversely affected.

In addition, we have registered on a Form S-8 registration statement all ordinary shares that we may issue under our equity incentive plans. As a result, these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ordinary shares could decline.

On June 30, 2023, we filed a shelf registration statement on a Form F-3. The Registration Statement was declared effective by the SEC on July 11, 2023. Because the price per share of each share sold under the Registration Statement will depend on the market price of our shares at the time of the sale and other market conditions, it is not possible at this stage to predict the number of shares that ultimately may be offered and sold under the Registration Statement. If we sell ordinary shares, convertible securities or other equity securities, existing shareholders may be diluted by such sales, and in certain cases new investors could gain rights superior to those of our existing shareholders. Any sales of our ordinary shares, or the perception that such sales could occur, could have a negative impact on the trading price of our shares.

We have broad discretion in the use of our cash on hand and may invest or spend it in a way with which you do not agree and in ways that may not yield a return on your investment

As of December 31, 2024, we had €18.4million in cash and cash equivalents and €36.8 million in marketable securities (as of December 31, 2023, we had €12.8 million in cash and cash equivalents and €85.7 million in marketable securities) . Our management will have broad discretion in the use of such cash and could spend it in ways that do not improve our results of operations or enhance the value of our ordinary shares. You will not have the opportunity to influence our decisions on how to use our cash on hand. The failure by our management to apply these funds effectively could result in financial losses that could harm our business, cause the price of our ordinary shares to decline and delay the development of our product candidates. Pending its use, we may invest our cash on hand in a manner that does not produce income or that loses value.

We are a foreign private issuer and, as a result, we are not subject to U.S. proxy rules and are subject to Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company

We will report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act, (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified

information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their Annual Report on Form 20-F until four months after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their Annual Report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

As a foreign private issuer and as permitted by the listing requirements of Nasdaq, we follow certain home country governance practices rather than the corporate governance requirements of Nasdaq

We are a foreign private issuer. As a result, in accordance with the listing requirements of Nasdaq we rely on home country governance requirements and certain exemptions thereunder rather than relying on the corporate governance requirements of Nasdaq. In accordance with Dutch law and generally accepted business practices, our Articles of Association do not provide quorum requirements generally applicable to general meetings of shareholders. To this extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock. Although we must provide shareholders with an agenda and other relevant documents for the general meeting of shareholders, Dutch law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally accepted business practice in the Netherlands; thus, our practice will vary from the requirement of Nasdaq Listing Rule 5620(b). As permitted by the listing requirements of Nasdaq, we have also opted out of the requirements of Nasdaq Listing Rule 5605(d), which requires, among other things, an issuer to have a compensation committee that consists entirely of independent directors and makes determinations regarding the independence of any compensation consultants, Nasdaq Listing Rule 5605(e), which requires independent director oversight of director nominations, and Nasdaq Listing Rule 5605(b)(2), which requires an issuer to have a majority of independent directors on its board. In addition, we have opted out of shareholder approval requirements, as included in the Nasdaq Listing Rules, for the issuance of securities in connection with certain events such as the acquisition of shares or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us and certain private placements. To this extent, our practice varies from the requirements of Nasdaq Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events. Accordingly, you may not have the same protections afforded to shareholders of companies that are subject to these Nasdaq requirements.

We do not anticipate paying any cash dividends on our share capital in the foreseeable future. Accordingly, shareholders must rely on capital appreciation, if any, for any return on their investment

We have never declared nor paid cash dividends on our share capital. We plan to retain all of our future earnings, if any, to finance the operation, development and growth of our business. In addition, the terms of any future debt or credit agreements and any restrictions imposed by applicable law may preclude us from paying dividends. As a result, capital appreciation, if any, of our ordinary shares will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our ordinary shares.

See “ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS —A. Major shareholders.” elsewhere in this Annual Report for more information regarding the ownership of our outstanding ordinary shares by our executive officers, directors and principal shareholders and their affiliates.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline

The trading market for our ordinary shares depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over such analysts. There can be no assurance that analysts will cover us or provide favorable coverage going forward. Securities or industry analysts may elect not to continue to provide research coverage of our ordinary shares, and such lack of research coverage may negatively impact the market price of our ordinary shares. In the event we do have analyst coverage, if one or more analysts downgrade our ordinary shares, change their opinion of our ordinary shares or publish inaccurate or unfavorable research about our business, our share price would likely decline. In addition, if one or more analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

Our ability to use our net operating loss carry forwards and other tax attributes may be limited

Our ability to utilize our NOLs, or NOLs, is limited, and may be limited further, under Section 8c of the German Corporation Income Tax Act (*Körperschaftsteuergesetz*), or *KStG*, and Section 10a of the German Trade Tax Act (*Gewerbesteuergesetz*), or *GewStG*. These limitations apply if a qualified ownership change, as defined by Section 8c KStG, occurs and no exemption is applicable. Generally, a qualified ownership change occurs if more than 50% of the share capital or the voting rights are directly or indirectly transferred to a shareholder or a group of shareholders within a period of five years. A qualified ownership change may also occur in case of a transaction comparable to a transfer of shares or voting rights or in case of an increase in capital leading to a respective change in the shareholding. In the case of such a qualified ownership change tax loss carry forwards expire in full. To the extent that the hidden reserves (*stille Reserven*) taxable in Germany exceed the tax loss carry forward, they may be further utilized despite a qualified ownership change. In case of a qualified ownership change within a group, tax loss carry forwards will be preserved if certain conditions are satisfied. Alternatively, tax loss carry forwards may be retained upon application under certain conditions, to the extent that the corporation has exclusively maintained the same business operations since its establishment or at least since the beginning of the third year prior to qualified ownership change (*fortführungsgebundener Verlustvortrag*). If the aforementioned application is made and, after the qualified change of ownership, this business operation is discontinued, the most recently determined tax loss carry forward (*fortführungsgebundener Verlustvortrag*) would be lost.

An appeal has been filed by the fiscal court of Hamburg dated August 29, 2017 – 2 K 245/17 with regard to Section 8c, paragraph 1, sentence 2 KStG (in its superseded version, now: Section 8c paragraph 1 sentence 1 KStG) that is, the forfeiture of all tax loss carryforwards in case more than 50% of shares/voting rights will be assigned to a new shareholder. The appeal is still pending. It is unclear when the Federal Constitutional Court will decide this case. According to statements in German legal literature, there are good reasons to believe that the Federal Constitutional Court may come to the conclusion that Section 8, paragraph 1, sentence 2 KStG (in its superseded version) is not in line with the German constitution.

As of December 31, 2024, we had NOL carry forwards for German corporate tax purposes of €238.4 million and for trade tax purposes €206.7 million available. Future changes in share ownership may also trigger an ownership change and, consequently, a Section 8c KStG, or a Section 10a GewStG limitation. Any limitation may result in the expiration of the complete tax operating loss carry forwards before they can be utilized. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carry forwards to reduce German income tax may be subject to limitations, which could potentially result in increased future cash tax liability to us.

As of December 31, 2024, our U.S. subsidiary, InflaRx Pharmaceuticals, Inc., had €15.75 million or $16.36 million of NOLs for U.S. federal income tax purposes. Transfers or issuances of our equity may impair or reduce the ability of InflaRx Pharmaceuticals, Inc. to utilize U.S. federal net operating loss carryforwards and certain other tax attributes in the future. Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, contains rules that limit the ability of a company that undergoes an "ownership change" to utilize its net operating loss and tax credit carry forwards and certain built-in losses recognized in years after the ownership change. An "ownership change" is generally defined as an increase in ownership of a corporation's stock by more than 50 percentage points over a rolling three-year period by stockholders that own (directly, indirectly or constructively) 5% or more of the stock of a corporation at any time during the relevant rolling three-year period. If an ownership change occurs, Section 382 imposes an annual limitation on the use of pre-ownership change NOLs, credits and certain other tax attributes to offset taxable income earned after the ownership change. The annual limitation is generally equal to the product of the applicable long-term tax-exempt rate in effect for the month in which the ownership change occurs and the value of the company's stock immediately before the ownership change (subject to some adjustments). For example, this annual limitation may be adjusted to reflect any unused annual limitation for prior years and certain recognized (or treated as recognized) built-in gains and losses for the year. In addition, Section 383 generally limits the amount of tax liability in any post-ownership change year that can be reduced by pre-ownership change tax credit carryforwards or capital loss carryforwards. No assurance can be given that prior transactions have not resulted in an ownership change for purposes of Section 382 of the Code or that future transactions will not result in an ownership change. Even if a subsequent transaction does not result in an ownership change, it may materially increase the likelihood that we will undergo an ownership change in the future. Sales of our ordinary shares by stockholders, whose interests may differ from our interests, may increase the likelihood that we or one of our subsidiaries undergoes an ownership change. If we or our subsidiaries have or were to undergo an ownership change, it could result in increased future tax liability to us.

We may become taxable in a jurisdiction other than Germany and this may increase the aggregate tax burden on us

Since incorporation we intend to have, on a continuous basis, our place of effective management in Germany. We will therefore be a tax resident of Germany under German national tax law. By reason of our incorporation under Dutch law, we are also deemed tax resident in the Netherlands under Dutch tax law. However, based on our current management structure and current tax laws of the United States, Germany and the Netherlands, as well as applicable income tax treaties, and current interpretations thereof, we should be tax resident solely in Germany for the purposes of the convention between the Federal Republic of Germany and the Netherlands of 2012 for the avoidance of double taxation with respect to taxes on income, or the German-Dutch tax treaty.

Our sole tax residency in Germany for purposes of the German-Dutch tax treaty is subject to the application of the provisions on tax residency as stipulated in the German-Dutch tax treaty as amended from time to time. The Multilateral Convention to Implement Tax Treaty Related Measures to Prevent Base Erosion and Profit Shifting or the MLI, Germany and the Netherlands entered into, among other countries, should not, as of this date, affect the German-Dutch tax treaty's rules regarding tax residency.

The applicable tax laws, tax treaties or interpretations thereof may change, including the MLI choices and reservation. Furthermore, whether we have our place of effective management in Germany and are as such solely tax resident in Germany is largely a question of fact and degree based on all the circumstances, rather than a question of law, which facts and degree may also change. Changes to applicable laws or interpretations thereof and changes to applicable facts and circumstances (for example, a change of board members or the place where board meetings take place), or changes to applicable tax treaties, including a change to the application of the MLI may result in us becoming a tax resident of a jurisdiction other than Germany. As a consequence, our overall effective income tax rate and income tax expense could materially increase, which could have a material adverse effect on our business, results of operations, financial condition and prospects, which could cause our share price and trading volume to decline.

We believe it is likely that we were a passive foreign investment company, or a PFIC, for U.S. federal income tax purposes in 2021, 2022, 2023 and 2024, and we may be a PFIC in one or more future taxable years, which could result in adverse U.S. federal income tax consequences to U.S. investors

Under the U.S. Internal Revenue Code of 1986, as amended, or the Code, we will be a PFIC for any taxable year in which, after the application of certain look-through rules with respect to subsidiaries, either (i) 75% or more of our gross income consists of "passive income" or (ii) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, "passive income." Passive income generally includes, among other things, dividends, interest, certain non-active rents and royalties, and capital gains. Based on the nature of our business, our financial statements, our expectations about the nature and amount of our income, assets and activities and the expected price of our ordinary shares in this offering, we believe it is likely we were a PFIC in 2021, 2022 and 2023 and 2024, and we may be a PFIC for our current taxable year or in one or more future taxable years. In addition, we may, directly or indirectly, hold equity interests in other PFICs. Whether we or any of our subsidiaries will be a PFIC in 2025 or any future year is a factual determination that must be made annually at the close of each taxable year, and, thus, is subject to significant uncertainty; because a determination of whether a company is a PFIC must be made annually after the end of each taxable year and will depend on the composition of our income and assets and the market value of our assets from time to time, we cannot assure you that we will not be a PFIC for the current or any future taxable year. Accordingly, there can be no assurance that we will not be a PFIC in 2025 or any future taxable year.

If we are a PFIC for any taxable year during which a U.S. Holder (as defined below in "Material U.S. Federal Income Tax Considerations") holds our ordinary shares, we generally would continue to be treated as a PFIC with respect to that U.S. Holder for all succeeding years during which the U.S. Holder holds our ordinary shares, even if we ceased to meet the threshold requirements for PFIC status, unless certain exceptions apply. Such a U.S. Holder may be subject to adverse U.S. federal income tax consequences, including (i) the treatment of all or a portion of any gain on disposition as ordinary income, (ii) the application of a deferred interest charge on such gain and the receipt of certain dividends and (iii) compliance with certain reporting requirements. There is no assurance that we will provide information that will enable investors to make a qualified electing fund election, also known as a "QEF Election," which could mitigate the adverse U.S. federal income tax consequences should we be classified as a PFIC.

For further discussion, see "ITEM 10. ADDITIONAL INFORMATION —E. Taxation — Material U.S. Federal Income Tax Considerations for U.S. Holders of Ordinary Shares."

We may lose our foreign private issuer status which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses

We are 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. If in the future we are not a foreign private issuer as of the last day of the second fiscal quarter in any fiscal year, we would be required to comply with all of the periodic disclosure, current reporting requirements and proxy solicitation rules of the Exchange Act applicable to U.S. domestic issuers. 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 directors and executive officers may not be United States 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. If we were to lose this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and stock exchange rules. The regulatory and compliance costs to us if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the costs we would 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. These rules and regulations could also make it more difficult for us to attract and retain qualified directors.

If we ever pay dividends, we may need to withhold tax on such dividends payable to holders of our shares in both Germany and the Netherlands

We do not intend to pay any dividends to holders of our shares. However, if we do pay dividends, we may need to withhold tax on such dividends both in Germany and the Netherlands. As an entity incorporated under Dutch law any dividends distributed by us are subject to Dutch dividend withholding tax on the basis of Dutch domestic law. However, on the basis of the double tax treaty between Germany and the Netherlands, the Netherlands will be restricted from imposing dividend withholding tax if we continue to be a tax resident of Germany and our place of effective management is in Germany. However, Dutch dividend withholding tax is still required to be withheld from dividends if and when paid to Dutch resident holders of our shares (and non-Dutch resident holders of our shares that have a permanent establishment in the Netherlands to which their shareholding is attributable). As a result, upon a payment (or deemed payment) of dividends, we will be required to identify our shareholders in order to assess whether there are Dutch residents (or non-Dutch residents with a permanent establishment to which the shares are attributable) in respect of which Dutch dividend tax has to be withheld. Such identification may not always be possible in practice. If the identity of our shareholders cannot be determined, withholding of both German and Dutch dividend tax from such dividend may occur, upon a payment of dividends.

Furthermore, the withholding tax restriction referred to above is based on the current choices and reservation made by Germany under the MLI. If Germany changes its MLI choices and reservation, we may not be entitled to any benefits of the double tax treaty between Germany and the Netherlands, including the withholding tax restriction, as long as Germany and the Netherlands do not reach an agreement on our tax residency for purposes of the double tax treaty between Germany and the Netherlands, except to the extent and in such manner as may be agreed upon by the authorities. As a result, any dividends distributed by us during the period no such agreement has been reached between Germany and the Netherlands, may be subject to withholding tax both in Germany and the Netherlands.

We are a Dutch public company with limited liability. The rights of our shareholders are different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions and may not protect investors in a similar fashion afforded by incorporation in a U.S. jurisdiction

We are a public company with limited liability (*naamloze vennootschap*) organized under the laws of the Netherlands. Our corporate affairs are governed by our Articles of Association and by the laws governing companies incorporated in the Netherlands. However, there can be no assurance that Dutch law will not change in the future or that it will serve to protect investors in a similar fashion afforded under corporate law principles in the United States, which could adversely affect the rights of investors.

The rights of shareholders and the responsibilities of directors may be different from the rights and obligations of shareholders and board members in companies governed by U.S. law. In the performance of its duties, our executive officers and board of directors are required by Dutch law to consider the interests of our company, its shareholders, its employees and other stakeholders, 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.

Provisions of our Articles of Association or Dutch corporate law might deter acquisition bids for us that might be considered favorable and prevent, delay or frustrate any attempt to replace or remove the members of our board of directors

Under Dutch law, various protective measures are possible and permissible within the boundaries set by Dutch law and Dutch case law. Our governance arrangements include several provisions that may have the effect of making a takeover of our company more difficult or less attractive. In this respect, our general meeting of shareholders granted the right to an independent foundation under Dutch law, or protective foundation, to acquire preferred shares pursuant to a call option agreement, or the call option agreement, entered into between us and such foundation. This call option under the call option agreement shall be continuous in nature and can be exercised repeatedly on multiple occasions.

If the protective foundation exercises the call option pursuant to the call option agreement, an amount of preferred shares up to 100% of our issued capital held by others than the protective foundation, minus one share, will be issued to the protective foundation. These preferred shares will be issued to the protective foundation under the obligation to pay up to 25% of their nominal value upon issuance. In order for the protective foundation to finance the issue price in relation to the preferred shares, the protective foundation is expected to enter into a finance arrangement with a bank. As an alternative to securing financing with a bank, subject to applicable restrictions under Dutch law, the call option agreement provides that the protective foundation may request us to provide, or cause our subsidiaries to provide, sufficient funding to the protective foundation to enable it to satisfy the payment obligation (or part thereof) in cash and/or to charge an amount equal to the payment obligation (or part thereof) against our profits and/or reserves in satisfaction of such payment obligation.

The protective foundation's articles of association provide that it will promote and protect the interests of the company, the business connected with the company and the company's stakeholders from time to time, and repressing possible influences which could threaten the strategy, continuity, independence and/or identity of the company or the business connected with it, to such an extent that this could be considered to be damaging to the aforementioned interests. These influences may include a third party acquiring a significant percentage of our ordinary shares, the announcement of an unsolicited public offer for our ordinary shares, shareholder activism, other concentration of control over our ordinary shares or any other form of undue pressure on us to alter our strategic policies. The protective foundation shall be structured to operate independently of us.

If the protective foundation were to exercise its call option, the preferred shares to be issued pursuant thereto would be issued against the obligation to pay up to 25% of their nominal value. The voting rights of our shares are based on nominal value and, as we expect our ordinary shares to trade substantially in excess of nominal value, preferred shares issued at 25% of their nominal value can carry significant voting power for a substantially reduced price compared to the price of our ordinary shares and thus can be used as a defensive measure. These preferred shares will have both a liquidation and dividend preference over our ordinary shares and will accrue cash dividends at a pre-determined rate. The protective foundation would be expected to require us to cancel its preferred shares once the perceived threat to the company and its stakeholders has been removed or sufficiently mitigated or neutralized. However, subject to the same limitations described above, the protective foundation would continue to have the right to exercise the call option in the future in response to a new threat to the interests of us, our business and our stakeholders from time to time.

In addition, certain provisions of our Articles of Association may make it more difficult for a third party to acquire control of us or effect a change in our board of directors. These provisions include: a provision that our directors are appointed on the basis of a binding nomination prepared by our board of directors which can only be overruled by a two-thirds majority of votes cast representing more than 50% of our issued share capital; a provision that our directors may only be removed by the general meeting of shareholders by a two-thirds majority of votes cast representing more than 50% of our issued share capital (unless the removal is proposed by the board in which case a simple majority of the votes can be sufficient); and a requirement that certain matters,

including an amendment of our Articles of Association, may only be brought to our shareholders for a vote upon a proposal by our board of directors.

We are not obligated to and do not comply with all the best practice provisions of the Dutch Corporate Governance Code, or DCGC. This may affect your rights as a shareholder.

We are a Dutch public company with limited liability (*naamloze vennootschap*), and we are subject to the DCGC. The DCGC contains both principles and best practice provisions that regulate relations between the board of directors and the shareholders (such as the general meeting of shareholders). The DCGC is based on a "comply or explain" principle. Accordingly, companies are required to disclose in their annual reports, filed in the Netherlands, whether they comply with the provisions of the DCGC. If they do not comply with those provisions (for example, because of a conflicting Nasdaq requirement), the company is required to give the reasons for such non-compliance.

The DCGC applies to all Dutch companies listed on a government-recognized stock exchange, whether in the Netherlands or elsewhere, including Nasdaq. We do not comply with all the best practice provisions of the DCGC. For a list of DCGC best practices that we do not comply with including explanations for why not doing so, see the section "Corporate Governance" in the Dutch Board Report published on the Company's website. This may affect your rights as a shareholder and you may not have the same level of protection as a shareholder in a Dutch company that fully complies with the DCGC.

Claims of U.S. civil liabilities may not be enforceable against us

We are incorporated under the laws of the Netherlands, and our headquarters are located in Germany. Substantially all of our assets are located outside the United States. The majority of our directors and executive officers reside 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 to enforce against them or us in U.S. courts, including judgements predicated upon the civil liability provisions of the federal securities laws of the United States.

There is no treaty between the United States and the Netherlands for the mutual recognition and enforcement of judgements (other than arbitration awards) in civil and commercial matters. Therefore, a final judgement for the payment of money rendered by any federal or state court in the United States based on civil liability, whether or not predicated solely upon the U.S. federal securities laws, would not be enforceable in the Netherlands unless the underlying claim is relitigated before a Dutch court of competent jurisdiction. Under current practice, however, a Dutch court will generally, subject to compliance with certain procedural requirements, grant the same judgement without a review of the merits of the underlying claim if such judgement (i) is a final judgement and has been rendered by a court which has established its jurisdiction vis-à-vis the relevant Dutch companies or Dutch company, as the case may be, on the basis of internationally accepted grounds of jurisdiction, (ii) has not been rendered in violation of principles of proper procedure (behoorlijke rechtspleging), (iii) is not contrary to the public policy of the Netherlands, and (iv) is not incompatible with (a) a prior judgement of a Netherlands court rendered in a dispute between the same parties, or (b) a prior judgement of a foreign court rendered in a dispute between the same parties, concerning the same subject matter and based on the same cause of action, provided that such prior judgement is capable of being recognized in the Netherlands. Dutch courts may deny the recognition and enforcement of punitive damages or other awards.

Moreover, a Dutch court may reduce the amount of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Enforcement and recognition of judgements of U.S. courts in the Netherlands are solely governed by the provisions of the Dutch Code of Civil Procedure. Based on the foregoing, there can be no assurance that U.S. investors will be able to enforce any judgements obtained in U.S. courts in civil and commercial matters, including judgements under the U.S. federal securities.

The United States and Germany do not have a treaty providing for the reciprocal recognition and enforcement of judgements in civil and commercial matters. Consequently, a final judgement for payment or declaratory judgements 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 Germany. German courts may deny the recognition and enforcement of a judgement rendered by a U.S. court if they consider the U.S. court not to be competent or the decision to be in violation of German public policy principles. For example, judgements awarding punitive damages are generally not enforceable in Germany. A German court may reduce the amount

of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages.

In addition, actions brought in a German court against us, our directors, our executive officers and the experts named herein to enforce liabilities based on U.S. federal securities laws may be subject to certain restrictions. In particular, German courts generally do not award punitive damages. Litigation in Germany is also subject to rules of procedure that differ from the U.S. rules, including with respect to the taking and admissibility of evidence, the conduct of the proceedings and the allocation of costs. German procedural law does not provide for pre-trial discovery of documents, nor does Germany support pre-trial discovery of documents under the 1970 Hague Evidence Convention. Proceedings in Germany would have to be conducted in the German language and all documents submitted to the court would, in principle, have to be translated into German. For these reasons, it may be difficult for a U.S. investor to bring an original action in a German court predicated upon the civil liability provisions of the U.S. federal securities laws against us, our directors, our executive officers and the experts named in this Annual Report.

Based on the lack of a treaty as described above, U.S. investors may not be able to enforce against us or directors, executive officers or certain experts named herein who are residents of or possessing assets in the Netherlands, Germany, or other countries other than the United States any judgements obtained in U.S. courts in civil and commercial matters, including judgements under the U.S. federal securities laws.

7. General Risk Factors

General economic, political and social conditions. Our business and results of operations may be adversely affected by disruptions in the financial markets, changes to political and regulatory policies and economic conditions generally

General economic, political and social conditions affect the United States, Europe and other global markets and our business. In particular, U.S., European and other global markets, as well as our access to financing, may be affected by factors, including economic growth or its sustainability, persistent inflation, supply chain disruptions, employment levels, work stoppages, labor shortages and labor disputes, labor costs, wage stagnation, energy prices, oil, gas and fuel prices, fluctuations or other significant changes in both debt and equity capital markets and currencies, liquidity of the global financial markets, the growth of global trade and commerce, trade policies, the availability and cost of capital and credit (including as a result of increased interest rates) and investor sentiment and confidence. Additionally, global markets may be adversely affected by the current or anticipated impact of cyber incidents or campaigns, military conflict, including the Russia-Ukraine conflict as well as the Hamas-Israel conflict and rising tensions between China and Taiwan and the relationship between China and the United States, or other geopolitical uncertainty and instability. Any sudden or prolonged market downturn in the United States or elsewhere could adversely affect our business, results of operations and financial condition, including capital and liquidity levels.

Legal, regulatory or market measures to address environmental and other objectives may negatively affect our business or operations

Regulatory and legislative bodies in the United States, Europe and elsewhere continue to focus on environmental, social and governance, or ESG, matters including increasing attention on relating to climate change, greenhouse gas emissions, carbon taxes, emissions trading schemes, sustainable manufacturing, human rights and equity matters, and disclosure regarding the foregoing, many of which policies may be ambiguous, inconsistent, dynamic or conflicting. We expect to experience increased restrictions, compliance costs, legal costs and expenses related to such new or changing legal or regulatory requirements. Moreover, compliance with any such legal or regulatory requirements would require us to devote substantial time and attention to these matters. In addition, we may still be subject to penalties or potential litigation if such laws and regulations are interpreted or applied in a manner inconsistent with our practices. Additionally, we are subject to increased attention from the media, stockholders, activists and other stakeholders on climate change, social and sustainability matters, which could negatively affect our reputation or investor confidence.

We may not be able to maintain sufficient insurance to cover us for potential litigation or other risks

We may not be able to maintain sufficient insurance on commercially reasonable terms or with adequate coverage levels against potential liabilities we may face in connection with potential claims, which could have a material adverse effect on our business. We may face a risk of loss from a variety of claims, including related to securities, antitrust, contracts, cybersecurity, fraud and various other potential claims, whether or not such

claims are valid. Insurance and other safeguards might only partially reimburse us for our losses, if at all, and if a claim is successful and exceeds or is not covered by our insurance policies, we may be required to pay a substantial amount in respect of such successful claim. Certain losses of a catastrophic nature, such as losses arising as a result of wars, earthquakes, typhoons, terrorist attacks or other similar events, may be uninsurable or may only be insurable at rates that are so high that maintaining coverage would cause an adverse impact on our business, our investment funds and their investments. In general, losses related to terrorism are becoming harder and more expensive to insure against. Some insurers are excluding terrorism coverage from their all-risk policies. In some cases, insurers are offering significantly limited coverage against terrorist acts for additional premiums, which can greatly increase the total cost of casualty insurance for a property. As a result, we, our products and their investments may not be insured against terrorism or certain other catastrophic losses.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates

We expect our expenses may increase in connection with expansion of operations. To the extent that we raise additional capital through the issuance of ordinary shares, convertible securities or other equity securities, your ownership interest may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as an ordinary shareholder. In addition, debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming shares or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

If we raise additional funds through collaborations or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do, and reducing or eliminating our commercial opportunity

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we, or any future collaborators, may develop. Our competitors also may obtain the FDA or other marketing approval for their products before we, or any future collaborators, are able to obtain approval for ours, which could result in our competitors establishing a strong market position before we, or any future collaborators, are able to enter the market.

Many of our existing and potential future competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining marketing approvals and marketing approved products than we do, and may be able to reduce the price at which they sell their products. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly if acquired by, or through collaborative arrangements with, large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the development of our product candidates.

The development and commercialization of new products is highly competitive. We expect that we, and any future collaborators, will face significant competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to any of our product candidates that we, or any future collaborators, may seek to develop or commercialize in the future. For example, other pharmaceutical companies may commence development efforts for product candidates targeting the same indications as vilobelimab, including PG and severe COVID-19 or any other indications we may

target. For a detailed analysis of the competitive environment in which we operate, see "ITEM 4. INFORMATION ON THE COMPANY — B. Business Overview — Competition."

If any product liability lawsuits are successfully brought against us or any of our collaboration partners, we may incur substantial liabilities and may be required to limit commercialization of our product candidates

We face an inherent risk of product liability lawsuits related to the testing of our product candidates in seriously ill patients and will face an even greater risk if our product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us or our partners by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities.

If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies.

Although we maintain product liability insurance coverage, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if we commercialize any product that receives marketing approval. In addition, insurance coverage is becoming increasingly expensive and difficult to obtain. If we are unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could harm our business, financial condition, results of operations and prospects.

We may be unsuccessful in evaluating material risks involved in future acquisitions

We may, in the future, acquire companies, products and/or platforms that are complementary to our operational and customer needs. As part of the process, we may conduct business, legal and financial due diligence to identify and evaluate material risks involved in any particular transaction. Despite these efforts, we may be unsuccessful in ascertaining or evaluating all such risks. As a result, the intended advantages of any given acquisition may not be realized. If we fail to identify certain material risks from one or more acquisitions we may be exposed to significant costs and our business could be negatively impacted.

Cyber incidents or other failures in IT systems could result in information theft, data corruption and significant disruption of our business operations

We utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including deliberate cyber-attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication, both internal and those provided by third-party service provider. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data. The wars in Europe and in the Middle East, as well as the tensions between China and Taiwan may also result in heightened cybersecurity risk across our networks and platforms. We have implemented processes, procedures and internal control to mitigate cybersecurity risks and cyber intrusions and rely on industry accepted security measures and technology to securely maintain confidential and proprietary information maintained on our information systems. However, these measures, as well as our increased awareness of the nature and extent of a risk of a cyber-incident, do not guarantee that a cyber-incident will not occur or that our financial results, operations or confidential information will not be negatively impacted by such an incident, especially because cyber threats change frequently or are not recognized until launched and because cyber incidents can originate from a wide variety of sources. Similarly, there can be no assurance that our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems.

If a cyber incident were to occur and cause interruptions in our operations or any destruction or loss, corruption or unavailability of data, it could result in loss or misappropriation of confidential information, including trade secrets, other intellectual property or financial information, and a material disruption of our development programs and business operations, any of which could lead to significant delays or setbacks in our research and other further development and commercialization of our product candidates. For example, the loss

of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Finally, there has been significant evolution and developments in the use of artificial intelligence technologies, such as artificial generative chatbots. We cannot fully determine the impact or cybersecurity risk of such evolving technology to our business at this time.

Any such cyber incident or destruction or loss of data could have a material adverse effect on our business and prospects. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber incidents, including cyber-attacks or other data security breaches, and may incur significant additional expense to implement further data protection measures.

The legal and regulatory environment related to data privacy is becoming stricter, which could result in additional costs or changes to the manner in which we handle personal information, and a failure to comply with such laws or regulations, or to otherwise protect personal data in our possession or control, could result in fines, litigation, or other penalties as well as reputational damage

We are subject to laws, regulations, and contractual obligations related to privacy, data protection, information security, including (i) the EU General Data Protection Regulation, which came into effect on May 25, 2018 and which provides for greater penalties for noncompliance than previous European data protection laws, with potential fines of up to the greater of €20 million or 4% of total annual worldwide turnover and (ii) the California Consumer Privacy Act, which came into effect on January 1, 2020 and provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation.

As privacy, data protection and information security laws evolve and are implemented, interpreted and applied, our compliance costs may increase, particularly in the context of ensuring that adequate data protection and data transfer mechanisms are in place. Additionally, compliance with such obligations and regulations could significantly impact our current and planned privacy and information security practices, our collection, use, sharing, retention and safeguarding of personal data, and our current and planned business activities and operations. A failure to comply with such obligations or regulations could result in fines, litigation, or other penalties and adversely impact our reputation.

If our internal controls over financial reporting fail to be effective, such failure could result in material misstatements in our financial statements, cause investors to lose confidence in our reported financial and other public information and have a negative effect on the trading price of our ordinary shares

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Section 404 of the Sarbanes-Oxley Act of 2002 requires management of public companies to develop and implement internal controls over financial reporting and evaluate the effectiveness thereof. If we fail to design and operate effective internal controls, it could result in material misstatements in our financial statements, impair our ability to raise revenue, result in the loss of investor confidence in the reliability of our financial statements and subject us to regulatory scrutiny and sanctions, which in turn could harm the market value of our ordinary shares.

Banking system risk

We regularly maintain cash balances at third-party financial institutions in excess of the FDIC or other comparable foreign country (i.e., Germany) deposit insurance limits. If any banks or financial institutions at which we maintain cash balances enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments, or to draw on our existing lines of credit, may be threatened and could have a material adverse effect on our business and financial condition.

ITEM 2: INFORMATION ON THE COMPANY

History and development of the Company

We are a biopharmaceutical company pioneering anti-inflammatory therapeutics by targeting the complement system. We do this by applying our proprietary technologies to discover, develop and commercialize first-in-class, highly potent and specific inhibitors of the complement activation factor known as C5a and its receptor C5aR. The complement system is an integral part of the innate immune system and protects the body, for example by recognizing and removing bacteria, viruses, and other infectious agents, collectively referred to as pathogens. Terminal complement activation, to which the cleavage of C5 by C5-convertases is also referred to, leads to the release of C5a, which acts through its receptor C5aR. In addition, terminal complement activation, i.e., the cleavage of C5a from C5, can also be achieved directly through the extrinsic pathway by naturally occurring enzymes present throughout the body but not considered part of the complement system. With our therapeutic product candidates, we target C5a and its receptor C5aR to selectively inhibit the powerful inflammatory response observed in a wide variety of autoimmune and other inflammatory diseases elicited through C5a/C5aR activation.

Our lead product candidate, vilobelimab, is a novel intravenously delivered first-in-class anti-C5a monoclonal antibody that selectively binds to free C5a and has demonstrated disease-modifying clinical activity and tolerability in multiple clinical settings. We are and have been developing vilobelimab in a wide array of complement-mediated diseases with significant unmet medical need. These include PG, a chronic inflammatory skin disorder for which we started a Phase 3 study with the first patient treated in November 2023, the treatment of critically ill COVID-19 patients, for which we concluded a Phase 3 study in March 2022 and subsequently were granted the EUA by the FDA in April 2023, and marketing authorization, under exceptional circumstances, by the European Commission in January 2025. GOHIBIC is also being evaluated in a Phase 2 clinical platform study in broader ARDS, funded by the Biomedical Advanced Research and Development Authority (BARDA).

We are also developing INF904, an orally administered, small-molecule inhibitor of C5aR, for which we have completed Phase 1 study in healthy volunteers. Based on its mode of action, INF904 is a promising product candidate for being developed in several disease areas of inflammation, where orally available therapeutics are not available or do not meet the medical need. We decided to initially focus the INF904 development at chronic spontaneous urticaria, or CSU, and HS, with a single Phase 2a basket study ongoing that targets both indications.

We are also developing IFX002, a life-cycle management product for vilobelimab, which is currently in advanced pre-clinical stage.

Our legal and commercial name is InflaRx N.V and we were incorporated under the laws of the Netherlands on June 6, 2017, and our headquarters, as registered with the local court of Jena, is located in Jena, Germany. InflaRx was founded in 2007 as InflaRx GmbH by Professor Niels Riedemann and Professor Renfeng Guo in Jena, Germany. Our agent for service of process in the United States is InflaRx Pharmaceuticals, Inc. located at 600 South Wagner Road, Ann Arbor, Michigan 48103. Our principal executive offices and laboratories are located in Winzerlaer Str. 2, 07745 Jena, Germany, telephone: (+49) 3641 508 180. We have additional offices in Planegg-Martinsried (Munich), Germany and in Ann Arbor, Michigan, United States, where we also have laboratories.

We employ a total of 74 employees, 21 of whom have M.D. or Ph.D. degrees. Our management team has extensive experience in the field of complement research, clinical research and the biopharmaceutical industry. Both our Chief Executive Officer and founder, Professor (Dr.) Niels Riedemann, and our Chief Scientific Officer and founder, Professor Renfeng Guo, have over 20 years of complement research experience, having published extensively on the role and function of C5a and its receptors. Our Chief Financial Officer, Dr. Thomas Taapken, has served in executive positions and boards for various private and public European biotechnology companies over the last 20 years and has over 25 years total experience in managerial roles in the biopharmaceutical and venture capital industries. Our Chief Medical Officer, Dr. Camilla Chong, has 25 years of experience in the global pharmaceutical industry in the areas of clinical development, medical affairs, clinical operations, regulatory and pharmacovigilance as well as the launch of new medicines.

The SEC maintains a website that contains reports and other information about issuers, like us, that file Electronically with the SEC. The address of that website is www.sec.gov. Our website can be found at www.inflarx.de. The information on our website is not incorporated by reference into this Annual Report, and you should not consider information contained on our website to be a part of this Annual Report.

Business overview

Overview

C5a is a central mediator of the complement system and therefore a critical component of the innate immune system. The most prominent role of the complement system is to help the body defend itself against invading microorganisms through several mechanisms, including the rapid creation of an inflammatory environment and the production of factors that directly kill pathogens and recruit immune cells to sites of infection. Activation of the complement system ultimately results in the generation of C5a by cleavage from C5. C5a creates an inflammatory environment by attracting and strongly activating neutrophils as well as by causing many different cell types to generate pro-inflammatory molecules. Such inflammation normally benefits the body by helping to fight infection, but excessive or uncontrolled generation of C5a, as it occurs in certain diseases, can cause severe damage to the body's own tissue, thereby contributing to the pathophysiology of many autoimmune and inflammatory diseases.

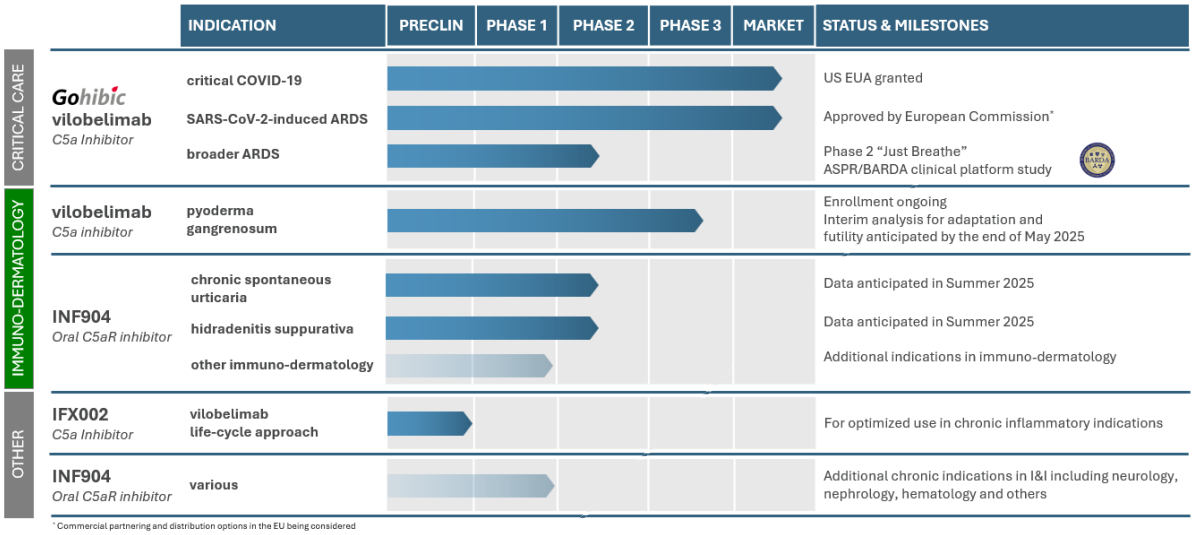
While the mode of action of C5a in inflammation has been intensely researched and confirmed, developing a highly specific antibody with the ability to fully block C5a while preserving a critical innate defense mechanism, the formation of the Membrane Attack Complex, or MAC, has been challenging. As such, there are currently no approved drugs other than vilobelimab that specifically target C5a. We identified antibodies, including our lead product candidate vilobelimab, that potently and selectively bind to a conformational epitope that is formed by C5a upon the cleavage of C5a from C5 that completely blocks C5a without compromising important upstream functions of the complement system, as well as MAC formation.

Unlike its ligand C5a, C5aR can also be pharmacologically inhibited by small molecules. It is generally believed that blockade of C5a using antibodies offers a fast, complete, and safe way to control C5a-induced inflammation. The advantage of a small molecule inhibitor to C5aR is that it can be administered orally, thereby offering broad, long-term ease of administration to patients, especially for the treatment of chronic diseases.

Through our in-house drug discovery efforts, we identified a potent inhibitor of the C5a receptor, INF904, which we believe is a promising candidate for development. We plan on targeting complement-mediated, chronic auto-immune and inflammatory conditions where an oral small molecule is needed for patients.

Given the different advantages of blocking C5a and C5aR, we believe that the development of both, C5a and C5aR blocking agents is possible and potentially helpful to address a broader range of C5a/C5aR-molecular signaling axis-associated diseases.

