InflaRx N.V.

Dutch statutory board report and financial statements

for the financial year ended December 31, 2020

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*Constitutes the statutory board (*bestuursverslag*) report as referred to in Section 2:391 DCC

1 INTRODUCTION

1.1 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, 2020 and, unless explicitly stated otherwise, information presented in this report is as at December 31, 2020.

The statutory board ("bestuursverslag") report as referred to in Section 2:391 DCC is formed by chapters 2, 3, 4, 7, 8, 9, 10 and OTHER INFORMATION.

The consolidated financial statements enclosed with this report (the "**Consolidated Financial Statements**") have been prepared in accordance with International Financial Reporting Standards as 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, 2020 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.

1.2 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 have 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:

- the timing, progress and results of clinical trials of vilobelimab (previously denominated as "IFX-1") and any other product candidates, including 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;

- the timing and outcome of any discussions or submission of filings for regulatory approval of vilobelimab or any other product candidate, and the timing of and our ability to obtain and maintain regulatory approval of vilobelimab for any indication;

- our ability to leverage our proprietary anti-C5a technology 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 and any other product candidates, and the scope of such protection;
- whether the Food and Drug Administration (FDA), European Medicines Agency (EMA) or 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 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, market opportunity for and clinical utility of vilobelimab or any other product candidates, if approved 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 potentially for commercial supply of vilobelimab;
- 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 costly and damaging liability claims resulting from the testing of our product candidates in the clinic or, if, approved, any commercial sales;
- our ability to commercialize vilobelimab or our other product candidates;
- if any of our product candidates obtain regulatory approval, our ability to comply with and satisfy ongoing obligations and continued regulatory overview;
- our ability to comply with enacted and future legislation in seeking marketing approval 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 inhibitors or our industry; and
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act or a foreign private issuer.

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 chapter 2 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 SEC after the date of this Annual Report.

2 RISK FACTORS

2.1 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 and commercialization of our product candidates.
- Dependence on third parties
- Our intellectual property
- Employee matters and managing growth
- COVID-19
- 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.

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

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

We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate 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, 2020 and December 31, 2019, we used €37.4 million and €43.2 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 and seek marketing 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, 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 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 IFX-2. 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 and marketing success of vilobelimab in any indication.

Our existing cash and cash equivalents will not be sufficient to fund all of 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. 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 24 months. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently 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 commercialization and commercialization activities for any of our product candidates that receive marketing 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 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 and development 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 no 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 technology, identifying and testing potential product candidates and conducting clinical trials of our lead product candidate, vilobelimab. We have not yet demonstrated an ability to successfully complete late-stage clinical trials, obtain marketing approvals, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. 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 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.

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 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. Currently, we do not have any exchange rate hedging arrangements in place.

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

We are at a very early stage in our development efforts, our approach of targeting C5a 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 inhibition to treat complement-mediated autoimmune and inflammatory diseases has not been validated. In the completed Phase IIb trial in HS in 2019, vilobelimab did not meet the primary endpoint as it did not demonstrate a statistically significant dose-dependent effect on Hidradenitis Suppurativa Clinical Response (HiSCR) rate at week 16. There is no approved therapy inhibiting C5a activation and, as a result, the regulatory pathway for vilobelimab may present novel issues that could cause delays in development or approval. For example, the results of the Phase IIb trial of vilobelimab call into question the validity of the HiSCR and how to measure the therapeutic benefit of vilobelimab in HS. If we cannot obtain alignment with regulatory authorities on the appropriate way for the further development of vilobelimab in HS, we may be unable to successfully develop, obtain regulatory approval for and commercialize vilobelimab for HS. 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 HS or any other indication. 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 are heavily dependent on the success of vilobelimab, our lead product candidate, and if vilobelimab does not receive regulatory approval or is not successfully commercialized, our business will be harmed.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to vilobelimab, which is currently our only product candidate in active clinical development. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of vilobelimab. We cannot be certain that vilobelimab will receive regulatory approval or be successfully commercialized even if we receive regulatory approval for any indication, due in part because vilobelimab remains in early stages of clinical development and a Phase IIb trial of vilobelimab in HS failed to reach its primary endpoint. Thus, it may be years before we are in a position to seek regulatory approval for vilobelimab in any indication. Moreover, we may not be successful in our efforts to expand the approval, if any, of vilobelimab for other indications. If we were required to discontinue development of vilobelimab for any indication or if vilobelimab does not receive regulatory approval or fails to achieve significant market acceptance, we would be delayed by many years in our ability to achieve profitability, if ever. In addition, our ability to develop additional product candidates in our pipeline could be significantly hindered.

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 currently 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 currently 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. For example, our Phase IIb trial for vilobelimab in HS did not meet its primary endpoint. A failure of a clinical trial to meet its predetermined endpoints 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, to the FDA, the marketing authorization application 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.

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 from the FDA. Foreign regulatory authorities, such as the EMA, impose similar requirements. 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. For instance, in the Phase IIb Shine trial completed in 2019, we failed to meet the primary endpoint utilizing the HiSCR clinical endpoint, due in part, to a placebo efficacy rate of approximately 47%. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of or intolerability caused by our product candidate, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case. In addition, our product candidates are all 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;
- 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.

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 for HS suffer from serious pre-existing disorders. While such disorders may lead to serious adverse events 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. For example, in our Phase IIa and IIb clinical trials of vilobelimab for HS, we observed several adverse events, even though they were judged not to be related to vilobelimab administration by the investigator.

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 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 IFX-2, respectively, can cause an immune response, resulting in the creation of antibodies against the therapeutic protein. These anti-drug antibodies 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 anti-drug antibodies 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 anti-drug antibodies 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 anti-drug antibodies were detected in the Phase IIB Shine Study completed in 2019.

Even if we complete the necessary preclinical studies and clinical trials for vilobelimab and any other product candidates, the marketing approval 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 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 from the FDA or marketing approval from applicable regulatory authorities outside the United States. 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. Further, there is no prior history of regulatory approval for product candidates targeting C5a inhibition. In addition, while in the past a product was approved for HS using HiSCR as the primary clinical endpoint, in our Phase IIb trial of vilobelimab in HS, for which HiSCR was the primary endpoint and was not met, we developed concerns about HiSCR as a clinical endpoint. In March 2021 we have submitted a Special Protocol Assessment, or SPA to the FDA outlining the clinical development pathway for vilobelimab in HS, including the use of an alternative endpoint to HiSCR as the primary endpoint in a potential future clinical trial of vilobelimab. However, there is no guarantee that the FDA will accept our request for an SPA. As a result, the regulatory pathway for vilobelimab remains unclear.

The process of obtaining marketing approvals, both in the United States and abroad, 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 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 also requires the submis-

sion 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 we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. 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 to the satisfaction of the FDA, the EMA or comparable foreign regulatory agencies;
- the FDA, EMA or comparable foreign regulatory authorities may require additional 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 of 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 for 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, such as the use of alternative clinical endpoints to HiSCR in our planned clinical trials of vilobelimab for HS;
- 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 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 current Good Clinical Practices, or 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 pharmaceutical 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 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 authority. The FDA or other regulatory authority 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 authority 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 authority, as the case may be, and may ultimately lead to the denial of marketing 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 HS, AAV, PG and cSCC for our planned clinical trials 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 would result in significant delays or may require us to abandon one or more clinical trials.

We have experienced slower recruitment in the clinical trials of vilobelimab for AAV and PG than anticipated because of low disease prevalence, difficulties in diagnosis or due to 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, 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 vilobelimab or any of our other product candidates is approved by the appropriate regulatory authorities for marketing and sale, it 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 (such as for the treatment of HS) even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching therapy or they are required to switch therapies due to lack of reimbursement for existing therapies. Adalimumab is the only drug approved for the treatment of HS, and even if we are able to obtain marketing approval of vilobelimab for the treatment of HS, we may not be able to successfully convince physicians or patients to switch from adalimumab to vilobelimab. 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 for HS. The duration of effect of vilobelimab has only been studied prospectively for durations less than the expected duration of any pivotal Phase III clinical trials that we may undertake in the future. 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 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 sale 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 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 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 approval could significantly harm our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

We currently have no marketing, sales or distribution infrastructure with respect to our product candidates. 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 currently have no marketing, sales or distribution capabilities and have limited sales or marketing experience within our organization. If any of our product candidates is approved, we intend either 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. 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. These risks may be particularly pronounced due to our focus on our initial indications of HS, severe COVID-19 and AAV for vilobelimab, as well as additional focus on PG and cSCC, 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, 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 approved products. If we are not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses.