Based on the broad anti-inflammatory properties, we are currently developing our lead anti-C5a antibody and our low molecular weight compound INF904 in several diseases. An overview can be found in the pipeline description below.



Vilobelimab for the treatment of PG

We are developing vilobelimab for the treatment of PG. PG is a rare, chronic inflammatory form of neutrophilic dermatosis characterized by accumulation of neutrophils in the affected skin areas. Vilobelimab was granted orphan drug designation for the treatment of PG by both the FDA in the United States and the EMA in Europe as well as fast track designation by the FDA. After a series of interactions with the FDA on the results of our successfully conducted Phase 2 clinical study and our plans for the further development towards a potential BLA submission, in 2023 we announced the start of a Phase 3 study with vilobelimab in ulcerative PG. In November 2023, we announced the enrollment of the first patient in the study. In March 2025, we announced that the Phase 3 blinded interim analysis is expected by the end of May 2025.

Vilobelimab for the treatment of severe COVID-19

In April 2023, we received an EUA from FDA for GOHIBIC (vilobelimab) for the treatment of critically ill, invasively mechanically ventilated COVID-19 patients. The EUA is supported by the previously announced results of the multicenter Phase 3 PANAMO trial, which demonstrated a relative reduction in 28-day all-cause mortality by 23.9%. Subsequently, in June 2023, we began the commercialization of GOHIBIC (vilobelimab) in the United States under the EUA. In January 2025, the European Commission (EC) granted marketing authorization under exceptional circumstances for GOHIBIC for the treatment of adult patients with SARS-CoV-2-induced acute respiratory distress syndrome (ARDS) who are receiving systemic corticosteroids as part of standard of care and receiving invasive mechanical ventilation (IMV) with or without extracorporeal membrane oxygenation (ECMO).

Anti-Ca5R inhibitor INF904

To expand the breadth of our anti-C5a/C5aR technologies, we are also developing INF904, a product candidate that targets the C5a receptor. In INF904, we discovered a small molecule C5aR inhibitor that in pre-clinical studies has shown potential for superior characteristics to the only approved C5aR inhibitor, avacopan. INF904 has provided higher plasma exposure in animals, including non-human primates, and improved inhibitory activity in a hamster neutropenia model compared to avacopan. Furthermore, in contrast to avacopan, in vitro experiments showed INF904 has substantially less inhibition of the cytochrome P450 enzymes 3A4/5 (CYP3A4/5). INF904 demonstrated potential for anti-inflammatory therapeutic effects in several preclinical disease models. In January 2024, we announced the positive results of a single and multiple ascending dose study with INF904 in healthy volunteers. In December 2024, we announced that the first patient was dosed in the Phase 2a basket study in CSU and HS with initial data anticipated in summer 2025. INF904 is a promising product candidate for being developed in several disease areas of inflammation, where orally available therapeutics are not available or a medical need exists despite availability of other therapies.

INF904 for the treatment of CSU

We are pursuing development of INF904 for the treatment of CSU in a Phase 2a trial. CSU is a debilitating and unpredictable skin disease characterized by intensely itchy hives / wheals and angioedema. The burden of this chronic disease is high and impacts sleep, mental health, quality of life and productivity due to absences from school and work. CSU is estimated to affect around 40 million people worldwide. CSU patients have been reported to show elevated C5a levels, a major activator of mast cells and basophils which are thought to be significant contributors to CSU pathogenesis. In addition, studies suggest that complement activation (including C5a) in CSU can lead to histamine release. Current treatments are limited, and a significant unmet need exists in a sizable proportion of patients.

INF904 for the treatment of HS

We are also pursuing development of INF904 for the treatment of HS in a Phase 2a trial. HS is a chronic, recurrent, debilitating neutrophil-driven inflammatory disease that can persist for years and tremendously impacts quality of life; it is characterized by abscesses, nodules and draining tunnels which can flare and cause scarring. INF904 inhibits the known C5a-induced effects on neutrophil activation and tissue accumulation of immune cells, including generation of tissue damaging mechanisms (enzyme release and oxidative radical formation) as well as induction of NETosis – mechanisms thought to be involved in HS progression and draining tunnel formation. Clinical evidence with existing C5a/C5aR products also supports that blocking this pathway reduces lesion counts. Patients' responses to treatment with approved anti-TNF-alpha or anti-IL17 drugs are known to wane over time in a significant number of cases; and treatment with new therapeutics acting through other molecular mechanisms are needed for these patients.

Anti-C5a antibody IFX002

We are developing IFX002 for the treatment of chronic inflammatory diseases. IFX002 is a highly potent anti- C5a antibody, which binds to the same domain of the C5a protein as vilobelimab, but which has a higher humanization grade and altered pharmacokinetic properties compared to vilobelimab. IFX002 is currently in preclinical development. We consider IFX002 to be a life-cycle management product to vilobelimab, given the long remaining patent life of IFX002.

For more information on our technology or our development programs please refer to the detailed information included herein below.

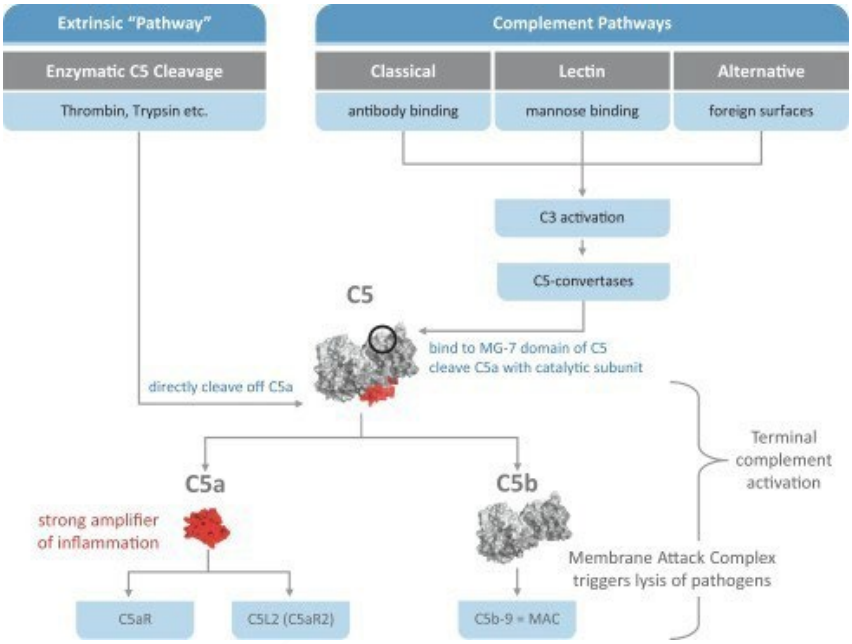
Our technology

C5a is a central mediator of the complement system and therefore a critical component of the innate immune system. The most prominent role of the complement system is to help the body defend itself against invading microorganisms through several mechanisms, including the rapid creation of an inflammatory environment and the production of factors that directly kill pathogens and recruit immune cells to sites of infection. Activation of the complement system ultimately results in the generation of C5a by cleavage from C5. C5a creates an inflammatory environment by attracting and strongly activating neutrophils as well as by causing many different cell types to generate pro-inflammatory molecules.

The complement system and role of the C5a/C5aR axis as critical component in the immune system and the need for control

The complement cascade consists of approximately 30 interacting proteins and forms a critical component of the innate immune system. This system protects the body, for example by recognizing and removing bacteria, viruses and other infectious agents, collectively referred to as pathogens. Activation of the complement system leads to a series of enzyme-like reactions that produce factors that both directly kill pathogens and recruit immune cells to sites of infection. This activation can be triggered via three major pathways: the so called classical pathway, the mannose binding lectin, or MBL, pathway and the so called alternative pathway. Activation of any of these three pathways will lead to the cleavage of C3 and formation of C5-convertases. Terminal complement activation, which is also referred to as cleavage of C5, can be achieved by these C5 convertases. In addition, terminal complement activation can also be achieved directly through the extrinsic pathway by naturally occurring proteolytic enzymes present throughout the body but not considered part of the complement system.

Cleavage of C5 results in the generation of C5a and C5b, two molecules with distinct biological activities. C5a is a strong inflammatory amplifier that exerts its biological functions by binding to two different receptors, C5aR and C5L2. C5b on the other hand assembles with C6, C7, C8 and many C9 molecules to form the MAC, an important intrinsic defense mechanism that causes the membranes of microorganisms to become permeable, leading to their disintegration, or lysis.



Overview of critical functions of the complement system

The complement system serves many crucial functions within the innate immune response, such as:

- **Rapid creation of an inflammatory environment.** Production of pro-inflammatory molecules, such as C5a, optimizes the conditions under which enzymatic and other processes can act against microorganisms. These inflammatory conditions include the onset of a fever or release of aggressive enzymes and oxygen radicals by neutrophils.

- **Lysis of microorganisms through formation of the MAC.** A rapid, first-line defense mechanism resulting in the formation of pores in the cell membranes of invading microorganisms, leading to their disintegration.

- **Bridge to the adaptive immune system.** This function is promoted by an activation product of C3, called C3b, which tags particles and makes them visible and more easily processed by immune stimulatory cells. Such cells then present these particles to B-cells, which in turn generate antibodies against the particles, leading to targeted elimination. This mechanism takes a few weeks to take full effect.

- **Clearance of dead cell particles.** The complement system also serves various other purposes, including the clearance of dead cell particles from the body. This function is especially important because uncleared cell particles are believed to potentially induce generation of antibodies against normal cells and tissues, leading to autoimmune inflammatory responses and diseases.

Need for control

Complement activation is a double-edged sword: the fast acting and relatively non-specific functions of pro-inflammatory responses driven by C5a and the lysis of microorganisms through MAC formation are usually very tightly controlled. However, inappropriate activation of the system can quickly turn it from a beneficial defense system into an uncontrolled inflammatory response. C5a's uncontrolled activity in certain disease states can generate an inflammatory environment within the body that results in tissue damage and promotes pro-inflammatory T-cell autoimmune responses. The resulting tissue damage is believed to critically contribute to the disease progression of many acute as well as chronic inflammatory and autoimmune diseases, particularly

during flare-up phases. Examples of this include Lupus disease, inflammatory bowel disease and neutrophil-driven diseases.

Despite the MAC's role as a rapid, first-line defense mechanism, MAC formation can also result in damage to our body's cells in some diseases. Normally, the body's cells and tissues are protected from MAC-mediated lysis through surface inhibitors that prevent MAC formation. However, in paroxysmal nocturnal hemoglobinurea, or PNH, the patients' cells lack the ability to hold MAC inhibitors on their cell surface, resulting in extreme susceptibility to MAC-related cell lysis. In addition, patients with diseases involving the kidney endothelial cells, such as atypical hemolytic uremic syndrome and certain forms of glomerulonephritis, also often appear to be burdened by MAC-related damage. Blockade of MAC formation in these very rare diseases can be lifesaving.

While blockade of MAC formation can be beneficial in certain circumstances, substantially blocking MAC formation can also result in susceptibility to life-threatening infections. For example, patients dosed with drugs that block MAC formation, such as with the marketed antibody eculizumab, must be immunized against meningococcal disease, which also carries the risk of side effects. Therefore, it is desirable to leave MAC formation intact when blocking complement-mediated damage in the broad variety of diseases in which an uncontrolled inflammatory response, and especially C5a, has been described as key driver of the damage.

We believe that C5a is a key inflammatory mediator driving tissue damage in many inflammatory diseases and thus represents a very meaningful drug target with large therapeutic potential. Therefore, we have conducted substantial research since our inception to generate highly specific antibodies targeting only C5a while leaving MAC formation intact, to deliver an ideal therapeutic approach for this attractive target.

Mechanisms of C5 activation

C5 can be produced by many cells, including epithelial cells of various organs, T-cells and other immune competent cells. Terminal C5 activation does not require activation of the three complement pathways and related formation of C5-convertases. Other enzymes can also directly cleave and activate C5, such that functionally active C5a can be generated in the complete absence of other complement components. For example, in the absence of other complement factors in the cell culture, lung epithelial cells can generate C5 upon stimulation, and lung macrophages can cleave and activate C5, leading to generation of C5a. This example illustrates that C5 can be activated and C5a can be generated independently from the complement pathways.

We further demonstrated that direct enzymatic cleavage of C5 occurs uninhibited in the presence of eculizumab, a known C5 inhibitor that binds to the MG-7 domain of C5 and hinders the C5 convertases from engaging and binding to C5. This research suggests that direct enzymatic cleavage of C5a from C5 works through a mechanism that is not blocked by C5 inhibitors such as eculizumab. Our studies further demonstrate that patients sufficiently dosed with eculizumab may still display elevated plasma C5a levels, implying that C5 inhibitors like eculizumab are not capable of fully blocking and controlling the C5a signaling pathway. Therefore, in diseases in which it plays a key promoting role, we believe targeting C5a directly may yield a meaningful therapeutic benefit.

C5a and its role in disease and inflammation

C5a is a small, 74-amino acid-spanning protein whose biochemical and immunological properties have been well documented in the scientific literature. C5a creates an inflammatory environment by attracting and strongly activating neutrophils as well as by causing many different cell types to generate pro-inflammatory and inflammation-related molecules. While this can help the body to respond strongly and rapidly to infections by optimizing the defense environment, uncontrolled C5a generation can induce damage to the body's tissues in a broad variety of diseases. As a result, we believe that controlling and limiting C5a generation in the body may prevent the negative effects of an over-activated C5a immune response.

C5a quickly interacts with at least two independent receptors—C5aR and C5L2 (sometimes referred to as C5aR2). C5aR and C5L2 serve as a large signaling pool for effects elicited by C5a. C5aR has been well characterized as a signaling receptor that can be strongly upregulated in almost any cell across a variety of disease settings. Although less understood, C5L2 has also been shown to promote inflammation and negatively affect outcomes in various experimental disease settings by promoting the adverse effects, or AEs, elicited by uncontrolled C5a. Importantly, various other complement activation products (e.g., C3a, C3a-desArg and C4a) have been shown to bind to C5L2 and elicit effects different from those elicited by C5a. Thus, blocking specifically C5a as achieved by use of vilobelimab will eliminate only C5a mediated effects.

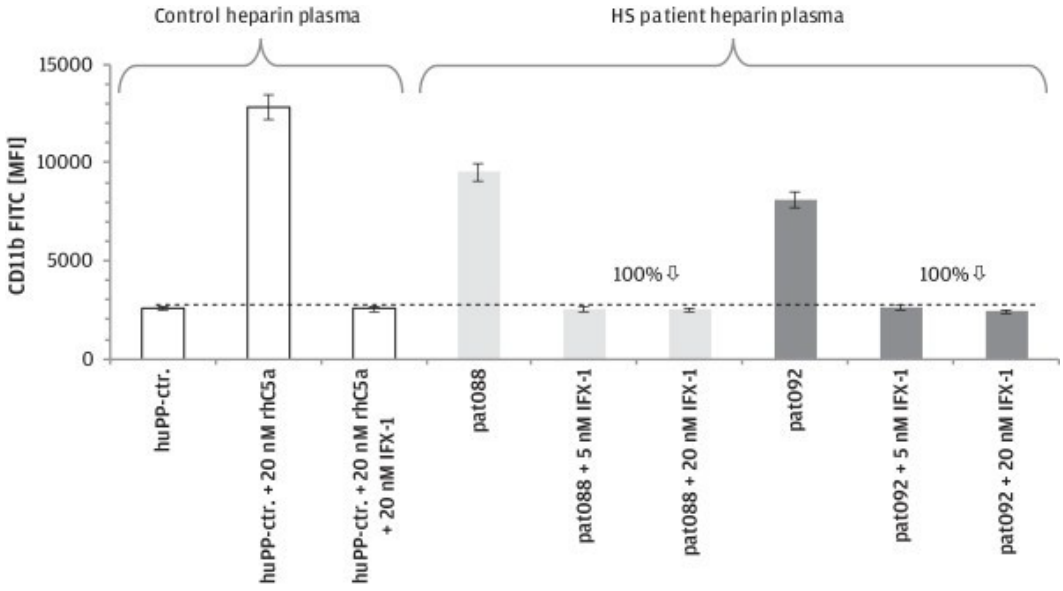
Role of C5a in neutrophil-driven inflammatory diseases

In the inflammatory response, C5a is an accelerator or "booster" of inflammation. This role of C5a extends to a broad variety of responses, including the following mechanisms:

- C5a boosts the generation of many different cytokines such as IL-8, IL-6, IL17, TNF-alpha and others in a variety of cell types as well as within the bloodstream;
- C5a induces a complex change in the cell-signaling cascade of immune-competent cells that leads to an altered and often intensified signal transduction of other known signaling stimuli, such as the toll-like receptor signaling;
- C5a affects T-cell responses and causes a pro-inflammatory response, leading to the generation of further pro-inflammatory cytokines; and
- C5a is capable of inducing adhesion molecule expression on the surfaces of blood vessels, leading to neutrophil adherence to the internal vessel wall and migration through the vessel to the site of infection.

When C5a binds to its receptors on neutrophils, they are strongly activated and move to the source of damage or infection, through a process referred to as chemotaxis, generating oxygen radicals and activated enzymes both believed to be major contributors to cellular and tissue damage in the body. In addition, C5a has been suggested to induce neutrophil extracellular trap, or NET, formation and a process in which neutrophils undergo a certain form of cell death while forming NETs called Netosis, which is believed to cause additional inflammation and damage in the tissue. Given this central function, C5a is a powerful tool that, when inappropriately activated, is capable of promoting damage to the body, ultimately leading to organ dysfunction and failure.

Neutrophil activation is assessed by observing the upregulation of the neutrophil surface marker CD11b (an established method to demonstrate neutrophil activation). In studies conducted in 2013 and 2014 as part of an investigative project in collaboration with an investigator from the University of Athens, we found that CD11b, as a marker for neutrophil activation, was greatly enhanced in fresh human whole blood from healthy volunteers when either recombinant human C5a was added or when plasma from HS patients was added. Vilobelimab, our highly specific anti-C5a antibody, completely inhibited neutrophil activation resulting from the addition of the HS plasma, suggesting that C5a may be the key mediator in plasma from patients affected by this disease, leading to neutrophil activation.



Flow cytometry assay in fresh human whole blood demonstrating CD11b increase on blood neutrophils as marker of neutrophil activation: recombinant human C5a strongly activates human neutrophils in whole blood (huPP-ctr + 20 nM rhC5a), which can be fully blocked by addition of vilobelimab ("IFX-1" in the above graph) (huPP-ctr + 20 nM rhC5a + 20 nM vilobelimab) (open white bars). Plasma from two

different HS patients (pat088 and pat092) also activates human neutrophils in whole blood and this effect can be fully blocked by the addition of vilobelimab (middle and darker grey bars) thus implying that C5a in HS patient plasma is the key neutrophil activating factor.

Various chronic inflammatory and autoimmune diseases in humans are characterized by flare-up phases during which substantial tissue damage occurs. Given C5a's numerous inflammatory promoting functions, blocking it in chronic inflammatory diseases may have a positive effect on T-cell function, overall control of the inflammatory status of the disease and a strong anti-inflammatory effect on neutrophils, which may reduce tissue damage during the flare-up phases. It has been demonstrated that in various inflammatory animal models that blocking the C5a/C5aR signaling axis leads to reduced inflammation, improved organ performance and favorable outcomes on clinical endpoints, including improved mortality rate, disease severity or damage scores.

C5a also has been described as a potential disturbing factor for a balanced T-cell response by down-regulating regulatory T-cells and promoting pro-inflammatory T-cell responses. Research published in 2013 in Nature Immunology and the Journal of Experimental Medicine demonstrated that blocking the C5a/C5aR signaling axis in mice restored regulatory T-cell function, inhibiting the progression of induced autoimmune diseases. Therefore, C5a is a potential drug target for the treatment of autoimmune and chronic inflammatory diseases associated with T-cell imbalance.

Role of C5aR in chronic spontaneous urticaria

C5a, a potent complement component, plays a crucial role in immune responses by activating mast cells and basophils, leading to their degranulation. This process results in the release of histamine and other inflammatory mediators, which contribute to the symptoms of chronic spontaneous urticaria, a condition characterized by recurrent hives and itching. Given its role in promoting inflammation and hypersensitivity reactions, C5a is considered a promising drug target for CSU. Therapeutic strategies aimed at inhibiting C5a signaling could potentially reduce mast cell and basophil activation, thereby limiting histamine release and alleviating CSU symptoms.

Role of C5aR as potential target for therapeutic intervention

Two C5a receptors, C5aR (also known as C5aR1 or CD88) and C5aR2 (also known as C5L2 or GPR77), mediate the biological activities of C5a. Activation of C5aR has broadly acknowledged proinflammatory effects, while the role of activation of C5aR2 remains less well understood and recent scientific work has suggested a potential regulatory role on C5aR1 activation. In animal models of sepsis, anti-C5a treatment ameliorated the development of inflammatory responses and improved survival. In addition, experimental evidence suggests that blockade of C5aR signaling similarly improves survival in animals with sepsis. Finally, C5aR antagonists have shown excellent therapeutic effects in numerous models of inflammatory diseases involving complement activation.

Unlike its ligand C5a, C5aR can be pharmacologically inhibited by small molecules. In October 2021, avacopan, an oral C5aR antagonist, received market approval in the United States as an adjunctive treatment in adults for severe active ANCA-associated vasculitis (specifically MPA and GPA) in combination with standard therapy including glucocorticoids.

It is generally believed that blockade of C5a using antibodies offers a fast, complete, and safe way to control C5a-induced inflammation. The advantage of a low molecular weight compound inhibitor to C5aR is that it can be administered orally, thereby offering broad, long-term ease of administration to patients.

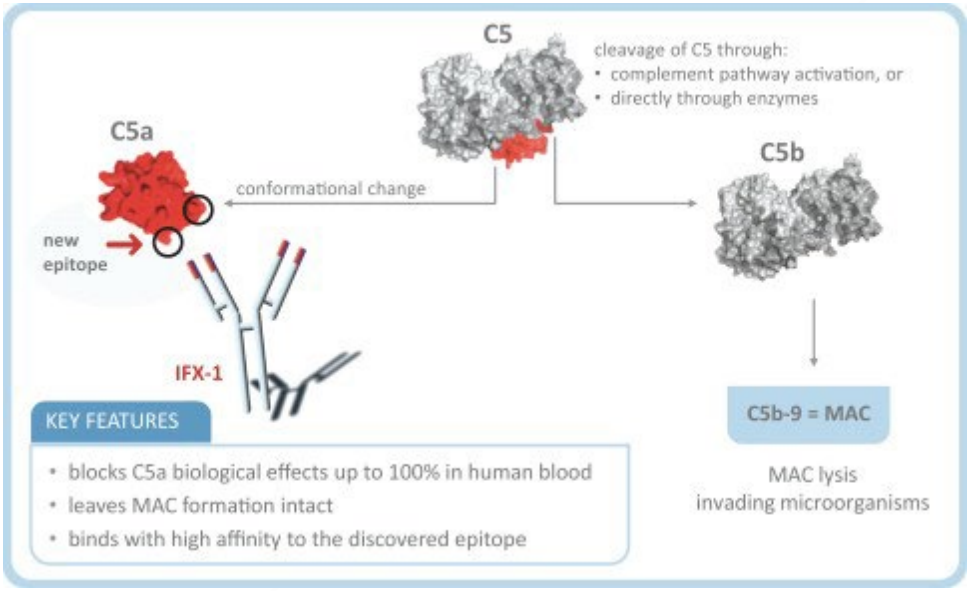
Our proprietary anti-C5a/C5aR technologies and product candidates

Our anti-C5a technology

Despite C5a's well-characterized role in promoting inflammation and related tissue and organ damage in different diseases, no marketed drug targeting C5a exists. Based on more than 17 years of research in this field, we believe the challenge in targeting C5a is to fully block the biological functions of C5a in its natural environment and leave MAC formation intact. We believe our proprietary anti-C5a technology enables us to overcome this challenge through our discovery of a novel epitope, or binding site, on C5a. We believe this conformational epitope is formed only after the cleavage of C5a from the C5 molecule, suggesting that the three-dimensional structure of C5a changes upon release from C5, creating new epitopes that are only present on the free C5a molecule. This permits binding to free C5a only after it is cleaved from C5 and thus allows

blocking of C5a while keeping MAC formation intact. We believe that this represents a breakthrough in the field of terminal complement C5a inhibition and that this may be particularly valuable when treating diseases that are driven by C5a, such as PG and severe COVID-19, cSCC, HS, AAV and others.

We identified antibodies, including our lead product candidate vilobelimab, that potently and selectively bind to a conformational epitope that is formed by C5a upon the cleavage of C5a from C5 to completely block C5a without compromising important upstream functions of the complement system, as well as MAC formation. We intend to discover and develop treatments leveraging our proprietary anti-C5a technology to address a wide array of complement-mediated diseases with significant unmet needs.



A conformational epitope on the surface of the C5a molecule allows for generation of highly specific blocking antibodies directed against C5a.

Our anti-C5a monoclonal antibodies are designed to have the following properties:

- **Complete immunological blockade and inhibition of C5a-induced effects:** The human body has an abundant capacity to generate C5a, and induce inflammatory effects through its two receptors, C5aR and C5L2. Therefore, our anti-C5a antibodies are designed to:
    - generate complete immunological blockade of the C5a molecule to achieve potent and effective treatments. Antibodies or inhibitors lacking this quality may leave a "signaling gap" for C5a, which, in a disease setting, will likely be sufficient to allow for strong pro-inflammatory effects. This signaling gap would limit the ability to silence the C5a/C5aR and C5a/C5L2 signaling axis to achieve the desired therapeutic effect; and
    - bind with high affinity to C5a to counteract the molecule's rapid interactions with its two receptors, C5aR and C5L2, which are abundantly present on the vast majority of cell types in the human body and that can be upregulated in various disease settings.
- **Limited effect on MAC formation:** C5 blocking molecules that inhibit MAC formation in the blood increase the risk of life-threatening infections caused by encapsulated bacteria such as meningococci. Therefore, leaving MAC formation intact may offer a significant advantage in C5a driven diseases.

We believe that all these features are necessary for any drug targeting C5a, in order to achieve clinically meaningful pharmacological performance for the treatment of C5a-driven diseases such as PG, severe COVID-19 or several others. Furthermore, we believe that C5a-driven diseases may not be effectively targeted with complement inhibitory approaches that do not specifically and fully block C5a. These approaches such as blocking the complement pathway-driven cleavage of C5 or inhibiting the complement pathways upstream of C5, are characterized by two fundamental shortcomings set forth below.

- **Inability to fully block C5a without targeting it directly:** C5a can be generated through C5 activation by various enzymes in the complete absence of the complement pathways. For example, blocking the complement C5-convertase-driven cleavage with the C5 inhibitor eculizumab cannot block direct enzymatic C5 activation and C5a generation in an experimental setting. This may explain why elevated C5a levels remain measurable in patients effectively dosed with eculizumab. Therefore, non-specific approaches that do not bind and inhibit C5a directly may fail to fully block its effects.

- **Lack of control over C5a's signaling ability:** C5a receptors are abundantly present on the majority of cells in humans and can be strongly and rapidly upregulated in certain disease states. As such, even with low levels of C5a, the receptors create a large "signaling sink" providing an abundant ability for even small amounts of C5a to transmit a signal. Therefore, a fully blocking targeted C5a approach is warranted in order to achieve full control over C5a-induced signaling events that may be especially important in highly acute inflammatory settings.

Vilobelimab as first-in-class anti-C5a monoclonal antibody

Our lead product candidate, vilobelimab, is an intravenously delivered monoclonal anti-C5a antibody. It is based on our proprietary anti-C5a technology and was the first C5a monoclonal antibody to enter clinical development. Vilobelimab is differentiated by its ability to:

- **fully inhibit C5a-induced signaling and derived biological functions**, as evidenced by its ability to completely prevent C5a-induced neutrophil activation in human whole blood; and

- **leave MAC formation intact**, as evidenced by testing the intact complement pathway driven MAC formation on red blood cells, leading to the lysis of these cells.

We completed one placebo-controlled, single-center Phase 1 study of vilobelimab in healthy volunteers and completed two double-blind, placebo-controlled, multi-center Phase 2a studies in two acute care indications, early septic organ dysfunction and complex cardiac surgery. We also completed a Phase 2a and a Phase 2b clinical study in HS, two Phase 2 studies in AAV, a Phase 2a study in PG and a Phase 2/3 clinical study in critically ill, mechanically ventilated COVID-19 patients.

In all completed studies, vilobelimab was observed to be well tolerated. The placebo-controlled, multi-center Phase 2a studies in the two acute care indications demonstrated that vilobelimab blocked C5a with high statistical significance (p-values < 0.001) and that MAC formation, as demonstrated by a CH50 assay (as described below), in the groups treated with vilobelimab was not influenced, with mean CH50 values for treatment groups and control groups within the normal range.

To determine whether data is statistically significant, we use a "p-value," which represents the probability that random chance could explain the results. The FDA utilizes the reported statistical measures when evaluating the results of a clinical trial, including statistical significance as measured by p-value as an evidentiary standard of efficacy, to evaluate the reported evidence of a product candidate's safety and efficacy. If not otherwise specified, we used a conventional 5% or lower p-value ($p < 0.05$) to define statistical significance for the clinical trials and studies and data presented in this Annual Report.

Based on our clinical trials completed to date as well as the results from an EpiScreen *ex vivo* immunogenicity T-cell response assay, we believe that vilobelimab carries a low risk of provoking an immune response following administration. The immunogenicity assay used peripheral blood mononuclear cells from 21 donors and tested how many donors' cells showed a CD4+ T-cell response following introduction of vilobelimab ex vivo. A response rate of over 10% (or more than three out of 21) means the applicable protein is considered to be high risk for immunogenicity, while a response rate of less than 10% means the protein is considered to be low risk. The results of the assay for vilobelimab showed that zero out of the 21 donors had a T-cell response rate, as compared to a control arm (using the A33 antibody), which showed a 30% response rate. In addition, based on an ADA detection assay conducted in connection with our Phase 2b clinical trial in HS, 10% of patients had ADAs at any time during the study. Only one participant the presence of ADAs was associated with any specific AE pattern indicating symptoms possibly related to the presence or emergence of ADAs leading to an immune reaction.

We are currently evaluating vilobelimab in various disease indications. In all ongoing and completed clinical studies so far, we have never observed effects that would raise doubts on the established safety of vilobelimab as a therapeutic drug candidate.

We will also continue to assess the potential for development of vilobelimab in other disease settings where we believe an anti-C5a antibody could be successfully developed into a marketed therapy.

Development of small molecule inhibitors of C5aR

Two C5a receptors, C5aR (also known as C5aR1 or CD88) and C5aR2 (also known as C5L2 or GPR77), mediate the biological activities of C5a. Activation of C5aR has broadly acknowledged proinflammatory roles, while activation of C5aR2 remains less well understood and recent scientific work has suggested a potential regulatory role on C5aR activation. C5aR is a G-protein-coupled-receptor expressed primarily by granulocytes, and, especially under disease conditions, broadly in various tissues and other immune cell types, which mediates the pathophysiological effects of C5a.

In animal models of sepsis, anti-C5a treatment ameliorated the development of inflammatory responses and improved survival. In addition, experimental evidence suggests that blockade of C5aR signaling similarly improves survival in animals with sepsis. Unlike its ligand C5a, C5aR can also be pharmacologically inhibited by low molecular weight compounds.

Low molecular weight C5aR antagonists have shown excellent therapeutic effects in numerous *in vitro* and *in vivo* animal models of inflammatory diseases involving complement activation. The advantage of a low molecular weight inhibitor of C5aR is that it can be administered orally, thereby offering broad, long-term ease of administration to patients, especially for the treatment of chronic diseases. Through proper clinical investigation of these small molecule C5aR antagonists in diseases induced by the activation of C5a/C5aR axis, the safety and efficacy of these agents can be established.

Avacopan is the first oral C5aR antagonist, which has market approval in the United States as an adjunctive treatment in adults for severe active ANCA-associated vasculitis (specifically MPA and GPA) in combination with standard therapy, including glucocorticoids.

Through our in-house drug discovery efforts, we identified a potent inhibitor of the C5a receptor, INF904, which we believe is a promising candidate for development. We are currently developing INF904, an oral, low molecular weight drug candidate that targets the C5aR receptor. We plan on targeting complement-mediated, chronic auto-immune and inflammatory conditions where an oral small molecule is needed for patients.

Given the different advantages of blocking C5a and C5aR, we believe that the development of both C5a and C5aR blocking agents is possible and potentially helpful to address a broader range of C5a/C5aR-molecular signaling axis-associated diseases.

Our preclinical and clinical development programs

Vilobelimab for the treatment of PG

We are developing vilobelimab for the treatment of PG. PG is a rare, chronic inflammatory form of neutrophilic dermatosis characterized by accumulation of neutrophils in the affected skin areas. The exact pathophysiology is not fully understood, but it is postulated that inflammatory cytokine production as well as neutrophil activation and dysfunction contribute to a sterile inflammation in the skin. PG often presents as painful pustule or papule, mainly on the lower extremities, which can rapidly progress to an extremely painful enlarging ulcer. Associated symptoms include fever, malaise, weight loss and myalgia. PG usually has a devastating effect on a patient's life due to the severe pain and induction of significant movement impairment depending on lesions' location. The exact prevalence of PG is not yet known but is estimated that up to 51,000 patients in the United States and Europe are affected by this disease.

There are 4 disease types recognized: ulcerative (the classical variant, which is the focus of our development), bullous (atypical), pustular, and vegetative (superficial, granulomatous). The ulcerative variant is the most frequent and typical form of PG, with lesions predominantly on the lower extremities.

There are currently no drugs approved for the treatment of PG in the US or in Europe. The only locally approved treatment is adalimumab, which has been approved in Japan but in no other country. There is no established standard of care based on controlled studies in PG. However, due to the high medical need associated with the disease, certain drugs are used in medical practice as treatment attempts for affected patients. These include certain orally administered drugs such as immunosuppressants, including cyclosporine or corticosteroids which are sometimes also used concomitantly, as well as topically applied drugs such as

tacrolimus and others. Lastly intravenously administered TNF-alpha inhibitors such as infliximab or adalimumab or other biological drugs are also used as treatment attempt, despite the fact that no formal regulatory approvals are in place.

In February 2019, we initiated an open label, multi-center Phase 2a exploratory study enrolling 19 patients with moderate to severe PG in Canada, the United States and Poland. The objectives of this study were to evaluate the safety and efficacy of vilobelimab in this patient population in three different doses and to determine the appropriate dose for the future development of vilobelimab in registrational Phase 3 studies for the treatment of PG.

In April 2021, the study reached its enrollment target with 19 patients. In October 2021, we announced preliminary results from the study. In the third dosing cohort at 2400mg biweekly, six of the seven patients achieved clinical remission with a PGA score of ≤ 1, which reflected a closure of the target ulcer. All patients in the third dosing cohort had elevated C5a levels at baseline that were continuously suppressed after initiation of treatment with vilobelimab.

From all three dose cohorts in the study, two patients had related SAEs that were reported: one patient experienced an erysipelas leading to hospitalization (judged as non-drug related by us), another developed a rash due to a delayed hypersensitivity reaction and withdrew from the study. No dose-related AEs were found. Overall, the observed AE profile was in line with the underlying disease.

Final results from all patients were presented at the American Academy of Dermatology Association, AAD), Annual Meeting in March 2022 in an oral late-breaker session by Afsaneh Alavi, MD, Associate Professor of Dermatology, Mayo Clinic. The reported final results showed a dose-dependent effect in the highest dose cohort of 2400 mg, confirming the preliminary results with six out of seven patients showing a clinical remission (Physician Global Assessment, or PGA, score ≤ 1) and closure of the target ulcer in this dose cohort. The seventh patient showed a slight improvement (PGA score 4) with a decrease of the target ulcer area of over 50%. During the follow-up period, ulcers remained closed two months after treatment completion in all but one patient, and a sustained suppression of C5a was observed for up to 20 days after the last dosing.

With these results, vilobelimab was granted orphan drug designation for the treatment of PG by both the FDA in the United States and the EMA in Europe as well as fast-track designation be the FDA. Furthermore, we announced that we had a productive end-of-phase 2 meeting with the FDA related to our plans for a Phase 3 development program in PG in June 2022. In January 2023, we announced details related to the design of our planned Phase 3 study with vilobelimab in ulcerative PG.

The Phase 3 study is designed to enroll patients in the United States, Europe and selected countries in other regions. The study design is based on detailed feedback and recommendations from the FDA Division of Dermatology and Dentistry and was developed in close collaboration with the Company´s advisors from the United States, Europe and other regions. The multi-national, randomized, double-blind, placebo-controlled Phase 3 trial has two arms: vilobelimab (2,400mg every other week) plus a low dose of corticosteroids and placebo plus the same low dose of corticosteroids. In both arms, corticosteroid treatment will be initiated on day one and will be tapered off within the first eight weeks of the treatment period. The primary endpoint of the study will be complete closure of the target ulcer at any time up to 26 weeks after initiation of treatment. Treatment will be discontinued for patients whose disease progresses or fails to improve at defined time points during the study. The study has an adaptive trial design with an interim analysis blinded for the sponsor and investigators (but unblinded for the independent data safety monitoring committee), which is planned upon enrollment of approximately 30 patients, divided equally between the two arms of the study. The interim analysis with a set of predefined rules will take into account the then-observed difference in complete target ulcer closure between the two arms and will then determine whether the trial sample size will be adapted or whether the trial should be stopped due to futility. The enrollment period is projected to last at least two years, and its overall period will depend on the total trial size after sample size adaptation.

In November 2023, we announced the enrollment of the first patient in the trial and in November 2024, we announced the achievement of the 30-patient recruitment milestone. An interim analysis that will define the final sample size for the trial, or declare the trial fuile, is expected to be completed and released in Q2 2025.

Vilobelimab for the treatment of critically ill, invasively mechanically ventilated COVID-19 patients

Severe COVID-19 is characterized by severe lung inflammation and activation of coagulation, frequently requiring mechanical ventilation while the patient is in the intensive care unit. Mortality and morbidity rates are high among critically ill, invasively mechanically ventilated patients with COVID-19, despite the established broad use of corticosteroids and other anti-inflammatory agents. Poor disease outcomes have been associated with activation of the complement system, specifically the C5a/C5aR molecular signaling axis. Experimental studies in other viral lung diseases have shown that C5a is a potent anaphylatoxin, attracting neutrophils and monocytes to the site of infection that causes tissue damage, endothelialitis, and micro- thrombosis. Mouse studies also showed that blockade of the C5a/C5aR1 molecular signaling axis limits the infiltration of myeloid cells in damaged organs and prevents excessive lung inflammation and endothelialitis.

During the COVID-19 pandemic, it became clear that effective therapies for the treatment of severely or critically ill COVID-19 patients were not available or had not tested for this indication. In an effort to provide a contribution to this medical emergency and based on our existing pre-clinical research on the role of C5a in viral-induced pneumonia, we decided to initiate a clinical development program with vilobelimab in critically ill COVID-19 patients with severely progressed pneumonia.

Clinical development

In March 2020, we initiated a randomized open label multi-center trial Phase 2/3 clinical development program with vilobelimab in severe COVID-19 patients with severely progressed pneumonia. In the Phase 2 part of the study, we evaluated vilobelimab treatment plus best supportive care compared to best supportive care alone for up to 28 days. Relative change (%) from baseline to day 5 in oxygenation index (defined as PaO2/FiO2 ratio) was assessed as the primary endpoint along with additional clinical parameters until day 28. In the study, patients were randomized to two treatment arms, either Arm A, best supportive care and vilobelimab or Arm B, best supportive care alone. The primary endpoint was the relative percentage change from baseline to day 5 in the oxygenation index (PaO2 / FiO2).

On June 17, 2020, we announced results from the Phase 2 part of the study. A total of 30 patients were randomized in the trial, and 15 patients were treated in each arm: vilobelimab plus best supportive care or best supportive care alone. Over a treatment period of 28 days, patients in the vilobelimab arm received a maximum of seven doses of 800 mg vilobelimab intravenously on separate days. At randomization, 18 patients were intubated (60%), and 12 patients (40%) had other oxygen supply. A higher number of patients with two or more comorbidities associated with increased COVID-19 mortality were reported in the vilobelimab treatment group compared to best supportive care group. Relative change in the oxygenation index at day 5 showed no differences between treatment groups. However, vilobelimab treatment was associated with a lower 28-day all-cause mortality when compared to the best supportive care group, along with trends in disease improvement, as evidenced by fewer patients experiencing renal impairment assessed by estimated glomerular filtration rates, more patients showing reversal of blood lymphocytopenia and a greater lowering of lactate dehydrogenase concentrations. In vilobelimab-treated patients, pulmonary embolisms reported as SAEs occurred less compared to the best supportive care arm. Also, a temporary increase of D-dimer levels, as potential expression of induction of blood clot lysis, was detected in the first days after initiation of vilobelimab treatment. Twenty-eight-day all-cause mortality in the vilobelimab treatment group was 13% (2 out of 15) versus 27% (4 out of 15) in the control group. In the best supportive care group, four patients died of COVID-19-induced multi-organ failure, and three of them had pulmonary embolisms reported as a SAE. In the vilobelimab arm, one patient died after an acute ventilator tube complication (leakage) and one patient with a history of severe chronic obstructive pulmonary disease died of pulmonary failure.

SAE rates were comparable between groups, but the rate of pulmonary embolisms reported as SAEs was substantially lower in the vilobelimab treatment group. Upon review of the safety data, the independent data safety monitoring board recommended continuation of the trial into the Phase 3 part.

In March 2022, we announced that the Phase 3 part of the Phase 2/3 PANAMO study which enrolled 369 mechanically ventilated patients with COVID-19 across sites in the European Union, South America and other regions was successfully completed and showed a relative reduction in 28-day all-cause mortality of 23.9% ($p = 0.094$), which was the primary endpoint. In the study, Patients were randomized 1:1 to receive either vilobelimab or placebo; most patients received standard of care (97% glucocorticosteroids, 98% anti-thrombotic agents). At the recommendation of regulatory authorities during the course of the trial, we changed the statistical analysis method for the primary endpoint. The original protocol specified a non-stratified Cox regression

analysis, and the final statistical analysis plan specified a site-stratified analysis intended to account for the site stratification of patients at randomization. The original protocol specified analysis would have resulted in a p-value of 0.027 (statistically significant), whereas the site-stratified Cox regression led to a p-value of 0.094 (not statistically significant). Additionally, pre-specified logistic regression analyses of the 28-day mortality resulted in p-values of <0.05 for three out of the four pre-specified analyses. Furthermore, a pre-specified analysis of patients from Western European countries (n=209) showed a relative reduction in 28-day all-cause mortality of 43% (vilobelimab 21.2% versus placebo 37.2%, hazard ratio: 0.5, p=0.014), suggesting an improvement in mortality in line with the reported Phase 2 data of the PANAMO Phase 2/3 study.

Regulatory activities

for vilobelimab for the treatment of critically ill, intubated, mechanically ventilated COVID-19 patients.

In April 2023, the FDA issued an EUA for GOHIBIC (vilobelimab) for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV or ECMO.

In January 2025, the EC granted marketing authorization under exceptional circumstances for GOHIBIC (vilobelimab) for the treatment of adult patients with SARS-CoV-2-induced ARDS who are receiving systemic corticosteroids as part of standard of care and receiving IMV (with or without ECMO).

To achieve full commercial scale and successfully reach the full market potential of the product in the future, we also aspire to obtain full market approval for GOHIBIC (vilobelimab) in the United States. We are therefore planning the submission of the BLA for full approval of GOHIBIC (vilobelimab) in our COVID-19 indication and potentially, in the future, in similar indications that may apply to other virally induced acute respiratory distress conditions. In October 2023, in furtherance of our continued efforts to obtain a BLA, we had an encouraging Type C meeting with the FDA. In that meeting, the FDA indicated their willingness to collaborate with us in identifying a development pathway towards a BLA for a broader ARDS label. To achieve this, we would need to conduct an additional well-controlled and adequately powered study in a broader ARDS setting that demonstrates the safety and efficacy of vilobelimab. During the meeting, we discussed different options for such a trial, including potential trial designs, patient population and trial power aspects. In June 2024, GOHIBIC (vilobelimab) was selected for a Biomedical Advanced Research Development Authority, or BARDA, sponsored clinical trial to evaluate novel host-directed therapeutics for ARDS.

Commercialization

In June 2023, we began the commercialization of GOHIBIC (vilobelimab) in the United States for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV or ECMO under the granted EUA. We entered into agreements with certain subsidiaries of Cencora Inc., or Cencora (formerly known as AmerisourceBergen Corp.) to act as our U.S. distributor and to make GOHIBIC (vilobelimab) available for order by U.S. hospital customers under the EUA. Cencora provides cold storage, cold-chain distribution services, inventory management and secondary labeling/packaging, among other services. To support our commercial efforts, we employ experts with relevant experience in the commercialization of medical products in the hospital market, including in the areas of sales, sales operations, marketing, market access, distribution, medical affairs and others in the United States. In addition, we are adapting and integrating our infrastructure, including IT systems, supply chain, financial reporting systems and inventory management systems both, internally and with the assistance of external service providers.We continue to refine our commercial strategic plan, preparing relevant promotional and medical education materials to target healthcare providers and other stakeholders, and continue refining our medical affairs strategy to increase awareness of the EUA among the medical community, while continuing our sales efforts.

Outside of the United States, we intend to seek partners to support our commercialization efforts, including partnerships in select regions. In Europe, we are currently considering commercial distribution partnerships for GOHIBIC and do not expect to establish internal infrstructure to support our commercialization beyond the minimally required investments to uphold our regulatory approval.

Vilobelimab for additional indications

In addition to PG, severe COVID-19 / ARDS and previous studies in HS, AAV and cSCC, we continue to explore the possibility of advancinng the clinical development of vilobelimab in additional inflammatory and complement-mediated disease indications for which a good pre-clinical or clinical proof of concept exists and

where C5a has been demonstrated as a critical disease promoting factor or where similar mechanisms, such as neutrophil-driven systemic diseases affecting the skin and or other organs, have been identified.

INF904 as orally administered low molecular weight molecule for inhibition of C5aR

Inhibition of the C5a/C5aR axis provides strong anti-inflammatory effects in a variety of diseases. Blockade of C5a using highly specific antibodies, such as vilobelimab, may offer a fast, effective, and safe way to control C5a-induced inflammation. In addition to this approach, inhibition of C5aR by oral small molecules may provide the ease of administration required for effective long-term treatment for more chronic inflammatory diseases. To expand the breadth of our anti-C5a/C5aR technologies, we are also developing INF904, an oral, small molecule drug candidate that targets the C5aR receptor. C5aR, a G-protein-coupled-receptor expressed primarily by granulocytes, mediates the pathophysiological effects of C5a. In INF904, we discovered a small molecule C5aR inhibitor that in pre-clinical studies has shown potential for superior characteristics to the only approved C5aR inhibitor, avacopan. INF904 has provided higher plasma exposure in animals, including non-human primates, and improved inhibitory activity in a hamster neutropenia model compared to avacopan. Furthermore, in contrast to avacopan, in vitro experiments showed INF904 has substantially less inhibition of the cytochrome P450 3A4/5 (CYP3A4/5) enzymes, which play an important role in the metabolism of a variety of drugs, including glucocorticoids. No obvious toxicological findings, even in the highest dose groups tested in required GLP toxicity analyses, were identified. INF904 demonstrated potential for anti-inflammatory therapeutic effects in several preclinical disease models.

Most IND-enabling studies, including certain GLP-toxicological studies, have been completed, and we conducted a Phase 1 single and multiple ascending dose clinical study from November of 2022 to January 2024.

In September 2023, we announced the topline results from the single ascending dose, or SAD part of a randomized, double-blind, placebo-controlled Phase 1 trial with INF904. The SAD part of the Phase 1 first-in-human trial enrolled 62 healthy volunteers within six different dosing groups from 3 mg to 240 mg who were randomly assigned to receive INF904 or a placebo. Different drug concentrations were tested for the 60 mg dosing group. The main objectives were to assess safety and tolerability of single ascending doses under fasting conditions. Secondary endpoints included several pharmacokinetic, or PK, parameters, and the effect of INF904 on C5a-induced neutrophil activation in blood samples from treated volunteer's ex vivo also was explored.

The results show that INF904 was well tolerated in treated patients and resulted in no safety signals of concern in single doses ranging from 3 mg to 240 mg. The overall percentage of adverse events (AEs) was lower in the INF904 treated patients compared to the placebo group, and no serious or severe AEs were observed at any dosing level. No related AEs were reported in conjunction with INF904 dosing.

Analysis of INF904 PK in subject plasma samples revealed sustained exposure to INF904 with six hours to maximum concentration, or tmax. INF904 plasma levels were dose proportional for systemic exposure (AUC_{last}) and nearly dose proportional for maximum concentration (C_{max}) over the dose range used in the study. With the 30 mg dose, INF904 reached a C_{max} of 289 ng/ml with an AUC_{last} of 5197 h.ng/ml, which are approximately 3-fold and 10-fold, respectively, higher than the published Phase 1 data from the only marketed comparator, avacopan.

Single doses of 30 mg or higher of INF904 achieved ≥90% blocking of C5a induced up-regulation of the activation marker CD11b on neutrophils in plasma samples from subject's ex vivo at 24 hours post dosing. This inhibition was achieved when 12.6 nM recombinant C5a was added as stimulus in this assay, a C5a concentration which can be observed in patients with severe inflammatory conditions such as the immuno-dermatological disease, HS, or during life-threatening inflammation (e.g., in critically ill COVID-19 patients or septic patients). Thus, INF904 inhibition of C5a-induced neutrophil activation in human plasma achieved the set goal for effective C5aR control at disease relevant C5a levels.

In January 2024, we announced topline results from the multiple ascending dose, or MAD, part a randomized, double-blind, placebo-controlled Phase 1 trial for INF904. The PK and pharmacodynamic, or PD parameters confirm the favorable data we observed during the SAD part of the study, which provides support for the best-in-class potential of INF904. INF904 was well tolerated and there were no adverse safety events of concern after repeated dosing in participants over the entire tested dose range.

In the MAD part of the randomized, double-blind, placebo-controlled Phase 1 trial, 24 participants received multiple doses of INF904 for 14 days of either 30 mg once per day, or QD, 30 mg twice per day, or BID, or 90

mg BID. The study's primary objective was to evaluate the safety and tolerability of repeated dosing. Several PK parameters were analyzed as secondary endpoints, and the effect of the dosing scheme on C5a-induced neutrophil activation in blood samples from the participants was also explored in an ex vivo assay.

The safety analysis of INF904 in the MAD part of the Phase 1 study demonstrated that it was well tolerated in participants over the entire dose range and resulted in no safety signals of concern. The overall percentage of AEs in INF904 treated participants was 77.8%, which was lower than the 83.3% observed in the placebo group. There were no serious or severe AEs observed at any dosing level.

Analysis of the PK profile showed that potential target AUC0-12h, C_{max}, and trough values were achieved rapidly within 14 days of 30 mg BID dosing. INF904 exposure further increased proportionally with dosing up to 90 mg BID. These results were demonstrated even when participants ingested the drug in a fasted state, suggesting that food is not required to achieve potentially therapeutic drug levels.

Analysis of the PD profile showed that the blocking activity of C5a-induced neutrophil activation by INF904 reached equal to or above 90% over the 14-day dosing period for all tested doses in an ex vivo challenge assay where physiological and disease- relevant levels of C5a were added to blood samples provided by the trial participants.

We are currently conducting additional required pre-clinical studies, including long-term chronic toxicology studies, to enable longer-term dosing of INF904 for chronic inflammatory diseases. In December 2024, we announced the first patient dosing of a Phase 2a basket study in CSU and HS, utilizing a commercially viable drug formulation. Data from this study are expected in the summer of 2025, with a goal of informing the planning and design of a larger, longer-term Phase 2b study by year-end 2025.

IFX002 as follow-on anti-C5a monoclonal antibody product candidate

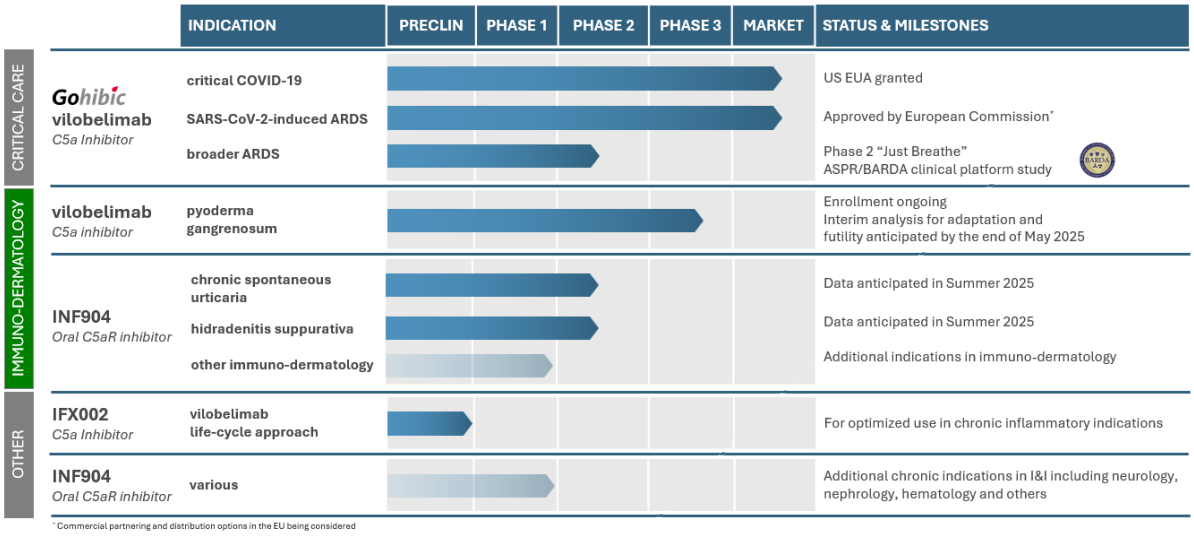
To expand the breadth of our anti-C5a technologies, we are also developing IFX002 for the treatment of chronic inflammatory indications. IFX002 is an advancement of the anti-C5a technology. It is a highly potent anti-C5a antibody with a higher humanization grade and altered pharmacokinetic properties and is currently in pre-clinical development.

IFX002 is an injectable product candidate with a prolonged blood plasma half-life than vilobelimab, making it potentially more amenable for the treatment of chronic inflammatory indications with less severe flares or closer to the onset of the disease. IFX002 shares the same mechanism of action as vilobelimab in its potential to block C5a with high specificity but is designed for a dosing regimen that may be more suitable for chronic therapy. Furthermore, IFX002 binds to the same epitope of free C5a as vilobelimab with comparable selectivity. The pre-clinical development of IFX002 was partly supported by a grant from the German government. IFX002 will keep the performance relevant properties to fully block C5a-induced biological effects while leaving MAC formation intact. We believe that IFX002 holds the potential to treat various chronic inflammatory diseases and could benefit from a dosing regimen more suitable for chronic therapy. We also consider IFX002 to be a life-cycle management product to vilobelimab, given the long remaining patent life of IFX002.

Pipeline

We intend to leverage our expertise within the complement field as well as our proprietary technologies to sustain our lead in the anti-C5a/anti-C5aR space by developing a diverse pipeline focused on complement-mediated autoimmune and inflammatory diseases with high unmet need. Rights to our proprietary anti-C5a/anti-C5aR technologies are currently expected to extend at least up to 2041 on the basis of our latest patents granted.

The figure below summarizes key information about and the development status of our current pipeline of product candidates:



Our strategy

Our goal is to maintain and further advance our leadership position within the anti-C5a/anti-C5aR complement space, delivering first-in-class autoimmune and anti-inflammatory therapies to market. To achieve this goal, we expect to execute the strategies set forth below.

- **Advance vilobelimab in PG**. Based on the positively concluded open label Phase 2a study, we are conducting a Phase 3 pivotal clinical program after having received advice related to the clinical trial design from the FDA.

- **Proceed with clinical development of INF904**. We have conducted a single and multiple ascending dose study of our C5aR antagonist INF904 and currently are conducting a Phase 2a trial and required non-clinical studies to proceed to Phase 2 trials in patients.

- **Continue to optimize the manufacturing process for vilobelimab**. We established a fully validated manufacturing process for vilobelimab with a reputable international CDMO, with the goal of fulfilling and upholding the quality criteria to gain and maintain regulatory approval for such process. We have established the final manufacturing of the finished pharmaceutical product (i.e., "fill and finish") in Germany and are considering the transfer of the drug substance manufacturing process or other steps of the manufacturing process from China to Germany or to other countries.

- **Assess development options for vilobelimab in further indications beyond PG.** Following our decision to halt development programs in HS, AAV and cSCC due to the resources required to conduct these on our own, we are nevertheless continously evaluating options regarding the development of vilobelimab in indications beyond PG. Based on the logistical and financial effort necessary to successfully complete pivotal Phase 3 development programs in each indication, such options include potential collaborations with a pharmaceutical partner.

- **Pursue the further development of IFX002** to get prepared for potential clinical development. We are developing IFX002, a fully humanized antibody version of vilobelimab, as an injectable with a longer half-life than vilobelimab, making it suitable for chronic inflammatory indications with less severe flares or closer to the onset of disease. Based on a patent lifetime potentially beyond 2040, we see this project as life-cycle management for vilobelimab and are conducting pre-clinical development work to get closer to the possible start of clinical development.

- **Solidify and continue to expand the breadth of our leadership position in the anti-C5a/anti-C5aR space by leveraging the full potential of our proprietary technologies and expertise in complement and inflammation research**. We intend to continue to discover and develop treatments that have the potential to address a broad spectrum of complement-mediated or immune response

mediated indications with significant unmet need, either internally or in collaboration with a partner. To accomplish this, we continue to supplement our research and development activities with our discovery unit in Ann Arbor, Michigan and we are further building out our intellectual property portfolio and our business development capabilities.

- **Commercialize GOHIBIC (vilobelimab) either independently or in collaboration with pharmaceutical partners.** We are commercializing GOHIBIC (vilobelimab) for severe COVID-19 in the United States independently, and assessing the options to commercialize our product in Europe in collaboration with potential partners. We have employed a targeted commercial infrastructure in the United States to promote access to vilobelimab through hospitals that treat patients suffering from the disease within core markets in United States. Outside of the United States and Europe, we have received approval in Europe and plan to commercialize the product in collaboration with partners. For other indications, we intend to develop and commercialize vilobelimab either independently or through collaborations with other parties.

- **Explore the possibility to expand the applications of vilobelimab in the area of ARDS.** We intend to explore the possibility of expanding the label into other critical care indications for which we have generated pre-clinical data in the past. Most notably, we are considering the utility of additional studies such as the Phase 2 BARDA study in broader ARDS, or studies with or commercial partners, to expand the label into a product for virally induced ARDS.

Our intellectual property

We aim to protect our product candidates and other commercially important proprietary anti-C5a and C5aR technologies by seeking and maintaining U.S. and foreign patents that are intended to cover our product candidates and compositions, and their methods of use, the methods used to manufacture them, the related therapeutic targets and associated methods of treatment and any other inventions that are commercially important to our business. We also rely on trade secrets and know-how and other intellectual property rights to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Furthermore, we aim to protect our trademarks, service marks, and trade names by seeking and maintaining U.S. and foreign trademark registrations. Our success will depend significantly on our ability to obtain and maintain such patent and other proprietary protection, defend and enforce our patents, preserve the confidentiality of our trade secrets and operate our business without infringing, misappropriating or otherwise violating any patents or other intellectual property, including any proprietary rights of third parties. See the section titled “ITEM 3. KEY INFORMATION — D. Risk factors—Risks related to our intellectual property” for additional information.

As of December 31, 2024, we owned 13 issued U.S. patents and three pending U.S. non-provisional patent applications, 46 issued foreign patents, including four granted European patents validated in 88 countries and three granted Eurasian patent validated in 25 countries, as well as 41 foreign patent applications, including six European patent applications and three Eurasian patent applications covering C5a and C5aR inhibitors and associated methods of use.

Our patent portfolio relating to vilobelimab, IFX002 and INF904, as of December 31, 2024, is summarized below.

As of December 31, 2024, we owned four issued U.S. patents covering the composition of matter of antibodies that block C5a and their use in blocking C5a-induced biological effects in patients with diseases that involve acute or chronic inflammation, which would include in their scope HS and AAV. In addition, we owned 20 issued foreign patents, including two granted European patents validated in 74 countries and one Eurasian patent validated in nine countries, two pending foreign patent applications, including one pending European patent application, covering the composition of matter of antibodies that block C5a and their use in the treatment of various diseases that involve acute or chronic inflammation, which would include in their scope HS and AAV, and, depending on the jurisdiction of the applicable patent, specifically cover the use of such antibodies in treating diseases such as ischemia and reperfusion related injuries, acute lung injury and pneumonia.

The issued U.S. and foreign patents are expected to expire in 2030, excluding any additional term for patent term adjustments or patent term extensions. If granted, the pending U.S. and foreign patents applications would be expected to expire in 2030, excluding any additional term for patent term adjustments or patent term extensions.

As of December 31, 2024, we owned two granted U.S. patents and four granted foreign patents, including one European patent validated in three countries and one foreign patent application covering the use of certain binding moieties, such as antibodies, that inhibit C5a for the treatment of viral pneumonia.

If issued, the U.S. and foreign patents are expected to expire in 2035, excluding any additional term for patent term adjustments or patent term extension.

As of December 31, 2024, we owned four granted U.S. patents, one pending U.S. non-provisional patent application, 16 granted foreign patents, including one European patent validated in 11 countries and one granted Eurasian patent validated in eight countries, nine pending foreign patent applications, including three pending European patent applications covering the use of an inhibitor of C5a activity, for example, vilobelimab, for treating HS and other cutaneous, neutrophilic inflammatory diseases.

The issued U.S. and foreign patents are expected to expire in 2038, excluding any additional term for patent term adjustments or patent term extensions.

As of December 31, 2024, we owned one U.S. patent application and seven foreign patent applications including one European patent application covering an improved C5a specific antibody.

If issued, the U.S. and foreign patents are expected to expire in 2041, excluding any additional term for patent term adjustments or patent term extensions.

As of December 31, 2024, we owned one granted foreign patent, one pending U.S. non-provisional patent application and nine foreign patent applications including one European and one Eurasian patent application covering the use of inhibitor of C5a activity, for example vilobelimab, for treating Corona viral diseases.

If issued, the U.S. and foreign patents based on the application under the PCT are expected to expire in 2040, excluding any additional term for patent term adjustments or patent term extensions.

As of December 31, 2024, we owned two granted U.S. patents, one pending U.S. non-provisional patent application, five granted foreign patents, including one granted Eurasian patent validated in eight countries, one pending U.S. non-provisional patent application, and 14 foreign patent applications including one European patent application covering inhibitors of C5aR.

The issued U.S. and foreign patents are expected to expire in 2040, excluding any additional term for patent term adjustments or patent term extensions.

As of December 31, 2024, we owned one issued U.S. patent application and one international patent application covering the use of an inhibitor of C5a activity and standard of care inhibitors in the treatment of infectious pneumonia and infectious ARDS.

The issued U.S. and foreign patents are expected to expire in 2043, excluding any additional term for patent term adjustments or patent term extensions.

As of December 31, 2024, we owned two European patent applications and one international patent application covering the use of inhibitors of C5aR for the treatment of various diseases.

The U.S. and foreign patents are expected to expire in 2043, excluding any additional term for patent term adjustments or patent term extensions.

As of December 31, 2024, we owned one trademark registration application for two trademarks, “GOHIBIC” and “Vilwaysi” in the United States and one international trademark registration designating the United States and covering 10 further registered and one pending 29 foreign countries, four foreign trademark applications and 12 foreign registered trademarks including 23 European trademark registrations covering 54 European countries and seven foreign trademark applications for goods and services in the field of pharmaceutical products, among others.

As of December 31, 2024, for “Vilwaysi”, we owned one International trademark registration designating the United States and covering 10 further registered and one pending foreign countries, one foreign trademark application and five foreign registered trademarks including one European trademark registration covering 27 European countries for goods and services in the field of pharmaceutical products, among others.

As of December 31, 2024, we owned two trademark registrations for “InflaRx” in the United States for goods and services in the field of pharmaceutical preparations for the treatment of inflammatory, inflammatory-related, oncological and neurological diseases. Outside the United States, as of December 31, 2023, we owned trademark registrations for “InflaRx” in 30 countries.

UPC

Twenty-four member states of the 27 member EU states, with the exception of Poland, Spain and Croatia have acceded to the Agreement on a Unified Patent Court, or UPCA, which provides for a Unitary Patent, or UP, and led to the establishment of a Unified Patent Court, UPC. The UPCA has entered into force on June, 1 2023. 17 out of the 24 member states have fully ratified the UPCA when it entered into force and participated in the UPCA from the start. Romania was the 18th state that ratified the UPCA on May 31, 2024. The remaining six EU member states are expected to join within the next years. Since the start of the UPCA, a conventional European patent can be enforced centrally at the UPC but may also face central revocation proceedings in the UPC, unless it is opted-out of the jurisdiction of the new court system.

The UPC has exclusive competence in respect of civil litigation on matters relating to European patents, Unitary Patents, supplementary protection certificates issued for a product covered by such patents and European patent applications (for details see Article 32 of the UPCA). Therefore, the UPC is not only competent to hear cases concerning UPs but also cases concerning traditional European patent applications and patents, or European patent(s), unless opted-out. The decision of the UPC in one country is binding in all other states participating in the UPCA. The decision, however, does not have any legally binding effect in EU member states not participating in the UPCA as well as in EPC contracting states which are not EU member states (e.g. Great Britain and Switzerland) and, therefore, are not eligible to participate in the new system.

It is generally expected that the UPC will be patent holder friendly both when it comes to assessment of validity of granted patents and infringement and that it may be beneficial for a patent holder to enforce and defend its patent at the UPC rather than at the EPO and/or national nullity court or civil court. Presently, however, there is no case law of the UPC that would allow a prediction of how the UPC may apply the patentability criteria when deciding on a central revocation action or a revocation counterclaim or how it will construe a claim in a central infringement proceeding. In view of these uncertainties, which are immanent to any new system on one hand, and the well-established practice of oppositions at the EPO as well as national invalidity and infringement proceedings on the other, we consider it a cautious and recommendable approach to opt-out all European patent applications and granted European patents from the UPC and to follow the case law of the UPC to determine the pros-and-cons of the UPC system. In case that the UPC appears to come to more favorable decision on validity and/or infringement than the EPO and national courts, it should be reconsidered to opt-in for one or more European patent or patent applications that have been previously opted out.

Our collaboration agreements

Co-development agreement with Staidson (Beijing) BioPharmaceuticals Co., Ltd. (as successor to Beijing Defengrei Biotechnology Co. Ltd, or BDB)

In December 2015, we entered into a co-development agreement, or the Co-Development Agreement, with Beijing Defengrei Biotechnology Co. Ltd., or BDB, for the use of the vilobelimab manufacturing cell line in BDB’s development of drug candidates for sale in China. Pursuant to the agreement, we granted BDB an exclusive, non-transferable license to use the vilobelimab cell line and related intellectual property solely to develop and commercialize in China BDB’s drug candidates BDB-001 and BDB-002, as well as molecules that bind or interact with certain specified targets, or target-binding molecules.

Pursuant to the agreement, we are entitled to receive mid-single-digit percentage royalties on net sales of BDB’s products containing BDB-001 or BDB-002. We retain the right to develop and manufacture vilobelimab and IFX002 in China solely for the purpose of commercializing products outside of China and to use the vilobelimab cell line and IFX002 cell line in China for non-commercial purposes. To the extent that we are granted regulatory approval outside of China for commercialization of a product using vilobelimab or IFX002 for an indication, and BDB does not pursue regulatory approval for BDB-001 or BDB-002 in the same or a substantially similar indication in China, by providing written notice to BDB, we may elect to pursue regulatory approval to commercialize such products in the relevant indication in China. Should we exercise such right, we would be required to pay BDB mid-single-digit percentage royalties on our net sales of such products.

Pursuant to the Co-Development Agreement, BDB has the right to use the vilobelimab cell line to manufacture an anti-C5a antibody, namely BDB-001. BDB-001 may only be commercialized in China (PRC) by BDB, and InflaRx is not directly involved in the BDB-001 development, which remains the sole responsibility of BDB. Pursuant to the Co-Development Agreement, InflaRx owns all global commercial rights outside China to any and all discoveries derived from the development of BDB-001. To support BDB's development of BDB-001, in 2020, InflaRx allowed BDB to conduct clinical studies with BDB-001 in Spain, India, Indonesia and Bangladesh. However, InflaRx remains the sole owner of all commercial rights to BDB-001 outside of China, including in countries in which BDB is conducting clinical trials. BDB has no rights to seek marketing authorization or to commercially exploit BDB-001 outside of China. Vilobelimab is not the product being tested in clinical trials by BDB in China. Rather, it is BDB's own antibody called BDB-001.

In addition, we reserved the right to commercialize products containing BDB-001 and BDB-002 outside of China in indications for which we elect not to commercialize vilobelimab or IFX002. To the extent that we exercise this right, we would be required to pay BDB low single-digit percentage royalties on our net sales of such products.

BDB must notify us without undue delay of tests it conducts on target-binding molecules. If any such test results in binding or interaction with targets in a satisfactory manner to both BDB and us, BDB must notify us of such results and may, within a six-month period following such notice, exercise an option to commence commercializing the successfully tested target-binding molecules in China. To the extent that BDB exercises such option, BDB would be required to pay us low single-digit percentage royalties on net sales of products containing such target-binding molecules. BDB also grants us the right to exploit any target-binding molecules outside of China or, to the extent that BDB does not pursue regulatory approval in the same or a substantially similar indication, in China. To the extent that we exercise such rights, we would be required to pay BDB low to mid single-digit percentage royalties on our net sales of such products.

In November 2021, we entered into a second addendum to the Co-Development Agreement with BDB and Staidson (Beijing) BioPharmaceuticals Co., Ltd., or Staidson. Under the second addendum, BDB, being a wholly-owned affiliate of Staidson, assigned the Co-Development Agreement to Staidson together with all rights and obligations thereunder.

In December 2022, we amended our existing co-development agreement with Staidson to support Staidson in its regulatory approval efforts for its proprietary drug candidate BDB-001 for the treatment of COVID-19 in China. Pursuant to the amendment, we will receive increased royalties of 10% on net sales of BDB-001 for the treatment of COVID-19 in China. We granted Staidson an exclusive license for use in China to certain of our clinical, manufacturing and regulatory data regarding vilobelimab in order to support and facilitate the regulatory filing for BDB-001 for the treatment of severely ill COVID-19 patients with the Chinese National Medical Products Administration, or NMPA. Under the existing Co-Development Agreement, BDB-001 is being developed by Staidson for the treatment of severe COVID-19 and other inflammatory diseases in China. The agreement continues to be in force unless earlier terminated. The agreement may be terminated upon the mutual agreement of the parties, or by one party upon a breach by the other party that is not cured within 30 days after receiving notice of such breach. In addition, either party may terminate the agreement if the other party challenges the terminating party's ownership of any intellectual property licensed to the non-terminating party under the agreement or undergoes certain bankruptcy or insolvency events.

Concomitantly to amending the Co-Development Agreement, in December 2022 we also entered into a share purchase agreement with Staidson Hong Kong Investment Company Limited, an affiliate of Staidson and a limited liability company organized under the law of Hong Kong, pursuant to which Staidson Hong Kong Investment Company Limited purchased ordinary shares from us for an aggregate amount of $2.5 million (€2.3 million) at a price of $5.00 per share, resulting in the sale of 500,000 shares. The share purchase agreement also includes an option pursuant to which Staidson Hong Kong Investment Company Limited may purchase additional ordinary shares, at our discretion, for an aggregate amount of an additional $7.5 million. The option for such subsequent purchase will expire on the twelve-month anniversary of Staidson receiving regulatory approval for BDB-001 in China. Such subsequent investment would be made at the greater of $5.00 per share or at a 20% premium to the weighted average share price over the 15 trading days prior to the closing date of such subsequent investment.

Cell line sales agreement with Catalent Pharma Solutions LLC

On March 18, 2010 we signed a cell line sales agreement with Catalent Pharma Solutions, LLC, New Jersey, USA in which InflaRx accepted a future milestone payment in the amount of $1m, independent of any transfer of the cell line in case of the receipt of an marketing approval of vilobelimab in any major market.

Clinical trial collaboration and supply agreement with Merck & Co., Inc.

On March 20, 2020, we entered into a clinical trial collaboration and supply agreement with Merck & Co., Inc. (known as MSD outside the United States and Canada) to evaluate the combination of vilobelimab and Merck's anti-PD-1 therapy, KEYTRUDA®[1] (pembrolizumab) in patients with cSCC. Under the terms of the agreement, we conducted a Phase 2 clinical study with two vilobelimab arms, including one with pembrolizumab. In November 2023, we announced the development stop of vilobelimab in cSCC to prioritize other programs. The trial has been finalized in 2024, all the patients recruited received therapy according to the protocol.

Clinical Trials Collaboration Agreement with the U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response, BARDA and PPD Development, L.P., or PPD

In June 2024, GOHIBIC (vilobelimab) was selected for the first BARDA-sponsored clinical trial to evaluate novel host-directed therapeutics for ARDS. The Company, BARDA and PPD Development L.P. executed the clinical trial collaboration agreement, according to which we will supply the amounts of investigational drug necessary to conduct the study. Vilobelimab, which we will suppy from our available stock under the terms of the agreement, will be one of three host-directed investigational drugs assessed in this study, with the safety and efficacy of each investigational drug to be studied in its own patient cohort and compared against placebo. Each cohort is expected to enroll 200 patients (100 on investigational drug and 100 on placebo), with both arms in each cohort including standard of care as background therapy. The Company will receive certain clinical data resulting from the study.

Sales and marketing

In June 2023, we began the commercialization of GOHIBIC (vilobelimab) in the United States for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV or ECMO. In connection with the start of the commercialization, we entered into agreements with certain subsidiaries of Cencora to act as our U.S. distributor and make GOHIBIC (vilobelimab) available for order by U.S. hospital customers under the EUA. Cencora provides cold storage, cold-chain distribution services, inventory management and secondary labeling/packaging, among other services.

To support our commercial efforts, we have hired and continue to utilize U.S. experts with relevant experience in the commercialization of medical products in the hospital market, including in the areas of sales, sales operations, marketing, market access, distribution, medical affairs and others.

We continue to refine our commercial strategic plan, preparing relevant promotional and medical education materials to target healthcare providers and other stakeholders, and continue refining our medical affairs strategy to increase awareness of the EUA among the medical community, while continuing our sales efforts. In Europe, InflaRx intends to commercialize and distribute GOHIBIC (vilobelimab) through a partnership.

In 2024, we recognized revenues in the amount of €0.2 million from product sales. Revenues reported are sales to end customers (hospitals) in the United States.

During the twelve months ended December 31, 2024 the Group incurred €6.8 million of sales and marketing expenses (2023: €4.0 million). These expenses are mainly composed of €1.8 million in personnel costs, €1.6 million in marketing costs and €2.1 million in external services for distribution of GOHIBIC (vilobelimab. The Group started with its commercialization activities when the EUA was granted in April 2023. Prior to that, no sales and marketing expenses had been incurred.

We also intend to independently pursue the commercialization of vilobelimab for PG in the United States and Europe, if and when approved by the applicable regulators, by employing a targeted commercial

[1] KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

infrastructure to promote access to vilobelimab through centers-of-excellence that treat PG in these core markets. We believe that such an organization will be able to address the community of physicians who are key specialists in treating the patient populations for which vilobelimab and any other product candidates are being developed. The responsibilities of the organization would include developing educational initiatives with respect to approved products and establishing relationships with key specialists in PG and any other relevant fields of medicine. Options to collaborate with larger pharmaceutical organizations with established commercial infrastructures will also be evaluated.

We might also consider pursuing the commercialization of vilobelimab in other indications or commercialization of our other development products independently. However, we are also considering potential partnerships with larger companies that have a more established infrastructure and greater financial resources in different areas, including in sales and marketing.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates. We intend to rely on existing third-party contract manufacturers to produce our products and intend to recruit additional personnel with experience to manage the third-party contract manufacturers producing our product candidates and other product candidates or products that we may develop in the future. In addition, we engaged additional third-party manufacturers in Germany, the United States and other countries for activities related to potential sales, e.g. packaging and labeling of any of our approved products in the United States and elsewhere. We hold a manufacturing and importing license and participate in the drug product release procedure for vilobelimab by running a key immunological release assay in-house, allowing us to release only drug product batches that demonstrate the necessary, pre-specified high biological blocking activity. Thus, we are responsible for overseeing the entire manufacturing process and we release final fill-finished drug product with our qualified person.

Competition

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technologies, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Competition in PG

There are currently no drugs approved for the treatment of PG in major markets. The only locally approved treatment is adalimumab, which has been approved in Japan but in no other country on the basis of a small, locally conducted clinical trial. However, due to the high medical need associated with the disease, certain drugs are used in regular medical practice as treatment attempts for affected patients. These include certain orally administered drugs such as immunosuppressants, including cyclosporine or corticosteroids or antibiotics such as dapsone. In addition, topically applied tacrolimus is used in certain cases. Lastly intravenously administered TNF-alpha inhibitors such as infliximab or adalimumab or other biological drugs are also used, despite the fact that no formal regulatory approvals are in place.

As of the date hereof, to our knowledge, other treatments in active clinical development include:

- Spesolimab, an intravenously administered anti-IL-36R monoclonal antibody currently being clinically tested in Phase 3
- Bactritinib, an orally administered JAK1/JAK2 inhibitor, currently in Phase 2 clinical trials
- Canakinumab, a subcutaneoulsy administereed anti-IL-1beta antibody, currently being tested in Phase 2 clinical trials in patients suffering from pyogenic arthritis, pyoderma gangreanosum and acne, or PAPA syndrome, which represents a specific sub-population of PG patients
- Deucravacitinib, an orally administered JAK2 inhibitor, currently being tested in an open label, exploratory Phase 1 clinical trial

Competition in the treatment of critically ill, invasively mechanically ventilated COVID-19 patients

For treatment of critically ill, invasively mechanically ventilated COVID-19 patients, vilobelimab faces competition from currently used or approved therapeutics such as corticosteroids, the interleukin-1, or IL-1, inhibitor anakinra, IL-6 inhibitors such as tocilizumab, JAK-inhibitors such as baricitinib and anti-thrombotic therapy. Given the high medical need for effective treatments during the times of the COVID-19 pandemic, many different therapeutic entities and targets have been assessed for the treatment of this patient population. While the performance of clinical trials in a particular patient population is the prerequisite to be able to gain regulatory approval for the treatment of that particular patient population, several clinical trials have been conducted in other patient populations (e.g., hospitalized patients as opposed to our targeted sub-group of critically ill, invasively mechanically ventilated patients) and results of these trials have partly been extrapolated into our targeted population. Therefore, we believe that competition will mainly be faced by products developed for the intended use population.

Competition in HS

The following systemically administered products are currently approved and marketed to treat moderate to severe HS patients in the United States and Europe:

- Adalimumab, a subcutaneously administered anti-TNF-alpha monoclonal antibody
- Secukinumab, a subcutaneously administered anti-IL-17 alpha monoclonal antibody
- Bimekizumab, a subcutaneously administered anti-IL-17A/F, monoclonal antibody

If we develop and receive approval for INF904 in HS, we would face competition from currently approved therapeutics such as adalimumab, secukinumab and bimekizumab, from topical therapies, including clindamycin, resorcinol and others, from intralesionally applied corticosteroids, from orally administered antibiotics such as tetracycline, clindamycin, rifampicin, metronidazole, cephalosporin, dapsone and others. In addition, a range of surgical procedures, laser and radiotherapy procedures are being investigated and used for the treatment of HS. Finally, we could face competition from additional systemically administered product candidates with different mechanisms of action currently under development that might receive approvals for HS before us:

- Povorcitinib, an orally administered JAK1 inhibitor, currently in Phase 3 clinical development
- Sonelokimab, a subcutaneoulsy administered anti-IL-17A, IL-17F nanobody, currently in Phase 3 clinical development
- Izokibep, a subcutaneoulsy administered small therapeutic protein inhibitor of IL-17A, currently in Phase 3 clinical development, one Phase 3 trial completed
- Udapacitinib, an orally administered JAK inhibitor, currently in Phase 3 clinical development
- Spesolimab, an intravenoulsy administered anti-IL-36R antibody, currently in Phase 3 clinical development
- Lutikizumab, a subcutaneoulsy administered anti-IL-1 alpha/beta antibody, currently in Phase 3 clinical development
- SAR442970, a subcutaneoulsy administered anti-TNF-OX40L nanobody, in Phase 2 clinical development
- SAR444656, an orally administered IRAK degrader, in Phase 2 clinical development
- Amlitelimab (SAR445229), a subcutaneoulsy administered anti-OX40L antibody, in Phase 2 clinical development
- Iscalimab, a subcutaneoulsy administered anti-CD40 antibody, in Phase 2 clinical development
- LYS006, an orally administered LTA4H inhibitor, in Phase 2 clinical development

- MAS825, an orally administered TIM3 inhibitor, in Phase 2 clinical development
- Remibrutinib, an orally administered BTK inhibitor, in Phase 2 clinical development
- Ianalumab, a subcutaneoulsy administered anti-BAFF-R antibody, in Phase 2 clinical development
- Eltrekibart, a subcutaneoulsy administered anti-CXC antibody, in Phase 2 clinical development
- AVTX-009, a subcutaneoulsy administered anti-IL-1beta antibody, in Phase 2 clinical development
- Ruxolitinib cream, a topically applied JAK1/JAK2 inhibitor in Phase 2 clinical development
- Orismilast, an orally administered PDE-4 inhibitor, in Phase 2 clinical development
- Tofacitinib, an orally administered JAK inhibitor, in an ongoing Phase 2 studies in patients with Down Syndrome

Competition in Chronic Spontaneous Urticaria (CSU)

As of today, only approved drugs for Chronic Spontaneous Urticaria are:

- Omalizumab, anti-IgE antibody (SC), on the market
- Dupilumab, anti IL-4/IL-13 antibody (SC) on the market

If we would develop and receive approval for INF904 in CSU, we would face competition from currently approved systemically delivered therapeutics such as omalizumab and dupilumab, from systemic and/or topical anti-histaminic drugs, corticosteroids and others. Finally, we could face competition from additional systemically administered product candidates with varying mechanisms of action currently under development that might receive approvals for CSU before us.