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 future product candidate we may develop.

The risk of failure for vilobelimab and any other future product candidates we may develop is high. It is impossible to predict when or if vilobelimab will prove to be effective and safe in humans or will receive regulatory approval for the treatment of HS, severe COVID-19, AAV, PG, and cSCC indication or other new indications. Additionally, before regulatory authorities grant marketing approval for vilobelimab, for any future indications, or any future product candidate that we seek to develop, we will be required to conduct 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. With regard to a potential Phase III clinical trial in HS, it is unclear whether FDA will accept our request for an SPA, approve an alternative primary clinical endpoint, change in dosage, and even in the event approval is received, how many trials and patients will be required for approval. 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 approval process that could delay or prevent our ability to receive marketing approval 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; and
- 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.

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 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 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 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 currently 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. 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.

2.2.3 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 contract research organizations, or 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 contract research organization

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.

2.2.4 Risks related to our intellectual property

Our success depends on our ability to protect our intellectual property and proprietary anti-C5a technology.

Our success depends in large part 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 worldwide 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 is 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 foreign 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 United States law does.

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.

Others may claim an ownership interest in our intellectual property and proprietary anti-C5a 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 currently 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 rights, 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.

2.2.5 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, 2020, we had 49 full-time or part-time employees. Our focus on the development 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 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 Professor Niels Riedemann, our Chief Executive Officer, Professor Renfeng Guo, our Chief Scientific Officer, Dr. Korinna Pilz, our Global Head of Clinical Development, Dr. Thomas Taapken, our Chief Financial Officer and Jordan Zwick, our Chief Strategy 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.

Our employees, independent contractors, consultants, collaborators and contract research organizations 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 contract research organizations 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) 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.

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 experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development and regulatory affairs, as well as to support our public company operations. To manage these growth activities, 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 and train additional qualified personnel. 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.

2.2.6 Risks related to COVID-19

COVID-19 has adversely impacted, and could continue to impact, our business, including our supply chain, clinical trials and commercialization of our product candidates.

The global COVID-19 pandemic is impacting almost every corner of the globe. The continued spread of the SARS-CoV-2 virus is adversely impacting clinical and preclinical trials globally and in different therapeutic areas. Our clinical trials or preclinical studies, including our ability to recruit and retain patients, principal investigators and site staff who, as healthcare providers, were impacted in 2020 and may be further significantly impacted. We or our third-party contractors manufacture our product candidates and perform clinical studies in different countries, including in Europe, Asia, the United States and South America. The impact of the COVID-19 pandemic varies among these countries; however, measures implemented by local or governmental authorities to counter the spread of the SARS-CoV-2 virus have affected the ability of clinical and other staff to access research sites, including hospitals, manufacturing plants and laboratories, which could significantly delay or impede our or our contractor's activities in such countries. Such delays or impediments could have a material adverse effect on our business, financial condition, results of operations, and prospects.

The negative impact of the pandemic has had and may continue to have on patient enrollment and treatment, and the timing and execution of our clinical trials, could cause costly delays to our clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to advance towards commercialization, increase operating expenses and have a material adverse effect on our business and financial results.

In response to the COVID-19 pandemic, we have implemented, and continue to implement, mitigation procedures designed to enable us to address the various issues that continue to arise from the COVID-19 pandemic, although there can be no assurance that these procedures will be successful or that we can avoid a material and adverse disruption to our business. As the pandemic continues, we experienced the prioritization of hospital resources toward the outbreak and further restrictions on travel. Furthermore, some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services.

The COVID-19 pandemic may also further negatively affect the operations of third-party contract research organizations that we rely upon to carry out our clinical trials or the operations of our third-party manufacturers, each of which could result in delays or disruptions in the supply of our product candidates. While our supply chain has not been significantly affected, there can be no assurances that we will not experience supply disruptions in the future.

In addition, the spread of COVID-19 has resulted in significant governmental measures being implemented to control the spread of the SARS-CoV-2 virus. Public health officials have recommended and mandated precautions to mitigate the spread of COVID-19, including prohibitions on congregating, traveling across borders, shelter-in-place orders and other similar measures. We have taken precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring some or all of our employees to work remotely, suspending all non-essential travel. Such measures have been implemented to warrant the health and well-being of our employees, but they could negatively affect our business as remote work may prove to be less effective in conducting our business operations.

The COVID-19 pandemic has also caused volatility in the global financial markets and has resulted in an associated recession in the global economy, which in the long term may negatively affect our ability to raise additional capital on attractive terms or at all.

Considering the evolving nature of the SARS-CoV-2 virus, the impact of the COVID-19 pandemic on our business, financial condition and results of operations could materially change in the future. The degree to which the COVID-19 pandemic affects us will depend on future developments that are highly uncertain, including, but not limited to, the duration and severity of the COVID-19 pandemic, the actions taken to reduce/cease the virus' transmission and the extent to which more stable economic

and operating conditions resume. If the COVID-19 pandemic and the associated recession continue for a prolonged period of time, our business, financial condition, results of operations, and clinical trial activities could be further negatively impacted.

2.2.7 General Risk Factors

Cyber-attacks or other failures in telecommunications or information technology 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 attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects. 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. Any cyber-attack 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-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

Dutch cooling-off period in face of shareholder activism or hostile take-over

As of the date of this board report, a bill is pending in Dutch Senate which, if enacted in its current form, would introduce a statutory cooling-off period of up to 250 days during which the general meeting of shareholders would not be able to dismiss, suspend or appoint members of the board (or amend the provisions in the articles of association dealing with those matters) unless those matters would be proposed by the management board. This cooling-off period could be invoked by the management board in case:

- shareholders, using either their shareholder proposal right or their right to request a general meeting of shareholders, propose an agenda item for the general meeting of shareholders to dismiss, suspend or appoint a member of the board (or to amend any provision in the articles of association dealing with those matters); or
- a public offer for the Company is made or announced without the Company's support, provided, in each case, that the management board believes that such proposal or offer materially conflicts with the interests of the Company and its business.

The cooling-off period, if invoked, ends at occurrence of the earliest of the following events:

- the expiration of 250 days from:
  - i) in case of shareholders using their shareholder proposal right, the day after the deadline for making such proposal expired;
  - ii) in case of Shareholders using their right to request a general meeting of shareholders, the day when they obtain court authorization to do so; or
  - iii) in case of a hostile offer being made, the first following day;
- the day after the hostile offer having been declared unconditional; or
- the board voluntarily terminating the cooling-off period.

In addition, shareholders representing at least 3% of the Company's issued share capital may request the Dutch Enterprise Chamber of the Amsterdam Court of Appeals for early termination of the cooling-off period. The Enterprise Chamber must rule in favor of the request if the shareholders can demonstrate that:

- the board, in light of the circumstances at hand when the cooling-off period was invoked, could not reasonably have come to the conclusion that the relevant shareholder proposal or hostile offer constituted a material conflict with the interests of the Company and its business;
- the board cannot reasonably believe that a continuation of the cooling-off period would contribute to careful policy-making;
- if other defensive measures have been activated during the cooling-off period and not terminated or suspended at the relevant shareholders' request within a reasonable period following the request (i.e., no 'stacking' of defensive measures).

During the cooling-off period, if invoked, the board must gather all relevant information necessary for a careful decision-making process. In this context, the board must at least consult with shareholders representing at least 3% of the Company's issued share capital at the time the cooling-off period was invoked. Formal statements expressed by these stakeholders during such consultations must be published on the Company’s website to the extent these stakeholders have approved that publication.

Ultimately one week following the last day of the cooling-off period, the board must publish a report in respect of its policy and conduct of affairs during the cooling-off period on the Company's website. This report must remain available for inspection by shareholders and others with meeting rights under Dutch law at the Company's office and must be tabled for discussion at the next general meeting of shareholders.

2.3 Risk Control Measures

Due to its size and history, the Company does not yet (i) set, report and monitor risk appetite levels for the risks that have been identified and (ii) have a fully deployed and formalized risk detection, evaluation, and management system in place. Management monitors operational risks as they arise and evolve, assesses their development and implements necessary countermeasures in regular internal meetings. The risks are reported and discussed during regular quarterly board meetings.

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

The Company has a budget and forecast process that monitors, plans and approves costs for at least the next 24 months. This planning process is supplemented by cash planning. The results are discussed regularly in management and at least on a quarterly basis with the Board. This enables the Company to prepare capital measures at the expected value inflection points and to adequately finance our future development activities.