- Remibrutinib, an orally administered BTK inhibitor, currently in Phase 3 clinical development
- Barzovolumab, a subcutaneously administered c-kit inhibitor, currently in Phase 3 clinical development
- TLL-018, an orally administered JAK1/TYK2 inhibitor, currently in Phase 3 clinical development
- Rilzabrutinib, an orally administered BTK inhibitor, currently in Phase 2 clinical development
- TAS5315, an orally administered BTK inhibitor, currently in Phase 2 clinical development
- Porvocitinib, an orally administered JAK1 inhibitor, currently in Phase 2 clinical development
- HWH486, an orally administered BTK inhibitor, currently in Phase 2 clinical development
- EP262, an orally administered MRGPRX2 antagonist, currently in Phase 2 clinical development
- Briquilimab, c-kit inhibitor, currently in Phase 2 clinical development
- AK006, an intravenoulsy and subcutaneously administered anti-Siglec-6 antibody, completign Phase 1 clinical trials

Summary

The key competitive factors affecting the success of our product candidates, if approved or authorized, are likely to be their efficacy, safety, dosing convenience, price and degree of market acceptance, as well as our or our partners marketing capabilities, the level of competition and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our

competitors establishing a strong market position before we are able to enter the market. In addition, even if our product candidates are approved for marketing and sale, they may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community, including if physicians are reluctant to switch their patients from existing therapies (such as adalimumab for the treatment of HS). See "ITEM 3. KEY INFORMATION — D. Risk factors — Risks related to the discovery, development and commercialization of our product candidates—Even if one of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable."

Government regulation and product approval

Government authorities in all major pharmaceutical markets extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing and import and export of pharmaceutical products such as those we are developing. Although our initial focus will be on the United States and Europe, we intend to develop and seek marketing approval for our products also in other countries and territories, such as Canada or Japan, and for markets that follow the leading authorities, such as Brazil or South Korea. The processes for obtaining regulatory approvals in the United States, Europe and other countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

FDA approval process

All of our current product candidates are subject to regulation in the United States by the FDA either as biological products, or biologics, or as new chemical entities, or NCEs. The FDA subjects biologics and NCEs to extensive pre- and post-market regulation. The Public Health Service Act, or PHSA, the Federal Food, Drug, and Cosmetic Act and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of biologics and NCEs. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending BLAs or NDAs, withdrawal of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines or civil or criminal penalties.

The PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

BLA and NDA application and approval

The process required by the FDA before a new biologic or NCE may be marketed in the United States is long, expensive, and inherently uncertain. Biologics and NCE development in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an IND (which must become effective before clinical testing may commence) and adequate and well-controlled clinical trials to establish the safety, purity and potency (safety and effectiveness) of the biologic or NCE for each indication for which FDA approval is sought. Developing the data to satisfy FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, as well as in vitro and animal studies to assess the safety and activity of the drug candidate for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

An IND must become effective before United States clinical trials may begin. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug or biologic to healthy volunteers or patients with the condition under investigation, all under the supervision of a qualified investigator. Clinical trials must be conducted (i) in compliance with federal regulations, (ii) in compliance with good clinical practice, or GCP, which is an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with requirements or presents an unacceptable risk to the clinical trial subjects. The study protocol and informed consent information for subjects in clinical trials must also be submitted to an institutional review board (IRB) for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. The study sponsor may also suspend a clinical trial at any time on various grounds, including a determination that the subjects or patients are being exposed to an unacceptable health risk.

Clinical trials to support BLAs or NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap or be combined. In Phase 1, the drug candidate is initially introduced into healthy human subjects or patients and is tested to assess its pharmacokinetic, or PK, properties, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, such as cancer treatments, initial human testing has to be conducted in the intended patient population. Phase 2 usually involves trials in a limited and well-specified patient population to determine the effectiveness of the biologic for a particular indication, dosage tolerance and optimum dosage, and to identify common AEs and potential safety risks. If a drug candidate demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain additional information about clinical efficacy and safety in a larger number of patients, representing the future intended use population, typically at geographically dispersed clinical trial sites. These Phase 3 clinical trials are intended to establish data sufficient to demonstrate substantial evidence of the efficacy and safety of the product to permit the FDA to evaluate the overall benefit-risk relationship of the biologic or NCE and to provide adequate information for the labeling of the drug. Trials conducted outside of the United States under similar, GCP-compliant conditions in accordance with local applicable laws may also be acceptable to the FDA in support of product licensing.

Sponsors of clinical trials for investigational drugs must publicly disclose certain clinical trial information, including detailed trial design and trial results in public government databases. These requirements are subject to specific timelines and apply to most controlled clinical trials of FDA-regulated products.

After completion of the required clinical testing, a BLA (for a biologic) or an NDA (for an NCE) is prepared and submitted to the FDA. FDA review and approval of the BLA or NDA is required before marketing of the product may begin in the United States. The BLA or NDA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls, and must demonstrate the safety and efficacy of the product based on these results. The BLA or NDA must also contain extensive manufacturing information. The cost of preparing and submitting a BLA or NDA is substantial. Under federal law, the submission of most BLAs or NDAs is additionally subject to a substantial application user fee, as well as an annual program user fee, which may total several million dollars and are typically increased annually.

The FDA has 60 days from its receipt of a BLA or NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of BLAs and NDAs. Most such applications for standard review drug candidates are reviewed within 10 months from the date the application is accepted for filing. Although the FDA often meets its user fee performance goals, it can extend these timelines if necessary, and its

review may not occur on a timely basis. The FDA usually refers applications for novel drugs, or drugs which present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it frequently follows such recommendations. Before approving a BLA or NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless it verifies that compliance with cGMP standards is satisfactory and the BLA or NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the BLA or NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA or NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. The FDA approval is never guaranteed, and the FDA may refuse to approve a BLA or NDA if applicable regulatory criteria are not satisfied.

Under the PHSA, the FDA may approve a BLA or NDA if it determines that the product is safe, pure and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure, and potent. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. The approval for a drug may be significantly more limited than requested in the application, including limitations on the specific diseases and dosages or the indications for use, which could restrict the commercial value of the product. The FDA may also require that certain contraindications, warnings, or precautions be included in the product labeling. In addition, as a condition of BLA or NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS or use of a companion diagnostic with a drug can materially affect the potential market and profitability of the drug. Moreover, product approval may require, as a condition of approval, substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

After a BLA or NDA is approved, the product may also be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of products. After approval of drugs, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection.

Emergency use authorization

The FDA can facilitate the availability and use of medical countermeasures needed during public health emergencies via EUA. When The United States Secretary of Health and Human Services, or HHS Secretary, declares that an EUA is appropriate, FDA may authorize unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological or nuclear threat agents. For example, in January 2020, the HHS Secretary determined that a public health emergency, or PHE, existed (and has subsequently extended the declaration on numerous occasions,) that had a significant potential to affect national security or the health and security of U.S. citizens due to the emergence and spread of COVID-19. Based on this determination, the HHS Secretary also declared that circumstances existed justifying EUA of certain medical products. The EUA declaration is distinct from the PHE declaration. As long as the applicable EUA declaration and determination remains in effect, an EUA may remain in effect beyond the duration of the PHE declaration if all other statutory conditions are met. Even if the EUA declaration remains in effect ,the FDA may revoke the

EUA at any time if certain circumstances or criteria are met.We have been granted the EUA for GOHIBIC (vilobelimab), for the treatment of COVID-19 in hospitalized adults when initiated within 48hours of receiving IMV or ECMO.

Adverse event reporting an cGMP compliance

Adverse event reporting and submission of periodic reports are required following FDA approval of a BLA or NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS and surveillance to monitor the effects of an approved product, or may place conditions on an approval that could restrict the distribution or use of the product. In addition, manufacture, packaging, labeling, storage and distribution procedures must continue to conform to current cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals, request product recalls or impose marketing restrictions through labeling changes or product removals if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Orphan drug designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to biologics or NCEs intended to treat a rare disease or condition—generally a disease or condition that affects fewer than 200,000 individuals annually in the United States. Orphan drug designation must be requested before submitting a BLA or NDA. After the FDA grants orphan drug designation, the generic identity of the drug candidate and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not necessarily convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first BLA or NDA applicant to receive FDA approval for a particular product to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition or, a drug that is otherwise the same drug which may be clinically superior. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA or NDA application user fee.

Fast track designation

Fast track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Fast track addresses a broad range of serious conditions. Determining whether a condition is serious is a matter of judgment, but generally is based on whether the drug will have an impact on such factors as survival, day-to-day functioning, or the likelihood that the condition, if left untreated, will progress from a less severe condition to a more serious one. Filling an unmet medical need is defined as providing a therapy where none exists or providing a therapy which may be potentially better than available therapy. Any drug being developed to treat or prevent a condition with no current therapy is directed at an unmet need. If there are available therapies, a fast track drug must show some advantage over available therapy, such as: showing superior effectiveness, effect on serious outcomes or improved effect on serious outcomes; avoiding serious side effects of an available therapy; improving the diagnosis of a serious condition where early diagnosis results in an improved outcome; decreasing a clinical significant toxicity of an available therapy that is common and causes discontinuation of treatment or ability to address an emerging or anticipated public health need. A drug that receives fast track designation is eligible for some or all of the following: more frequent meetings with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval; more frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers; eligibility for Accelerated Approval and Priority Review, if relevant criteria are met; Rolling Review, which means that a drug company can submit completed sections of its BLA or NDA for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. BLA or NDA review usually does not begin until the drug company has submitted the entire application to the FDA. Fast track designation must be requested by the drug company. The request can be

initiated at any time during the drug development process. FDA will review the request and make a decision within sixty days based on whether the drug fills an unmet medical need in a serious condition. Once a drug receives fast track designation, early and frequent communication between the FDA and a drug company is encouraged throughout the entire drug development and review process. The frequency of communication assures that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients.

We have been granted orphan drug status and fast track designation for the PG indication in the United States for vilobelimab. We have also been granted fast track designation for the COVID-19 indication in the United States. Depending on the outcome and available data of vilobelimab studies in the other indications, we may apply for orphan drug status in the United States.

Accelerated approval

The FDA instituted its accelerated approval program to allow for earlier approval of drugs that treat serious conditions, and fill an unmet medical need based on a surrogate endpoint. A surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. The use of a surrogate endpoint can considerably shorten the time required prior to receiving FDA approval. Drug companies are still required to conduct studies to confirm the anticipated clinical benefit. These studies are known as Phase 4 confirmatory trials. If the confirmatory trial shows that the drug actually provides a clinical benefit, then the FDA grants traditional approval for the drug. If the confirmatory trial does not show that the drug provides clinical benefit, FDA has regulatory procedures in place that could lead to removing the drug from the market.

Priority review

In 1992, under the Prescription Drug User Act, or PDUFA, FDA agreed to specific goals for improving the drug review time and created a two-tiered system of review times – standard review and priority review. A priority review designation means FDA's goal is to take action on an application within six months (compared to 10 months under standard review). A priority review designation will direct overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. Significant improvement may be demonstrated by the following examples: evidence of increased effectiveness in treatment, prevention, or diagnosis of condition; elimination or substantial reduction of a treatment-limiting drug reaction; documented enhancement of patient compliance that is expected to lead to an improvement in serious outcomes; or evidence of safety and effectiveness in a new subpopulation. FDA decides on the review designation for every application. However, an applicant may expressly request priority review. It does not affect the length of the clinical trial period. FDA informs the applicant of a priority review designation within 60 days of the receipt of the BLA or NDA. Designation of a drug as "priority" does not alter the scientific/medical standard for approval or the quality of evidence necessary.

Other healthcare laws and compliance requirements

In the United States, our activities are potentially subject to regulation by federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services (for example, the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments.

EU approval process

The European Medicines Agency, or EMA is a decentralized scientific agency of the European Union. It coordinates the evaluation and monitoring of centrally-authorized medicinal products. It is responsible for the scientific evaluation of applications for European marketing authorizations, as well as the development of technical guidance and the provision of scientific advice to sponsors. The EMA decentralizes its scientific assessment of medicines by working through a network of about 4,500 experts throughout the European Union, nominated by the member states. The EMA draws on resources of over 40 National Competent Authorities, or the NCAs, of EU member states. The Paul Ehrlich Institute, or PEI, is one of the NCAs for Germany, and regulates, among others, antibody products.

The process regarding approval of medicinal products in the European Union follows roughly the same lines as in the United States and generally involves satisfactorily completing each of the following:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the applicable EU Good Laboratory Practice regulations;
- submission to the relevant national authorities of a clinical trial application or CTA for each trial in humans, which must be approved before the trial may begin in each country where patient enrollment is planned;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;
- submission to the relevant competent authorities of a MAA, which includes the data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labelling;
- satisfactory completion of an inspection by the relevant national authorities of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with strictly enforced cGMP;
- potential audits of the non-clinical and clinical trial sites that generated the data in support of the MAA; and
- review and approval by the relevant competent authority of the MAA before any commercial marketing, sale or shipment of the product.

Preclinical studies

Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animal studies, in order to assess the quality and potential safety and efficacy of the product. The conduct of the preclinical tests and formulation of the compounds for testing must comply with the relevant international, EU and national legislation, regulations and guidelines. The results of the preclinical tests, together with relevant manufacturing information and analytical data, are submitted as part of the CTA.

Clinical trial approval

The Clinical Trials Regulation (EU) No 536/2014 repealed the Clinical Trials Directive 2001/20/EC, on January 31, 2022 and applies to all new clinical trials from January 31, 2023. All ongoing trials must be transitioned to the new processes by 31 January 2025. The Clinical Trials Regulation harmonizes the processes and supervision of clinical trials throughout the EU. Sponsors submit one application via the Clinical Trials Information System, or CTIS, for approval to run a clinical trial in several European countries. The evaluation, authorization and supervision of clinical trials are the responsibilities of EU member states and European Economic Area, or EEA, countries. The CTIS application must be supported by an investigational medicinal product dossier, or IMPD, the study protocol and further supporting information prescribed by the Clinical Trials Regulation and other applicable guidance documents. The CTIS process has predetermined timelines which may vary depending on the phase of the study. The process includes timelines for one or more rounds of questions to be answered or requests to be met by the regulatory authority.

Regulation (EU) No 536/2014, includes transparency requirements (the proactive publication of clinical trial data in the EU database) with associated rules on the timing of the publication of submitted documents at the time of, during and after completion of the clinical trial. The transparency requirement can apply to documents included in the clinical trial application, or CTA, dossier provided in CTIS, and all the clinical trial information submitted during the trial life cycle, with the exception of the quality related documents, financial arrangements and some supervision related information.

Manufacturing and import into the EU of investigational medicinal products is subject to the holding of appropriate authorizations and must be carried out in accordance with cGMP.

Marketing authorization application

Authorization to market a product in the EU member states proceeds under one of four procedures: a centralized authorization procedure, a mutual recognition procedure, a decentralized procedure or a national procedure. Since our products by their virtue of being antibody-based biologics or NCEs, fall under the centralized procedure, only this procedure will be described here.

Centralized authorization procedure

Certain drugs, including medicinal products developed by means of biotechnological processes, must be approved via the centralized authorization procedure for marketing authorization. A successful application under the centralized authorization procedure results in a marketing authorization from the EC, which is automatically valid in all EU member states as well as in the other EEA, member states (namely Norway, Iceland and Liechtenstein). The EMA and the EC administer the centralized authorization procedure.

Under the centralized authorization procedure, the CHMP serves as the scientific committee that renders opinions about the safety, efficacy and quality of human products on behalf of the EMA. The CHMP is composed of experts nominated by each member state's national drug authority, with one of them appointed to act as Rapporteur for the co-ordination of the evaluation with the possible assistance of a further member of the committee acting as a Co-Rapporteur. After approval, the Rapporteur(s) continue to monitor the product throughout its life-cycle. The CHMP is required to issue an opinion within 210 days of receipt of a valid application, though the clock is stopped when it is necessary to ask the applicant for clarification or further supporting data. The process is complex and involves extensive consultation with the regulatory authorities of member states and a number of experts. Once the procedure is completed, a European Public Assessment Report, or EPAR, is produced. If the CHMP concludes that the quality, safety and efficacy of the medicinal product is sufficiently proven, it adopts a positive opinion. The CHMP's opinion is sent to the EC, which uses the opinion as the basis for its decision whether or not to grant a marketing authorization. If the opinion is negative, information is given as to the grounds on which this conclusion was reached.

Policy 0070, which is intended to promote transparency of EMA decision making and clinical data, governs how EMA collects, reviews and publishes clinical data submitted by applicants and Marketing Authorization Holders, or MAHs, through the centralized procedure.

After a drug has been authorized and launched, it is a condition of maintaining the marketing authorization that all aspects relating to its quality, safety and efficacy must be kept under review. Sanctions may be imposed for failure to adhere to the conditions of the marketing authorization. In extreme cases, the authorization may be revoked, resulting in withdrawal of the product from sale.

Marketing authorization under exceptional circumstances

In exceptional circumstances and following consultation with the applicant, an authorisation may be granted subject to certain conditions, so called specific obligations (SOBs), in particular relating to the safety of the medicinal product, notification to the national competent authorities of any incident relating to its use, and action to be taken. MAs under exceptional circumstances can be granted under Article 14(8) of Regulation (EC) No 726/2004. An MA under exceptional circumstances is a type of marketing authorisation granted to medicines where the applicant is unable to provide comprehensive data on the efficacy and safety under normal conditions of use, because the condition to be treated is rare or because collection of full information is not possible or is unethical.

Gohibic (vilobelimab) has been granted an MA under exceptional circumstances on 13 January 2025 for the treatment of adult patients with SARS-CoV2-induced acute respiratory distress syndrome (ARDS) who are receiving systemic corticosteroids as part of Standard of Care and receiving invasive mechanical ventilation (IMV) (with or without extracorporeal membrane oxygenation (ECMO)). The Specific Obligation to complete post authorisation measures for the Gohibic MA under exceptional circumstances is to submit annually (within the annual reassessment) results for the vilobelimab cohort in Just Breathe platform study, a double-blind, placebo controlled study enrolling patients with moderate to severe ARDS caused by COVID-19 and other viral and bacterial pulmonary infections and to submit updates on any new information concerning the efficacy and safety of Gohibic.

Continuation of the MA for Gohibic is linked to the annual re-assessment by EMA of the conditions mentioned above. The outcome of the annual re-assessment will reflect the status of fulfilment of the SOB(s)

and the impact of the SOB data on the benefit / risk profile of the medicinal product and will conclude on whether the marketing authorisation should be maintained, varied or suspended based on the review of these two elements.

Accelerated assessment procedure

When an application is submitted for a marketing authorization in respect of a drug for human use which is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may request an accelerated assessment procedure pursuant to Article 14(9) of Regulation (EC) 726/2004. Under the accelerated assessment procedure, the CHMP is required to issue an opinion within 150 days of receipt of a valid application, subject to clock stops. We believe that some of the disease indications in which our product candidates are currently being or may be developed in the future qualify for this provision, and we will take advantage of this provision as appropriate.

Conditional approval

As per Article 14(7) of Regulation (EC) 726/2004, a medicine that would fulfill an unmet medical need may, if its immediate availability is in the interest of public health, be granted a conditional marketing authorization on the basis of less complete clinical data than are normally required, subject to specific obligations being imposed on the authorization holder. These specific obligations are to be reviewed annually by the EMA. The list of these obligations shall be made publicly accessible. Such an authorization shall be valid for one year, on a renewable basis.

Period of authorization and renewals

A marketing authorization is initially valid for five years and may then be renewed on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder shall provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variants introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization shall be valid for an unlimited period, unless the Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization shall cease to be valid (the so-called sunset clause).

Orphan drug designation

Regulation (EC) 141/2000 states that a drug shall be designated as an orphan drug if its sponsor can establish:

- that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union when the application is made, or;

- that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment; and

- that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the drug will be of significant benefit to those affected by that condition.

Regulation (EC) 847/2000 sets out criteria for the designation of orphan drugs. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a 10-year period of market exclusivity, which means that no similar medicinal product can be authorized in the same indication. This period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify continued market exclusivity. In addition, derogation from market exclusivity may be granted on an individual

basis in very selected cases, such as consent from the marketing authorization holder, inability to supply sufficient quantities of the product or demonstration of "clinically relevant superiority" by a similar medicinal product. Medicinal products designated as orphan drugs pursuant to Regulation (EC) 141/2000 are eligible for incentives made available by the European Union and by the member states to support research into, and the development and availability of, orphan drugs.

If the MAA of a medicinal product designated as orphan drug pursuant to Regulation (EC) 141/2000 includes the results of all studies conducted in compliance with an agreed PIP, and a corresponding statement is subsequently included in the marketing authorization granted, the 10-year period of market exclusivity will be extended to 12 years.

We have been granted orphan drug status for the PG indication in the European Union for vilobelimab. Depending on the outcome and available data of vilobelimab studies in the other indications, we may also apply for orphan drug status in Europe for these indications.

Regulatory data protection

Without prejudice to the law on the protection of industrial and commercial property, marketing authorizations for new medicinal products benefit from an 8+2+1 year period of regulatory protection.

This regime consists of a regulatory data protection period of eight years plus a concurrent market exclusivity of 10 years plus an additional market exclusivity of one further year if, during the first eight years of those 10 years, the marketing approval holder obtains an approval for one or more new therapeutic indications which, during the scientific evaluation prior to their approval, are determined to bring a significant clinical benefit in comparison with existing therapies. Under the current rules, a third party may reference the preclinical and clinical data of the reference product beginning eight years after first approval, but the third party may market a generic version of the reference product after only 10 (or 11) years have lapsed.

Other international regulations

In addition to regulations in the United States and Europe, a variety of foreign regulations govern clinical trials, commercial sales, and distribution of pharmaceutical products. The approval process varies from country to country and the time to approval may be longer or shorter than that required for FDA or EC approval.

Pharmaceutical coverage, pricing and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of our products will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial private and public health insurers and managed care organizations, provide coverage and establish adequate reimbursement levels for, such products. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any pharmaceutical product approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. Additionally, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures,

and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Outside the United States, ensuring adequate coverage and payment for our products will face challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of our products or products to other available therapies. The conduct of such clinical trials could be expensive and result in delays in our commercialization efforts.

In the European Union, pricing and reimbursement schemes to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug product to currently available therapies. EU member states may also require approval of a specific price for a drug product or, instead, may adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other EU member states allow companies to fix their own prices for drug products but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the market entry of new pharmaceutical products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Organizational structure

InflaRx N.V. has two direct wholly-owned subsidiaries, InflaRx GmbH and InflaRx Pharmaceuticals, Inc., that are each listed in Exhibit 8.1 filed herewith..

Property, plant and equipment

Our headquarters are in Jena, Germany, where we occupy approximately 8,000 square feet of office and laboratory space under a lease that expires in December 2025. In addition, we occupy approximately 13,700 square feet of office space in Planegg-Martinsried (near Munich), Germany under a lease that expires in May 2027. Furthermore, we have leased office and laboratory space in Ann Arbor, Michigan, United States under a lease that expires in April 2026.

Stakeholder dialogue

We believe communication with our key stakeholders is crucial. Key stakeholders of the Company are shareholders, employees, suppliers, patients and regulatory authorities. We communicate with our shareholders regularly via press releases and webcasts. We also regularly communicate with our employees, among other things on major changes and achievements. We conduct transparent communication with suppliers, patients and regulatory authorities. To ensure that the interests of relevant stakeholders of the Company are considered, including in connection with the sustainability aspects of the Company's strategy, the Company has established a Stakeholder Dialogue Policy, which is published on the Company's website. Dialogue between the Company on the one hand and one or more of its shareholders on the other hand is governed by the Company's Shareholder Bilateral Dialogue Policy, which is published on the Company's website.

Operating and financial review and prospects

8. Operating results

You should read the following discussion and analysis of our financial condition and results of operations together with the information in our Consolidated Financial Statements and the notes thereto.

The following discussion is based on our financial information prepared in accordance with IFRS accounting standards as issued by the IASB, which may differ in material respects from generally accepted accounting principles in the United States and other jurisdictions. The following discussion includes forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward- looking statements as a result of many factors, including but not limited to, those described under “ITEM 1: C. Risk factors” and “ITEM 1: B. Forward-Looking Statements.”

9. Overview

We are a biotechnology company pioneering anti-inflammatory therapeutics focused on applying our proprietary anti-C5a and C5aR technologies to discover, develop and commercialize first-in-class, potent and specific inhibitors of the complement activation factor known as C5a and its receptor C5aR. C5a is a powerful inflammatory mediator involved in the progression of a wide variety of autoimmune and other inflammatory diseases. Our lead product candidate, vilobelimab, is a novel intravenously delivered first-in-class anti-C5a monoclonal antibody that selectively binds to free C5a and has demonstrated disease-modifying clinical activity and tolerability in multiple clinical settings. In April 2023, we received the EUA from the FDA for GOHIBIC (vilobelimab) for the treatment of critically ill, invasively mechanically ventilated COVID-19 patients. Subsequently, in June 2023, we began the commercialization of GOHIBIC (vilobelimab) in the United States. In January 2025, we received EC approval for vilobelimab for the treatment of SARS-CoV-2-induced ARDS, under exceptional circumstances.

We are also developing vilobelimab for the treatment of PG, a chronic inflammatory skin disorder for which we are currently conducting a Phase 3 study.

Beyond PG, we have been developing vilobelimab to generate proof of concept data in a wide array of complement-mediated diseases with significant unmet medical needs. For this purpose, we have previously conducted Phase II studies with vilobelimab in HS, a chronic debilitating systemic inflammatory skin disease, in ANCA-associated vasculitis, or AAV, a rare and life-threatening autoimmune disease and in cSCC, where we have recently decided to cease the development for the time being, since further clinical development would require substantial resources and significantly extend the timeline of the ongoing clinical program. We decided to prioritize our efforts and to reallocate our resources towards the development of our orally available C5aR inhibitor INF904, an oral small-molecule drug candidate that targets the C5aR receptor. We plan on targeting complement-mediated, chronic autoimmune and inflammatory conditions for which an oral small molecule is the preferred route of administration for patients. We have recently completed a Phase I single ascending dose, or SAD, and multiple ascending dose, or MAD, study in healthy volunteers in which we were able to confirm the favorable safety profile and the superior pharmacokinetic and pharmacodynamic profile of INF904. We are currently conducting a Phase IIa trial with INF904 in CSU and HS, as well as additional required pre-clinical studies, including long-term chronic toxicology studies, to enable longer-term dosing of INF904 for chronic inflammatory diseases. We are also developing IFX002, a life-cycle management product for vilobelimab.

Since our inception in December 2007, we have devoted substantially all our resources to establishing our company, raising capital, developing our proprietary anti-C5a/C5aR technologies, identifying and testing

potential product candidates and conducting clinical trials of our lead product candidate, vilobelimab and additional product candidates IFX002 and INF904. To date, we have only generated minimal product revenue and so far have primarily financed our operations through the issuance of securities in public offerings and private placements and through other income from various grants, including a grant awarded by the German federal government for certain research and development activities during the period from October 2021 to June 2023. Through this grant, we had received a total of €33.3 million to support the development of vilobelimab for the treatment of critically ill COVID-19 patients.

As of December 31, 2024, we had cash and cash equivalents of €18.4 million and €36.8 million in marketable securities.

Through an underwritten public offering in February 2025, we sold and issued an aggregate of 8,250,000 ordinary shares, at a price of $2.00 per share which have a nominal value of €0.12 per share and and in lieu of ordinary shares to certain investors, pre-funded warrants to purchase up to 6,750,000 of the Company's ordinary shares. The purchase price of each pre-funded warrant was equal to the price per share at which ordinary shares were sold to the public in this offering, minus $0.001, which is the exercise price of each pre-funded warrant. The aggregate gross proceeds from the offering were approximately $30 million, before deducting underwriting discounts and offering expenses.

As of December 31, 2024, we had an accumulated deficit of €332.2 million. We have incurred significant net operating losses in every year since our inception and expect to continue to incur comparable or increasing net operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year.

10. Financial operations overview

Revenue

In June 2023, we began the commercialization of GOHIBIC (vilobelimab) in the United States. In connection with the start of the commercialization, we entered into agreements with certain subsidiaries of Cencora Inc. to act as a Group's U.S. distributor to make GOHIBIC (vilobelimab) available for order by U.S. hospital customers.

Revenues reported are sales to end customers (hospitals). Sales to distributors do not constitute completion of the earnings process and, thus, do not result in the recognition of revenue for the Company under IFRS 15.

Cost of sales

Cost of sales consists of material, personnel and other costs associated with inventory sold and inventory write-downs in the period.

Other income

Other income as described herein results predominantly from government grants and research allowances recognized as income during the period.

Sales and marketing expenses

Sales and marketing expenses have consisted principally of:

- external services for distribution of GOHIBIC to build the necessary commercial and logistical infrastructure, including external sales professionals;
- marketing activities;
- employee-related expenses, including salaries, benefits and stock-based compensation expense based upon employees' role within the organization; and
- professional services fees in conjunction with making GOHIBIC available to hospitals and patients in the U.S.

Research and development expenses

Research and development expenses have consisted principally of:

- expenses incurred under agreements with CROs, contract development and manufacturing organizations, or CDMOs, consultants and independent contractors that conduct research and development, preclinical and clinical activities on our behalf;
- employee-related expenses, including salaries, benefits and stock-based compensation expense based upon employees' role within the organization; and
- professional fees for lawyers related to the protection and maintenance of our intellectual property.

We expense research and development costs as incurred. We recognize costs for certain development activities, such as preclinical studies and clinical trials, based on an evaluation of the progress to completion of specific tasks. We use information provided to us by our vendors such as status of patient enrollment or clinical site activations for measuring services received and efforts expended. Research and development activities are central to our business model.

General and administrative expenses

Our general and administrative expenses consist principally of:

- employee-related expenses, including salaries, benefits and stock-based compensation expense based upon employees' role within the organization;
- insurance expenses including directors´ and officers´ liability insurance premiums;
- professional fees for auditors and consulting expenses not related to research and development activities;
- professional fees for lawyers not related to the filing, prosecution, protection and maintenance of our intellectual property; and
- cost of facilities, travel, communication and office expenses.

Results of operations

The Group is exposed to the exchange rate between Euros and U.S. dollars. As a result of the Company's various registered offerings of ordinary shares in U.S. dollars, the Group holds significant cash, cash equivalents and marketable securities in U.S. dollars. This could have a material impact on our operating results.

The numbers below have been derived from our consolidated financial statements included elsewhere herein. The discussion below should be read along with these consolidated financial statements, and it is qualified in its entirety by reference to them.

Comparison of the years ended December 31, 2024 and 2023

	2024	2023	Change
		(in €)	
Revenues	165,789	63,089	102,700
Cost of sales	(3,317,039)	(532,262)	(2,784,777)
Gross profit	**(3,151,250)**	**(469,173)**	**(2,682,077)**
Marketing and sales expenses	(6,756,595)	(4,001,299)	(2,755,296)
Research and development expenses	(35,363,897)	(41,024,131)	5,660,234
General and administrative expenses	(13,024,441)	(12,628,756)	(395,685)
Other income and expenses (net)	5,287,319	13,215,264	(7,927,945)
Loss before interest and income taxes	**(53,008,864)**	**(44,908,096)**	**(8,100,768)**
Net financial result	6,949,679	2,240,566	4,709,113
Loss before tax	**(46,059,185)**	**(42,667,529)**	**(3,391,656)**
Income tax expense	(5,217)	—	(5,217)
Loss for the period	**(46,064,402)**	**(42,667,529)**	**(3,396,873)**
Exchange differences on translating operations in foreign currency	58,344	125,085	(66,741)
Total comprehensive loss	**(46,006,058)**	**(42,542,444)**	**(3,463,614)**

Revenues

	2024	2023	Change
		(in €)	
Revenues	165,789	63,089	102,700
Total	**165,789**	**63,089**	**102,700**

For the twelve months ended December 31, 2024, we realized revenues from product sales of GOHIBIC (vilobelimab) in the amount of €0.2 million, which represents an increase of €0.1 million compared to the prior year.

Cost of Sales

	2024	2023	Change
		(in €)	
Cost of sales	3,317,039	532,262	2,784,777
Total	**3,317,039**	**532,262**	**2,784,777**

Cost of sales expenses increased by €2.8 million for the year ended December 31, 2024 compared to the corresponding costs for the year ended December 31, 2023 primarily due to higher inventory write-downs of €2.8 million. The write-down of inventories is due to quantities on-hand exceeding quantities expected to be sold prior to expiry.

Sales and marketing expenses

	2024	2023	Change
		(in €)	
Third-party expenses	2,010,120	1,021,082	989,038
Marketing expenses	1,573,628	830,078	743,552
Personnel expenses	1,806,151	1,040,587	765,564
Legal and consulting fees	910,146	1,054,971	(144,825)
Other expenses	456,550	54,581	401,969
Total marketing and sales expenses	**6,756,595**	**4,001,299**	**2,755,296**

Marketing and sales expenses for the twelve months ended December 31, 2024 increased by €2.8 million compared to the twelve months ended December 31, 2023. This increase is due to 2024 being the first full year of commercial efforts for GOHIBIC (vilobelimab) in the United States. For the twelve months ended December 31, 2023 marketing and sales expenses were only incurred during the second half of the year.

Other expenses include mainly travel and related expenses.

Research and development expenses

	2024	2023	Change
		(in €)	
Third-party expenses	23,113,874	31,802,983	(8,689,109)
Personnel expenses	8,390,010	6,776,853	1,613,157
Other expenses	3,860,013	2,444,295	1,415,718
Total	**35,363,897**	**41,024,131**	**(5,660,234)**

Research and development expenses decreased by €5.7 million for the year ended December 31, 2024 compared to the year ended December 31, 2023 primarily due to lower third-party costs from manufacturing development activities and from clinical trials, which decreased by €8.7 million, offset by €1.6 million higher personnel expenses and €1.4 million higher other expenses compared to the previous year. Personnel expenses increased mainly due to increasing headcount as well as higher equity-settled share-based compensation.

Other expenses include a one-off milestone payment of $1.0 million (€1.0 million) which became payable upon receiving marketing authorization in Europe in 2025.

General and administrative expenses

	2024	2023	Change
		(in €)	
Personnel expenses	6,339,421	5,392,905	946,516
Legal, consulting and audit fees	2,851,390	3,239,809	(388,419)
Other expenses	3,833,630	3,996,042	(162,412)
Total	**13,024,441**	**12,628,756**	**395,685**

General and administrative expenses increased by €0.4 million to €13.0 million for the year ended December 31, 2024, from €12.6 million for the year ended December 31, 2023. This increase is comprised of higher personnel expense by €0.9 million and offset by € 0.4 million lower other expenses associated with insurance expenses, as well as by €0.4 million lower legal, consulting and audit fees.

Other income

	2024	2023	Change
		(in €)	
Other income from government grants and research allowances	5,081,772	13,155,250	(8,073,478)
Further other income	205,844	64,453	—
Total	**5,287,616**	**13,219,704**	**(7,932,088)**

Other income decreased by €7.9 million for the year ended December 31, 2024 compared to the year ended December 31, 2023 due primarily to lower income from government grants and research allowances. In June 2023, our grant from the German Ministry of Education and Research and the German Ministry of Health to support the development of vilobelimab for the treatment of severe COVID-19 patients ended. In 2024, upon qualifying for an allowance under the German Research Allowance Act, we recognized €5.1 million in income relating to expenses, eligible for reimbursement, which were incurred in the years 2020 to 2024. We remain eligible for reimbursement of eligible expenses to be incurred from 2025 to 2027.

Net financial result

	2024	2023	Change
		(in €)	
Interest income	3,196,813	3,804,827	(608,014)
Interest expenses	(885)	(16,538)	15,653
Interest on lease liabilities	(19,770)	(19,090)	(680)
Net interest result	**3,176,159**	**3,769,199**	**(593,040)**
Foreign exchange income	6,876,161	5,529,389	1,346,772
Foreign exchange expense	(3,205,926)	(7,371,261)	4,165,335
Net foreign exchange result	**3,670,235**	**(1,841,872)**	**5,512,107**
Other financial result	103,285	313,240	(209,955)
Net financial result	**6,949,679**	**2,240,566**	**4,709,114**

Net financial result increased by €4.7 million to €6.9 million for the year ended December 31, 2024 compared to €2.2 million for the year ended December 31, 2023. This overall net increase is mainly attributable to an increase of €5.5 million in foreign exchange result, offset by €0.6 million lower interest income from marketable securities compared to the year ended December 31, 2023.

Comparison of the years ended December 31, 2023 and 2022

A discussion of the financial results for the year ended December 31, 2023 as compared to the year ended December 31, 2022 can be found in the section entitled “Item 5. Operating and Financial Review and Prospects—A. Operating Results— Financial operations overview—Comparison of the years ended December 31, 2023 and 2022” in our annual report on form 20-F, filed with the SEC on March 21, 2024.

11. Liquidity and capital resources

Overview on cash requirements and sources of liquidity

Since inception, we have incurred significant operating losses mainly from our research and development activities and G&A costs. For the years ended December 31, 2024 and 2023, we incurred net losses of €46.1 million and €42.7 million, respectively. Our primary uses of cash are for working capital, operating leases and general corporate purposes.

Our primary sources of funds are proceeds from the sale of our shares including our initial public offering and follow-on offerings. Additionally, in 2021, we were awarded a grant from the German federal government under which we received €33.3 million between October 2021 and June 2023. The grant period ended on June 30, 2023.

In 2024, we qualified for an allowance under the *Forschungszulagengesetz* (Research Allowance Act) in Germany, a law designed to promote research and development. Under this allowance, we became eligible for reimbursement, by the German federal government, of a portion of certain eligible R&D expenses incurred from 2020 through 2027. For financial reporting purposes, under IFRS accounting standards, we recognize the allowance as a government grant. Upon qualifying for the allowance, we recognized €5.1 million in income relating to eligible expenses which were incurred in the years 2020 to 2024. We remain eligible for reimbursement of expenses to be incurred from 2025 to 2027.

Historically, we have been able to fund our capital needs with cash from equity financing through placement of shares.

On July 8, 2020, we filed a Form F-3 registration statement with the SEC with respect to the offer and sale of securities of the Company, or 2020-Shelf Registration Statement. We also filed a prospectus supplement with the SEC relating to an at-the-market program providing for the sales of our stock over time of up to $50.0 million of our ordinary shares pursuant to a Sales Agreement with SVB Leerink LLC. During the fiscal year 2023, we issued 3,235,723 ordinary shares under its at-the-market program resulting in €14.4 million or $15.7 million in net proceeds. As of December 31, 2023, and throughout the term of the at-the-market program, we have issued an aggregate total of 5,803,931 ordinary shares, resulting in a total of €26.2 million in net proceeds to us. The term of the at-the-market program expired on July 8, 2023.

Through an underwritten public offering in April 2023, we sold and issued an aggregate of 10,823,529 ordinary shares, at a price of $4.25 per share and have a nominal value of €0.12 per share, of which 1,411,764 were sold pursuant to the exercise of an overallotment option by the underwriters. Net proceeds of this offering amounted to €38.7 million, after accounting for underwriting discounts and other offering expenses.

During the fiscal year 2023, we issued and registered a total of 120,257 ordinary shares resulting from the exercise of stock option rights by former employees. All stock option rights had been granted under the 2017 Long-Term Incentive Plan. 14,930 stock options thereof were already exercised in December 2022 and 105,327 were exercised during fiscal year 2023. The ordinary shares have a nominal value of €0.12 per share. 98,754 ordinary shares were sold at a price of $1.85 per share, and 21,503 ordinary shares were sold at a price of $3.35 per share.

On June 30, 2023, we filed a Form F-3 (2023-Registration Statement) with the SEC with respect to the offer and sale of securities of the Company, which became effective on July 11, 2023. The aggregate initial offering price of the securities that the Company may offer and sell under this prospectus will not exceed $250 million. In 2024, we subsequently filed a prospectus supplement with the SEC relating to an at-the-market program providing for the sale of up to $75.0 million of our ordinary shares over time pursuant a sales agreement with Leerink Partners LLC, or the Sales Agreement.

We did not issue any ordinary shares under the 2023-Registration Statement in 2023. As of December 31, 2024, we had issued 468,438 ordinary shares under the Sales Agreement, resulting in €0.8 million in net proceeds with a remaining value authorized for sale under the Sales Agreement of $73.8 million.

In January and February 2025, we issued an additional 145,420 ordinary shares under its Sales Agreement, resulting in $353k in net proceeds.

In February 2025, we completed an underwritten public offering of an aggregate of 8,250,000 ordinary shares and pre-funded warrants to purchase 6,750,000 ordinary shares. The ordinary shares were sold at a price of $2.00 per share with a nominal value of €0.12 per share. The public offering price for each pre-funded

warrant was equal to the price per share at which the ordinary shares were sold to the public, minus $0.001, which is the exercise price of each pre-funded warrant. The gross proceeds from the offering amounted to approximately $30 million before deducting underwriting discounts and offering expenses.

Our working capital did not include any indebtedness in 2024 or in 2023.

Our cash and cash equivalents amounted to €18.4 million as of December 31, 2024 (2023: €12.8 million). We also held marketable securities valued at €36.8 million (2023: €85.6 million) as of December 31.2024. Our cash and cash equivalents primarily consist of cash denominated in U.S. dollars and euros in bank deposit accounts. Our marketable securities consist of quoted debt securities issued by financial institutions with investment grade credit ratings (BBB+ to AAA). Our cash is deposited at banks with equally high credit ratings as assessed by international rating agencies.

We expect to finance our future operations and working capital needs in the near future predominantly with our cash and cash equivalents and proceeds from the sale of our marketable securities and with the sale of new shares.

12. Cash flows - Comparison of the years ended December 31, 2024and 2023

The table below summarizes our consolidated statement of cash flows for the years ended December 31, 2024 and 2023:

	2024	2023
	(in €)	
Net cash used in operating activities	(48,556,690)	(37,812,966)
Net cash (used in)/from investing activities	52,364,354	(17,696,616)
Net cash from financing activities	386,446	52,986,269
Cash and cash equivalents at the beginning of the period	12,767,943	16,265,355
Exchange (losses)/gains on cash and cash equivalents	**1,413,926**	**(974,099)**
Cash and cash equivalents at the end of the period	**18,375,979**	**12,767,943**

Net cash used in operating activities

The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital.

Net cash used in operating activities increased to €48.6 million in the year ended December 31, 2024, from €37.8 million in the year ended December 31, 2023, mainly due to lower income recognized from the German federal government grant.

Net cash used in investing activities

Net cash used from investing activities during the year ended December 31, 2024 amounted to €52.4 million due to lower purchases than proceeds of sales of marketable securities. During the previous year ending on December 31, 2023, , we had a net cash outflow of €-17.7 million due to more cash outflows from the purchase of marketable securities than inflows from the proceeds from sales of marketable securities..

Net cash from financing activities

Net cash generated from financing activities decreased to €0.4 million in the year ended December 31, 2024 from €53.0 million in the year ended December 31, 2023 primarily due to lesser proceeds from share issuances. In 2023, we had share issuances through the underwritten public offering of April 2023 and through utilization of the at-the market offering program in 2023. Net cash generated from our at-the market offering program in 2024 amounted to €0.8 million..

13. Contractual obligations and commitments

The table below sets forth our operating expenses and capital expenditures from contractual obligations as of December 31, 2024.

	Payments due by Period				
	Total	Less than 1 year	Between 1 and 3 Years	Between 3 and 5 Years	More than 5 years
			(in €)		
Unavoidable contractual (CRO, CDMO) commitments and other contractual obligations under operating contracts or services:	12,692,379	9,420,813	3,236,931	34,635	—
Contractual lease obligations (incl. capitalized leases)	838,139	424,328	413,811	—	—
Total	**13,530,518**	**9,845,141**	**3,650,742**	**34,635**	**—**

We enter into contracts with CROs and clinical sites for the conduct of clinical trials, professional consultants for expert advice and other vendors like CDMOs for clinical supply manufacturing or other services in the normal course of business. These contracts can usually be terminated with 30 to 180 days notice. In addition to this minimum duration, these contracts require full payment for services already commenced. In the table above, the amounts for unavoidable contractual obligations assumes that the contracts were terminated on December 31, 2024 and would then continue to run for approximately 30 to 360 days.

Contractual lease obligations

Contractual lease obligations mainly consist of payments pursuant to non-cancellable lease agreements relating to our leases of office and laboratory space. The lease term of our premises in Jena, Germany expires in December 2025. The lease term of our premises in Planegg-Martinsried, Germany expires in May 2027. The lease term of our premises in Ann Arbor, Michigan, United States expires in April 2026.

Funding requirements for future capital expenditure

We believe that our existing cash and cash equivalents and financial assets will enable us to fund our operating expenses and capital expenditure requirements under our current business plan for at least the next 18 months.

We anticipate that our expenses will increase in the next years in connection with our ongoing activities. In particular, we anticipate that we might expand our sales and marketing efforts for GOHIBIC (vilobelimab) in the United States, we might advance our Phase 3 clinical development program with vilobelimab in PG, pursue the further clinical development for INF904 and will advance preparation of necessary submission documents for additional regulatory submissions to the EMA and for a full BLA submission to the FDA beyond the received EUA as granted by the FDA in April 2023 for GOHIBIC (vilobelimab). We will also explore clinical development of vilobelimab in several other indications. We also plan to continue clinical development of INF904 and to initiate Phase 2 clinical trials once we selected the appropriate indications. We also plan to continue preclinical development of IFX002. We plan to initiate new research and preclinical development efforts. If clinical data is supportive, we may seek marketing approval for any product candidates that we successfully develop. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to establishing sales, marketing, distribution and other commercial infrastructure to commercialize such products. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce, or eliminate our research and development programs or future commercialization efforts.

Until such time, if ever, that we can generate substantial meaningful product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, royalty-based financings, future collaborations, strategic alliances, licensing arrangements and government grants. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the interest of our current

shareholders will be diluted, and the terms of these securities may include voting or other rights that adversely affect your rights as an ordinary shareholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. Money received through government grants may require us to provide our product, if approved by regulatory authorities, at unfavorable conditions in such jurisdictions.

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14. Legal proceedings

From time to time we are involved in legal proceedings that arise in the ordinary course of business. We believe that the outcome of these proceedings, if determined adversely, will not have a material adverse effect on our financial position. During the period covered by the audited and approved financial statements contained herein, we have not been a party to or paid any damages in connection with litigation that has had a material adverse effect on our financial position. Any future litigation may result in substantial costs and be a distraction to management and our employees. No assurance can be given that future litigation will not have a material adverse effect on our financial position. For an additional discussion of certain risks associated with legal proceedings, see “ITEM 1: C. Risk factors.”

15. Controls and procedures

a. Disclosure controls and procedures

Our board of directors is responsible for reviewing the Company's risk management and control systems in relation to the financial reporting by the Company. The board of directors has charged its audit committee with the periodic oversight of these risk management and control systems, with reports being provided to the board of directors. Our audit committee assists the board of directors, among other things, in reviewing and discussing with the board of directors and the independent external auditor, the audit plan as well as our annual audited financial statements and quarterly financial statements prior to the filing of the respective annual and quarterly reports and the effectiveness of the Company's internal control over financial reporting.

The activities of the Company are continuously subject to external and internal developments and changes in circumstances that translate into risk potentials. Preventing or minimizing risks and thus ensuring the long-term existence of the Company is the central task of systematic risk management. Risk management is a dynamic process that can be broken down into sub-processes. These sub-processes are risk identification, risk evaluation, risk management and risk control.

We define a “risk” as an unexpected or adverse event arising from a specific business activity of the Company, that may have a negative impact on the Company's operations, adverse effects on the net assets, financial position or results of operations or adverse effects on the further positive development of the Company. In general, one can categorize risks in strategic, operational, external and financial risks.

Entrepreneurial action is generally associated with risks. We practice a conscious approach to our risks, i.e. their identification, evaluation, active management and control. Risks are regularly monitored. Risky developments are systematically counteracted promptly by targeted measures. In detail, this also includes the early and, above all, regular information of executive management with regard to relevant risks by the responsible risk owners as well as the regular information of the audit committee and doard of directors about essential risks, as well as regular reporting in our mandatory financial disclosures. Preventively defined processes, clearly defined structures and the sense of responsibility of each individual executive management member and employee are the foundation of an effective risk management. In order to constantly optimize processes and ensure compliance with our internal requirements as well as the external rules, laws and regulations we have to follow as publicly listed company on the NASDAQ stock exchange, each department or division must continuously review, evaluate and, if necessary, adapt its risks to changing conditions.

The risk management system at InflaRx is implemented across all organizational levels of the Company. For each identified risk area, an individual risk owner is named who is responsible for all organizational processes in connection with the RMS in her/his area.

Regular meetings between the executive management and the individual risk owners are held for efficient and timely communication. In order to identify and evaluate the risks, a comprehensive risk analysis is carried out once a calendar quarter at a company-wide level, which includes all departments and projects of the Company (including the assessment of external risks). The risks identified and evaluated by the risk owners are then included in a risk catalogue.

The risk owners are responsible to name and describe all individual risks that impair the functionality of the Company or individual areas, as well as to identify their causes. The risk principles relevant to the Company, basic procedures and responsibilities in the risk management process, but also the definition of risk assessment standards are known to those responsible for risks. Internal risk reporting by means of a risk catalogue is used for systematic and complete identification. The identified risks are recorded, described, documented and evaluated in the risk catalogue and provided with appropriate measures specifying a time window. Changes are also documented accordingly.

When identifying a risk, the respective risk owner has to decide if the risk is ongoing (permanent) or project related (transient). Going forward, within the next quarterly risk review, potential newly identified risks have to be included as well as obsolete risks to be deleted.

According to the priority of the risks as result of the risk evaluation, they are addressed by concrete actions and, if appropriate and possible, necessary countermeasures. In principle, the following different approaches are possible risk avoidance, risk reduction, risk acceptance and risk passing.

In order to be able to react quickly and flexibly to risks, risk management is integrated into existing processes and reporting channels. Risk owners appointed are responsible for targeted and regular monitoring of

risks. They must independently and continuously monitor the identified risks and the measures taken and, in the event of danger, immediately inform the next higher hierarchical level (usually the management).

Major and critical risks that have a loss potential of more than €750,000 as well as significant ad-hoc risks must be reported directly to management and, if applicable, to the audit committee of the Company. The executive management is responsible for the early detection, countermeasures and monitoring of significant risks. Furthermore, risk awareness is an integral part of the corporate culture in all departments and in all projects.

The risk catalogue is approved by the executive management at the latest at the beginning of the audit of the respective financial year by the auditors or the audit review of the respective quarterly figures.

The willingness to assume risks is called the "risk appetite". The level of risk appetite indicates as to whether the Company will take counter-measures to control such risks. The general risk overview table outlines the appetite as well as the potential probability of materialization and impact on the Company's objectives. The categories of impact, probability and risk appetite are: low (+), medium (++) and high (+++).

Risk	Impact	Probability	Risk Appetite
Risks related to our financial position and need for additional capital	++	+	+
Risks related to the discovery, development and commercialization of our product candidates	+++	++	++
Risks related to our dependence on third parties	+	+	+
Risks related to our intellectual property	++	+	+
Risks related to employee matters and managing growth	+	+	++
Risks related to our ordinary shares and our status as a public company	++	+	++
General Risk Factors	+	+	+

Our success as a business depends on our ability to identify opportunities while assessing and maintaining an appropriate risk approach. Our risk management considers a variety of risks, including those related to our industry and business, those related to our ongoing relationship with our shareholders and those related to our intellectual property. Our approach to risk management is designed to provide reasonable, but not absolute, assurance that our assets are safeguarded, the risks facing the business are being assessed and mitigated and all information that may be required to be disclosed is reported to our senior management including, where appropriate, to our Chief Executive Officer and Chief Financial Officer.

As of December 31, 2024, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act). There are inherent limitations to the effectiveness of any disclosure controls and procedures system, including the possibility of human error and circumventing or overriding them. Even if effective, disclosure controls and procedures can provide only reasonable assurance of achieving their control objectives.

We implemented an Investment Policy, which is under the supervision of the audit committee and subject to at least a yearly review. The investment policy applies to all cash investment decisions, regarding the investment of available cash amounts and the maintenance of the cash investment portfolio of all Group entities, including all currency exchange transactions. The purpose of this investment policy is to define applicable policies for the Group Companies' Liquidity and Investment Management. Our main goal is the secure preservation of its cash and short-term investments while minimizing and mitigating risks associated with Liquidity and Investment Management including the loss of financial assets in connection with these activities. Specifically, these risks include, but are not limited to (i) credit default risks, (ii) interest rate risks, (iii) concentration risks, and (iv) currency exchange risks. We maintain cash reserves to accommodate present and future capital needs for operating requirements at the level of each Group Company. Available and invested cash reserves shall be managed to meet the following objectives to the maximum extent possible at the time of the decision under consideration of the financial market situation: (i) avoidance of loss of financial assets, (ii) liquidity and solvency, and (iii) profit to ensure a reasonable return for the Group consistent with the risk mitigation goals and liquidity requirements. The Investment Policy includes guidelines for the liquidity and investment management covering, amongst others, maturities, credit default risks by defining high credit

rating financial institutions and a list of permitted investments and transactions.

Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective to provide reasonable assurance that the information we are required to disclose in the reports we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management to allow timely decisions regarding required disclosures.

On the basis of the reports and information provided to our board of directors and with reference to chapters 2.1, 2.2 and 2.3 Risk Control Measures, our board of directors is of the opinion that:

a. this report provides sufficient insight into any failings in the effectiveness of the Company's risk management and control systems;

b. the Company's risk management and control systems provide reasonable assurance that the Company's financial reporting does not contain material inaccuracies;

c. based on the Company's state of affairs as at the date of this report (please also be referred to the statement in the first paragraph under "Funding requirements for future Capital Expenditure" in chapter 4.2), it is justified that the Company's financial reporting is prepared on a going concern basis; and

d. this report states those material risks and uncertainties that are relevant to the expectation of the Company's continuity for a period of twelve months after the date of this report.

No material failings in, material changes to, and/or material improvements (in each case, if any) of the Company's risk management and control systems have been observed, made and/or planned, respectively, during the fiscal year to which this report relates.

b. Internal auditors

We have an internal audit function in place reporting to the audit committee on a quarterly basis regarding the overall effectiveness of the internal control system, control deficiencies regarding effectiveness and design as well as control deficiency remediation. The internal audit function provides additional assurance to the audit committee, on behalf of the board of directors, and to the Company's executive officers, with respect to the Company's key controls. The internal audit function independently and objectively carries out audit assignments in accordance with the annual internal audit plan, as approved by the audit committee. The internal audit function reports primarily to the Company's Chief Financial Officer and to the chair of the audit committee.

March 27, 2025

/s/ Nicolas Fulpius

Chairman of the Board of Directors

/s/ Prof. Dr. Niels Riedemann

Executive member of the Board and CEO

ITEM 3: CORPORATE GOVERNANCE

Dutch Corporate Governance Code 2022 ("DCGC")

For the fiscal year to which this report relates, the DCGC applied to the Company. The text of the DCGC can be accessed at http://www.mccg.nl.

Except as set out below, during the fiscal year to which this report relates, the Company complied with the principles and best practice provisions of the DCGC, to the extent that these are directed at our board of directors.

Target figures in Diversity & Inclusion policy for senior management (best practice provision 2.1.5)

The DCGC recommends that the D&I policy should set specific, appropriate and ambitious targets in order to achieve a good balance in gender diversity and the other D&I aspects of relevance to the company not only with regard to the composition of the board of directors, but also for employees in managerial positions ("senior management"). The Company's D&I policy does not include either a definition of senior management nor targets for senior management. A senior management was consciously not defined in the light of the current size of the Company and the respective structure of the Company, which would not be meaningful and appropriate. The definition of only one level in the form of the board of directors reflects existing reporting lines to the executive management. A senior management level of employees in managerial positions which would be meaningful in the sense of the DCGC does not exist and cannot meaningfully defined through titles or other definitions such as responsibility over personnel. As a consequence, appropriate targets were not defined.

Committee chairmanship and committee composition (best practice provision 2.3.4 and 5.1.4)

The DCGC recommends that the audit committee or the remuneration committee should not be chaired by the chairman of the board or by a former member of the management board of the Company. Given the current composition of our board of directors, the independence of our directors and their qualifications (as well as the rules applicable to the Company with respect to the composition of our board of directors and its committees), all committees of our board of directors are chaired by Mr. Fulpius, who is also the chairman of our board of directors (except for the audit committee, for which Mr. Gibney is acting as the committee's chair). Our board of directors regularly evaluates its composition and that of its committees.

Vice chairman (best practice provision 2.3.7)

The DCGC recommends that a vice chairman should deputize for the chairman when the occasion arises. Given the current organization of the Company, our board of directors has not appointed a vice chairman. Our board of directors is of the opinion that the tasks and duties of the chairman will sufficiently be done by the other non-executive directors. If the Company continues to grow, additional positions within the Board, such as a vice-chairman, may be considered.

Company secretary (best practice provision 2.3.10)

The DCGC recommends that the board of directors should be supported by a company secretary appointed by the executive directors with approval of non-executive directors. The Company has not appointed a company secretary in the meaning of 2.3.10, although the board of directors is supported by the Head of Legal Affairs of the Company for selected items including support of the chairman in administrational tasks.

Compensation (best practice provisions 3.1.2, 3.2.3, 3.3.2, 3.3.3 and 3.4.1)

For as long as the United States is the trading jurisdiction of our ordinary shares, and in order to further support our ability to attract and retain the right highly qualified candidates for our board of directors:

options awarded to our executive directors as part of their compensation could (subject to the terms of the option awards) vest and become exercisable during the first three years after the date of grant;

our directors may generally sell our ordinary shares held by them at any point in time, subject to applicable law, Company policy and applicable lock-up arrangements;

our non-executive directors may be granted compensation in the form of shares, options and/or other equity-based compensation; and

our executive directors may be entitled to a severance payment in excess of their respective annual base salaries. The maximum severance payments applicable (a) to our CEO equals 1.5 times of the fixed gross yearly base compensation, and (b) to our CSO equals to 1.5 times of the fixed gross yearly base compensation and a pro-rata portion of the short-term incentive bonus payment for the year of termination.

Though individual and Company performance are considered when granting any variable pay, no predefined measurable performance criteria apply, and no scenario analyses have been performed in relation to variable pay. Nevertheless, the Company established internal procedures for granting a bonus payment to executive directors of the Company (taking into account the individual performance of the respective executive director during the respective calendar year) as well as for granting options as long-term incentive component to non-executive and executive directors of the Company (taking into account peer group models and considering a buffer for unexpected allocation).

Compensation committee's proposal on executive director remuneration (best practice provision 3.2.2)

The DCGC recommends that when drafting the proposal for the remuneration of the executive directors, the remuneration committee should take note of individual executive management board members' views with regard to the amount and structure of their own remuneration. The compensation committee does not discuss executive management board members' views regarding amount and structure of their remuneration, because the Company is of the opinion, that the amount and structure of the remuneration can be shaped and proposed based upon the committee's members expertise and knowledge of the industry standards of the biopharmaceutical industry while being in constant contact with the executive management.

Majority requirements for dismissal and overruling binding nominations (best practice provision 4.3.3)

The DCGC recommends that (i) the general meeting can pass a resolution overruling a binding nomination by the board by simple majority, representing no more than one-third of the issued share capital and (ii) the general meeting of shareholders can pass a resolution to dismiss a member of the board by simple majority, representing no more than one-third of the issued share capital. Our directors are appointed by our general meeting of shareholders upon the binding nomination by our board of directors. Our general meeting of shareholders may only overrule the binding nomination by a resolution passed by a two thirds majority of votes cast, provided such majority represents more than half of the Company's issued share capital. In addition, except if proposed by our board of directors, our directors may be suspended or dismissed by our general meeting of shareholders at any time by a resolution passed by a two thirds majority of votes cast, provided such majority represents more than half of the Company's issued share capital. The possibility to convene a new general meeting of shareholders as referred to in Section 2:120(3) DCC in respect of these matters has been excluded in the Company's Articles of Association. We believe that these provisions support the continuity of the Company and its business and that those provisions, therefore, are in the best interests of our shareholders and our other stakeholders.

Code of ethics and other corporate governance practices

The Company has adopted a code of ethics, which explicitly incorporates and refers to core values of the Company, being honesty, accountability, integrity, professionalism and fairness. These values contribute to sustainable long-term value creation for the Company and its stakeholders.

Promoting ethical behavior and the strong commitment of the company to CSR does enhance the organization´s reputation, is fostering trust among customers, employees and other stakeholders. Ethical business practices contribute to long-term sustainability by avoiding legal issues, regulatory penalties, and damage to the brand. Adherence to ethical standards, regulatory compliance, and strong corporate governance practices are crucial for maintaining the organization's credibility and sustainability.

The text of the Company's code of ethics can be accessed at https://www.inflarx.de/Home/Investors/Corporate-Governance.html. The Company does not voluntarily apply other formal codes of conduct or corporate governance practices, except that the Company implemented various internal guidelines regarding compliance practices such as an insider trading policy, signature guideline and anti-corruption guideline.

Risk management and control systems

See chapters ITEM 1: C.and ITEM 2: C. of this report for an overview of the main characteristics of the

Company's risk management and control systems relating to the process of financial reporting by the Company and the Company's subsidiaries whose financial information is included in the Consolidated Financial Statements.

A culture that encourages prudent risk-taking and effective risk management helps the organization navigate uncertainties without compromising its long-term goals. Balancing risk and reward is essential for sustained value creation.

General meeting of shareholders

16. Functioning of our general meeting of shareholders

Annually, at least one general meeting of shareholders of the Company must be held. This annual general meeting must be held within six months after the end of the Company's fiscal year. A general meeting of shareholders must also be held within three months after our board of directors has decided that it is likely that the Company's equity has decreased to or below 50% of its paid up and called up share capital. In addition, without prejudice to the relevant best practice provisions of the DCGC with respect to invoking a 'response period', a general meeting of shareholders must be held when requested by one or more shareholders and/or others with meeting rights under Dutch law collectively representing at least 10% of the Company's issued share capital, provided that certain criteria are met. Any additional general meeting of shareholders shall be convened whenever our board of directors would so decide. Each general meeting of shareholders must be held in Amsterdam, Arnhem, The Hague, Rotterdam, Schiphol (Haarlemmermeer) or Utrecht.

For purposes of determining who have voting rights and/or meeting rights under Dutch law at a general meeting of shareholders, our board of directors may set a record date. The record date, if set, shall be the 28th day prior to that of the general meeting of shareholders. Those who have voting rights and/or meeting rights under Dutch law on the record date and are recorded as such in one or more registers designated by our board of directors shall be considered to have those rights at the general meeting of shareholders, irrespective of any changes in the composition of the shareholder base between the record date and the date of the meeting. Our Articles of Association require shareholders and others with meeting rights under Dutch law to notify the Company of their identity and their intention to attend our general meeting of shareholders. This notice must be received by the Company ultimately on the seventh day prior to our general meeting of shareholders, unless indicated otherwise when the meeting is convened.

17. Powers of our general meeting of shareholders

All powers that do not vest in our board of directors pursuant to applicable law, our Articles of Association or otherwise, vest in our general meeting of shareholders. The main powers of our general meeting of shareholders include, subject in each case to the applicable provisions in our Articles of Association:

a. the appointment, suspension and dismissal of our directors;

b. the approval of certain resolutions of our board of directors concerning a material change to the identity or the character of the Company or its business;

c. the reduction of the Company's issued share capital through a decrease of the nominal value, or cancellation, of shares in its capital;

d. the adoption of the Company's statutory annual accounts;

e. the appointment of the Dutch independent auditor to examine the Company's statutory annual accounts;

f. amendments to the Company's Articles of Association;

g. approving a merger or demerger by the Company, without prejudice to the authority of our board of directors to resolve on certain types of mergers and demergers if certain requirements are met; and

h. the dissolution of the Company.

In addition, our general meeting of shareholders has the right, and our board of directors must provide, any information reasonably requested by our general meeting of shareholders, unless this would be contrary to an

overriding interest of the Company.

18. Shareholder rights

Each share in the Company's capital, irrespective of its class, carries one vote. Shareholders, irrespective of whether or not they have voting rights, have meeting rights under Dutch law (including the right to attend and address our general meeting of shareholders, subject to the concept of a record date as described in Section 7.4.1 of this report). Furthermore, each share in the Company's capital carries an entitlement to dividends and other distributions as set forth in our Articles of Association. Pursuant to our Articles of Association, any such dividend or other distribution shall be payable on such date as determined by our board of directors and our board of directors may also set a record date for determining who are entitled to receive any such dividend or other distribution (irrespective of subsequent changes in the shareholder base). The record date for dividends and other distributions shall not be earlier than the date on which the dividend or other distribution is announced. In addition, shareholders have those rights awarded to them by applicable law.

Board of directors

The Company has a one-tier board, consisting of executive directors and non-executive directors. Our executive directors are charged primarily with the Company's day-to-day business and operations and the implementation of the Company's strategy. Our non-executive directors are charged primarily with the supervision of the performance of the duties of our board of directors. Each director is charged with all tasks and duties of our board of directors that are not delegated to one or more other specific directors by virtue of Dutch law, our Articles of Association or any arrangement catered for therein (e.g., the internal rules of our board of directors). In performing their duties, our directors shall be guided by the interests of the Company and of the business connected with it.

Our executive directors have developed a view on sustainable long-term value creation by the Company and have formulated a strategy consistent with that view (please see chapter 3.2 Our strategy). The non-executive directors have been actively engaged at an early stage in formulating the Company's strategy and supervise the manner in which the strategy is implemented. We intend to leverage our expertise within the complement field as well as our proprietary technology to sustain our lead in the anti-C5a space by developing a diverse pipeline focused on complement-mediated autoimmune and inflammatory diseases with high unmet need.

As at December 31, 2024, our board of directors was composed as follows:

Name and age	Gender	Nationality	Date of initial appointment	Expiration of current term of office	Participation rate (5 meetings)
Nicolas Fulpius (51)**	Male	Swiss	8 November 2017	2026 AGM	100%
Niels Riedemann (53)*	Male	German	6 June 2017	2026 AGM	100%
Mark Kubler (50)***	Male	Swiss	8 November 2017	2028 AGM	100%
Renfeng Guo (54)*	Male	American	8 November 2017	2026 AGM	100%
Richard Brudnick (68**	Male	American	23 May 2019	2026 AGM	100%
Anthony Gibney (53)**	Male	American	19 May 2021	2028 AGM	80% ***
Hege Hellstrom (59) **	Female	Norwegian	26 April 2023	2026 AGM	100%

* Executive director

** Non-executive director

*** Anthony Gibney could not attend in one out of five Board meetings due to personal reasons

Nicolas Fulpius, Chairman. One of the co-founders of InflaRx, Nicolas Fulpius has served as Chairman of the Board since its inception in 2007. Long active in the venture capital field between the US and Europe, for the

Lombard Odier Immunology fund, for Ultreia Capital and as Partner at Affentranger Associates, Nicolas has become an entrepreneur at heart: he created, developed and helped finance several companies in the Biotech, cleantech and ICT field. Recently, Mr. Fulpius was - among others - CEO of Veltigroup, CDO of Swisscom and member of the Swisscom Ventures investment committee. In 2020 Nicolas Fulpius co- founded the Ansam Group one of the leading ICT services company in Switzerland for which he is acting as CEO and Chairman. Nicolas Fulpius holds an MBA from the University of St. Gallen, Switzerland, and a Masters in Science in Engineering from Stanford University, USA.

Mark Kubler. Mr. Kubler has served as a director on our board since 2015. Mr. Kubler has been a partner with the GIG Ltd., a venture capital advisory firm with offices in Switzerland and Malta, since 2012. He previously served on the boards of WWM AG and Jobydu AG, each based in Switzerland. Mr. Kubler was a managing director and corporate secretary of a private equity holding company from 2003 to 2010. Before 2003, he held various roles in international investment banks and boutiques. Mr. Kubler has a master's degree in business and economics, as well as a master's degree in law from the University of St. Gallen, in Switzerland.

Richard Brudnick. Richard Brudnick currently serves as Chief Business Officer for Prime Medicine, Inc., a leader in the field of gene editing. Prior to joining Prime Medicine, Mr. Brudnick was Chief Business Officer and Head of Strategy for Codiak BioSciences, a leader in the field of exosome therapeutics. Before Codiak, Mr. Brudnick was Executive Vice President of Business Development and Alliance Management at Bioverativ, Inc., a company he helped found in 2016. Until Bioverativ's acquisition by Sanofi in March 2018, Mr. Brudnick led business development efforts to build a significant pipeline in rare blood disorders, including an acquisition, a multi-product collaboration and additional scientific collaborations and licenses. Mr. Brudnick joined Bioverativ at its spin-off from Biogen where, over the course of nearly 15 years, he initiated, led and completed transactions that led to several of the company's marketed products and late-stage pipeline. Mr. Brudnick also was CEO of a regional pharmaceutical distribution business, which he sold to a strategic buyer; co-founded two companies; and was a strategy consultant at Bain & Company. He holds bachelor and advanced degrees from MIT and serves on the board of directors of Scholar Rock, Inc.

Anthony Gibney. Tony Gibney has served as a director of InflaRx since April 2021. Mr. Gibney is an experienced biotechnology executive and former investment banker who brings over 25 years of experience dedicated to advising biotechnology companies in the U.S. and Europe on business strategy, collaboration transactions, financings, and mergers and acquisitions. Most recently, Mr. Gibney served as the Executive Vice President, Chief Business & Strategy officer of Iveric Bio, Inc. until the company's acquisition by Astellas Pharma Inc. in July 2023. Prior to that, Mr. Gibney served as Chief Financial Officer and Chief Business Officer at Fog Pharmaceuticals, Inc., where he oversaw its business development, strategy and finance functions, and he served as Executive Vice President and Chief Business Officer at Achillion Pharmaceuticals, where he led the sale of Achillion to Alexion Pharmaceuticals, Inc. in 2020. Before Achillion, Mr. Gibney was a Managing Director and Co-head of the biotechnology investment banking team at Leerink Partners LLC, and Managing Director of Merrill Lynch's healthcare group. He currently serves on the boards of directors of LAPIX Therapeutics, Inc. and Clearside Biomedical, Inc. Mr. Gibney received a B.A. in Economics and a B.A. in History from Yale University.

Hege Hellstrom is currently Chief Commercial Officer in Advicenne, a French pharmaceutical company specializing in the development of innovative treatments in Nephrology. She is a non-executive board member of Vivesto AB since 2019 and Camurus AB since 2020, both public Swedish companies and she is also a member of the Audit Committee in both companies. Mrs. Hellstrom is a non-executive board member of Guard Therapeutics, a Swedish public company since 2024. She is the founder and managing director of Belnor BV, an investment and consulting company. Mrs. Hellstrom has more than 30 years' experience in sales, marketing, strategy development, commercialization, partner alliances and executive management. From 2013 to 2018, she worked as President Europe, Middle East, North Africa and Russia in Sobi, a Swedish biopharmaceutical company where she led several launches in rare diseases such as haemophilia and metabolic diseases. Before Sobi, she worked in Genzyme for 11 years in roles ranging from General manager in Benelux to head of Renal and Endocrine business in Europe, LATAM and JAPAC. When Genzyme was acquired by Sanofi she continued as Global Vice-president of Cardiovascular products in Sanofi. Before Genzyme she worked in Baxter Healthcare for 13 years. Mrs. Hellstrom holds a B.Sc., Biomedical Laboratory Scientist from Oslo Metropolitan University, Norway.

Niels Riedemann, Chief Executive Officer. Prof. Riedemann has over 15 years of experience in the biotech industry and drug development as well as over 20 years of experience in complement immunology research. He founded InflaRx in 2007 and has served as Chief Executive Officer since inception of the company. He has been instrumental in and led numerous private and public financing rounds of the company and has been the

responsible lead for its Nasdaq IPO in 2017. He is named inventor on several internationally granted core patents of InflaRx. As physician he has been appointed Vice Director ("Leitender Oberarzt") of Intensive Care Medicine, and he has led a 50-bed University ICU unit for over 6 years at Friedrich Schiller University, Jena, Germany until 2015. Before that, he received his board certification as General Surgeon upon completion of his surgical fellowship at MHH (Hannover Medical School, Germany) in 2007 where he also received his habilitation (equivalent to Ph.D.) and where he still holds an Adjunct Professorship (APL Professor). He spent three years as postdoctoral research fellow at the University of Michigan, USA until 2003. He received his medical training at Albert Ludwig University (ALU), Freiburg, Germany, and Stanford University, USA and graduated as Dr. med. (equivalent to M.D.) from ALU in 1998. His research has been awarded with several national and international awards. He has received extensive extra-mural funding and published over 60 peer reviewed scientific publications in highly ranked journals. He has served as a member on a Board of Directors and a Scientific Advisory Board of two large scientific governmental funded programs. He currently serves as Co-Chair of the Health Politics working group of Bio-Deutschland and he serves as member of the board of trustees for the German Sepsis Foundation.

Renfeng Guo, Chief Scientific Officer. Prof. Renfeng Guo co-founded InflaRx in 2007. Since its inception, he has headed scientific development at InflaRx as the full-time CSO. Prof. Guo leverages his expertise in antibody research and inflammation, bringing together a highly effectual research team for drug development to build a focused pipeline based on cutting-edge technology. His early research led to the discovery of InflaRx's leading drug, vilobelimab. He continues to be the driving force for the development of other pipeline drugs as well as a key inventor for InflaRx's intellectual property portfolio. Prof. Guo received his M.D. degree from Norman Bethune Medical School in China and conducted post-doctoral research in the laboratory of Prof. Peter Ward at the University of Michigan, Ann Arbor. After stints as a junior and senior faculty member beginning in 2001 at the University of Michigan, he is currently an Adjunct Research Associate Professor. Prof. Guo has over 80 high-impact, peer reviewed publications in the fields of cancer, infectious disease, and inflammation research.

All of our non-executive directors are independent within the meaning of the DCGC.

Committees

19. General

Our board of directors has established an audit committee, a compensation committee and a nomination and corporate governance committee. Each committee operates pursuant to its charter.

As at December 31, 2024, the committees were composed as follows:

Name	Audit committee meetings (and participation rate)	Compensation Committee meetings (and participation rate)	Nomination and corporate governance committee meetings (and participation rate)
Nicolas Fulpius	4 (80%)	1* (100%)	2* (100%)
Mark Kubler	4(80%)	1 (100%)	2 (100%)
Richard Brudnick	5 (100%)	1 (100%)	n.a.
Anthony Gibney	5*(100%)	n.a.	n.a.
Hege Hellstrom	n.a.	n.a.	2 (100%)

* Chairman

20. Audit committee

The responsibilities of our audit committee include:

recommending the appointment of the independent auditor to the general meeting of shareholders;

the appointment, compensation, retention and oversight of any accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit services;

pre-approving the audit services and non-audit services to be provided by our independent auditor before the auditor is engaged to render such services;

evaluating the independent auditor's qualifications, performance and independence, and presenting its conclusions to the full supervisory board on at least an annual basis;

reviewing and discussing with the board of directors, the Company's internal audit function and the independent auditor the audit plan as well as our annual audited financial statements and quarterly financial statements prior to the filing of the respective annual and quarterly reports;

overseeing the effectiveness and integrity of the internal audit function, ensuring its independence, objectivity, and adherence to established policies and procedures;

reviewing our compliance with laws and regulations, including major legal and regulatory initiatives and also reviewing any major litigation or investigations against us that may have a material impact on our financial statements;

reviewing internal audit results with the Company's internal audit function, including the effectiveness of the design and operation of our internal controls;

reviewing the operation of and our compliance with our code of ethics;

reviewing the operation of our compliance with our investment policy regulating all cash investment decisions regarding the investment of available cash amounts and the maintenance of the cash investment portfolio of all Company’s entities including all currency exchange transactions; and

reviewing the operation of our risk management system;

approving or ratifying any related person transaction (as defined in our related person transaction policy) in accordance with our related person transaction policy and reviewing potential conflicts of interest involving our directors.

During the fiscal year to which this report relates, our audit committee met seven times in order to carry out its responsibilities. The main items discussed at those meetings related to annual and quarterly financial statements, budgetary planning, financial forecast information, development of R&D projects, risk management, SOX-404 oversight, internal audit function reports, and external auditor report & engagement.

21. Compensation committee

The responsibilities of our compensation committee include:

identifying, reviewing and approving corporate goals and objectives relevant to compensation of our executive officers and directors;

analyzing the possible outcomes of the variable remuneration components and how they may affect the remuneration of our executive officers;

determining any long-term incentive component of each executive officer's compensation in line with the compensation policy and reviewing our executive officer compensation and benefits policies generally;

preparing periodic compensation reports for our board of directors;

- review and recommendation to the Board of Directors for approval of the amendment or modification of the Company’s “clawback” policy.
- reviewing and assessing risks arising from our employee compensation policies and practices and whether any such risks are reasonably likely to have a material adverse effect on us; and
- retaining or obtaining advice from a compensation consultant, legal counsel or other advisor as the compensation committee deems necessary or appropriate to carry out its responsibilities.

During the fiscal year to which this report relates, our compensation committee met three times in order to carry out its responsibilities. The main items discussed at those meetings related to the review of compensation levels in the industry and to compensation of our directors and executive officers.

22. Nomination and corporate governance committee

The responsibilities of our nomination and corporate governance committee include:

- preparing and reviewing selection criteria and appointment procedures for our board of directors;
- reviewing the size and composition of our board of directors by taking into account any diversity and inclusion criteria and submitting proposals for the composition profile of our board of directors;
- leading the board of directors in self-evaluation to determine whether it and its committees are functioning effectively;
- preparing and reviewing a plan for succession of directors by taking into account any diversity and inclusion criteria;
- submitting proposals for the appointment or reappointment of directors; and
- Review of Company guidelines and policies in the responsibility of the board of directors

During the fiscal year to which this report relates, our nomination and corporate governance committee met once in order to carry out its responsibilities. The main items discussed at those meetings related to the nomination of board and committee members.

Evaluation

During the financial year to which this report relates, our board of directors has evaluated its own functioning, the functioning of its committees and that of the individual members of the board of directors on the basis of self-evaluation form distributed to, and completed by, the directors. As part of these evaluations, the board of directors has considered (i) substantive aspects, mutual interaction and the interaction between the non-executive directors and the executive directors, (ii) events that occurred in practice from which lessons may be learned and (iii) the desired profile, composition, competencies and expertise of the board of directors. These evaluations are intended to facilitate an examination and discussion by the board of directors of its effectiveness and potential areas for improvement. The 2024 board self-evaluation led to the following main finding and conclusions: (i) in general, the board and its committees are assessed by its respective members to function well to very well, (ii) communication between the executive management and the board of directors inbetween board meetings could be intesified , (iii) the overall board composition is considered to be effective with a broad set of competences, and (iv) further improvement in terms of diversity and regulatory experience would have a positive impact. On the basis of these evaluations, the board of directors has concluded that it is functioning properly. The board of directors further believes that its committees have functioned well in carrying out their duties.

Diversity and Inclusion

We established a Diversity and Inclusion Policy, which is published on the Company's website. This policy sets out our targets relating to diversity in the composition of the board of directors and the Company's senior management (being: the group of employees and officers of the Company and its subsidiaries, excluding the members of the board of directors, at or above vice-president level), as detailed in a through d below. We believe that diversity and Inclusion encompasses acceptance and respect, recognizing that each individual is unique. We are committed to supporting, valuing and leveraging diversity and inclusion in the composition of the board of directors and senior management. We are committed to promoting gender diversity in the board of directors and senior management.

The Company believes that it is important for our board of directors to represent a diverse composite mix of personal backgrounds, experiences, qualifications, knowledge, abilities and viewpoints. The Company seeks to combine the skills and experience of long-standing members of our board of directors with the fresh perspectives, insights, skills and experiences of new members. To further increase the range of viewpoints, perspectives, talents and experience within our board of directors, the Company strives for a mix of ages in the composition of those bodies, but also does not set a specific target in this respect. The Company recognizes and welcomes the value of diversity with respect to race, ethnicity, nationality, sexual orientation and other important cultural differences. The Company is committed to seeking broad diversity in the composition of our board of directors and will consider these attributes when evaluating new candidates in the best interests of the Company and its stakeholders. In terms of experience and expertise, the Company intends for our board of directors to be composed of individuals who are knowledgeable in one or more specific areas detailed in the

Company's diversity and inclusion policy.

The Company is committed to promoting diversity and inclusion in the board of directors and within senior management. This includes the following objectives:

a. for as long as the board of directors comprises of not more than six members, at least one member shall be a woman or a underrepresented minority in the home country of the board member;

b. for as long as the board of directors comprises of at least seven and not more than nine members, at least two members shall be women or one woman and one member of an underrepresented minority in the home country of the board member;

c. for as long as the board of directors comprises 10 or more members, at least 20% of its members shall be women or women and members of an underrepresented minority in the home country of the board member;

d. for senior management at least 20% of that group shall be women or women and members of an underrepresented minority in the home country of the member.