Our activities incur costs predominantly in USD and Euros. We finance these activities through USD from our financing activities. About half of our expenses are incurred in USD can be paid by our USD funds without exchange rate risks. Further currency hedging of expenses in Euro is not performed. Management believes that the cost of currency hedging as well as the uncertainty in future cash outflows argue against efficient currency hedging. The remaining risk is closely monitored.

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

We use highly experienced staff for our research and clinical studies, as well as very experienced consultants. The results of our studies are constantly, closely and systematically monitored. This enables us to react early to new findings in manufacturing process, as well as in the conduct of pre-clinical

and clinical studies. The close monitoring of the costs associated with these activities through our regular internal forecasting process further allows us to recognize any deviations from our financial plans early on in the conduct of these activities and initiate appropriate countermeasures in time.

2.3.3 Risks related to our dependence on third parties

Since we are highly dependent on third parties, we take special care in selecting these contractors. Before we select a contractor, the company convinces itself of the quality and experience in a detailed selection process, moreover, several service providers are considered. Major clinical trial and manufacturing service providers are selected through a stringent selection process including all management team members. The operational performance of third parties is subject to constant review and assessment by management.

2.3.4 Risks related to our intellectual property

We use only highly specialized consultants and attorneys to secure and monitor our IP. In addition, Management monitors ongoing patent protection and potential conflicts on a regular basis.

2.3.5 Risks related to employee matters and managing growth

Our management pays very close attention to the fact that the respective department heads announce personnel requirements at an early stage and that adequate resources are available. Personnel planning is discussed by the Board every quarter. In addition, we take care to retain key employees in our company with suitable instruments like share options and other measures.

2.3.6 Risks related to COVID-19

The company has implemented a series of measures to protect employees and third-party service providers from the risks of infection while attending our premises for the performance of their duties. The measures are in line with the generally recommended measures of the governmental and regulatory authorities. Furthermore, we are closely monitoring the progress of our clinical trials and production of vilobelimab to anticipate any negative developments resulting from the pandemic. To date, there have been isolated delays in the conduct of clinical trials. However, these delays have not had a significant impact on the studies.

2.3.7 General Risk Factors

We work with renowned IT service providers to control and monitor our IT-related risks. Large parts of our IT infrastructure are managed by external specialists with appropriate certification levels and many years of experience and a good reputation in the market. In addition, our IT controls are documented and evaluated as part of the process and control documentation implemented in 2020 and will be regularly audited starting 2021.

3 INFORMATION ON THE COMPANY

3.1 History and development of the Company

We are a clinical-stage biopharmaceutical company focused on applying our proprietary anti-C5a technology to discover and develop first-in-class, potent and specific inhibitors of the complement activation factor known as C5a. 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 (previously denominated as “IFX-1”), 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 developing vilobelimab for the treatment of Hidradenitis Suppurativa, or HS, a rare and chronic debilitating systemic inflammatory skin disease, for which we completed a Phase IIb clinical trial in the fourth quarter of 2019. Beyond HS, we intend to develop vilobelimab and other proprietary antibodies to address a wide array of complement-

mediated diseases with significant unmet medical needs, including severe COVID-19, ANCA-associated vasculitis, or AAV, a rare and life-threatening autoimmune disease and Pyoderma Gangrenosum, a chronic inflammatory skin disorder, Cutaneous Squamous Cell Carcinoma (cSCC) and potentially other new indications.

Our legal and commercial name is InflaRx N.V. 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 S Wagner Rd, Ann Arbor, MI 48103. Our principal executive offices and laboratories are located in Winzerlaer Str. 2, 07745 Jena, Germany, telephone: (+49) 3641 508 180, and our additional offices are located in Planegg-Martinsried (Munich), Germany and in Ann Arbor, Michigan, United States where we also have laboratories. We employ 49 employees, 19 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 19 years of complement research experience, having published extensively on C5a and its receptors. Additionally, our Chief Financial Officer, Dr. Thomas Taapken, has served in executive positions for various private and public European biotechnology companies over the last 15 years and 25 years total in the biopharmaceutical and venture capital industries.

In connection with our initial public offering in the fourth quarter of 2017, InflaRx executed a corporate reorganization whereby InflaRx N.V. became the holding company for InflaRx GmbH, which remains the principal operating subsidiary and InflaRx Pharmaceutical Inc. which was subsequently founded in 2018.

The SEC maintains an Internet 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.

3.2 Business overview

Overview

Role of C5a as critical component in the immune system

C5a is a central part of the complement system and 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 cleavage of C5, which leads to the generation of C5a and C5b. 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 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 that specifically target C5a.

Our discovery of a novel epitope, or binding site, on C5a allowed us to overcome this challenge. We have identified antibodies that potently and selectively bind to this conformational epitope 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.

Vilobelimab

Hidradenitis Suppurativa

Vilobelimab is currently being developed for the treatment of HS, a chronic debilitating systemic inflammatory skin disease, where we estimate that moderate to severe HS has a prevalence of up to 200,000 patients, while increasing evidence exists that the prevalence may be higher. HS results in painful inflammation of the skin and hair follicles, especially in the armpit, groin and genitalia regions. In the more chronic form of the disease, patients experience draining fistulas, often requiring the use of bandages and diapers to absorb the constant flow of pus, thus adversely affecting quality of life. We have demonstrated that HS patients have significant complement activation, and in particular that C5a is a key promoter of neutrophil activation, believed to play a potential disease promoting role.

The only approved drug in the United States and in Europe to treat HS is adalimumab, an inhibitor of tumor necrosis factor-alpha, or TNF-alpha. Although adalimumab provides clinical benefit to a portion of moderate to severe HS patients, a high unmet medical need still persists.

On June 5, 2019, we announced the top-line results of the international SHINE Phase IIb study, investigating the safety and efficacy of vilobelimab in patients suffering from moderate to severe Hidradenitis Suppurativa (HS). The randomized, double-blind, placebo-controlled, multicenter study enrolled a total of 179 patients in four active dose arms and a placebo arm at over 40 sites in 9 countries in North America and Europe. The primary endpoint of the trial was a dose response signal, assessed by HiSCR at week 16. The primary endpoint was not met and statistical analysis by multiple-comparison procedure modelling (MCP-mod) showed no significant dose response for vilobelimab treatment on the HiSCR, but it was well tolerated.

On July 18, 2019 we published a post-hoc analysis showing multiple signals of efficacy for the vilobelimab high dose group compared to the placebo group within the initial phase of the SHINE study, including reductions in all combined inflammatory lesions and draining fistula and on the IHS4. The IHS4 scores all inflammatory lesions and has been developed by an international expert group to score severity and track treatment response, although it has not been utilized as a primary endpoint in late-stage clinical trials in HS nor has it served as the basis of regulatory approval of a product for HS. The IHS4 weights the most fluctuating lesions such as inflammatory nodules (1 point), less than abscesses (2 points) or draining fistulas (4 points).

On November 6, 2019, we reported additional encouraging data from the open label extension (OLE) phase of the international SHINE Phase IIb study. The data were from a snapshot analysis at the end of the overall 9-month study treatment period (week 40). A total of 156 patients entered the 6-month OLE period upon completion of the 16-week initial phase of the SHINE study. Overall, patients completing the OLE period showed a sustained improvement in inflammatory lesion count at week 40 compared to baseline counts of the OLE treatment group on day 1 of the SHINE study.

In June 2020, we completed an end-of-Phase II meeting with the FDA and discussed the possible design of a pivotal Phase III program for vilobelimab for the treatment of HS. The FDA agreed to key proposals to support a Biologics License Application (BLA) submission, including certain aspects of the Phase III clinical trial design, vilobelimab dosing, target study population, and the nonclinical and clinical pharmacology packages. While the FDA did not agree that the IHS4 should be used as a primary efficacy endpoint to support labeling, the FDA recommended that we obtain HS patient input to help determine the validity of the IHS4 score. The Company has been assessing different strategies to progress the clinical development of vilobelimab for HS in the United States. In March 2021 InflaRx has submitted a Special Protocol Assessment (SPA) to the FDA for the Phase III trial in Hidradenitis Suppurativa. Details on the Phase III design will be provided once an agreement has been reached with the FDA.

Additionally, we requested scientific advice from the EMA about a potential pathway for regulatory approval in Europe and received feedback in July 2020. The EMA acknowledged that HiSCR response does not account for the clinical relevance of a reduction in draining fistulas and the effort to construct a new endpoint that better captures these changes was endorsed in principle. According to the EMA, although HiSCR was used as an endpoint in previous studies, IHS4 could be an appropriate clinical endpoint to evaluate the efficacy of a novel compound in HS.

We are working diligently to address the additional feedback received from regulatory agencies so far and analyzing the strategy for our Phase III development in HS.

COVID-19

We are also developing vilobelimab in severe COVID-19. On March 31, 2020, we initiated a randomized open label multicenter trial Phase II/III clinical development program with vilobelimab in severe COVID-19 patients with severely progressed pneumonia and enrolled the first patient at the Amsterdam University Medical Centers in the Netherlands. In the Phase II 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. On June 17, 2020, we announced results from the Phase II part of the study. 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. 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.

On September 14, 2020, we announced the first patient enrolled in the Phase III part of the study. The randomized, double-blinded and placebo-controlled Phase III part of the Phase II/III trial plans to enroll up to 400 early intubated, critically ill patients with severe COVID-19 across sites in the US, EU, South America and other regions. Patients will be randomized 1:1 to receive either vilobelimab or placebo; all patients will receive standard of care. The primary endpoint will be 28-day all-cause mortality; key secondary endpoints will include assessment of organ support and disease improvement. An interim analysis is planned after enrollment of 180 patients, with a potential for an early stop for efficacy or futility. Patients are currently being enrolled and undergoing treatment.

Anti-neutrophil cytoplasm antibody associated vasculitis

We are also developing vilobelimab for the treatment of AAV, a rare, life-threatening autoimmune disease associated with powerful inflammatory flares that impair kidney function and lead to fatal organ dysfunction. This disease affects approximately 40,000 and 75,000 patients in the United States and Europe, respectively. In addition, this disease has a reported incidence of 4,000 and 7,500 new patients per year in the United States and Europe, respectively.

In October 2018, we dosed the first patient in the randomized, triple blind, placebo-controlled US Phase II IXPLORE study with vilobelimab in patients with AAV. The main objective of the study was to evaluate the efficacy and safety of two dosing regimens of vilobelimab in patients with moderate to severe AAV, when dosed in addition to standard of care, which includes treatment with high dose glucocorticoids and either cyclophosphamide or rituximab. The primary endpoint of the study is the number and percentage of subjects who experience at least one treatment-emergent adverse event (TEAE) per treatment group at week 24. It was originally planned that we would enroll approximately 36 patients at centers in the US. After a blinded interim analysis was conducted as well as an assessment of the potential impact of the COVID-19 pandemic, we decided to finalize enrollment at 19 patients. In October 2020, we announced that the 19 patients had finished treatment and final data will be available in the first half of 2021.

In May 2019, we initiated a randomized, double-blind, placebo-controlled European Phase II IXCHANGE clinical study with vilobelimab in patients with AAV. The main objective of the study is to evaluate the efficacy and safety of vilobelimab in patients with moderate to severe AAV. The primary endpoint of the study is a 50% reduction in Birmingham Vasculitis Activity Score (BVAS) at week 16. We originally planned to enroll approximately 80 patients at about 60 sites in up to 12 European countries and Russia. The study was being conducted in two parts. In Part 1, patients were randomized to receive either vilobelimab plus a reduced dose of glucocorticoids, or placebo plus a standard dose of glucocorticoids. Patients in both arms will receive standard of care dosing of rituximab or cyclophosphamide. In Part 2 of the study, patients will be randomized to receive either vilobelimab plus placebo, glucocorticoids or placebo plus a standard dose of glucocorticoids (both in addition to standard of care therapy consisting of rituximab or cyclophosphamide). After analyzing the impact of the ongoing COVID-19 pandemic on the study, we conducted a blinded interim analysis of Part 1. Based on our analysis, we decided to continue with Part 2 of the study but decreased the number of enrolled patients. Both Part 1 and Part 2 of the study are fully enrolled. The final data read-out is planned for the end of 2021.

We believe that this streamlined development strategy will provide important information on safety and efficacy using vilobelimab in AAV, while concurrently mitigating perceived or actual risks to the effective conduct of the clinical trial in conjunction with the COVID-19 pandemic. Our goal remains to gain Phase III readiness for this program with this strategy.

We plan to seek orphan drug designation for AAV in the United States and Europe once we obtain data from the running clinical Phase II trials in the United States and Europe.

Pyoderma Gangraenosum

We are also developing vilobelimab for the treatment of PG, a rare neutrophilic dermatosis associated with chronic cutaneous ulcerations. PG usually has a devastating effect on patient's life due to severe pain and induction of significant movement impairment depending on lesions' location. The exact prevalence of PG is not yet known, but it is estimated that up to 50,000 patients in the US and Europe are affected by this disease. We plan to seek orphan drug designation for PG in the United States and Europe.

In February 2019, we initiated an open label, multi-centric Phase IIa exploratory study enrolling 18 patients with moderate to severe PG in Canada, the U.S. and Poland. The objectives of this study are to evaluate the safety and efficacy of vilobelimab in this patient population. In February 2020, we announced initial data from the first five patients in this trial two patients achieved complete closure of the target ulcer. The drug was well tolerated, and no drug-related severe adverse events (SAE) have been recorded to date in the study. The study continues to enroll with the addition of two higher dose cohorts.

Oncology

We are also developing vilobelimab for the treatment of PD-1/PD-L1 inhibitor resistant/refractory locally advanced or metastatic cutaneous Squamous Cell Carcinoma (cSCC). CSCC is the second most common skin cancer. The incidence of cSCC increases with increasing sun exposure and age and individuals with fair skin and hair are more often concerned. Approximately 200,000 to 400,000 cases of cSCC per year are being reported in the United States reaching up to estimates as high as 1 million per year. Estimates in Europe vary by geographic location from approximately 30/100,000 per year in Northern Europe to approximately 10/100,000 in Southern Europe. The incidence of cSCC is increasing dramatically around the world. The potential for local recurrence or metastasis of cSCC varies with the pathologic variant and localization of the primary lesion, the risk for metastasis in cSCC is approximately 2-5%. Advanced SCC 10-year survival rates are less than 20% with regional lymph node involvement and less than 10% with distant metastases. Distant metastases have median survival of less than 2 years. We plan to initiate an open-label non-comparative 2-arm Phase II proof of concept study within the first half of 2021.

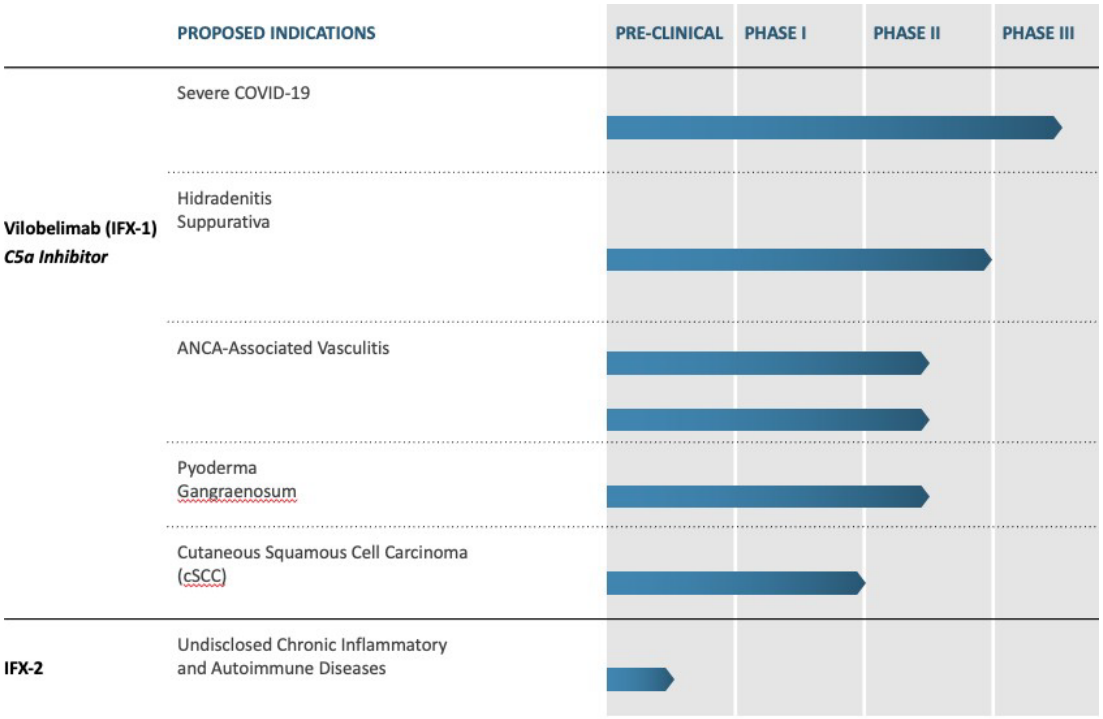
IFX-2

To expand the breadth of our anti-C5a technology, we are developing IFX-2 for the treatment of chronic inflammatory indications. IFX-2 shares the same mechanism of action as vilobelimab, blocking C5a with high specificity, but is designed with a dosing regimen that may be more suitable for chronic therapy. IFX-2 is in pre-clinical development.