The board of directors will take the D&I policy into account regarding set targets, when and if the composition of the board of directors and/or the senior management is about to be changed.

As of December 31, 2024, the board of directors and senior management (Senior Vice President or above, except executive directors of the board) comprises of the following genders, members of an underrepresented minority in the home country of the member and applicable ratios in the light of the self-set objectives:

	number of members	Male (number of members)	Female	Divers	members of an underrepresented minority in the home country of the member
Board of Directors	7	86% (6)	14% (1)	0% (0)	14% (1)
Senior Management	3	33% (1)	66% (2)	0% (0)	1% 33%)

As of December 31, 2024, the Company fulfilled its self-set objectives as set forth in the Diversity and Inclusion Policy for the senior management, whereas the self-set objectives were not fulfilled for board of directors . The composition of the board of directors did not change in the financial year 2024.

Sustainability

The assessment of sustainability objectives requires a comprehensive analysis of the impact of a company's products, services, and activities on both people and the environment, as well as an evaluation of how stakeholder interests are considered. Such assessment including set objectives was not yet formalized by us. To help achieve this, in 2024 we began drafting a Corporate Sustainability Policy. This draft will be refined in 2025 and evaluated to determine to what extent and with what measures it can be implemented. We plan to implement this policy by the end of 2025.Our company is committed to sensitive travel arrangements, activities to reduce use of electricity, and promoting working from home to reduce the carbon print.

However, we acknowledge the environmental footprint associated with our operations, including resource consumption and waste generation.

Stakeholder interests are being considered and an integral to our decision-making process. We actively engage with customers, employees and suppliers to understand their concerns and expectations.

We address environmental impacts by reducing energy consumption and waste. We improved the sustainability of our supply chain by engagements of CMO´s in Germany to reduce the carbon print of shipment necessities and support German employment ships. Socially, we ensured fair wages for employees, and promoted diversity and inclusion within our workforce.

Recognizing the evolving nature of sustainability challenges, our commitment to continuous improvement

remains steadfast. Regular monitoring, external audits, and collaboration with stakeholders are integral to refining our strategies and ensuring that our operations align with our sustainability objectives.

In conclusion, our company acknowledges the importance of the impact of our products, services, and activities on people and the environment. Regarding the effects of our products and research actives on people, we refer to Item 2.B. This section describes the mode of action of vilobelimab and INF904 as well as various indications of patients with unmeet high medical needs.

Corporate values and code of conduct

We have adopted a code of ethics (see chapter 7.2 of this report) applicable to all directors, managing directors and employees of InflaRx N.V. and its affiliates implementing our main corporate values, being honesty, accountability, integrity, professionalism and fairness. These values contribute to sustainable long-term value creation for the Company and its stakeholders. Our commitment to the highest level of ethical conduct should be reflected in all of the Company's business activities, including, but not limited to, relationships with employees, customers, suppliers, competitors, the government, the public and our shareholders. All of our employees, officers and directors must conduct themselves according to the language and spirit of the code of ethics and seek to avoid even the appearance of improper behavior. The code of ethics is available for all employees and is additionally published on the Company's website (www.inflarx.com). The Company strives for a culture of the "tone from the top". The board of directors measures the extent to which the code is complied with by the number of reports that are made in relation to the code of ethics. In the financial year to which this board report relates, no reports were made in relation to the code of ethics. Our board of directors has no reason to believe that the code of ethics would not be functioning effectively.

Compensation report

23. Compensation policy

Pursuant to Section 2:135(1) DCC, our general meeting of shareholders has adopted a compensation policy. Our compensation policy is designed to (i) attract, retain and motivate directors with the leadership qualities, skills and experience needed to support and promote the growth and sustainable success of the Company and its business, (ii) drive strong business performance, promote accountability and incentivize our directors to achieve short and long-term performance targets with the objective of increasing the Company's equity value and contributing to the Company's strategy for sustainable long-term value creation, (iii) assure that the interests of our directors are closely aligned to those of the Company, its business and its stakeholders, and (iv) ensure the overall market competitiveness of the compensation packages which may be granted to our directors, while providing our board of directors sufficient flexibility to tailor the Company's compensation practices on a case-by-case basis, depending on the market conditions from time to time. We believe that this approach and philosophy benefits the realization of the Company's (sustainable) long-term objectives while keeping with the Company's risk profile.

24. Compensation Structure

The compensation structure for the directors should (a) attract, retain, motivate and fairly and appropriately compensate qualified directors with the leadership qualities, skills and experience needed to support and promote the growth and sustainable success of the Company and its business; (b) drive strong business performance, promote accountability and incentivize directors to achieve short and (sustainable) long-term performance targets with the objective of increasing the Company's equity value and contributing to the Company's strategy for (sustainable) long- term value creation; (c) assure that the interests of the directors are closely aligned to those of the Company, its business and its stakeholders; and (d) ensure the overall market competitiveness and comparability to peer groups of the compensation packages which may be granted to the directors, while providing the board of directors sufficient flexibility to tailor the Company's compensation practices on a case-by-case basis, depending on the market conditions from time to time. The compensation of the non-executive directors should reflect the time spent and the responsibilities of their role on the board of directors.

In determining the level and structure of the compensation of the directors, the board of directors (a) shall take into account, among other things, the results performance, the share price performance and non-financial indicators relevant to the Company's long-term objectives, all with due observance of the risks for the Company's business which may result from variable compensation; and (b) may take into account market information such as industry standards and peer group data, pre-existing arrangements with the directors, the

respective positions and level of responsibility which the directors take on within the Company's organization and any compensation payable by the Company or any of its subsidiaries to the directors in any other capacity.

The mix of short and long-term incentive awards should be intended to support both long- term value creation and the achievement of short-term Company objectives.

Annual Fix Salary

The annual fixed salary of a director shall be determined on the basis of such director's performance, his/her position and level of responsibility within the Company's organization, the Company's performance and/or such other factors as the board of directors deems appropriate.

Bonus & Clawback

The board of directors may decide that directors shall be eligible for bonuses as part of their variable compensation, based on such financial and/or non-financial metrics as may be established, or amended (subject to the terms of any contractual arrangements with the director concerned). The Company may demand repayment of a bonus, in whole or in part, to the extent that such bonus was paid on the basis of incorrect information regarding the achievement of the targets underlying the bonus or regarding the circumstances on which the bonus was dependent. The non-executive directors, or a special representative designated by the general meeting, may demand such repayment on the Company's behalf. With respect to all variable incentive awards, subject to the terms of any contractual arrangements with the directors, the board of directors shall (a) set and, if appropriate, amend the applicable targets, objectives and/or conditions, and their respective weighting; (b) set and, if appropriate, amend the maximum amount for any cash incentive and the maximum number of securities for any equity incentive which may be awarded to individual directors; and (c) determine the extent to which the applicable targets, objectives and/or conditions are attained and incentive awards vest. The board of directors may award bonuses to a director for specific transactions or other achievements that the board of directors deems exceptional in terms of strategic importance and effect on the Company's results.

Options

The number of options to be granted to a director as part of his compensation shall be dependent on the direct involvement, the responsibility taken on within and the achievement of challenging and predetermined targets.

25. Compensation of directors and senior management

The aggregate compensation, including benefits in kind, accrued or paid to our senior management with respect to the year ended December 31, 2024, for services in all capacities was €5,763,630. In 2024, we granted options to purchase 1,450,000 ordinary shares to our senior management. In determining the level and structure of the compensation of the directors in the fiscal year to which this report relates relevant scenario analyses carried out in advance have been considered as follows:

The individual percentage of the cash bonus an executive director is entitled to as well as applicable conditions are stipulated in the respective service agreements. Annual bonus (short term incentive, STI) subject to and in accordance with the Compensation Policy, up to a maximum of 50% of the then-applicable gross fixed annual base compensation before the application of the performance factor. The Compensation Committee has defined a performance factor in form of a percentage to multiply the respective bonus for the executive board members (as stipulated in the respective service agreements) based on the individual performance of the respective executive director during the calendar year. This performance factor is recommended to the non-executive members of the board of directors. Taking the recommendation of the compensation committee into account, the non-executive members of the board of directors resolved after evaluation and discussion upon a specific applicable performance percentage of the contractually stipulated bonus. The resulting bonus amount is determined by multiplication of the annual fixed salary for the year in question by the contractually stipulated bonus and by the performance percentage agreed upon by the non-executive members of the board of directors.

We have established a policy in respect of the remuneration of our directors in accordance with Dutch law. Such policy addresses the following topics: the fixed and variable components of the remuneration (if any), remuneration in the form of shares and severance payments. The policy for our board of directors was adopted and approved by the general meeting of shareholders prior to the consummation of our initial public offering.

The board of directors determines the remuneration of the directors in accordance with the compensation policy, with the understanding that executive directors will not participate in the decision-making process regarding the determination of the compensation of executive directors. Compensation schemes in the form of shares or rights to shares must be submitted by the board of directors to the general meeting for its approval. Any such proposal must set out at least the maximum number of shares or rights to shares to be granted to the directors and the criteria for granting or amendment.

As of December 31, 2024, we have no amounts set aside or accrued to provide pension, retirement or similar benefits to our senior managers or directors, and in 2024, our non-executive directors received €601,879 in total compensation, including benefits in kind, from us for services in such capacity. Furthermore in 2024, we granted options to purchase 165,000 ordinary shares to our non-executive directors under the 2017-Long Term Incentive-Plan.

Pay Ratio

According to the methodology used in SEC`s Item 402 of Regulation S-K we have determined a pay ratio of [9.5] as of December 31, 2024 (2023: [10.1], 2022: [9.9], 2021: [9.2], 2020: [9.8], We have used the SEC guidance for pay ratio determination as we are listed on Nasdaq, which is maybe different to guidance provided in this regard in the DCGC . The decrease in the pay ratio is the result of an increase of FTE in 2024.

The ratio describes the relation between the CEO`s compensation and the compensation of median employee. Statutory charges and expenses for share-based compensation have not been included. The latter was omitted as share-based compensation is not a widely spread compensation feature in the Company or its subsidiaries. The median employee was determined by listing all annual salaries by size. The median divides the population in on half of employees that have a higher annual salary and the other with lower salaries. We calculated the median employee's total compensation for 2024 with annual total compensation of €96.3 thousand (2023: €89.3 thousand). This annual total compensation includes the annual base salary and bonuses accrued.

Management and director service agreements

We have entered into management services agreements with each of our executive directors that became effective upon the consummation of our initial public offering. The management services agreements contain a termination notice period for us, and the executive directors appointed as such by a general meeting of shareholders. All of the management services agreements provide that the executive director may be terminated in the event of an urgent cause (*dringende reden*) without advance notice. In the event that an executive director no longer serves as an executive director but remains employed in his role as an executive employee of the Company, the executive director will not be entitled to any contractual severance or termination payments. Rather, we will enter into an employment agreement with the executive director, which may include substantially similar compensation terms as provided under the management services agreements. The management services agreements contain post-termination restrictive covenants, including perpetual confidentiality, and post-termination non-competition and non-solicitation covenants.

In addition, we have entered into letter agreements with each of our non-executive directors which became effective upon the consummation of our initial public offering, or upon election by the annual general meeting. The letter agreements may be terminated, without advance notice, if the non-executive director is removed from the board of directors, resigns from the board of directors or such director's term of office on the board of directors expires without his reappointment as a non-executive director. Additionally, each letter agreement provides for compensation, including an annual cash fee, an annual equity grant, a discretionary annual fee for membership on a committee of the board of directors, and a discretionary annual fee for acting as a chairperson of a committee of the board of directors. Also, the letter agreements contain a perpetual confidentiality covenant.

2016 option plan

Under the Stock Option Plan 2016 Terms and Conditions, or the 2016 Plan, we have granted rights to subscribe for our ordinary shares to directors, senior management and key employees.

All outstanding option awards under the 2016 Plan automatically vested upon closing of our initial public offering.

In conjunction with the corporate reorganization undertaken prior to our initial public offering, all outstanding awards granted under the 2016 Plan or otherwise converted into awards exercisable for ordinary shares of InflaRx N.V. and will be governed by the terms of the 2016 Plan.

2017 equity incentive plan

In conjunction with the closing of our initial public offering, we established a new omnibus plan, or the 2017 Plan, with the purpose of advancing the interests of our shareholders by enhancing our ability to attract, retain and motivate individuals who are expected to make important contributions to us. The 2017 Plan governs issuances of equity incentive awards from and after the closing of our initial public offering. The initial maximum number of ordinary shares available for issuance under equity incentive awards granted pursuant to the 2017 Plan equals 2,341,097 ordinary shares. On January 1, 2021 and on January 1 of each calendar year thereafter, an additional number of shares equal to 4% of the total outstanding ordinary shares on December 31 of the immediately preceding year (or any lower number of shares as determined by the board of directors) will become available for issuance under equity incentive awards granted pursuant to the 2017 Plan.

Plan Administration. The 2017 Plan is administered by a committee appointed by the board of directors, which committee will consist of not less than three directors (the "plan committee" or "LTI Committee").

Eligibility. Equity incentive awards may be granted to our employees, non-employee directors, consultants or other advisors, as well as holders of equity compensation awards granted by a company that may be acquired by us in the future.

Awards. Equity incentive awards under the 2017 Plan may be granted in the form of stock options, stock appreciation rights, restricted stock, restricted stock units, performance awards or other share-based awards. Stock options and stock appreciation rights will have an exercise price determined by the plan committee but that is no less than fair market value of the underlying ordinary shares on the date of grant.

Vesting. The vesting conditions for grants under the equity incentive awards under the 2017 Plan will be set forth in the applicable award documentation. However, subject to the acceleration provisions under certain circumstances described below, awards (other than replacement awards) may not vest in full prior to the first anniversary of the grant date, with the exception that up to five percent of the shares available for issuance under the 2017 Plan may provide for alternative vesting conditions.

Termination of Service and Change in Control. In the event of a participant's termination of employment, the plan committee may, in its discretion, determine the extent to which an equity incentive award may be exercised, settled, vested, paid or forfeited. In the event of a change in control of the company (as defined in the 2017 Plan), any then successor or surviving corporation may continue outstanding awards, or convert or substitute such awards for award or right with respect to the stock of the successor or surviving corporation, in which case, if a participant is terminated by the successor or surviving corporation without "cause" or for "good reason" (in each case, as defined in the 2017 Plan) within 24 months following the change in control, all equity incentive awards held by the participant will immediately vest. If any outstanding awards are not continued or converted following a change in control of the company, then such awards will immediately vest, and options and stock appreciation rights will become fully exercisable. In connection with a change of control, the plan committee may, in its discretion, take a number of other actions, including accelerating the vesting of any equity incentive award or terminating or cancelling any equity incentive award for cash payment.

2019 repricing of option plans

On July 3, 2019, the board approved an amendment of the 2016 Option Plan and the 2017 equity incentive plan. Following the amendment, the strike price of all vested and unvested options, other than those held by persons who were not employees or directors at the time of the amendment, was reduced to $3.35 per share.

Please also see note 14 to the Company only financial statements regarding Remuneration of the Board of Directors, which forms part of this compensation report.

2022 repricing of option plans

On April 13, 2022, the LTI Committee, acting on behalf of the board, approved a repricing of all unexercised options outstanding which have an exercise price below the Company's stock price as of April 13, 2022, irrespective of whether or not those options have vested, provided that they are held by active employees or directors of the Company or its affiliates whose contracts have not been terminated (as defined in the 2017 plan), such that the exercise price of the re-adjusted options shall be $1.86.

Related Party Transactions

Since January 1, 2024we did not enter in related party transactions with any of our officers, directors and the holders of more than 5% of our ordinary shares.

Protective Measures

Under Dutch law, various protective measures are possible and permissible within the boundaries set by Dutch law and Dutch case law. Our governance arrangements include several provisions that may have the effect of making a takeover of our Company more difficult or less attractive. In this respect, our general meeting of shareholders granted the right to the protective foundation to acquire preferred shares pursuant to the call option agreement entered into between us and such foundation. This call option under the call option agreement shall be continuous in nature and can be exercised repeatedly on multiple occasions.

If the protective foundation exercises the call option pursuant to the call option agreement, an amount of preferred shares up to 100% of our issued capital held by others than the protective foundation, minus one share, will be issued to the protective foundation. These preferred shares will be issued to the protective foundation under the obligation to pay up to 25% of their nominal value upon issuance. In order for the protective foundation to finance the issue price in relation to the preferred shares, the protective foundation is expected to enter into a finance arrangement with a bank. As an alternative to securing financing with a bank, subject to applicable restrictions under Dutch law, the call option agreement provides that the protective foundation may request us to provide, or cause our subsidiaries to provide, sufficient funding to the protective foundation to enable it to satisfy the payment obligation (or part thereof) in cash and/or to charge an amount equal to the payment obligation (or part thereof) against our profits and/or reserves in satisfaction of such payment obligation.

The protective foundation's articles of association provide that it will promote and protect the interests of the company, the business connected with the company and the company's stakeholders from time to time, and repressing possible influences which could threaten the strategy, continuity, independence and/or identity of the company or the business connected with it, to such an extent that this could be considered to be damaging to the aforementioned interests. These influences may include a third party acquiring a significant percentage of our ordinary shares, the announcement of an unsolicited public offer for our ordinary shares, shareholder activism, other concentration of control over our ordinary shares or any other form of undue pressure on us to alter our strategic policies. The protective foundation shall be structured to operate independently of us.

If the protective foundation were to exercise its call option, the preferred shares to be issued pursuant thereto would be issued against the obligation to pay up to 25% of their nominal value. The voting rights of our shares are based on nominal value and, as we expect our ordinary shares to trade substantially in excess of nominal value, preferred shares issued at 25% of their nominal value can carry significant voting power for a substantially reduced price compared to the price of our ordinary shares and thus can be used as a defensive measure. These preferred shares will have both a liquidation and dividend preference over our ordinary shares and will accrue cash dividends at a pre-determined rate. The protective foundation would be expected to require us to cancel its preferred shares once the perceived threat to the company and its stakeholders has been removed or sufficiently mitigated or neutralized. However, subject to the same limitations described above, the protective foundation would continue to have the right to exercise the call option in the future in response to a new threat to the interests of us, our business and our stakeholders from time to time.

In addition, certain provisions of our Articles of Association may make it more difficult for a third party to acquire control of us or effect a change in our board of directors. These provisions include: a provision that our directors are appointed on the basis of a binding nomination prepared by our board of directors which can only be overruled by a two-thirds majority of votes cast representing more than 50% of our issued share capital; a provision that our directors may only be removed by the general meeting of shareholders by a two-thirds majority of votes cast representing more than 50% of our issued share capital (unless the removal is proposed by the board in which case a simple majority of the votes can be sufficient); and a requirement that certain matters, including an amendment of our Articles of Association, may only be brought to our shareholders for a vote upon a proposal by our board of directors.

ITEM 4: FINANCIAL STATEMENTS

APPENDIX A - InflaRx N.V. Consolidated financial statements

INFLARX N.V.

CONSOLIDATED FINANCIAL STATEMENTS

FOR THE FINANCIAL YEAR ENDED DECEMBER 31, 2024

These financial statements are consolidated financial statements for the Group consisting of InflaRx N.V. and its subsidiaries. The financial statements are presented in Euro (€).

InflaRx N.V. is a company limited by shares, incorporated and domiciled in Amsterdam, The Netherlands. Its registered office and principal place of business is in Germany, Jena, Winzerlaer Str. 2.

All press releases, financial reports and other information are available in the investor's register on our website: www.inflarx.com

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

InflaRx N.V. and subsidiaries

Consolidated statements of operations and comprehensive loss for the years ended December 31, 2024, 2023 and 2022

	Note	2024	2023	2022
		(in €, except for share data)		
Revenues	C.1.	165,789	63,089	—
Cost of sales	C.2.	(3,317,039)	(532,262)	—
Gross profit		**(3,151,250)**	**(469,173)**	**—**
Sales and marketing expenses	C.3.	(6,756,595)	(4,001,299)	—
Research and development expenses	C.4.	(35,363,897)	(41,024,131)	(37,526,090)
General and administrative expenses	C.5.	(13,024,441)	(12,628,756)	(14,869,564)
Other income	C.6.	5,287,616	13,219,704	20,159,169
Other expenses		(297)	(4,440)	(1,381)
Operating result		**(53,008,864)**	**(44,908,096)**	**(32,237,866)**
Finance income	C.8.	3,196,813	3,804,827	608,679
Finance expenses	C.8.	(20,655)	(35,628)	(45,250)
Foreign exchange result	C.8.	3,670,235	(1,841,872)	2,442,297
Other financial result	C.8.	103,285	313,240	(252,471)
Income taxes		**(5,217)**	—	—
Loss for the period		**(46,064,402)**	**(42,667,529)**	**(29,484,611)**
Other comprehensive income (loss) that may be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of foreign currency		58,344	125,085	4,206,810
TOTAL COMPREHENSIVE LOSS		**(46,006,058)**	**(42,542,444)**	**(25,277,801)**
Share information	C.9.			
Weighted average number of shares outstanding		58,919,958	54,940,137	44,207,873
Loss per share (basic/diluted)		(0.78)	(0.78)	(0.67)

The accompanying notes are an integral part of these consolidated financial statements.

InflaRx N.V. and subsidiaries

Consolidated statements of financial position as of December 31, 2024 and 2023

	Note	December 31, 2024	December 31, 2023
ASSETS		**(in €)**	
Non-current assets			
Property and equipment	D.1.	256,280	289,577
Right-of-use assets	D.2.	758,368	1,071,666
Intangible assets	D.3.	50,781	68,818
Other assets	D.6.	204,233	257,267
Financial assets	D.8.	3,092,290	9,052,741
Total non-current assets		**4,361,952**	**10,740,069**
Current assets			
Inventories	D.5.	6,897,666	11,367,807
Current other assets	D.6.	5,103,402	4,036,649
Other assets from goverment grants and research allowance	D.6.	5,081,772	—
Tax receivable	D.7.	1,735,335	3,791,564
Other financial assets	D.8.	34,462,352	77,504,518
Cash and cash equivalents	D.9.	18,375,979	12,767,943
Total current assets		**71,656,505**	**109,468,482**
TOTAL ASSETS		**76,018,457**	**120,208,551**
EQUITY AND LIABILITIES			
Equity	**D.10.**		
Issued capital	D.10.(a).	7,122,205	7,065,993
Share premium	D.10.(a).	334,929,685	334,211,338
Other capital reserves	D.10.(a).	44,115,861	40,050,053
Accumulated deficit	D.10.(a).	(332,192,221)	(286,127,819)
Other components of equity	D.10.(a).	7,440,510	7,382,166
Total equity		**61,416,039**	**102,581,730**
Non-current liabilities			
Lease liabilities	E.2.	399,066	745,716
Other liabilities		36,877	36,877
Total non-current liabilities		**435,943**	**782,593**
Current liabilities			
Trade and other payables	D.11.	11,394,232	11,974,362
Lease liabilities	E.2.	406,020	374,329
Employee benefits		2,064,678	1,609,766
Other liabilities	D.11.	301,544	2,885,772
Total current liabilities		**14,166,475**	**16,844,228**
Total liabilities		**14,602,417**	**17,626,822**
TOTAL EQUITY AND LIABILITIES		**76,018,457**	**120,208,552**

The accompanying notes are an integral part of these consolidated financial statements.

InflaRx N.V. and subsidiaries

Consolidated statements of changes in shareholders' equity for the years ended December 31, 2024, 2023 and 2022

	Note	Shares outstanding	Issued capital	Share premium
			(in €)	
Balance as of January 1, 2022		**44,203,763**	**5,304,452**	**280,310,744**
Loss for the period		—	—	—
Exchange differences on translation of foreign currency		—	—	—
Total comprehensive loss		**—**	**—**	**—**
Issuance of ordinary shares	D.10.(a).	500,000	60,000	2,289,624
Transaction costs		—	—	(47,735)
Equity-settled share-based payments	C.10.	—	—	—
Balance as of December 31, 2022		**44,703,763**	**5,364,452**	**282,552,633**
Loss for the Period		—	—	—
Exchange differences on translation of foreign currency		—	—	—
Total comprehensive loss		**—**	**—**	**—**
Issuance of ordinary shares	D.10.(a).	14,059,252	1,687,110	54,796,819
Transaction costs		—	—	(3,360,626)
Equity-settled share-based payments	C.10.	—	—	—
Share options exercised		120,257	14,431	222,512
Balance as of December 31, 2023		**58,883,272**	**7,065,993**	**334,211,338**
Loss for the Period		—	—	—
Exchange differences on translation of foreign currency		—	—	—
Total comprehensive loss		**—**	**—**	**—**
Issuance of ordinary shares	D.10.(a).	468,438	56,213	1,042,076
Transaction costs		—	—	(323,729)
Equity-settled share-based payments	C.10.	—	—	—
Balance as of December 31, 2024		**59,351,710**	**7,122,205**	**334,929,685**

The accompanying notes are an integral part of these consolidated financial statements.

InflaRx N.V. and subsidiaries

Consolidated statements of changes in shareholders' equity for the years ended December 31, 2024, 2023 and 2022

	Note	Other capital reserves	Accumulated deficit	Other components of equity	Total equity
			(in €)		
Balance as of January 1, 2022		**30,591,209**	**(213,975,679)**	**3,050,270**	**105,280,996**
Loss for the period		—	(29,484,611)	—	(29,484,611)
Exchange differences on translation of foreign currency		—	—	4,206,810	4,206,810
Total comprehensive Loss		**—**	**(29,484,611)**	**4,206,810**	**(25,277,801)**
Issuance of ordinary shares	D.10.(a).	—	—	—	2,349,624
Transaction costs		—	—	—	(47,735)
Equity-settled share-based payments	C.10.	6,044,356	—	—	6,044,356
Balance as of December 31, 2022		**36,635,564**	**(243,460,290)**	**7,257,080**	**88,349,440**
Loss for the period		—	(42,667,529)	—	(42,667,529)
Exchange differences on translation of foreign currency		—	—	125,085	125,085
Total comprehensive loss		**—**	**(42,667,529)**	**125,085**	**(42,542,444)**
Issuance of ordinary shares	D.10.(a).	—	—	—	56,483,929
Transaction costs		—	—	—	(3,360,626)
Equity-settled share-based payments	C.10.	3,414,489	—	—	3,414,489
Share options exercised		—	—	—	236,943
Balance as of December 31, 2023		**40,050,053**	**(286,127,819)**	**7,382,166**	**102,581,730**
Loss for the period		—	(46,064,402)	—	(46,064,402)
Exchange differences on translation of foreign currency		—	—	58,344	58,344
Total comprehensive loss		**—**	**(46,064,402)**	**58,344**	**(46,006,058)**
Issuance of ordinary shares	D.10.(a).	—	—	—	1,098,289
Transaction costs		—	—	—	(323,729)
Equity-settled share-based payments	C.10.	4,065,807	—	—	4,065,807
Balance as of December 31, 2024		**44,115,861**	**(332,192,221)**	**7,440,510**	**61,416,039**

The accompanying notes are an integral part of these consolidated financial statements.

InflaRx N.V. and subsidiaries

Consolidated statements of cash flows for the years ended December 31, 2024, 2023 and 2022

	Note	2024	2023	2022
			(in €)	
Operating activities				
Loss for the period		(46,064,402)	(42,667,529)	(29,484,611)
Adjustments for:				
Depreciation & amortization of property and equipment, right-of-use assets and intangible assets		485,114	567,780	596,597
Net finance income	C.8.	(6,949,679)	(2,240,566)	(2,753,255)
Share-based payment expense	C.10.	4,065,807	3,414,489	6,044,356
Net foreign exchange differences		(37,101)	413,017	385,359
Changes in:				
Other assets from government grants and research allowances	D.6.	(5,081,772)	732,971	(732,971)
Other assets		1,042,513	7,825,181	(3,308,485)
Employee benefits		454,912	297,518	(64,024)
Other liabilities		(2,584,228)	2,738,164	9,403
Liabilities from government grants received	D.6.	—	(6,209,266)	(2,090,734)
Trade and other payables	D.11.	(580,129)	6,986,824	(3,586,706)
Inventories	D.5.	4,470,141	(11,367,807)	—
Interest received		2,243,197	1,732,284	1,287,200
Interest paid		(21,064)	(36,025)	(44,946)
Net cash used in operating activities		**(48,556,690)**	**(37,812,966)**	**(33,742,817)**
Investing activities				
Purchase of intangible assets and property and equipment		(46,871)	(81,100)	(162,391)
Purchase of current and non-current financial assets		(35,340,107)	(104,051,972)	(64,474,543)
Proceeds from the maturity of current financial assets		87,751,331	86,436,456	83,995,029
Net cash from/ (used in) investing activities		**52,364,354**	**(17,696,616)**	**19,358,095**
Financing activities				
Proceeds from issuance of ordinary shares	D.10.	1,098,289	56,483,929	2,349,624
Transaction costs from issuance of ordinary shares		(323,729)	(3,360,626)	(47,735)
Proceeds from exercise of share options	C.10.	—	236,943	—
Repayment of lease liabilities		(388,114)	(373,977)	(364,430)
Net cash from financing activities		**386,446**	**52,986,269**	**1,937,459**
Net in-/decrease in cash and cash equivalents		4,194,110	(2,523,313)	(12,447,262)
Effect of exchange rate changes on cash and cash equivalents		1,413,926	(974,099)	2,462,622
Cash and cash equivalents at beginning of period		12,767,943	16,265,355	26,249,995
Cash and cash equivalents at end of period	**D.9.**	**18,375,979**	**12,767,943**	**16,265,355**

The accompanying notes are an integral part of these consolidated financial statements.

InflaRx N.V. and subsidiaries

A. Notes to the consolidated financial statements

1. Corporate information

The consolidated financial statements of InflaRx N.V. and its subsidiaries (collectively, the "Group") for the year ended December 31, 2024 were authorized for issue in accordance with a resolution of the Board of Directors on March 19, 2025. InflaRx N.V. (the "Company") is a Dutch public company with limited liability (*naamloze vennootschap*) with its corporate seat in Amsterdam, The Netherlands, and is registered in the Commercial Register of The Netherlands Chamber of Commerce Business Register under CCI number 68904312. The Company's registered office is at Winzerlaer Straße 2 in 07745 Jena, Germany. Since November 10, 2017, the Company's ordinary shares have been listed on the Nasdaq Global Select Market under the symbol "IFRX".

The Company and its subsidiaries, collectively, are a biotechnology group pioneering anti-inflammatory therapeutics by applying its proprietary anti-C5a and anti-C5aR technologies to discover, develop and commercialize highly potent and specific inhibitors of the complement activation factor known as C5a and its receptor C5aR.

Subsidiaries are all entities over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and could affect those returns through its power to direct the activities of the entity. Subsidiaries are fully consolidated from the date on which control is obtained by the Group. They are deconsolidated from the date control ceases. The acquisition method of accounting is used to account for business combinations by the Group. Intercompany transactions, balances and unrealized gains on transactions between Group companies are eliminated. Unrealized losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset.

The Group's subsidiaries as at December 31, 2024 are set out below. Unless otherwise stated, such subsidiaries have share capital consisting solely of ordinary shares that are held directly by the Company, and the proportion of ownership interests held equals the voting rights held by the Company.

			Ownership interest held by the Company		
Name	**Place of business/ country of incorporation**	**Functional currency**	**2024**	**2023**	**Principal activities**
InflaRx GmbH	Jena and Munich, Germany	EUR	100%	100%	Operating subsidiary, R&D, holder of all IP
InflaRx Pharmaceuticals, Inc.	Ann Arbor, MI, United States	USD	100%	100%	Operating subsidiary, R&D, US commercialization

B. Material accounting policies

1. Basis of preparation

The consolidated financial statements of the Group have been prepared in accordance with IFRS Accounting Standards as issued by the International Accounting Standards Board (IASB). The consolidated financial statements have been prepared on a historical cost basis. These consolidated financial statements of the Group comprise the Company and its wholly owned subsidiaries, InflaRx GmbH and InflaRx Pharmaceuticals, Inc. The consolidated financial statements are presented in Euro (€). The presentation currency of the Group is the Euro, as the functional currency of the largest operating company, InflaRx GmbH, continues to be the Euro. Effective January 1, 2023, the functional currency of InflaRx N.V. changed from the U.S. dollar to the Euro due to a change in the Company's operational function and, in turn, a change in the primary currency of its underlying transactions. This change in functional currency has been accounted for prospectively. The functional currency of InflaRx Pharmaceuticals, Inc. is the U.S. dollar ($), as most of their income and expenses occur in U.S. dollars in 2024. All financial information presented in Euro has been rounded to the nearest Euro, unless stated otherwise. We have prepared the financial statements on the basis that the company will continue to operate as a going concern.

2. Summary of material accounting policies

This section describes material accounting policies adopted in the preparation of these consolidated financial statements. These policies have been consistently applied to all the years presented, unless otherwise stated.

(a) New and amended standards adopted by the Group

The following amendments were adopted effective January 1, 2024, and do not have a material impact on the consolidated financial statements of the Group:

- Amendments to IFRS 16 Leases: leases on sale and leaseback
- Amendments to IAS 1 presentation of financial statements: classification of liabilities as current or non-current and non-current liabilities with covenants
- Amendments to IAS 7, statement of cash flows and IFRS 7, -supplier finance arrangements

(b) New standard not yet adopted

The following standards issued will be adopted in a future period, and the potential impact on the Group's consolidated financial statements, if any, is being assessed:

- Amendments to IAS 21 effects of changes in foreign exchange rates: lack of exchangeability
- IFRS 18 presentation and disclosure in financial statements

(c) Current and non-current classification

The Group presents assets and liabilities in the statement of financial position based on current/non-current classification.

Current assets include assets that are sold, consumed or realized as part of the normal operating cycle (operating cycle is assumed to be 12 months), or cash and cash equivalent unless restricted from being exchanged or used to settle a liability for at least 12 months after the reporting period. All other assets are classified as non-current.

Current liabilities, such as trade payables, lease liabilities or employee benefits with a term of up to 12 months, and payables for operating costs or social security charges, are part of the working capital used in the Company's normal operating cycle. Such operating items are classified as current liabilities even if they are due to be settled more than 12 months after the reporting period. All other liabilities are classified as non-current.

(d) Foreign currency transactions

Transactions in a foreign currency are initially translated into the respective functional currency using the spot rate prevailing on the dates of the transaction. Monetary items which are not denominated in the functional currency are subsequently translated using the rate applicable at the end of the period. The resulting currency gains and losses are recognized directly in profit or loss.

On consolidation, the assets and liabilities of operations in a currency other than Euro (the presentation currency of the Company) are translated into Euros at the rate of exchange prevailing at the reporting date and their statements of operations are translated with monthly average exchange rates during the reporting period. The exchange differences arising on translation for consolidation are recognized in 'other comprehensive income' (OCI). On disposal of a foreign operation, the component of OCI relating to that particular foreign operation is reclassified to profit or loss. OCI is disclosed as 'other components of equity' in consolidated statements of financial position.

(e) Grants from government and similar bodies

The Group receives grants from government agencies and similar bodies for the active participation in specific research and development projects. The grants are recognized when there is reasonable assurance that the grant will be received and all grant conditions will be met.

According to the terms of the grants, grantors generally have the right to audit qualifying expenses submitted by the Group up to five years after concluding the project sponsored by the government.

(f) Notes to the cash flow statement, cash, and cash equivalents

The consolidated statements of cash flows have been prepared using the indirect method for cash flows from operating activities. The cash disclosed in the consolidated statements of cash flows is comprised of cash and cash equivalents. Cash comprises cash on hand and demand deposits. Cash equivalents are short-term bank deposits that are readily convertible to a known amount of cash and are not subject to a significant risk of changes in value with an original maturity of three months or less. Interest paid and received is included in the cash from operating activities.

(g) Research and development expenses

Research and development expenses comprise third party services, wages and salaries, cost of materials, intellectual property related expenses, depreciation and amortization of relevant equipment and intangibles as well as overhead. Research and development expenses mainly consist of costs for clinical trials and manufacturing of the Company's clinical drug products; additionally, costs are incurred for pre-clinical activities as well as basic research activities.

Development expenses must be capitalized if the criteria of IAS 38 are met. In the periods presented, no development expenses were capitalized because management assessed that not all the recognition criteria of IAS 38 had been met. This assessment is due to the general uncertainties in drug development and the unpredictability of regulatory requirements. Therefore, research and development expenditures are expensed when incurred.

(h) Employee benefits

(i) Short-term employee benefits

Liabilities for wages and salaries and cash bonuses are measured at the amounts expected to be paid when the liabilities are settled. The liabilities are presented as employee benefits in the consolidated statements of financial position. A liability is recognized if the Group has a present legal or constructive obligation to pay such amount as a result of past service provided by the employee and if such obligation can be estimated reliably.

(ii) Share-based payment transactions

The grant-date fair value of equity-settled share-based payment arrangements granted to employees is generally recognized as an expense, with a corresponding increase in equity, over the vesting period of the awards. The amount recognized as an expense is adjusted to reflect the number of awards for which the related service conditions are expected to be met, including an estimate of forfeitures, such that the amount ultimately recognized is based on the number of awards that meet the related service conditions at the vesting date. For share-based payment awards with immediate vesting, the grant-date fair value of the share-based payment is measured to reflect such conditions and there is no gain or loss recognized for differences between expected and actual outcomes.

(i) Lease arrangements

The Group leases various properties, laboratory and office equipment and cars. Rental contracts are typically made for fixed periods of one to three years but may have renewal options. The lease agreements do not impose any covenants, but leased assets may not be used as collateral for borrowing purposes.

(i) Right-of-use assets

The Group recognizes right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any re-measurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Unless the Group is reasonably certain to obtain ownership of the leased asset at the end of the lease term, the recognized right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term. On December

31, 2024, the remaining useful lives of the Company's right-of-use assets ranged between 3 and 38 months. Right-of-use assets are subject to impairment.

(ii) Lease liabilities

At the commencement date of the lease, the Group recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments which depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for terminating a lease, if the lease term reflects the Group exercising the option to terminate. The variable lease payments that do not depend on an index or a rate are recognized as expense in the period on which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses the incremental borrowing rate at the lease commencement date, since the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is re-measured if there is a modification, a change in the lease term, a change in the in-substance fixed lease payments or a change in the assessment to purchase the underlying asset.

(iii) Short-term leases and leases of low-value assets

The Group applies the short-term lease recognition exemption to its short-term leases of equipment (i.e., those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the lease of low-value assets recognition exemption to leases of office equipment that are considered of low value. Lease payments on short-term leases and leases of low-value assets are recognized as expense on a straight-line basis over the lease term.

(iv) Determining the lease term of contracts

After the commencement date, the Group reassesses the lease term if there is a significant event or change in circumstances that is within its control and affects its ability to exercise the option to renew.

The Group further determines the lease term as the non-cancellable term of the lease, together with any periods covered by an option to extend the lease if it is reasonably certain to be exercised, or any periods covered by an option to terminate the lease, if it is reasonably certain not to be exercised.

The leases which currently also result in the capitalization of a right of use asset, do not include any renewal options. For future lease contracts with potential renewal options the Company applies judgement in evaluating whether it is reasonably certain to exercise the option to renew. In doing so, management would consider all relevant factors that create an economic incentive for it to exercise the renewal.

(j) Interest income

Interest income is derived from interest-bearing financial assets, including cash equivalents. Interest income on cash and cash equivalents, financial assets at amortized cost calculated using the effective interest rate method is recognized in the consolidated statements of operations and comprehensive loss as part of finance income.

(k) Intangible assets

Intangible assets mainly comprise purchased IT software. Intangible assets are initially measured at acquisition cost, including any directly attributable costs of preparing the asset for its intended use less accumulated amortization and accumulated impairment losses, if any. Amortization begins when an asset is available for use and amortization is calculated using the straight-line method to allocate cost over the estimated useful lives. The useful lives of intangible assets are reviewed at each reporting date. Software is amortized over three years. The effect of any adjustment to useful lives is recognized prospectively as a change of accounting estimate. The Group only owns intangible assets with a definite useful life.

(l) Property and equipment

Laboratory and office equipment are stated at historical cost less accumulated depreciation and accumulated impairment losses, if any. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

All repairs and maintenance are recognized in profit or loss during the financial period in which they are incurred, because they do not constitute a separate asset.

Depreciation on laboratory and office equipment is calculated using the straight-line method to allocate their cost over their estimated useful lives, as follows:

- Laboratory equipment: three to 13 years
- Office equipment: one to five years

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at the end of each reporting period.

Gains and losses on disposals are determined by comparing the proceeds with the carrying amount and are recognized within 'other income' or 'other expenses' in the consolidated statements of operations and comprehensive loss.