Pipeline

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. Rights to our proprietary anti-C5a technology are currently expected to extend up to 2038 if our latest filed patent applications are granted.

The figure below summarizes key information about our current pipeline of product candidates:



Our programs

Vilobelimab for Hidradenitis Suppurativa

HS is a chronic debilitating systemic skin disease which results in painful inflammation of the hair follicles, most notably in the armpit, groin and genitalia regions. The clinical hallmarks of this disease include very painful inflammatory nodules, boils or abscesses that typically open and release odorous inflammatory fluids. In the more chronic form of the disease, patients experience draining fistulas, also referred to as sinus tracts, which ultimately lead to scarring and related functional disability in certain areas. HS patients suffer primarily from pain and significant discomfort resulting from the constant formation of pus, often requiring the use of bandages and diapers, resulting in social isolation. Not surprisingly, HS severely adversely affects patients' quality of life. The Hurley system is a classification system used to characterize the disease from early and easier to-treat forms of HS in Hurley stage 1 to the chronic and difficult to treat forms in Hurley stages 2 and 3.

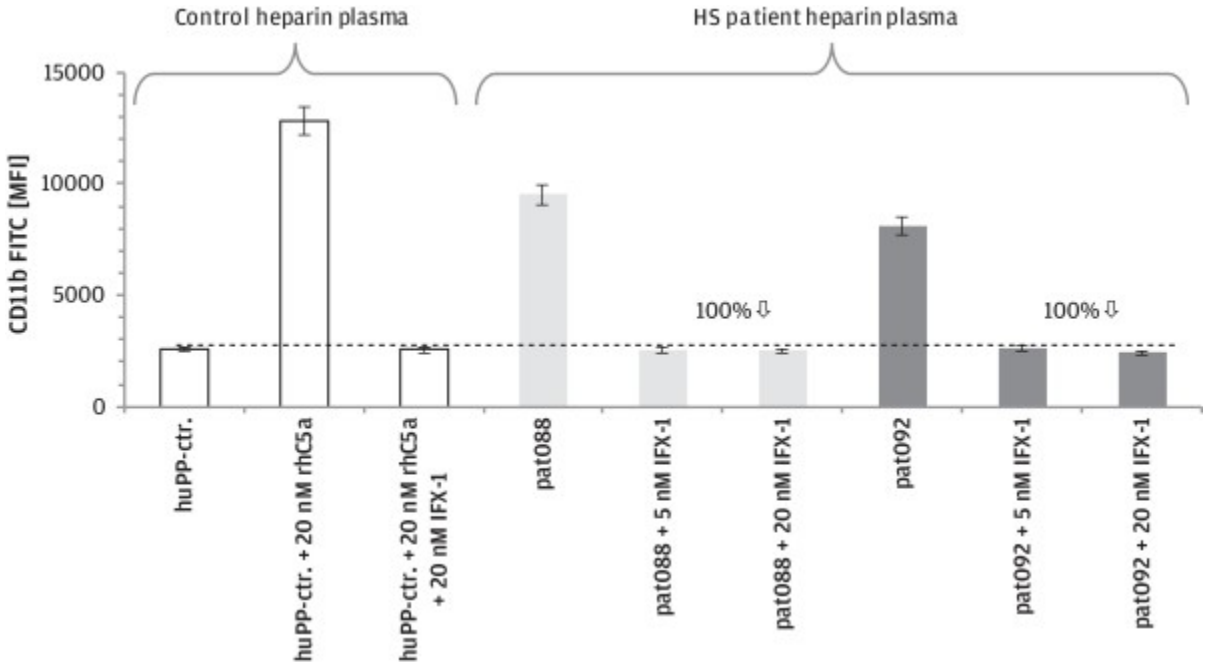
HS typically presents in the second and third decade of a patient's life and often develops into a life-long debilitating chronic disease. The target patient population for vilobelimab is HS patients displaying a moderate to severe form of the disease. In the United States we estimate that moderate to severe HS has a prevalence of up to 200,000 patients, although recent publications suggest a higher prevalence.

In Europe, the number of affected patients is also believed to be greater, with higher prevalence and incidence of HS in countries with warmer climates. The diagnosis and treatment are in most countries handled by dermatologists even though patients often first present with early symptoms to primary care physicians or even to emergency departments in order to seek surgical relief of formed abscesses.

The accepted (but not approved) standard of care for HS patients includes topical, oral or intravenous antibiotic treatment, as well as surgery, which often provide only temporary symptomatic relief. In some cases, patients also undergo different types of surgery. HS is recognized as a systemic autoimmune disease, for which there are numerous suggested etiological factors, including genetics. Neutrophils are believed to play a potential disease-promoting role as well as certain cytokines and mediators commonly found in autoimmune diseases such as TNF-alpha, IL-17, IL-1 and others. This rationale is supported by the 2015 approval in the United States and Europe of adalimumab, an anti-TNF-alpha monoclonal antibody, for the treatment of patients with moderate to severe HS (Hurley stage 2 and 3). The Hurley system is a classification system used to characterize the disease from early and easier-to-treat forms of HS in Hurley stage 1 to the chronic and difficult to treat forms in Hurley stages 2 and 3. The system has been used as the basis for clinical trials. Combined results from the two pivotal adalimumab trials, which enrolled a total of 633 patients, showed that approximately 50% of the 316 patients who were treated with adalimumab achieved a response in the HiSCR, while approximately 27% of the 317 patients who received placebo achieved a HiSCR response, in each case at the end of a 12-week treatment period. Patients are HiSCR responders when they achieve a 50% or higher reduction of the combined abscess and nodule, or AN, count from baseline, but no increase of the abscess or draining fistula count from baseline. The HiSCR is the primary endpoint that was used to support regulatory approval by the FDA and EMA of adalimumab for the treatment of HS patients. Despite having demonstrated clinical benefit, approximately 50% or more of the patients with moderate to severe HS did not respond to adalimumab, thus a high unmet need remains among HS patients.

C5a promotes inflammatory mediators and is a strong activator of neutrophils, which was the basis for our investigation of our C5a blocking drug candidate vilobelimab in patients with HS. We established that patients suffering from HS show proof of significant systemic complement activation with elevated plasma concentrations of C5a and other markers.

We further elaborated that C5a is activated in the plasma of HS patients and appears to be the main factor activating neutrophils in human whole blood from healthy humans. Neutrophil activation was assessed by observing the upregulation of the neutrophil surface marker CD11b (an established method to demonstrate neutrophil activation). These data were derived from studies conducted in 2013 and 2014 as part of an investigative project in collaboration with an investigator from the University of Athens, who provided HS patient plasma samples for the studies. In these studies, 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 HS patients 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 (previously denominated as "IFX-1") (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.

Vilobelimab was evaluated in a Phase IIa, single center open-label study in 12 patients who were diagnosed with Hurley stage 3 and had failed to respond to prior treatment attempts, including adalimumab, to which nine out of the 12 patients failed to respond. Patients received weekly intravenous injections of vilobelimab for eight consecutive weeks and were subject to follow up for three months thereafter. Results from the trial demonstrated a HiSCR response in 75% of patients at the end of eight weeks of treatment and in 83% of patients at the end of the 12-week trial observation period, demonstrating initial clinical evidence of the product candidate's disease-modifying effect. The results from the trial revealed that weekly injections of vilobelimab resulted in reduced C5a levels at 22 days and 50 days following the start of treatment while leaving MAC formation intact. The results also demonstrated that vilobelimab administration was well tolerated, with no drug-related adverse events detected and no infusion-related, allergic or anaphylactic reactions were observed.