(m) Inventory

Inventories are valued at the lower of cost or net realizable value. Net realizable value for product inventories comprises the estimated sales proceeds from final products less the necessary expected costs up to the time of sale. Inventories are comprised of raw materials, unfinished goods, and finished goods. Costs incurred in bringing each product to its present location and condition are accounted for, as follows:

- Raw materials: purchase cost on a first-in/first-out basis
- Finished goods and work in progress: cost of direct materials and labor and a proportion of manufacturing overhead based on normal operating capacity

(n) Impairment of assets

At each reporting date, the Group assesses whether there is an indication that an asset may be impaired. If there is any indication of impairment or if an annual impairment test is required, the Group estimates the recoverable amount of the asset. The recoverable amount of an asset is the higher of the asset's fair value less costs of disposal and its value-in-use. It is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets, in which case it is determined at the level of the cash-generating unit. If the carrying amount of an asset exceeds its recoverable amount, the asset is impaired and written down to its recoverable amount. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset.

When there has been a change in the estimates used to determine the asset's recoverable amount since the last impairment loss was recognized, any impairment loss previously recognized is reversed. The reversal may not exceed the carrying amount that would have been determined after amortization or depreciation had no impairment loss been recognized for the asset in prior periods. The amount of the reversal is recognized in profit or loss for the period.

There were no impairments or reversals of impairments in 2022, 2023 or 2024.

(o) Financial assets and liabilities (financial instruments)

(i) Definition

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity. The Group's financial assets include predominantly quoted fixed-interest

debt securities. The financial liabilities comprise trade and other payables (incl. accrued liabilities from the R&D projects).

(ii) Criteria for the recognition and derecognition, initial measurement

In general purchases or sales of financial assets are recognized on the settlement date, i.e., the date that the Group renders or receives the counter performance (typically cash). The Group initially measures a financial asset at its fair value plus transaction costs.

The Group initially recognizes non-derivative financial liabilities on the date that they are originated at fair value net of directly attributable transaction costs. The Group derecognizes a financial liability when its contractual obligations are discharged, cancelled, or expire.

(iii) Subsequent measurement method

Considering the Group's business model for managing the financial assets, with an objective to hold them in order to collect contractual cash flows, and their contractual cash flow characteristics, that are solely payments of principal and interest on the principal amount outstanding, the Group classifies the quoted debt securities with fixed interest rates as subsequently measured at amortized cost using the effective interest method (EIR). The financial assets are also subject to impairment.

The Group's financial liabilities are classified as subsequently measured at amortized cost which is calculated by considering any discount or premium on acquisition and fees or costs that are an integral part of the EIR.

An analysis of the carrying amounts from the consolidated statements of financial position by measurement category is disclosed under 'under 'D.8 Financial assets and financial liabilities.'

(iv) Criteria for realization of income and expenses

Interest income is accrued using the relevant effective interest rate. Interest expense on liabilities, if any, is also accrued based on the effective interest rate.

Gains and losses on the disposal of financial instruments are recognized in full when all significant risks and rewards have been transferred. In the case of a partial transfer of risks and rewards, a distinction would be made as to whether control remains with the company or is transferred.

Impairment losses on financial assets are recognized in profit or loss. The Group recognizes an allowance for expected credit losses (ECLs) for the financial assets held, see Note 'C.8. Net Financial Result'.

ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. ECLs are generally recognized in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next 12-months (a 12-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL). For the quoted debt securities with fixed interest rates, which have high credit ratings and no significant increases in credit risk since initial recognition, the Group determines the exposure to credit default using CDS pricing information (i.e., credit default swap values) published by credit agencies and recognizes a 12-month ECL.

(p) Fair value measurement

The Group does not measure any financial asset or liability at fair value. The carrying amount of all financial instruments approximates their fair value, with the exception of quoted debt securities for which fair values are disclosed (see Note'D.8. Financial assets and financial liabilities').

When measuring the fair value of an asset or a liability, the Group would use observable market data as far as possible. Fair values are categorized into different levels in a fair value hierarchy based on the inputs used in the valuation techniques as follows:

- Level 1, quoted prices in active markets for identical assets or liabilities.

- Level 2, inputs other than quoted prices included within Level 1 that are observable for the instrument, either directly (as prices) or indirectly (derived from prices).

- Level 3, inputs for instruments that are not based on observable market data (unobservable inputs).

If the inputs used to measure the fair value of an asset or a liability fall into different levels of the fair value hierarchy, then the fair value measurement is categorized in its entirety in the same level of the fair value hierarchy as the lowest level input that is significant to the entire measurement.

The Group would recognize transfers between levels of the fair value hierarchy at the end of the reporting period during which the change has occurred.

(q) Income tax

Income taxes comprise current and deferred taxes. Current and deferred taxes are recognized in profit or loss except to the extent that they relate to items recognized directly in equity or in other comprehensive loss.

(i) Current income tax

Current income tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities. Expected tax payable or receivable on the taxable income or loss for the year, are calculated using tax rates enacted or substantively enacted at the reporting date, and any adjustment to tax payable in respect of previous years.

In the periods presented; the Group did not incur income tax expense. Taxes withheld by banks and remitted to tax authorities were reimbursed after filing of the annual tax declaration.

(ii) Deferred income tax

Deferred tax is recognized in respect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. Deferred tax is not recognized for temporary differences associated with assets and liabilities if the transaction which led to their initial recognition is a transaction that is not a business combination and that affects neither accounting nor tax profit or loss.

Deferred tax is measured at the tax rates that are expected to be applied to temporary differences when they reverse, based on the laws that have been enacted or substantively enacted by the reporting date.

Deferred tax assets arising from tax loss carryforwards are recognized only to the extent that the Group has sufficient taxable temporary differences or there is convincing evidence that sufficient future taxable profit will be available against which the unused tax losses can be utilized. As of December 31, 2024 and 2023, based on management’s judgment, it was not probable that taxable profit will be available against which the unused tax losses can be utilized; no deferred tax assets were therefore recognized in the consolidated statements of financial position.

3. Significant accounting judgements, estimates and assumptions

The preparation of the consolidated financial statements in conformity with IFRSaccounting standards requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates.

Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected. In preparing these consolidated financial statements, the critical judgments made by management in applying the Group's accounting policies involve the following areas:

(a) Accounting for share-based payments

When determining the grant date fair value of share-based payment awards, assumptions must be made regarding the key parameters of the calculation (see Note 'C.10.(b). Measurement of fair values of share options granted'). In 2024, the Company's share price volatility for the purposes of the calculation was determined on the basis of the 5-year annualized average share price (since October 2024 5.5-year annualized share price), which management believes will be indicative of the share price development of the Company in future periods. This led to a range of applied volatility rates in 2024 of 143% to 147% for the different options granted during the year of this report.

Additionally, the Company must estimate the number of equity instruments which will vest in future periods as awards may be forfeited prior to vesting due to an awardee's failure to satisfy a performance condition, including due to employment termination. An assumption of the forfeiture rate is regularly made on the basis of historical information and adjusted to reflect future expectations. Revisions to the forfeiture rate could result in a cumulative effect of the change in estimate for current and prior periods to be recognized in the period of change.

(b) Measurement of third-party R&D clinical trial and contracted manufacturing expense

In measuring R&D expenses for the reporting period, the Company estimates the amount of expense to recognize and liability to accrue to the extent that invoices of the Company's contract research organizations ("CROs") and contract manufacturing organizations ("CDMOs") are not yet received and exceed any prepayments made. The timing of the invoicing of project services by CROs follow contractual billing schedules and can occur several months prior to or following a reporting period. This estimation involves determining a percentage-of-completion whereby the degree to which services have been rendered for the individual project activities contracted from the CRO and CDMOs is assessed and estimated by in-house R&D project managers and reviewed by the controlling department. This percentage-of-completion is used to measure the amount of the unbilled project activities which have already been rendered by the reporting date and the associated R&D expense and liability to recognize as a result.

The percentage-of-completion estimates are based on the best information available at the time. However, additional information may become available in the future and management may adjust the estimate in such future periods. In this event, the Company may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain. The Company recognizes the resulting increases or decreases in expenses as changes in estimates and reflects such changes in research and development expenses in the period identified.

The Company accrued €6.6 million as of December 31, 2024 and €4.4 million as of December 31, 2023 (see Note D.11. Trade and other payables) in third-party accruals in relation to its ongoing clinical trials and manufacturing activities. As of these dates, prepayments were recorded for payments made to CROs and CDMOs against which no services had yet been rendered (2024: €4.6 million, 2023: €3.7 million, see Note D.6. Other assets).

(c) Realizability of inventories

For determining the net realizable value, at each reporting date, the Company estimates excess and obsolete inventory primarily using a model of expected future sales and using assumptions with significant estimation uncertainty such as expected medical need and expected market penetration.

Additionally, these estimates rely, in part, on management's assumptions about future events outside of the Company's control, such as continuation of the emergency use authorization in the United States and marketing authorization in the European Union. In making these assumptions, management assesses the probability of these authorizations remaining in place or, by considering correspondence with the relevant regulatory authorities and the Company's actions to achieve any required conditions for the authorizations.

Furthermore, the possible alternative uses for raw materials, unfinished and finished products is taken into consideration.

Management regularly assesses market and sales trends, market conditions, disease prevalence, competitive landscape, and regulatory environment to refine estimates for excess and obsolete inventory. To the extent that inventories on-hand at the reporting date exceed the amount recoverable from expected future sales prior to

expiry of their shelf-life, inventories are written-down to their net realizable value with the corresponding expense recognized in cost of sales.

Inventory write-downs for the year ended December 31, 2024 amounted to €3.3 million (prior year: €0.5 million) and were mainly due to the expiration of shelf life of finished and unfinished goods.

Assumptions included in the model of expected future demand may require revision in future periods which could result in changes to the estimate of excess and obsolete inventory and in inventory write-downs.

C. Consolidated statements of operations and comprehensive loss

1. Revenues

	2024	2023	2022
		(in €)	
Revenues	165,789	63,089	—
Total	**165,789**	**63,089**	**—**

For the twelve months ended December 31, 2024 and 2023, the Company realized revenues from product sales of GOHIBIC (vilobelimab) in the amount of €0.2 million and €0.1 million respectively.

Revenues reported are sales to end customers (hospitals). Sales to distributors do not constitute revenue for the Company under IFRS 15. All revenues are attributed to sales made in the United States.

2. Cost of sales

	2024	2023	2022
		(in €)	
Cost of sales	3,317,039	532,262	—
Total	**3,317,039**	**532,262**	**—**

Cost of sales expenses increased by €2.8 million for the year ended December 31, 2024 compared to the corresponding costs for the year ended December 31, 2023 due primarily due to higher inventory write-downs of €2.8 million (Note B.5 for additional information).

3. Marketing and sales expenses

Marketing and sales expenses in 2024 compared to 2023 increased by €2.8 million. The table below shows the composition of sales and marketing expenses.

	2024	2023	2022
		(in €)	
Third-party expenses	2,010,120	1,021,082	—
Marketing expenses	1,573,628	830,076	—
Employee benefits expenses	1,806,151	1,040,587	—
of which equity-settled share-based payment expense	*191,111*	*67,462*	
Legal and consulting fees	910,146	1,054,971	—
Other expenses	456,550	54,583	—
Total sales and marketing expenses	**6,756,595**	**4,001,299**	**—**

During the twelve months ended December 31, 2024 the Group incurred €6.8 million of marketng and sales expenses in the United States. These expenses are mainly composed of €1.8 million in personnel costs and €2.0 million in external services for distribution and €1.6 million in marketing expenses of GOHIBIC (vilobelimab).

During the twelve months ended December 31, 2023 the Group incurred €4.0 million of sales and marketing expenses in the United States of America . These expenses are mainly composed of €1.0 million in personnel costs and €1.0 million in external services for distribution of GOHIBIC (vilobelimab).

The Group started with its commercialization activities when the EUA was granted in 2023. Prior to that, no sales and marketing expenses had been incurred.

4. Research and development expenses

Research and development expenses in 2024 compared to 2023 decreased by €5.7 million. The table below shows the composition of research and development expenses.

	2024	2023	2022
		(in €)	
Third-party services	23,113,874	31,802,983	28,543,503
of which clinical material and related manufacturing services	*4,619,437*	*18,109,345*	*16,194,152*
of which clinical, pre-clinical studies	*18,494,437*	*13,693,638*	*12,349,351*
Employee benefits expenses	8,390,010	6,776,853	6,957,866
of which equity-settled share-based payment expense	*1,873,958*	*1,500,670*	*2,456,571*
Legal and consulting fees	1,362,029	1,758,283	1,690,448
Other expenses	2,497,983	686,012	334,273
Total	**35,363,897**	**41,024,131**	**37,526,090**

5. General and administrative expenses

General and administrative expenses in 2024 compared to 2023 increased by €0.4million. The table below shows the composition of general and administrative expenses.

	2024	2023	2022
		(in €)	
Employee benefits expenses	6,339,421	5,392,905	7,125,798
of which equity-settled share-based payment expense	*2,000,739*	*1,846,356*	*3,587,785*
Legal and consulting fees	2,851,390	3,239,809	3,104,624
Insurance expenses	1,570,343	1,934,880	2,330,624
Depreciation & amortization expense	455,497	507,905	526,325
Compensation expense for non-executive directors	321,500	305,984	248,724
Other expenses	1,486,290	1,247,273	1,533,469
Total	**13,024,441**	**12,628,756**	**14,869,564**

6. Other income

Other income decreased in 2024 compared to the prior year due to the end, in June 2023, of the German federal government grant for the development of vilobelimab in severe COVID-19 patients under which the Group recognized income in 2023 and 2022.

In 2024, the Group qualified for an allowance under the *Forschungszulagengesetz* (Research Allowance Act) in Germany, a law designed to promote research and development. Under this allowance, the Group became eligible for reimbursement in cash, by the German federal government, of a portion of certain eligible R&D expenses incurred 2020 through 2027. Under IFRS accounting standards, the allowance is recognized as a government grant. Upon qualifying for the allowance, the Group recognized €5.1 million in income relating to eligible expenses which were incurred in the years 2020 to 2024. The Group remains eligible for reimbursement of expenses to be incurred from 2025 to 2027.

	2024	2023	2022
		(in €)	
Other income from government grants and research allowances	5,081,772	13,155,250	20,097,496
Further other income	205,844	64,453	61,672
Total	**5,287,616**	**13,219,704**	**20,159,169**

7. Employee benefits expenses

The following table shows the items of employee benefits expenses:

	2024	2023	2022
		(in €)	
Wages and salaries	10,416,490	8,192,143	6,863,423
Social security contributions (employer's share)	1,282,973	944,712	672,534
Equity-settled share-based payment expenses (see Note C.10. Share-based payments)	4,065,807	3,414,488	6,044,356
Other	770,311	659,002	503,351
Total	**16,535,582**	**13,210,345**	**14,083,664**

8. Net financial result

	2024	2023	2022
		(in €)	
Interest income	3,196,813	3,804,827	608,679
Interest expenses	(885)	(16,538)	(23,303)
Interest on lease liabilities	(19,770)	(19,090)	(21,947)
Financial result	**3,176,159**	**3,769,199**	**563,429**
Foreign exchange income	6,876,161	5,529,389	6,924,697
Foreign exchange expense	(3,205,926)	(7,371,261)	(4,482,399)
Foreign exchange result	**3,670,235**	**(1,841,872)**	**2,442,298**
Other financial result	103,285	313,240	(252,471)
Net financial result	**6,949,680**	**2,240,566**	**2,753,256**

Net financial result increased by €4.7million from 2023 to 2024. This overall increase was comprised of lower interest income of €0.6 million from marketable securities and short-term deposits in U.S. dollars held by the Company and its subsidiaries (from €3.8 million in 2023 to €3.2 million in 2024), and an increase in foreign exchange result by €5.5 million (from €-1.8 million in 2023 to €3.7 million in 2024).

Foreign currency income and expenses arise from the translation of cash and cash equivalents, marketable securities and other financial assets and liabilities denominated in foreign currencies at the exchange rates prevailing at the balance sheet date. All resulting translation differences are recognized in the income statement. These gains and losses are caused by a change in exchange rates at the reporting dates and may not ultimately be realized.

9. Loss per share

Loss per ordinary share is calculated by dividing the loss of the period by the weighted average number of ordinary shares outstanding during the period. The weighted number of ordinary shares outstanding for the financial year 2024 was 58,919,958, for 2023 it amounted to 54,940,137 and for 2022 it was 44,207,873. Loss per share was €0.78, €0.78 and €0.67 in 2024, 2023 and 2022, respectively.

As the Company is in a loss-making situation, the diluted loss per share is the same as basic loss per share, because the weighted average number of shares to be issued upon the exercise of the stock options, the only dilutive instruments issued, would produce an anti-dilutive effect. Refer to Note C.10. for the balances of outstanding share options.

10. Share-based payments

a) Equity-settled share-based payment arrangements

In the course of its historical financing rounds prior to 2016, InflaRx GmbH established equity-settled share-based payment programs. Those InflaRx GmbH options were converted into options for ordinary shares of InflaRx N.V. in November 2017:

	2024 Options	2024 WAEP*	2023 Options	2023 WAEP*
Outstanding at January 1	**148,433**	**€0.01**	**148,433**	**€0.01**
Exercised during the year	—	—	—	—
Outstanding at December 31	**148,433**	**€0.01**	**148,433**	**€0.01**
Exercisable at December 31	148,433	€0.01	148,433	€0.01

* Weighted average share price (WAEP)

The exercise price for all options granted prior to 2016 outstanding at the end of the year was €0.01 per share or less (2023: €0.01 or less).

Under the terms and conditions of the share option plan of 2016 (the "2016 Plan"), InflaRx GmbH granted rights to subscribe for InflaRx GmbH's common shares to directors, senior management, and key employees. Those InflaRx GmbH options were converted into options for ordinary shares of the Company in November 2017:

	2024 Options	2024 WAEP*	2023 Options	2023 WAEP*
Outstanding at January 1	**888,632**	**$1.86/€1.68**	**888,632**	**$1.86/€1.74**
Exercised during the year	—		—	
Outstanding at December 31	**888,632**	**$1.86/€1.79**	**888,632**	**$1.86/€1.68**
Exercisable at December 31	888,632	$1.86/€1.79	888,632	$1.86/€1.68

*Conversion rates used for one €: December 31,2024 $0.9626, average rate 2024 $0.9242, December 31,2023 $0.9050, average rate 2023 $0.9246

The weighted average remaining contractual life for the share options outstanding under the 2016 Plan as of December 31, 2024 was 6.93 years (2023: 7.94 years).

In conjunction with the closing of its initial public offering, InflaRx N.V. established a new incentive plan (the "2017 Plan"). The initial maximum number of ordinary shares available for issuance under equity incentive awards granted pursuant to the 2017 Plan equals 2,341,097 ordinary shares. On January 1, 2021 and on January 1 of each calendar year thereafter, an additional number of shares equal to 4% of the total outstanding ordinary shares on December 31 of the immediately preceding year (or any lower number of shares as determined by the Board of Directors) will become available for issuance under equity incentive awards granted pursuant to the 2017 Plan:

	2024 Options	2024 WAEP*	2023 Options	2023 WAEP*
Outstanding at January 1	**6,584,946**	**$2.12/€1.92**	**4,985,523**	**$1.97 /€1.84**
Granted during the year	2,332,500	$1.78/€1.65	1,735,750	$2.58/€2.39
Forfeited during the year	(12,000)	$3.02/€2.79	(31,000)	$2.70/€2.50
Exercised during the year	—	0	(105,327)	$2.16/€2.00
Outstanding at December 31	**8,905,446**	**$2.03/€1.95**	**6,584,946**	**$2.12/€1.92**
Exercisable at December 31	8,129,196	$2.03/€1.96	5,577,384	$2.01/€1.82

*Conversion rates used for one €: December 31,2024 $0.9626, average rate 2024 $0.9242, December 31,2023 $0.9050, average rate 2023 $0.9246

The weighted average remaining contractual life for the share options outstanding under the 2017 Plan as of December 31, 2024 was 6.5 years (2023: 6.61 years).

All Options granted in 2024 vest over one year. Options granted before 2024 vest over a period of one, two or three years, depending on the grant, with 1/2 or 1/3, respectively, of the options vesting after the end of the 1st year from vesting start and the remaining options vesting quarterly in equal portions thereafter. Vesting of these unvested share options is subject to a service condition at the time of vesting, and no market or performance conditions are applicable.

The weighted average fair value of options granted during 2024 was $1.78/€1.65 (2023: $2.58/€2.39). The range of exercise prices for options outstanding at the end of the year was $1.51/€1.45 to $5.14/€4.95 (2023: $1.86/€1.74 to $5.14/€4.82).

b) Measurement of fair values of share options granted under the 2017 Plan

The fair value of options granted under the 2017 Plan was determined using the Black-Scholes valuation model. As the Company's ordinary shares are listed on the Nasdaq Global Select Market, the closing price of the ordinary shares at grant date was used.

Other significant inputs into the model are as follows (weighted average):

Share options granted	Options	Fair value per share option	FX rate as of grant date	Fair value per share option	Share price at grant date/ Exercise price	Expected volatility	Expected life (midpoint based)	Risk-free rate (interpolated, U.S. sovereign strips curve)
2022								
January 12	1,516,666	$3.66	0.8795	€3.22	$4.13	1.35	5.31	1.57%
January 12	45,000	$3.68	0.8795	€3.24	$4.13	1.35	5.50	1.59%
Repricing, April 13	—	$1.20-$1.63	0.9237	€1.11-€1.50	$1.86	1.35	1.83-4.94	2.6%
November 21	405,000	$2.04	0.9760	€1.99	$2.44	1.35	4.0	4.15%
	1,966,666							

Of the 1,966,666 options granted in 2022, 1,223,500 were granted to members of the executive management or the Board of Directors. In 2022, 136,259 options were forfeited, 14,930 were exercised.

Share options granted	Options	Fair value per share option	FX rate as of grant date	Fair value per share option	Share price at grant date/ Exercise price	Expected volatility	Expected life (midpoint based)	Risk-free rate (interpolated, U.S. sovereign strips curve)
2023								
January 24	1,454,250	$2.11	0.9008	€1.90	$2.37	1.35	5.30	3.571%
January 24	52,500	$2.13	0.9008	€1.92	$2.37	1.35	5.50	3.565%
May 31	60,500	$3.61	0.9361	€3.38	$4.19	1.35	4.50	3.820%
July 7	57,000	$3.59	0.9184	€3.30	$3.89	1.46	5.50	4.320%
July 7	100,000	$3.64	0.9184	€3.34	$3.89	1.46	6.10	4.286%
July 19	4,000	$3.55	0.8911	€3.16	$3.99	1.46	5.50	4.320%
September 18	7,500	$3.15	0.9378	€2.95	$3.54	1.46	5.50	4.320%
	1,735,750							

Of the 1,735,750 options granted in 2023, 1,136,000 were granted to members of the executive management or the Board of Directors. In 2023, 31,000 options were forfeited, 105,327 were exercised.

Share options granted	Number	Fair value per share option	FX rate as of grant date	Fair value per share option	Share price at grant date/ Exercise price	Expected volatility	Expected life (midpoint based)	Risk-free rate (interpolated, U.S. sovereign strips curve)
2024								
January 05	2,245,000	$1.65	0.9160	€1.51	$1.79	1.47	5.30-5.50	4.023-4.025%
February 21	30,000	$1.40	0.9250	€1.30	$1.51	1.47	5.50	4.308%
October 30	57,500	$1.44	0.9246	€1.33	$1.57	1.43	5.50	4.155%
	2,332,500							

Of the 2,332,500 options granted in 2024, 1,300,000 were granted to members of the executive management or the Board of Directors. In 2024, 12,000 options were forfeited, no options were exercised.

Expected dividends are nil for all share options listed above.

Share price volatility is calculated on the basis of annualized monthly volatility rate of the Company's share price over the last five years preceding the valuation date. From October 2024 on we calculated the annualized daily volatility rate of the Company's share price over the last five and a half years preceding the valuation date due to the change of a service provider.

The range of outcomes for the expected life of the instruments has been based on expectations on option holder behavior in the scenarios considered.

The dividend yield has no impact due to the anti-dilution clause as defined in the 2017 Plan.

D. Notes to the consolidated statements of financial position

1. Property and equipment

	Property and equipment
Cost	
At January 1, 2023	**1,453,339**
Additions	55,123
Disposals	(2,595)
Exchange differences	(14,342)
At December 31, 2023	**1,491,525**
Additions	22,723
Disposals	—
Exchange differences	25,822
At December 31, 2024	**1,540,070**
Accumulated depreciation	
At January 1, 2023	**(1,124,419)**
Depreciation charge for the year	(93,791)
Disposals	2,594
Exchange differences	13,668
At December 31, 2023	**(1,201,948)**
Depreciation charge for the year	(56,077)
Disposals	—
Exchange differences	(25,765)
At December 31, 2024	**(1,283,790)**
Net book value	
At December 31, 2023	**289,577**
At December 31, 2024	**256,280**

2. Right-of-use assets

	Buildings	Cars	Total
Cost		**(in €)**	
At January 1, 2023	**2,579,342**	**125,130**	**2,704,472**
Additions	91,125	49,004	140,129
Disposals	—	—	—
Exchange differences	(9,349)	—	(9,349)
At December 31, 2023	**2,661,118**	**174,134**	**2,835,252**
Additions	—	68,604	68,604
Disposals	—	—	—
Exchange differences	20,101	—	20,101
At December 31, 2024	**2,681,219**	**242,738**	**2,923,957**
Accumulated depreciation			
At January 1, 2023	**(1,286,625)**	**(106,039)**	**(1,392,664)**
Depreciation charge for the year*	(353,398)	(24,527)	(377,925)
Disposals	—	—	—
Exchange differences	7,003	—	7,003
At December 31, 2023	**(1,633,020)**	**(130,566)**	**(1,763,586)**
Depreciation charge for the year	(353,426)	(33,427)	(386,852)
Disposals	—	—	—
Exchange differences	(15,151)	0	(15,151)
At December 31, 2024	**(2,001,597)**	**(163,993)**	**(2,165,590)**
Net book value			
At December 31, 2023	**1,028,098**	**43,568**	**1,071,666**
At December 31, 2024	**679,622**	**78,745**	**758,367**

3. Intangible assets

	Purchased IT-software	Advances paid for software	Total
Cost		**(in €)**	
At January 1, 2023	723,250	—	723,250
Additions	—	25,977	25,977
Disposals	(7,009)	—	(7,009)
Exchange differences	(111)	—	(111)
At December 31, 2023	**716,130**	**25,977**	**742,107**
Additions	6,607	17,541	24,148
Disposals	—	—	—
Exchange differences	439	—	439
At December 31, 2024	**723,176**	**43,518**	**766,694**
Accumulated amortization			
At January 1, 2023	(584,345)	—	(584,345)
Amortization charge for the year*	(96,063)	—	(96,063)
Disposals	7,009	—	7,009
Exchange differences	111	—	111
At December 31, 2023	**(673,289)**	**—**	**(673,289)**
Amortization charge for the year	(42,185)	—	(42,185)
Disposals	—	—	—
Exchange differences	(439)	—	(439)
At December 31, 2024	**(715,913)**	**—**	**(715,913)**
Net book value			
At December 31, 2023	**42,841**	**25,977**	**68,818**
At December 31, 2024	**7,263**	**43,518**	**50,781**

Amortization of intangible assets is included in the line items 'research and development expenses' (2024: €785, 2023: €858, 2022: €858) and 'general and administrative expenses' (2024: €41,400, 2023: €95,205, 2022: €97,413) in the consolidated statements of operations and comprehensive loss.

4. Leases

Lease obligations consist of payments pursuant to non-cancellable lease agreements mainly relating to the Company's leases of office space. The lease terms of the Company's premises expire as follows: Jena, Germany in December 2025, Martinsried, Germany in May 2027 and Ann Arbor, Michigan, United States in April 2026.

Set out below, are the carrying amounts and the movements of the Group's lease liabilities:

Lease liabilities	**2024**	**2023**
	(in €)	
As of January 1	1,120,048	1,356,684
Additions	68,604	140,128
Derecognition	—	(20,555)
Payments	(388,114)	(353,422)
Short-term liability for accrued interest expense	(409)	(396)
Foreign exchange difference	4,959	(2,391)
As of December 31	**805,086T**	**1,120,048**

The following are the amounts recognized in profit or loss:

	2024	**2023**	**2022**
		(in €)	
Depreciation expense of right-of-use assets (see Note E.2.)	386,853	377,925	384,432
Interest expense on lease liabilities	19,770	19,090	21,947
Rental expense from leases	10,429	6,261	6,261
Thereof short-term leases (included in administrative expenses)	*4,168*	—	—
Thereof leases of low-value assets (included in administrative expenses)	*6,261*	*6,261*	*6,261*
Total amounts recognized in profit or loss	**417,052**	**403,276**	**412,640**

The Group had total cash outflows for leases of €0.4 million in 2024 (€0.4 million in 2023, €0.4 million in 2022).

5. Inventory

	2024	**2023**	**2022**
		(in €)	
Raw material and supplies	82,087	423,560	—
Unfinished goods	6,758,952	10,614,159	—
Finished goods	56,627	330,087	—
Total	**6,897,666**	**11,367,807**	**—**

As of December 31, 2024, inventory amounted to €6.9 million compared to €11.4 million as of December 31, 2023. In 2024, €1.2 million in unfinished inventory was recognized as research and development expense due to use in clinical studies.

In 2024 the Group recorded in cost of sales write downs of raw materials and supplies of €0.3 million (€0 million in 2023 and 2022), write downs of unfinished goods of €2.7 million (€0 million in 2023 and 2022) and write downs of finished goods of €0.5 million (€0.5 million in 2023, €0 million in 2022) due primarily to quantities on-hand exceeding quantities expected to be sold prior to expiry.

6. *Other assets*

	December 31, 2024	December 31, 2023
	(in €)	
Non-current other assets		
Prepaid expenses	204,233	257,267
Total	**204,233**	**257,267**
Current other assets		
Prepayments on research & development projects	4,628,878	3,670,167
Prepaid expenses	354,948	272,999
Others	119,576	93,482
Total	**5,103,402**	**4,036,648**
Total other assets	**5,307,635**	**4,293,915**
Non-current and current other assets from goverment grants ans research allowance		
Current other assets from goverment grants ans research allowance	5,081,772	—
Total non-current and current other assets from goverment grants ans research allowance	**5,081,772**	**—**

Prepayments on research & development projects consists of prepayments on CRO and CDMO contracts. Prepaid expenses mainly consist of prepaid insurance expenses. At December 31, 2024, other assets from government grants and research allowances contains €5.1 million in research allowances are reimbursements we qualify for under the German Research Allowance Act.

7. *Income tax*

The table below shows a reconciliation between the product of loss before tax multiplied by the Company's applicable tax rate and current income taxes recognized in profit or loss.

InflaRx Group	2024	2023	2022
		(in €)	
Loss for the period (accounting profit before income tax)	(46,059,185)	(42,667,529)	(29,484,611)
Tax rate	28.6%	28.6%	29.2%
Tax benefits at tax rate	13,159,368	12,160,545	8,610,381
Temporary differences and tax losses for which no deferred tax asset was recognized	(14,577,752)	(12,127,977)	(7,480,169)
Non-recognition of tax effect on share-based payments	—	(32,182)	(1,251,830)
Non-deductible expenses for tax purposes	(56,721)	(46,907)	(22,067)
Tax free income	1,475,105	—	—
Taxes prior years	(5,217)	—	—
Other differences due to tax rate	—	46,521	143,686
Income tax	**(5,217)**	**—**	**—**

The tax rate applied above represents the weighted average of the statutory tax rates in Germany and the United States. In Germany, InflaRx N.V. and its subsidiary InflaRx GmbH are subject to corporate income tax (2024/2023/2022: 15%), a solidarity surcharge (2024/2023/2022: 0.8%) and trade taxes (2024: 13.202%; 2023: 13.065%; 2022: 13.7%). This equals an average total tax rate of 29.03 % in 2024 (2023: 28.99%; 2022: 29.5%). In 2023, the InflaRx GmbH established a managing director's permanent establishment (PE) in the UK. The taxable remuneration is subject to a tax rate of 25% less a deduction (small profits relief). The taxes prior year result from the established PE. InflaRx Pharmaceuticals, Inc., Ann Arbor, Michigan, United States is subject to an average total tax rate of 25.74% in 2024 (2023 25.74%; 2022: 25.74%), which is made up of U.S. federal tax (2024, 2023, 2022: 21%) and state tax of 4.74% in 2024 (2023 and 2022: 4.74%).

a) Tax losses carried forward

The Group has total tax loss carryforwards of €288,95 million (2023: €243.8 million) from three areas that cannot be utilized outside these areas:

As of December 31, 2024 the Group had €238.4 million (2023: €196.2 million) for corporate income purposes and €206.7 million (2023: €164.4 million) for trade tax purposes of unrecognized and unused tax losses carried forward attributable to the tax group formed by InflaRx N.V. since 2018; these tax losses do not expire and may not be used to offset taxable income elsewhere in the Group. Since January 1, 2018, InflaRx GmbH has distributed its losses to the parent Company InflaRx N.V. under a profit and loss transfer agreement. This tax group was formed in Germany and is subject to German tax legislation.

- Tax losses of InflaRx GmbH until December 31, 2017 (€34.8 million) are frozen from 2018 onwards due to the creation of a tax group with InflaRx N.V. Those losses of InflaRx GmbH do not expire and may be used to offset future taxable income of InflaRx GmbH only.

- In addition, the Group still has tax loss carryforwards of $16.36 million or €15.75 million (2023: $14.3 million or €12.97 million) from the operations of InflaRx Pharmaceuticals, Inc. which can also only be utilized there, generally do not expire, but are generally limited to offset tax obligation for 80% of taxable income.

As of December 31, 2024, 2023 and 2022, no deferred tax assets were recognized for the carryforward of unused tax losses.

b) Current income tax receivable

Current income tax receivable includes tax claims because of income tax withheld on interest income earned by the Group on the financial assets (2024: €1,281,649, 2023: €1,390,280). The Company is reimbursed for the payments after filing a tax return.

8. Financial assets and financial liabilities

Set out below is an overview of financial assets and liabilities, other than cash and short-term deposits included in cash equivalents, held by the Group as at December 31, 2024 and December 31, 2023:

	December 31, 2024	December 31, 2023
	(in €)	
Financial assets at amortized cost		
Non-current financial assets	3,092,290	9,052,741
Thereof marketable securities	*2,854,405*	*8,815,120*
Current financial assets	34,462,352	77,504,518
Thereof marketable securities	*33,969,390*	*76,803,111*
Financial liabilities at amortized cost		
Trade and other payables	11,549,150	14,716,441

The fair value of current and non-current financial assets amounted to €42.6 million (level 1; 2023: €85.6 million). The Group's financial assets at amortized cost consist mainly of quoted debt securities with fixed interest rates with high credit rating (investment grade securities) by international rating agencies such as S&P Global and, therefore, are considered low credit risk investments.

The maturities of all securities held as of December 31, 2024 are between one and thirteen months (2023: between one and seventeen months); they bear nominal fixed interest in the range of 0.3% to 6.250% (2023: 0.4% to 4.125%).

9. Cash and cash equivalents

	December 31, 2024	December 31, 2023
	(in €)	
Short-term deposits		
Deposits held in U.S. dollars	13,408,478	4,120,951
Deposits held in Euro	700,000	1,020,000
Total	**14,108,478**	**5,140,951**
Cash at banks		
Cash held in U.S. dollars	2,805,655	5,041,802
Cash held in Euro	1,461,847	2,585,190
Total	**4,267,501**	**7,626,991**
Total cash and cash equivalents	**18,375,979**	**12,767,942**

10. Equity

a) Issued capital

As of December 31, 2024, the issued capital of the Company is divided into 59,351,710 ordinary shares (2023: 58,883,272). The nominal value per share is €0.12. All shares issued are fully paid and have the same rights on the distribution of dividends and the repayment of capital.

On June 30, 2023, the Company filed a Form F-3 (2023Registration Statement) with the U.S. Securities and Exchange Commission (the "SEC") with respect to the offer and sale of securities of the Company, which became effective on July 11, 2023. The aggregate initial offering price of the securities that the Company may offer and sell under this prospectus will not exceed $250 million. The Company also filed with the SEC a prospectus supplement relating to an at-the-market program providing for the sale of up to $75.0 million of its ordinary shares over time pursuant the Sales Agreement with Leerink Partners LLC (the "Sales Agreement"). No ordinary shares were issued by the Company under the 2023-Registration Statement within the fiscal year 2023. As of December 31, 2024, the Company had issued 468,438 ordinary shares resulting in €0.8 million in net proceeds to the Company with a remaining value authorized for sale under the Sales Agreement of $73.8 million.

During 2024, the Company issued no ordinary shares for the exercise of stock option rights granted under the 2017 Long-Term Incentive Plan. We also refer to G. Significant events after the reporting date.

On July 8, 2020, the Company filed a Form F-3 (2020-Registration Statement) with the U.S. Securities and Exchange Commission (the "SEC") with respect to the offer and sale of securities of the Company. The Company also filed with the SEC a prospectus supplement relating to an at-the-market program (2020) providing for the sale of up to $50.0 million of its ordinary shares over time pursuant a sales agreement with SVB Leerink LLC (the "Leerink Sales Agreement"). As of December 31, 2022, the Company had issued 2,568,208 ordinary shares resulting in €11.8 million in net proceeds to the Company with a remaining value authorized for sale under the Leerink Sales Agreement of $35.2 million.

During the fiscal year 2023, the Company issued 3,235,723 ordinary shares under its at-the-market program (2020) resulting in €14.4 million or $15.7 million in net proceeds. Following these and previous issuances under this at-the-market program (2020), the remaining value authorized for sale under the Leerink Sales Agreement amounted to $19.0 million as of July 8, 2023; the term of the at-the-market program (2020) expired on July 8, 2023.

Through an underwritten public offering in April 2023, the Company sold and issued an aggregate of 10,823,529 ordinary shares, of which 1,411,764 were sold pursuant to the exercise of an overallotment option by the underwriters. The ordinary shares were sold at a price of $4.25 per share and have a nominal value of €0.12 per share. Proceeds of this offering after deducting €2.5 million ($2.8 million) in underwriting discounts amounted to €39.1 million ($43.2 million). Other offering expenses amounted to €0.4 million, resulting in a total of €38.7 million in net proceeds from this offering.

In connection with amending the Co-Development Agreement with Staidson (Beijing) BioPharmaceuticals Co., Ltd. ("Staidson") on December 21, 2022, the Company entered into a share purchase agreement with Staidson pursuant to which Staidson purchased ordinary shares of the Company for an aggregate amount of $2.5 million (€2.3 million) at a price of $5.00 per share, resulting in the sale of 500,000 additional shares. Under the terms of the share purchase agreement, at the Company's option, Staidson may purchase additional shares for an aggregate purchase price of $7.5 million, which is subject to certain conditions. The accounting impact of this put option is not material.

During 2023, the Company issued a total of 120,257 ordinary shares after former employees exercised stock option rights granted under the 2017 Long-Term Incentive Plan. The ordinary shares have a nominal value of €0.12 per share. Therefrom, 98,754 ordinary shares were sold at a price of $1.85 per share, and 21,503 ordinary shares were sold at a price of $3.35. The ordinary shares were registered in 2023, except 14,930 stock options which were exercised in December 2022 with resulting ordinary shares having been registered in January 2023.

b) Authorized capital

According to the articles of association of the Company, up to 147,200,000 ordinary shares and up to 147,200,000 preferred shares with a nominal value of €0.12 per share are authorized to be issued. All shares are registered shares. No share certificates shall be issued.

In order to deter acquisition bids, the Company's general meeting of shareholders approved the right of an independent foundation under Dutch law, or protective foundation, to exercise a call option pursuant to the call option agreement, upon which preferred shares will be issued by the Company to the protective foundation of up to 100% of the Company's issued capital held by others than the protective foundation, minus one share. The protective foundation is expected to enter into a finance arrangement with a bank or, subject to applicable restrictions under Dutch law, the protective foundation may request the Company to provide, or cause the Company's subsidiaries to provide, sufficient funding to the protective foundation to enable it to satisfy its payment obligation under the call option agreement.

These preferred shares will have both a liquidation and dividend preference over the Company's ordinary shares and will accrue cash dividends at a pre-determined rate. The protective foundation would be expected to require the Company to cancel its preferred shares once the perceived threat to the Company and its stakeholders has been removed or sufficiently mitigated or neutralized. The Company believes that the call option does not represent a significant fair value based on a level 3 valuation since the preferred shares are restricted in use and can be cancelled by the Company.

For the year ended December 31, 2024, the Company expensed €50,000 of ongoing costs to reimburse expenses incurred by the protective foundation.

c) Nature and purpose of equity reserves

In addition to the issued capital, the Company discloses the following other reserves:

- *Share premium records* the amounts paid in upon issuance of ordinary shares in excess of nominal value of €0.12 per share, net of related transaction costs.
- The *other capital reserves* include the expense resulting from the issue of share options.
- *Accumulated deficit* includes the losses of previous reporting periods.

Other components of equity exclusively include currency reserves from the conversion of financial statements in foreign currencies.

11. Trade and other payables

	December 31, 2024	December 31, 2023
	(in €)	
Accrued liabilities from R&D projects	6,609,925	4,414,142
Accrued liabilities from commercial activities	69,250	1,400,382
Accounts payable	3,413,064	5,102,700
Other accrued liabilities and payables	1,603,538	3,942,909
Total trade and other payables	**11,695,777**	**14,860,134**

Accrued liabilities from R&D projects include third party services from the Company's ongoing R&D projects that have not yet been invoiced to the Company as of the reporting date.

Accrued liabilities from commercial activities include services provided by commercial manufacturing partners that have not yet been invoiced to the Company as of the reporting date.

E. Risk

1. Financial risk management

a) Financial risk management objectives and policies

The Group's financial risks are predominantly controlled by central treasury activities under an investment policy approved by the Board of Directors on October, 27, 2023 as revised on July 31, 2024. Those treasury

activities identify, evaluate and manage financial risks consistent with the Group's operating needs. The Board of Directors provides policies for overall risk management, covering specific areas, such as foreign exchange risk and credit risk. The Company does not intend to use derivative financial instruments because the Group's future risk exposures cannot be reliably forecasted (volume of business activity, liquidity needs, foreign exchange exposure).

Hedging is not applied as most of the business activity is intended to be executed in U.S. dollars and paid with the U.S. dollars funds raised in public offerings. The foreign exchange exposure from costs incurred in currencies other than Euro is deemed immaterial.

The Group's principal financial assets comprise quoted debt securities with high credit ratings. Besides these financial assets, the Group has significant cash and cash equivalents. The Group's principal financial liabilities comprise trade and other payables. The main purpose of these financial assets, cash/cash equivalents and liabilities are to finance the Group's development activities.

The Group is exposed to market risk, credit risk and liquidity risk. The Board of Directors reviews and adopts policies for managing each of these risks, which are summarized below. The Group's senior management oversees the management of these risks.

	Exposure	**Measurement**	**Risk Management**
Market risk	Future development costs; Recognized financial assets and liabilities not denominated in Euro	Forecasted cash flows Sensitivity analysis	Achievement of a natural hedge in the future
Credit risk	Cash and cash equivalents, current and non-current financial assets	Credit rating	Diversification of bank deposits, Investment guidelines for debt investments
Liquidity	R&D and G&A cost, equity, trade and other payables	Rolling cash flow forecast	Availability of funds through financing rounds or public offerings

b) Market risk

Market risk is the risk that changes in market prices (e.g., due to foreign exchange rates) will affect the Group's income, expenses or the value of its holdings of financial instruments. The objective of market risk management is to identify, manage and control market risk exposures within acceptable parameters.

Foreign exchange risk arises when commercial transactions or recognized assets or liabilities are denominated in a currency that is not an entity's functional currency. The Group is exposed to transactional foreign currency risk to the extent that there is a mismatch between the currencies in which costs and purchases are denominated and the respective functional currencies of Group companies. The functional currencies of Group companies are primarily the Euro and U.S. dollars. The currencies in which these transactions and financial assets are primarily denominated are Euro and U.S. dollars. The Group is exposed to the exchange rate between the Euro and the U.S. dollars. Due to the Company's various registered offerings of ordinary shares in U.S. dollars, the Group has significant cash and cash equivalents in U.S. dollars. Currently the Group does not hedge U.S. dollars but intends to achieve a natural hedge by contracting suppliers in U.S. dollars in the future. In 2024, the Group recognized significant foreign exchange gains and losses as the natural hedge is not yet achieved and the functional currency for InflaRx N.V. and InflaRx GmbH is Euro.

The Group is primarily exposed to changes in U.S. dollar to Euro exchange rates. The sensitivity of profit or loss to changes in the exchange rates arises mainly from U.S. dollar denominated financial instruments at InflaRx N.V. and InflaRx GmbH.

In 2024, if the Euro had weakened/strengthened by 10% against the U.S. dollar with all other variables held constant, the Group's loss would have been €5.8 million higher/€4.7 million lower, mainly as a result of foreign exchange on translation of U.S. dollar-denominated assets of InflaRx N.V. and InflaRx GmbH.

Cash, cash equivalents and financial assets denominated in U.S. dollars, InflaRx N.V. and InflaRx GmbH	December 31, 2024	December 31, 2023
	(in €)	
Current and non current financial assets (securities and accrued interest)	37,316,756	80,935,197
Cash and cash equivalents	14,983,597	8,051,366
Total assets exposed to the risk	**52,300,353**	**88,986,563**
Conversion rate Euro to U.S. dollars at reporting date 1/1.0389		

Sensitivity analysis:	Conversion rate	Profit/(loss)	Carrying amount
		(in €)	
Euro strengths against U.S. dollars	1.1428	(4,754,578)	47,545,7759
Euro weakens against U.S. dollars	0.9350	5,811,150	58,111,503

Based on the exchange rate fluctuations from the last three years, the Company expects that exchange rate fluctuations of the Euro to the U.S. dollar between 0.9350 and 1.1428 could be reasonably possible. Compared to the exchange rate on the statement of financial position date (Euro to U.S. dollar at reporting date is 1/1.0389), these rates could have a material impact on the Company's total loss of the period.

c) Credit risk

Credit risk is the risk that a counterparty will not meet its obligations leading to a financial loss for the Company. The Company is exposed to credit risk mainly from its financing activities, including deposits with banks and financial institutions, foreign exchange transactions and other financial instruments.

Credit risk from balances with banks and financial institutions is managed by the Company in accordance with the Company's investment policy. Investment of financial resources which are currently not used to fund R&D or G&A activities, are made only with counterparties within the credit limits approved by the investment policy. For investments in Euro or U.S. dollar debt securities, a BBB+ to AAA credit rating (Standard & Poors and Fitch ratings; or equivalent ratings by Moody's and DBRS) is required. Complex financial products as well as other investments denominated in currencies other than Euros or U.S. dollars are not permitted by the investment policy. Counterparty credit limits and the investment policy are discussed with the Company's Audit Committee on an annual basis and may be updated throughout the year subject to approval of the Company's Audit Committee. The limits are set to minimize the concentration of risks and therefore mitigate financial loss through a counterparty's potential failure to make payments.

The maximum exposure to counterparty credit risk is €61.0 million at December 31, 2024 (December 31, 2023: €99.3 million). This amount equals the carrying amount at year end of cash and cash equivalents (2024:€18.4 million; 2023: €12.8 million) and financial assets (2024:€42.6 million; 2023: €86.6 million).

d) Liquidity risk

The Company monitors its risk of a shortage of funds in every quarterly forecast as well as on an ongoing basis. The Company disclosed the maturities of its principal liabilities under Note E 'Commitments'. Prudent liquidity risk management involves maintaining sufficient cash and marketable securities and the availability of funding to meet obligations when due. The Group continually monitors its risk of a shortage of funds using short and mid-term liquidity planning. This takes into account of the expected cash flows from all activities. The management team performs regular reviews of the budget.

The Company has a history of significant operating losses. Management expects that the Company incurs significant and increasing losses for the foreseeable future; as the Company may not achieve or maintain profitability in the near future, it is dependent on capital contributions or other funding.

The Group raised significant funding from various registered offerings, most recently from an underwritten public offering in February 2025, that it estimates will enable the Group to fund operating expenses and capital expenditure requirements for at least 18 months from December 31, 2024. The Group expects to require additional funding to continue to advance the development of product candidates. In the event regulatory approval is received and the Company implements a strategy to commercialize the products itself, the Group would require additional capital.

At the end of the reporting period, the Group held the following deposits that are expected to readily generate cash inflows to meet the outstanding financial commitments.

Liquidity	December 31, 2024	December 31, 2023
	(in €)	
Short-term deposits	14,108,478	5,140,951
Cash at banks	4,267,501	7,626,992
Marketable Securities (current and non-current)	36,829,741	85,727,461
Other (non-current portion)	237,886	237,621
Other (current)	5,574,734	701,407
Total funds available	**61,018,339**	**99,434,432**

2. Capital management

The Group's policy for capital management is to ensure that it maintains its liquidity in order to finance its operating activities, future business development and meet its liabilities when due. The Group manages its capital structure primarily through equity. The Group does not have any financial liabilities, other than trade and other payables or leasing liabilities.

No changes were made in the objectives, policies or processes for managing capital during the year.

F. Commitments

1. Operating contracts or services

The Group enters into contracts in the normal course of business with CROs and clinical sites for the conduct of clinical trials, professional consultants for expert advice and other vendors for clinical supply manufacturing or other services. These contracts can usually be terminated with 30 to 180 days' notice. In addition to this minimum duration, these contracts require full payment for services already rendered.

During 2024, the Group did not have any commitments to purchase property, plant and equipment or patents and trademarks (respectively nil in 2023).

2. Lease obligations

The maturity analysis of lease liabilities is disclosed in the following table:

Maturity analysis for capitalized leases in 2024	Contractual minimum lease obligations	Effect of discounting	Lease liabilities
		(in €)	
Within one year	416,347	10,327	406,020
After one year but not more than five years	405,722	6,656	399,066
More than five years	—	—	—
Total	**822,069**	**16,983**	**805,086**

Maturity analysis for capitalized leases in 2023	Contractual minimum lease obligations	Effect of discounting	Lease liabilities
		(in €)	
Within one year	391,158	16,829	374,329
After one year but not more than five years	760,275	14,559	745,716
More than five years	—	—	—
Total	**1,151,434**	**31,389**	**1,120,045**

Maturity analysis for all lease obligations in 2024	Total	Low value leases	Short-term leases	Capitalized leases
Within one year	424,328	6,592	1,389	416,347
After one year but not more than five years	413,811	8,089	—	405,722
More than five years	—	—	—	—
Total	**838,139**	**14,681**	**1,389**	**822,069**

Maturity analysis for all lease obligations in 2023	Total	Low value leases	Short-term leases	Capitalized leases
		(in €)		
Within one year	397,942	4,816	1,968	391,158
After one year but not more than five years	760,421	146	—	760,275
More than five years	—	—	—	—
Total	**1,158,363**	**4,962**	**1,968**	**1,151,434**

Anticipated future lease expenses were converted with the exchange rate as of December 31, 2024, 1 Euro 1.0389 U.S. dollar.

The Group applies the 'lease of low-value assets' recognition exemptions. The Group also applied the 'short-term lease' exemption for leases with a maturity of less than 12 months.

G. Other information

1. Segment reporting

The Group predominantly operates as a R&D focused biopharmaceutical company developing novel therapeutic products targeting diseases of high unmet medical need. Since the EUA of the Company's lead product vilobelimab for the treatment of severe COVID-19 patients in April 2023, it also has commercial activities around the marketing and sales of GOHIBIC (vilobelimab) in the U.S. However, the Group is not steered by segments. The Board of Directors is the chief operating decision maker. Management of resources and reporting to the decision maker is based on the Group as a whole.

All operational activities are conducted in Germany and the United States. Revenues in the amount of $0.2 million (€0.2 million) were generated in 2024 ($0.1 million in 2023 and Nil in 2022). All revenues were generated in the United States. The geographic location of the Group's non-current assets are as follows:

- December 31, 2024: €4.3 million in Germany and €0.1 million in the United States; and
- December 31, 2023: €10.6 million in Germany and €0.1 million in the United States.

None of the non-current assets are in the country where the Company is incorporated (the Netherlands).

2. Related party transactions

Compensation of the Group's executive management for the 12 months ending December 31:

Executive and Board compensation	2024	2023	2022
		(in €)	
Executive management			
Short-term employee benefits	3,193,141	2,783,675	2,774,485
Share-based payments	2,570,489	2,507,453	4,808,094
Sub-total	**5,763,630**	**5,291,128**	**7,582,579**
Non-executive Board of Directors members			
Short-term employee benefits	321,500	305,983	248,725
Share-based payments	280,379	285,177	529,859
Sub-total	**601,879**	**591,160**	**778,584**
Total compensation	**6,365,509**	**5,882,288**	**8,361,163**

Executive management comprises executive Directors of the Board of Directors and members of the senior management of the Company.

The table above discloses short-term employee benefits that were contractually agreed for the Board of Directors and executive management. As of December 31, 2024, €0.8 million were not paid but accrued (2023: €0.8 million) for executive management and €0.1 million (2023: €0.1 million) for non-executive members of the Board of Directors.

Remuneration of the Group's executive management comprises fixed and variable components and share-based payment awards. In addition, executive management receive supplementary benefits and allowances.

The Company entered into indemnification agreements with its directors and senior management. The indemnification agreements and the Company's Articles of Association require the Company to indemnify its directors to the fullest extent permitted by law.

The Company's current and future directors (and such other officer or employee as designated by the Board of Directors) have the benefit of indemnification provisions in the Articles of Association of InflaRx N.V. These provisions give the indemnified persons the right to recover from the Company amounts, including, but not limited to, litigation expenses, and any damages they are ordered to pay, in relation to acts or omissions in the performance of their duties. However, there is no entitlement to indemnification for acts or omissions which are considered to constitute malice, gross negligence, intentional recklessness and/or serious culpability attributable to such indemnified person. These agreements also provide, subject to certain exceptions, for indemnification for related expenses including, among others, attorneys' fees, judgements, penalties, fines and settlement amounts incurred by any of these individuals in any action or proceeding. In addition to such indemnification, the Company provides its directors with directors' and officers' liability insurance.

H. Significant events after the reporting date

On January 15, 2025, InflaRx received European Comission approval for GOHIBIC (vilobelimab) for the treatment of SARS-CoV-2-Induced ARDS. The "marketing authorization under exceptional circumstances" for GOHIBIC is valid in all 27 EU member states as well as Iceland, Liechtenstein, and Norway.

In January and February 2025, the Company issued 145,420 ordinary shares under its ATM program, resulting in $353k in net proceeds. The remaining value available under the ATM program is $73.48m.

In February 2025, the company completed an underwritten public offering of an aggregate of 8,250,000 ordinary shares and pre-funded warrants to purchase 6,750,000 Ordinary Shares. The ordinary shares were sold at a price of $2.00 per share with a nominal value of €0.12 per share. The public offering price for each pre-funded warrant was equal to the price per share at which the ordinary shares were sold to the public, minus $0.001, which is the exercise price of each pre-funded warrant. The gross proceeds from the offering were approximately $30 million before underwriting discounts and offering expenses.

APPENDIX B - InflaRx N.V. Company financial statements

Appendix B - InflaRx N.V. Company Financial Statements

Balance sheet as of 31 December 2024

(before appropriation of result)

	note	2024		2023	
EUR					
Non-current assets					
Intangible Fixed Assets		36,903		21,987	
Tangible Fixed Assets		15,584		18,677	
Financial fixed assets	6	13,129,286		14,140,764	
Other assets	7	204,233		257,267	
Total non-current assets			**13,386,006**		**14,438,695**
Current assets					
Other receivables and prepaid expenses	7	12,026,143		14,379,691	
Securities	8	25,346,272		67,629,750	
Cash and cash equivalents	9	12,527,947		8,103,546	
Total current assets			49,900,362		**90,112,987**
Total assets			**63,286,368**		**104,551,682**
Shareholders' equity	10				
Issued capital		7,122,205		7,065,993	
Share premium reserve		295,887,245		295,168,898	
Other legal reserve		7,440,510		7,382,166	
Other reserves		(202,969,520)		(164,367,798)	
Net Result for the period		(46,064,402)		(42,667,529)	
			61,416,039		**102,581,730**
Current liabilities	11		1,870,330		1,969,952
Total equity and liabilities			**63,286,368**		**104,551,682**

Company only profit and loss account for the year ended 31 December 2024

	Note	2024	2023
EUR			
Share of result of participating interests after tax	5	(40,092,830)	(33,528,887)
Other result, after tax	13	(5,971,572)	(9,138,642)
Net loss		**(46,064,402)**	**(42,667,529)**

Notes to the 2024 Company only financial statements

General

These Company only financial statements and the consolidated financial statements together constitute the statutory financial statements of InflaRx N.V. (hereafter: 'the Company'). The financial information of the Company is included in the Company's consolidated financial statements.

Financial reporting period

The Company financial statements cover the year 2024, which ended at the balance sheet date of December 31, 2024. These are the eighth year's financial statements of the Company and the comparative period relates to the year 2023, which ended at the balance sheet date of December 31, 2023.

Basis of preparation

These Company only financial statements have been prepared in accordance with Title 9, Book 2 of The Netherlands Civil Code. For setting the principles for the recognition and measurement of assets and liabilities and determination of results for its separate financial statements, the Company makes use of the option provided in section 2:362(8) of The Netherlands Civil Code. This means that the principles for the recognition and measurement of assets and liabilities and determination of the result (hereinafter referred to as principles for recognition and measurement) of the separate financial statements of the Company are the same as those applied for the consolidated EU-IFRS financial statements. These principles also include the classification and presentation of financial instruments, being equity instruments or financial liabilities. In case no other principles are mentioned, refer to the accounting principles as described in the consolidated financial statements. For an appropriate interpretation of these statutory financial statements, the separate financial statements should be read in conjunction with the consolidated financial statements.

The Company applies the exemption under article 2:402 of the Dutch Civil Code to present a condensed version of the Company only profit and loss account.

Information on the use of financial instruments and on related risks for the group is provided in the notes to the consolidated financial statements of the group.

Effective January 1, 2023, the functional currency of InflaRx N.V. changed from U.S. dollars to Euro due to a change in its operational function and, in turn, a change in the primary currency of its underlying transactions. A change in functional currency is accounted for prospectively.

All amounts in the company financial statements are presented in Euro (€), unless stated otherwise. Financial information presented has been rounded to the nearest Euro. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that precede them or may deviate from other tables by one Euro at a maximum.

Participating interests in group companies

Group companies are all entities in which the Company has directly or indirectly control. The Company controls an entity when it is exposed, or has rights, to variable returns from its involvement with the group companies and has the ability to affect those returns through its power over the group companies. Group companies are recognized from the date on which control is obtained by the Company and derecognized from the date that control by the Company over the group company ceases. Participating interests in group companies are accounted for in the separate financial statements according to the equity method, with the principles for the recognition and measurement of assets and liabilities and determination of results as set out in the notes to the consolidated financial statements.

Participating interests with a negative net asset value are valued at nil. This measurement also covers any receivables provided to the participating interests that are, in substance, an extension of the net investment. In particular, this relates to loans for which settlement is neither planned nor likely to occur in the foreseeable future. A share in the profits of the participating interest in subsequent years will only be recognized if and to the extent that the cumulative unrecognized share of loss has been absorbed. If the Company fully or partially guarantees the debts of the relevant participating interest, or if has the constructive obligation to enable the participating interest to pay its debts (for its share therein), then a provision is recognized accordingly to the amount of the estimated payments by the Company on behalf of the participating interest.

Share of result of participating interests

The share in the result of participating interests consists of the share of the Company in the result of participating interests. Results on transactions involving the transfer of assets and liabilities between the Company and its participating interests are eliminated to the extent that they can be considered as not realized.

The Company makes use of the option to eliminate intragroup expected credit losses against the book value of loans and receivables from the Company to participating interest, instead of elimination against the equity value of the participating interests.

Financial fixed assets

Financial assets include long term securities of €2,854,405 (€4,459,412 at 31 December 2023) (note 8), as well as the 100% investments of the Company in its fully owned subsidiary InflaRx GmbH, with statutory seat in Jena, Germany, and its fully owned subsidiary InflaRx Pharmaceuticals Inc., a Delaware corporation, US. The latter was established on January 5, 2018 by the Company. Capital contributions in the total amount of €13.8 million ($15.0 million) were conducted in the year 2024) The 2024 capital contribution was done in four tranches,$5.0 million (on 1st of February 2024), $3.0 million (on 1st of June 2024), $1.0 million (on 20th of June 2024 and $6.0 million (on 17th of July 2024).

A summary of the movement in the value of the investments is given below:

	InflaRx GmbH	InflaRx Pharmaceuticals Inc.	Total Investments
EUR			
Net asset value at December 31, 2023	9,681,352	—	9,681,352
Contribution InflaRx GmbH (settlement 2023 result)	26,870,811		26,870,811
Contribution InflaRx Pharmaceutical Inc.		13,810,368	13,810,368
Exchange difference on translating foreign operations		58,344	58,344
Share in result subsidiaries	(31,856,086)	(8,236,744)	(40,092,830)
Reversal of 2023 written off receivables		(53,164)	(53,164)
Net asset value at December 31, 2024	**4,696,077**	**5,578,804**	**10,274,881**

On March 2, 2018 InflaRx N.V. as controlling company and InflaRx GmbH as controlled company entered into a domination and loss transfer agreement for an indefinite period of time. The final settlement between the Company and its subsidiary takes place right after determination of the annual result of the subsidiary.

For the fiscal year 2023 InflaRx Pharmaceuticals Inc. generated a negative result of €4.2million, this resulted in a negative equity of €0.1 million on December 31, 2023. Due to this negative equity InflaRx N.V. wrote off the intercompany receivable position with InflaRx Pharmaceutical Inc. for this amount, resulting in an investment book value of €0 on December 31, 2023

During the fiscal year 2024 several capital increasements in the total sum of €13.8 million ($15.0 million) were implemented at InflaRx Pharmaceutical Inc. As a result of this capital increasements, the investment in InflaRx Pharmaceutical Inc. has recovered in value and the write-down of the investment value from 2023 has been reversed. For the fiscal year 2024 InflaRx Pharmaceuticals Inc. generated a negative result of €8.2 million,

Other receivables and prepaid expenses

	December 31, 2024	December 31, 2023
EUR		
Receivables group parties	10,511,716	11,594,223
Prepaid expense (current & non-current)	258,100	410,441
Corporate income tax	1,075,630	1,063,239
Accrued interest on securities	269,420	651,691
VAT receivables	115,510	917,363
Total other receivables on prepaid expenses at December 31, 2024	**12,230,376**	**14,636,957**

Receivables from Group companies mainly result from the short-term disposal of cash and cash equivalents to InflaRx GmbH. These receivables are generally transferred back to the company in the near future.

Prepaid expenses in the amount of €204,324 relate to IPO insurance and will be reversed in equal installments until 2030. All other receivables and prepaid expenses are due within one year.

Securities

The securities relate to listed debt securities (with credit ratings ranging from BBB+ to AA+ (Standard & Poors ratings; or equivalent ratings by Moody's and Fitch) measured at amortized cost using the effective interest rate method. The market value of these securities amounts to €28,211,198 at 31 December 2024 (€71,955,307 at 31 December 2023). Amortized costs of securities disclosed at December 31, 2024 were €28,200,677 (€72,089,162 at 31 December 2023). None of the securities have been pledged.

The maturities of all securities are between one and thirteen months and their nominal interests ranges between 1.125% and 6.250%.

Long term securities amount on December 31, 2024 to €2,851,590 fair value and €2,854,405 amortized costs and are presented as Financial fixed assets (note 6). In 2023 long term securities amount to €4,459,593 fair value and €4,444,845 amortized costs.

Cash and cash equivalents

Cash and cash equivalents are at free disposal of the Company. Deposits included under cash and cash equivalents only represent deposits that are available on demand.

Shareholders' equity

a. Movement in shareholder's equity

The structure of the equity components for the Company only financial statements is predominately based on legal aspects, accordingly the presentation of the movement in the shareholders' equity is different from the presentation in the consolidated financial statements. The movement in shareholder's equity is as follows:

EUR	Issued capital	Share premium	Other legal reserves	Other reserves	Unappro-priated result	Total equity
January 1, 2023	**5,364,452**	**243,510,194**	**7,257,081**	**(138,297,676)**	**(29,484,611)**	**88,349,440**
Appropriation of the result	—	—	—	(29,484,611)	29,484,611	—
Issue of ordinary shares	1,687,110	54,796,818	—	—	—	56,483,928
Transaction costs	—	(3,360,626)	—	—	—	(3,360,626)
Equity-settled share-based payment	—	—	—	3,414,489	—	3,414,489
Share options exercised	14,431	222,512	—	—	—	236,943
Net Loss for the period	—	—	—	—	(42,667,529)	(42,667,529)
Exchange differences on translation in presentation currency	—	—	125,085	—	—	125,085
December 31, 2023	**7,065,993**	**295,168,898**	**7,382,166**	**(164,367,798)**	**(42,667,529)**	**102,581,730**
Appropriation of the result	—	—	—	(42,667,529)	42,667,529	—
Issue of ordinary shares	56,212	1,042,076	—	—	—	1,098,288
Transaction costs	—	(323,729)	—	—	—	(323,729)
Equity-settled share-based payment	—	—	—	4,065,807	—	4,065,807
Net Loss for the period	—	—	—	—	(46,064,402)	(46,064,402)
Exchange differences on translation in presentation currency	—	—	58,344	—	—	58,344
December 31, 2024	**7,122,205**	**295,887,245**	**7,440,510**	**(202,969,520)**	**(46,064,402)**	**61,416,038**

b. Ordinary and preferred shares

According to the articles of association of the Company, up to 147,200,000 ordinary shares and up to 147,200,000 preferred shares with a nominal value of €0.12 (€12 cent) per share are authorized to be issued. All shares are registered shares. No share certificates shall be issued.

As of December 31, 2024, the issued capital of the Company is divided into 59,351,710 ordinary shares (2023: 58,883,272). The nominal value per share is €0.12. All shares issued are fully paid and have the same rights on the distribution of dividends and the repayment of capital. The Company`s general meeting of shareholders approved the right of an independent foundation under Dutch law, or protective foundation, to acquire through preferred shares up to 100% of the Company`s issued share capital held by others than the protective foundation, minus one share, pursuant to a call option agreement entered into between the Company and such foundation, in order to deter acquisition bids. The protective foundation is expected to enter into a finance arrangement with a bank or, subject to applicable restrictions under Dutch law, the protective foundation may request the Company to provide, or cause the Company`s subsidiaries to provide, sufficient funding to the protective foundation to enable it to satisfy its payment obligation under the call option agreement.

These preferred shares will have both a liquidation and dividend preference over the Company`s ordinary shares and will accrue cash dividends at a pre-determined rate. The protective foundation would be expected to require us to cancel its preferred shares once the perceived threat to the Company and its stakeholders has been removed or sufficiently mitigated or neutralized. At year-end the call option does not represent a significant fair value due to the fact that the preference shares are restricted in use and can be cancelled by us as stated above.

The preferred shares in the Company's capital carry a limited entitlement to the Company's profit and reserves. As at 31 December 2024, 147,200,000 preferred shares in the Company's capital are recorded in the Company's articles of association, and no preferred shares are issued.

c. Issued capital and share premium

As of December 31, 2024, the issued capital of the Company is divided into 59,351,710 ordinary shares (2023: 58,883,272). The nominal value per share is €0.12. All shares issued are fully paid and have the same rights on the distribution of dividends and the repayment of capital.

On June 30, 2023, we filed a Form F-3 registration statement with the SEC with respect to the offer and sale of securities of the Company of up to $250.0 million of securities of the Company, or 2023-Shelf Registration Statement. We also filed a prospectus supplement with the SEC relating to an at-the-market program providing for the sales of our stock over time of up to $75.0 million of our ordinary shares pursuant to a Sales Agreement dated June 28, 2024, with Leerink Partners LLC. During the fiscal year 2024, we issued 468,438 ordinary shares under its at-the-market program resulting in €1.1 million (or $1.2 million) in gross proceeds with a remaining value authorized for sale under the Sales Agreement of $73.8 million. Net proceeds, including transaction cost were €0.8 million.

During the financial year 2024, the Company issued no ordinary shares regarding the exercise of employee stock option rights granted under the 2017 Long-Term Incentive Plan.

d. Other legal reserve

Besides the minimum amount of share capital to be held under Dutch law and the translation reserve (2024: €7,440,510 2023: €7,382,167), there are no distribution restrictions applicable to equity of the Company.

e. Other Reserves

The Company has adopted share-based compensation plans, pursuant to which the Company's directors, selected employees and consultants are granted the right to acquire ordinary shares of the Company (note 3.7 of the consolidated financial statements). The share-based payment expenses are recorded in the profit and loss account. The plans are equity-settled. In case of an equity-settled plan, there is no obligation to transfer economic benefits, therefore the credit entry should be recognized as an increase in equity. The Company uses "Other reserves" as the equity classification.

f. Equity-settled share-based payment arrangements

During its historical financing rounds prior to 2016 as well as in 2016 InflaRx GmbH established equity-settled share-based payment programs. Those InflaRx GmbH options were converted into options for ordinary shares of the Company in November 2017. Furthermore, the Company established an incentive plan (the "2017 Long-Term Incentive Plan") in conjunction with the closing of its initial public offering. From the before mentioned plans 9,942,511 share options were outstanding as of December 31, 2024 (2023: 7,622,011). Further details to options are disclosed in the table below and in Appendix A of this report under 'share-based payments'.

EUR	January 1, 2024	Granted in 2024	Exercised in 2024	Forfeited in 2024	December 31, 2024
Share options outstanding 2024					
Plans prior to 2016	148,433				148,433
thereof exercisable	*148,433*				*148,433*
2016 Plan	888,632				888,632
thereof exercisable	*888,632*				*888,632*
2017 Long-Term Incentive Plan	6,584,946	2,332,500	—	(12,000)	8,905,446
thereof exercisable	***5,577,384***				***8,129,196***
	7,622,011	**2,332,500**	**—**	**(12,000)**	**9,942,511**

EUR	January 1, 2023	Granted in 2023	Exercised in 2023	Forfeited in 2023	December 31, 2023
Share options outstanding 2023					
Plans prior to 2016	148,433				148,433
thereof exercisable	*148,433*				*148,433*
2016 Plan	888,632				888,632
thereof exercisable	*888,632*				*888,632*
2017 Long-Term Incentive Plan	4,985,523	1,735,750	(105,327)	(31,000)	6,584,946
thereof exercisable	***4,157,148***				***5,577,384***
	6,022,588	1,735,750	(105,327)	(31,000)	**7,622,011**

g. Unappropriated result

Appropriation of result of 2023:

The financial statements for the reporting year 2023 have been adopted by the General Meeting on April 25, 2024. The General Meeting has adopted the appropriation of the result after tax as proposed by the Board of Directors.

h. Proposal for result appropriation:

The General Meeting will be proposed to carry forward the loss after tax for 2024 and deduct €46,064,402 from the other reserves.

The result after tax for 2024 is included in the item unappropriated result within equity.

Current liabilities

	December 31, 2024	December 31, 2023
EUR		
Accounts payable	107,578	231,471
Salaries	650,450	663,467
Liabilities to affiliated companies	232,179	—
Other liabilities	880,123	1,075,014
Total	**1,870,330**	**1,969,952**

Liabilities to affiliated companies resulted mainly from the charging of personnel expenses between the Company and its subsidiary InflaRx Pharmaceuticals Inc.

Other liabilities include €763,608, accrued liabilities, for services rendered but not yet invoiced (2023: €963,240), €84,637 German income taxes on salaries and board compensation withheld by the Company (2022: €79,897) and accruals for statutory archive requirements (2024: €31,877, 2023: €31,877).

All current liabilities are due within one year.

Financial instruments

The Company's principal financial assets comprise securities and short-term deposits at commercial banks with a maturity on inception of 18 months or less. The main purpose of these financial instruments is to provide funds for the subsidiaries development activities. The Company's other financial instruments relate to other receivables and liabilities.

The risks associated with the Company financial instruments are like the ones disclosed in notes to the consolidated financial statements.

Other result, after tax

Other result, after tax includes general and administrative expenses as well as income and expenses related to transactions with subsidiaries InflaRx GmbH or InflaRx Pharmaceuticals Inc, as detailed below:

	December 31, 2024	December 31, 2023
EUR		
Result from intercompany charges	1,176,164	1,872,459
FX-result on intercompany accounts	283,513	67,006
Total (Income)	**1,459,677**	**1,939,465**

The result from intercompany charges comprises income from the charging of services by the company to its subsidiaries and expenses from the charging of services by the subsidiaries to the company. In 2024, the company generated income of €1,624,419 (2023: €1,922,502) from the charge of corporate services for finance, HR, legal and IT to its subsidiaries InflaRx GmbH and InflaRx Pharmaceuticals Inc. Expenses in the amount of €448,255 (2023: €50,043) were generated from services charged to the company by InflaRx Pharmaceuticals Inc. These costs relate to employees of InflaRx Pharmaceutical Inc. who mainly worked for the company, such as business development services for the Group.

FX-result on intercompany accounts increased by €216,507 to €283,513 for the twelve months ended December 31, 2024, from €67,006 for the twelve months ended December 31, 2023. This decrease is mainly attributable to the strengthening of the EUR to USD during the first 6 month of 2024.

Remuneration of the Board of Directors

The emolument as referred to in Section 2:383(1) of The Netherlands Civil Code, charged in the financial period to the company can be detailed as follows.

a. 2024 Board of Directors' remuneration

In 2024 stock options were granted to the Board of Directors under the 2017 Equity Incentive Plan.

EUR	Periodically paid compensation	Retirement benefit expenses	Variable compensation*	Share based expense**	Total
Executive directors					
Prof. Niels C. Riedemann, CEO	605,588	24,000	314,600	1,011,389	1,955,577
Prof. Renfeng Guo, CSO	488,849	15,944	244,425	805,649	1,554,867
Non-executive directors					
Nicolas Fulpius, Chairman, and Member of the Audit Committee	112,500	-	-	60,347	172,847
Anthony Gibney, Chairman of the Audit Committee	52,500	-	-	45,830	98,330
Richard Brudnick, Member of the Audit Committee	53,500	-	-	45,830	99,330
Mark Kübler, Member of the Audit Committee	59,500	-	-	45,830	105,330
Hege Hellstrom	43,500	-	-	74,125	117,625
Total	**1,415,937**	**39,944**	**559,025**	**2,089,001**	**4,103,905**

* variable compensation is not based on pre-determined and measurable performance targets
** total share base expense in 2024 for 2017 Long Term Incentive Plan

	Share options outstanding as of January 1, 2024	Share options granted in 2024	Share options exercised in 2024	Share options outstanding as of December 31, 2024	weighted average exercise price in €	weighted average remaining contractual life
Share options not exercised 2024						
Executive directors						
Prof. Niels C. Riedemann, CEO	2,837,714	635,000		3,472,714	1.73	5.97
Prof. Renfeng Guo, CSO	2,244,697	500,000		2,744,697	1.79	6.05
Non-executive directors						
Nicolas Fulpius, Chairman, and Member of the Audit Committee	164,065	45,000		209,065	1.81	6.51
Anthony Gibney, Chairman of the Audit Committee	88,085	30,000		188,085	1.82	7.14
Richard Brudnick, Member of the Audit Committee	104,850	30,000		134,850	1.81	6.85
Mark Kübler, Member of the Audit Committee	128,172	30,000		158,172	1.72	5.81
Hege Hellstrom	22,500	30,000		52,500	2.60	8.76
	5,590,083	**1.300,000**		**6,590,083**		

b. 2023 Board of Directors' remuneration

In 2023 stock options were granted to the Board of Directors under the 2017 Equity Incentive Plan.

EUR	Periodically paid compensation	Retirement benefit expenses	Variable compensation *	Share based expense**	Total
Executive directors					
Prof. Niels C. Riedemann, CEO	605,588	24,000	314,000	990,068	1,933,656
Prof. Renfeng Guo, CSO	445,282	15,413	286,024	801,794	1,548,513
Non-executive directors					
Nicolas Fulpius, Chairman, and Member of the Audit Committee	113,750	-	-	81,301	195,051
Anthony Gibney, Chairman of the Audit Committee	51,250	-	-	54,201	105,451
Richard Brudnick, Member of the Audit Committee	52,000	-	-	54,201	106,201
Mark Kübler, Member of the Audit Committee	59,500	-	-	54,201	113,701
Hege Hellstrom	29,483	-	-	41,273	70,756
Total	**1,356,853**	**39,413**	**600,024**	**2,077,039**	**4,073,329**

* *variable compensation is not based on pre-determined and measurable performance targets*

** *total share base expenses in 2023 for 2017 Long Term Incentive Plan*

	Share options outstanding as of January 1, 2023	Share options granted in 2023	Share options exercised in 2023	Share options outstanding as of December 31, 2023	weighted average exercise price in €	weighted average remaining contractual life
Share options not exercised 2023						
Executive directors						
Prof. Niels C. Riedemann, CEO	2,289,714	548,000		2,837,714	1.75	6.24
Prof. Renfeng Guo, CSO	1,814,197	430,500		2,244,697	1.82	6.39
Non-executive directors						
Nicolas Fulpius, Chairman, and Member of the Audit Committee	119,065	45,000		164,065	1.85	6.82
Anthony Gibney, Chairman of the Audit Committee	58,085	30,000		88,085	1.88	7.50
Richard Brudnick, Member of the Audit Committee	74,850	30,000		104,850	1.85	7.24
Mark Kübler, Member of the Audit Committee	98,172	30,000		128,172	1.73	6.0
Hege Hellstrom (from April 2023)	-	22,500		22,500	3.87	9.4
	4,454,083	**1,136,000**		**5,590,083**		

For further details and other information regarding related-party transactions as well as the Executive and Non-executive directors' compensation, reference is made to note G.2 of the consolidated financial statements.

c. Employees

In addition to the board of directors the Company employed 20 employees as of December 31, 2024, (in 2023 20 employees). We do not employ any employees in the Netherlands.

Audit fees

With reference to Section 2:382a(1) and (2) of The Netherlands Civil Code, the following fees for the financial year have been charged to the Company, its subsidiaries and other consolidated entities.

EUR	EY Accountants B.V. 2024	Other EY network 2024	Total EY 2024
Audit of the financial statements	127,000	1,022,383	1,149,383
Other audit engagements	—	78,618	78,618
Tax-related advisory services	—	—	—
Other non-audit services	—	—	—
	127,000	**1,101,001**	**1,228,001**

EUR	Ernst & Young Accountants LLP 2023	Other EY network 2023	Total EY 2023
Audit of the financial statements	190,455	890,210	1,080,665
Other audit engagements	—	119,743	119,743
Tax-related advisory services	—	—	—
Other non-audit services	—	—	—
	190,455	**1,009,953**	**1,200,408**

Income taxes

Since January 1, 2018 InflaRx GmbH has distributed its losses to the Company under a profit and loss transfer agreement (tax group). Future losses of InflaRx GmbH will be transferred to the Company, reference is made to note 4.6 of the consolidated financial statements.

The Company has not recorded income tax gain or deferred tax assets in view of the negative operating results. The accumulated tax losses for the year amount to €238,376,748 (2023: €196,154,795).

Subsequent events

We refer to Appendix A, InflaRx N.V. Consolidated Financial Statements, H. Significant events after the reporting date.

(signature page follows)

Signature page to the Dutch statutory board report of InflaRx N.V. for the fiscal year ended December 31, 2024.

With reference to section 5:25c paragraph 2 under c of the Dutch Financial Markets Supervision Act, the executive members of the Board of Directors confirm to the best of their knowledge that:

The annual financial statements for the year ended December 31, 2024, give a true and fair view of the assets, liabilities, financial position and profit or loss of InflaRx N.V. and its consolidated companies.
The Dutch statutory board report of InflaRx N.V. gives a true and fair view of the situation on the balance sheet date and of developments during the financial year of InflaRx N.V. and its consolidated companies, together with a description of the main risks facing InflaRx N.V.

The members of Board of Directors have signed the financial statements pursuant to their statutory obligation under article 2:101(2) of the DCC.

By signing this signature page, the Dutch statutory board report of InflaRx N.V. for the fiscal year ended December 31, 2024, the InflaRx N.V. 2024consolidated financial statements and the InflaRx N.V. 2024 company financial statements (appendices A and B, respectively) are approved.

_____	_____
N.C. Riedemann	R. Guo
_____	_____
N.F. Fulpius	M. Kubler
_____	_____
R. Brudnick	A. Gibney
_____	
H. Hellstrom	

ITEM 5: OTHER INFORMATION

Profit appropriation provisions

Pursuant to our Articles of Association, any profits shown in the adopted statutory annual accounts of the Company shall be appropriated as follows, and in the following order of priority:

- to the extent that any preferred shares have been cancelled without full repayment as described in the articles of association and without such deficit subsequently having been paid in full, an amount equal to any such (remaining) deficit shall first be distributed to those who held those preferred shares at the moment of such cancellation becoming effective;

- if preferred shares are issued and outstanding and to the extent that the mandatory annual distribution on the preferred shares (i.e., an amount equal to the applicable interest rate calculated over the aggregate amount paid up on those preferred shares, calculated in accordance with the relevant provisions of the articles of association), or part thereof, in relation to previous financial years has not yet been paid in full, an amount equal to any such (remaining) deficit shall be distributed on the preferred shares;

if preferred shares are issued and outstanding, the mandatory annual distribution (as described above under b.) payable on preferred shares shall then be distributed on the preferred shares;

following those distributions, our board of directors shall determine which part of the remaining profits shall be added to the Company's reserves; and

subject to a proposal by our board of directors to that effect, the remaining profits shall be at the disposal of our general meeting of shareholders for distribution on our ordinary shares.

Shares carrying limited economic entitlement

The preferred shares in the Company's capital carry a limited entitlement to the Company's profit and reserves. As at 31 December 2024, no preferred shares in the Company's capital were issued.

Branches

InflaRx N.V. has a branch in Jena registered in the commercial register of Jena, Germany.