In addition to the HiSCR response, we observed additional trends for the disease-modifying effect of vilobelimab treatment in HS patients. We investigated the absolute and percentage change from day one in the total combined count of abscesses and nodules, or AN count. The median AN count was 6.0 at baseline and decreased during the treatment period: at day 50 the AN count had decreased by a median of 3.5 (69.70%), and at the end of the trial observation period (day 134) the AN count had decreased by 4.5 (76.39%). At baseline, none of the 12 patients had an AN count of zero, one or two. At day 50, the end of the treatment period, the number of patients displaying an AN count of zero, one or two increased to eight patients and, by day 134 (end of the trial observation period) to 10 patients.[1]

Based on the initial Phase IIa results, we completed a larger multi-center, international Phase IIb study to determine the efficacy and safety of vilobelimab in moderate to severe HS patients. The trial was a randomized, double-blind and placebo-controlled multicenter study with five dose groups, including one placebo group. After a placebo-controlled double-blind period of 16 weeks, each patient

[1] In order to assess the potential long-lasting effect of vilobelimab (previously denominated as "IFX-1") treatment at the end of the three months observations period of the initial Phase IIa study, an observational study was conducted on 10 of the 12 clinical subjects. The data revealed that the time after concluding vilobelimab treatment to the first flare, defined as need for antibiotic treatment upon worsening of HS symptoms, was 209 days (range 54 to 318 days) and that, while being off of medication, 50% of patients had no flares until day 203.

received vilobelimab open label for additional 28 weeks to assess long-term efficacy and safety. The main objective of the study was to evaluate a dose response signal assessed by the HiSCR score at week 16 as the primary endpoint. Secondary objectives included evaluation of safety and tolerability of vilobelimab.

On June 5, 2019, we announced the top-line results of the international SHINE Phase IIb study, in which we failed to meet our primary endpoint utilizing HiSCR at week 16. The randomized, double-blind, placebo-controlled, multicenter study enrolled a total of 179 patients in four active dose arms and a placebo arm at over 40 sites in 9 countries in North America and Europe. The primary statistical analysis by multiple-comparison procedure modelling (MCP-mod) showed no significant dose response for the vilobelimab treatment.

The individual HiSCR rates at week 16 for the four different dose arms and the placebo arm are outlined below:

vilobelimab				**Placebo**
Minimal dose	**Low dose**	**Medium dose**	**High dose**	placebo Q2W
400mg every 4 weeks (Q4W)	**800mg every 4 weeks (Q4W)**	**800mg every 2 weeks (Q2W)**	**1200mg every 2 weeks (Q2W)**	
40.0%	51.5%	38.7%	45.5%	47.1%

A statistically significant reduction of the dermatology life quality index (DLQI) could be detected comparing the overall treatment arms with the placebo arm at week 16 (p=0.031). The median DLQI reduction at week 16 compared to pre- dose values was highest in the medium dose group (-5.5 points) when compared to the reduction in the placebo group (-1.5 points). There was a trend in the reduction of the overall AN count comparing the placebo group (median reduction of -3.0) and the low, medium and high dose group (-5.0, -5.0, and -4.5, respectively).

Vilobelimab was well tolerated. No difference could be detected in treatment emergent adverse events between placebo and treatment groups. Overall, 72% of placebo treated patients experienced a treatment emergent adverse event when compared to 66% of the combined vilobelimab treated groups. The most common treatment emergent adverse events were exacerbation of HS and nasopharyngitis.

On July 18, 2019 we published a post-hoc analysis. This analysis showed multiple additional signals of efficacy for the vilobelimab high dose group compared to the placebo group within the initial phase of the SHINE study, which demonstrated significant reductions in all combined inflammatory lesions, on draining fistula and on the IHS4 [2] which also scores all inflammatory lesions and has been developed by an international expert group to score severity and track treatment response, although it has not be utilized in late stage clinical studies in HS. The IHS4 weights the most fluctuating lesions such as inflammatory nodules (1 point), less than abscesses (2 points) or draining fistulas (4 points).

At week 16, there was a statistically significant reduction of draining fistulas ("DF") relative to baseline in the high dose vilobelimab group when compared to placebo (Figure 1 – relating to all patients with at least 1DF at baseline).

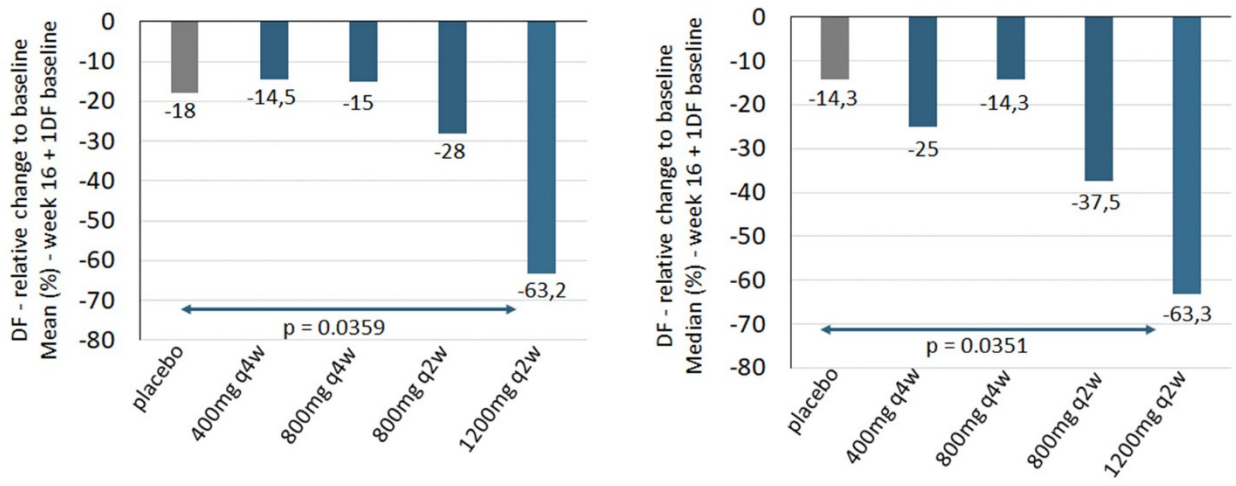


Figure 1: Draining Fistula (DF) reduction relative to baseline at week 16 (left: Mean, right: Median) in all patients with at least 1 draining fistula at baseline. For mean comparisons and the p-value of high dose versus placebo, an ANCOVA model adjusted for DF and Hurley stage at baseline was calculated. The p-value for the median comparison of high dose versus placebo was based on the Wilcoxon rank-sum test. Complete case analysis, no imputation of missing values.

This reduction in DF was visible as early as 2 weeks after induction of high dose vilobelimab therapy and consistent over time with the strongest observed reductions seen at weeks 6, 8 and 16 (Figure 2). A temporary weakening of the strong reduction was observed between weeks 10 to 14 which could not be explained by pharmacokinetic or pharmacodynamic parameters. The strong relative reduction of draining fistulas observed in the SHINE trial was consistent with earlier findings in the open label Phase IIa study (manuscript under revision for publication).

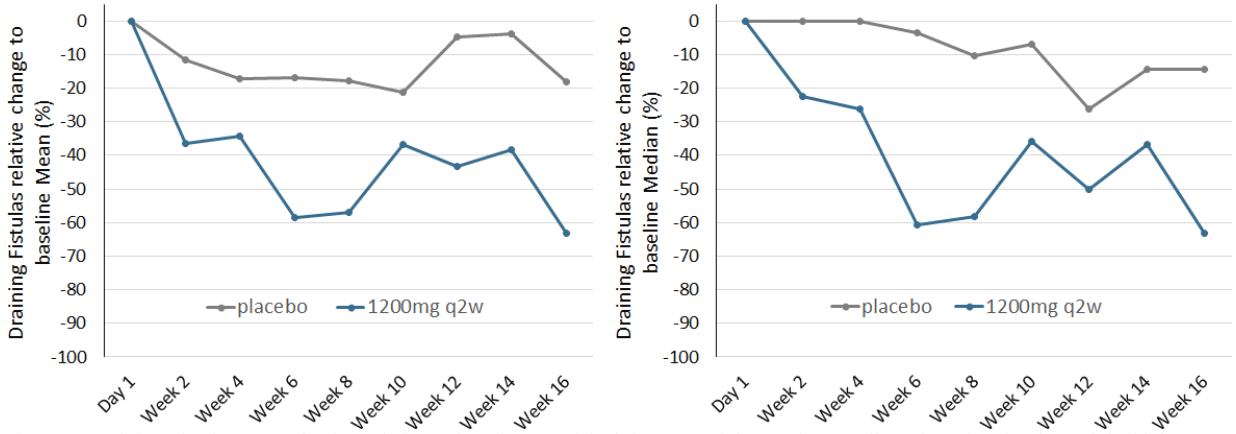


Figure 2: Draining Fistula (DF) reduction relative to baseline per visit (left: Mean, right: Median) until week 16 for placebo and the high dose group (vilobelimab 1200mg q2w) in all patients with at least one DF at baseline. For mean comparisons of high dose versus placebo, an ANCOVA model adjusted for DF and Hurley stage at baseline was calculated. Complete case analysis, no imputation of missing values.

Vilobelimab therapy also reduced the AN count at week 16 relative to baseline with a trend to a dose dependent effect. Further analysis showed that high dose vilobelimab therapy reduced abscesses and inflammatory nodule counts over time (Figure 3):

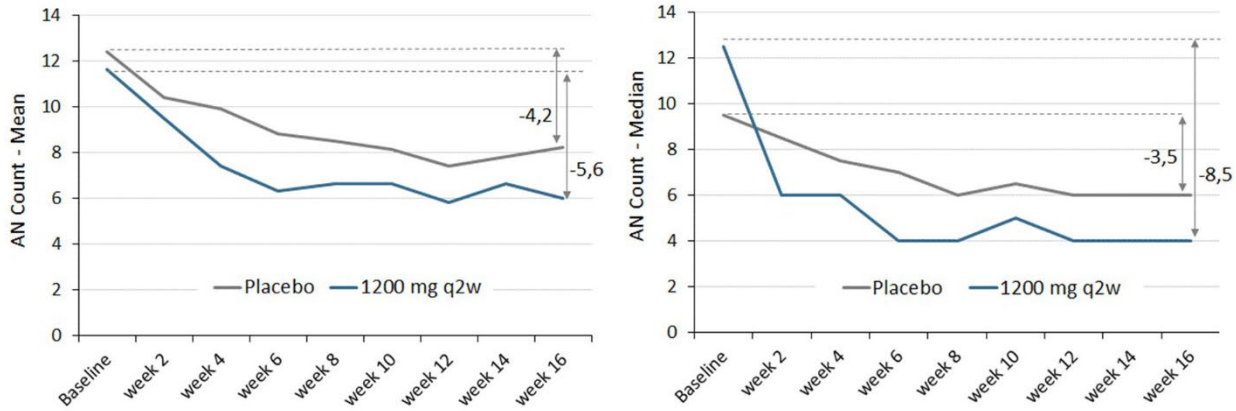


Figure 3: AN count per patient visit (left: Mean, right: Median) until week 16 for placebo and high dose group (vilobelimab 1200mg q2w). Complete case analysis, no imputation of missing values.

On November 6, 2019, we reported positive results of the open label extension (OLE) part of the international SHINE Phase IIb study. The data were from a analysis at the end of the overall 9-month study treatment period (week 40). A total of 156 patients entered the 6-month OLE period upon completion of week 16 of the first part of the SHINE study. Patients participating in the OLE part of the study remained blinded to their initial treatment regimen and were grouped into two arms, responders and non-responders, according to the HiSCR at week 16. The Responder Group received a maintenance vilobelimab treatment dose of 800 mg every 4 weeks to investigate if they would maintain their response. The Non-responder Group received a vilobelimab treatment of 800 mg every 2 weeks to investigate if they would become responders. As induction therapy, patients transitioning from the former minimal dose or placebo groups received one or two additional 800 mg infusions, respectively. The endpoint for the OLE part of the study was HiSCR response rate at week 40. Key results include:

- 70.6% of the Responder Group maintained their HiSCR response during the OLE, and
- 41.8% of the Non-responder Group became responders at week 40.

Thus, at the end of the 9-month treatment period, 56.3% of all patients who completed the OLE were HiSCR responders.

Overall, patients completing the OLE period showed a sustained improvement in inflammatory lesion count at week 40 compared to baseline counts of the OLE treatment group on day 1 of the SHINE study. There was a relative reduction in the total body count of:

- abscesses and inflammatory nodules (AN count) of -66.9% (mean) and -75.0% (median), and
- draining fistula of -46.0% (mean) and -51.5% (median)

These results were also reflected in IHS4, which demonstrated an improvement with a relative change of - 54.5% (mean) and -64.1% (median) when compared to the day 1 baseline values of the OLE patient group.

In June 2020, we completed an end-of-Phase II meeting with the FDA and discussed the possible design of a pivotal Phase III program for vilobelimab for the treatment of HS. The FDA agreed to key proposals to support a Biologics License Application (BLA) submission, including certain aspects of the Phase III clinical trial design, vilobelimab dosing, target study population, and the nonclinical and clinical pharmacology packages. While the FDA did not agree that the IHS4 is should be used as a primary efficacy endpoint to support labeling, the FDA recommended that we obtain HS patient input to help determine the validity of the IHS4 score. We have been assessing different strategies to progress the clinical development of vilobelimab for HS in the United States. In March 2021 InflaRx has sub-

mitted a Special Protocol Assessment (SPA) to the FDA for the Phase III trial in Hidradenitis Suppurativa. Details on the Phase III design will be provided once an agreement has been reached with the FDA.

Additionally, we requested scientific advice from the EMA about a potential pathway for regulatory approval in Europe and received feedback in July 2020. The EMA acknowledged that HiSCR response does not account for the clinical relevance of a reduction in draining fistulas and the effort to construct a new endpoint that better captures these changes was endorsed in principle. According to the EMA, although HiSCR was used as an endpoint in previous studies, IHS4 could be an appropriate clinical endpoint to evaluate the efficacy of a novel compound in HS.

We are working diligently to address the feedback received from regulatory agencies so far and analyzing the strategy for our Phase III development in HS.

Vilobelimab for the treatment of Severe COVID-19

We are also developing vilobelimab for the treatment of severe COVID-19. On March 31, 2020, we initiated a Phase II/III clinical development program with vilobelimab in patients with severe COVID-19 and enrolled the first patient at the Amsterdam University Medical Centers in the Netherlands. The Phase II part of the study 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 II 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 2 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 serious adverse events 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 serious adverse event. 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.

Serious adverse event (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 III part.

The Phase II part of the trial was exploratory in nature and was not powered to show statistically significant differences in clinical endpoints. Relative change (%) from baseline to day 5 in the oxygenation index, chosen as the primary endpoint for the Phase II part, showed a large variability and dependency on patient positioning and intubation status which excludes this endpoint from being used in a confirmatory study.

On September 14, 2020, we announced the first patient enrolled in the Phase III part of the study. The randomized, double-blinded and placebo-controlled Phase III part of the Phase II/III trial plans to enroll up to 400 early intubated, critically ill patients with severe COVID-19 across sites in the US, EU, South America and other regions. Patients will be randomized 1:1 to receive either vilobelimab or placebo; all patients will receive standard of care. The primary endpoint will be 28-day all-cause mortality; key secondary endpoints will include assessment of organ support and disease improvement. An interim analysis is planned after enrollment of 180 patients, with a potential for an early stop for efficacy or futility. Patients are currently enrolling and undergoing treatment.

Vilobelimab for ANCA-associated Vasculitis

AAV is a rare, life-threatening autoimmune disease with a relapsing nature, characterized by necrotizing vasculitis, an inflammation of blood vessels. The disease is characterized by life-threatening flare phases affecting the kidney function and other organs leading to organ dysfunction and failure, a potentially fatal outcome unless treated appropriately. AAV predominantly affects small vessels associated with anti-neutrophil cytoplasmic antibodies, or ANCA. It comprises three disease entities: GPA, or granulomatosis with polyangiitis (known as Wegener's Granulomatosis); MPA, or microscopic polyangiitis; and eGPA, or eosinophilic granulomatosis with polyangiitis (known as Churg-Strauss syndrome).

AAV is designated as an orphan disease and affects approximately 40,000 and 75,000 patients in the United States and Europe, respectively. In addition, AAV has a reported incidence of 4,000 and 7,500 new patients per year in the United States and Europe, respectively.

Because of the life-threatening character of this disease, it is crucial to induce remission rapidly when a flare presents. The treatment to induce remission differs from maintenance therapy. The current treatment regimen to induce remission uses a combination of High Dose Corticosteroids, or HDCS, together with either rituximab or cyclophosphamide. The long lasting HDCS therapy is associated with significant side effects and additional life-threatening risks for the patients.

The disease promoting role of C5a for AAV is well established. A priming effect of C5a for neutrophils appears to be the essential factor leading to neutrophil-related damage of the endothelial cells in the vessels. In addition, patients with acute AAV disease have significantly elevated complement activation parameters in their plasma when compared to AAV patients in remission. In an experimental AAV disease model in mice, it was shown that while C5aR deficiency leads to reduction in disease activity, C6 deficiency does not lead to such improvement, suggesting that MAC formation might not play a major role in this disease. However, additional research is warranted to confirm this conclusion.

Our clinical development strategy for vilobelimab in AAV will first focus on acutely ill AAV patients, where we believe vilobelimab has the potential to successfully induce remission and reduce or eliminate the need for HDCS therapy, leading to reduction or elimination of HDCS therapy and providing an improved safety profile. Thereby we also intend to focus on speed of induction of remission and reducing rate of renal replacement and kidney dysfunction. An additional focus could address the maintenance of remission in patients.

We conducted a pre-IND meeting for vilobelimab therapy in AAV patients in February 2018 and, based on this, we initiated a US clinical Phase II study with vilobelimab in AAV patients primarily investigating safety and tolerability of vilobelimab in AAV patients as well as exploring efficacy of vilobelimab when added to standard of care therapy. In addition, we have initiated a second Phase II study with vilobelimab in AAV patients outside the US focusing on safety as well as on investigating

the potential to reduce and avoid high dose glucocorticoid treatment during the induction phase of acute AAV. Part of the development strategy will also be submission of an orphan drug application to the FDA and EMA once first data are available.

In October 2018, we dosed the first patient in the randomized, triple blind, placebo-controlled US Phase II IXPLORE study with vilobelimab in patients with AAV. The main objective of the study is to evaluate the efficacy and safety of two dosing regimens of vilobelimab in patients with moderate to severe AAV, when dosed in addition to standard of care, which included treatment with high dose glucocorticoids and either cyclophosphamide or rituximab. Patients were randomized to either receive a low dose of vilobelimab in combination with a standard dose of glucocorticoids, a high dose of vilobelimab in combination with a standard dose of glucocorticoids or placebo in combination with a standard dose of glucocorticoids. Patients in all three groups received the standard of care dosing therapy consisting of rituximab or cyclophosphamide. The primary endpoint of the study is the number and percentage of subjects who experience at least one treatment-emergent adverse event (TEAE) per treatment group at week 24. The key secondary endpoint of the study is a 50% reduction in Birmingham Vasculitis Activity Score (BVAS) at week 16, a well-established endpoint that has been used in the previous AAV studies, along with clinical remission. It was originally planned that we would enroll approximately 36 patients at centers in the US. After a blinded interim analysis was conducted as well as an assessment of the potential impact of the ongoing COVID-19 pandemic, a decision was made to finalize enrollment at 19 patients. In October 2020, we announced that the 19 patients had finished treatment and final data will be available in the first half of 2021.

In May 2019, we initiated a randomized, double-blind, placebo-controlled European Phase II IXCHANGE study with vilobelimab in patients with AAV. The main objective of this study is to evaluate the efficacy and safety of vilobelimab in patients with moderate to severe AAV. The primary endpoint of the study is a 50% reduction in Birmingham Vasculitis Activity Score (BVAS) at week 16. Secondary efficacy endpoints being analyzed include clinical remission, evaluation of the Vasculitis Damage Index, reduction of glucocorticoid toxicity, several relevant biomarkers like glomerular filtration rate, and patient reported outcomes. We originally planned that we would enroll approximately 80 patients at about 60 sites in up to 12 European countries and Russia. The study is being conducted in two parts. In part 1, patients are being randomized to receive either vilobelimab plus a reduced dose of glucocorticoids, or placebo plus a standard dose of glucocorticoids. Patients in both arms will receive the standard of care dosing of immunosuppressive therapy (rituximab or cyclophosphamide). This part has been fully enrolled with 30 patients. After analyzing the impact of the ongoing COVID-19 pandemic on the study, we conducted a blinded internal interim analysis, in addition to obtaining review by an independent data monitoring committee related to safety and efficacy.

In part 2 of the study, patients are randomized to receive either vilobelimab plus placebo glucocorticoids or placebo plus a standard dose of glucocorticoids (both in addition to standard of care immunosuppressive therapy with rituximab or cyclophosphamide). Based on the results of the blinded interim analysis of part 1 of the IXCHANGE study, we have streamlined our development strategy for vilobelimab in AAV. We decided to continue with part 2 of the study but decrease the number of enrolled patients. Part 2 of the study is now fully enrolled with 27 patients. The final data read-out is planned for the end of 2021.

We believe that this streamlined development strategy will provide important information on safety and efficacy using vilobelimab in AAV, while concurrently mitigating perceived or actual risks to the clinical trial associated with the COVID-19 pandemic. The goal of this strategy remains for the program to obtain Phase III readiness.

We believe that the potential advantages of treatment with vilobelimab in AAV are the following:

- **Rapid onset of action:** vilobelimab has fast onset of action such that after its intravenous administration, vilobelimab inhibits C5a-induced signaling completely, providing immediate protection from C5a induced priming and activation of neutrophils in this disease. This may

result in a faster response rate and a potentially quicker induction of remission when compared to the currently available treatment options.

- **Potential potency advantages (over receptor inhibition):** vilobelimab blocks the upstream ligand C5a, which inhibits signaling through both receptors, C5aR and C5L2; C5a pro-inflammatory MoA through both C5aR and C5L2 has been shown to be important for ANCA-primed and C5a-induced neutrophil degranulation as key disease-driving mechanism in AAV (published by Hao and Wang et al 2013, PloS ONE).

Vilobelimab for the treatment of Pyoderma Gangraenosum

We are also developing vilobelimab for the treatment of Pyoderma Gangraenosum (PG). PG is a 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 presents as painful pustule or papule, mainly on the lower extremities which 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 50,000 patients in the US and Europe are affected by this disease. We plan to seek orphan drug designation for PG in the United States and Europe.

In February 2019, we initiated an open label, multi-centric Phase IIa exploratory study enrolling 18 patients with moderate to severe PG in Canada, the U.S. and Poland. We dosed the first patient in this trial in June 2019 and we plan to study 3 different dosing regimens of vilobelimab in a dose-escalation manner. The objectives of this study are to evaluate the safety and efficacy of vilobelimab in this patient population. The objectives of this study are to evaluate the safety and efficacy of vilobelimab in this patient population. The primary endpoint of the study is safety while the key secondary endpoints focus on the responder rate defined as a Physicians Global Assessment ≤ 3 of the target ulcer at visits V4, V6, V10, and V16 (end of treatment) as well as time to complete closure of Pyoderma Gangraenosum target ulcer (investigator assessment). In February 2020, we announced initial data from the first five patients in this trial. Patients in this first dosing group are being treated with 800mg of vilobelimab biweekly for 12 weeks after an initial run-in phase with three doses of 800mg on day 1, 4 and 8 of the study, with a three-month observational period. Out of the first five initial patients dosed with vilobelimab, two patients achieved complete closure of the target ulcer. Both patients in remission had previously failed to respond to different therapeutic treatment attempts, including high dose glucocorticoids, and both patients showed elevated C5a levels in plasma at baseline. Pharmacodynamic analysis of the C5a levels over time of treatment indicated that a dose escalation may provide better control over C5a levels throughout the treatment period. The drug was well tolerated and no drug-related severe adverse events (SAE) have been recorded to date in the study. We are continuing to enroll the study with the addition of higher dose cohorts. Data from the additional cohorts is expected by the end of 2021.

Vilobelimab for the treatment of oncological diseases

We are also developing vilobelimab for the treatment of PD-1/PD-L1 inhibitor resistant/refractory locally advanced or metastatic cutaneous Squamous Cell Carcinoma (cSCC). CSCC is the second most common skin cancer. The incidence of cSCC increases with increasing sun exposure and age and individuals with fair skin and hair are more often concerned. Approximately 200,000 to 400,000 cases of cSCC per year are being reported in the United States reaching up to estimates as high as 1 million per year. Estimates in Europe vary by geographic location from approximately 30/100,00 per year in Northern Europe to approximately 10/100,000 in Southern Europe. The incidence of cSCC is increasing dramatically around the world. The potential for local recurrence or metastasis of cSCC varies with the pathologic variant and localization of the primary lesion, the risk for metastasis in cSCC is approximately 2-5%. Advanced SCC 10-year survival rates are less than 20% with regional lymph

node involvement and less than 10% with distant metastases. Distant metastases have median survival of less than 2 years. We plan to initiate an open-label non-comparative 2-arm Phase II proof of concept study within the first half of 2021.

Our strategy

Our goal is to develop new treatment options for patients affected by inflammatory diseases driven by strong neutrophil activation. In such diseases, the activation of the complement system, which is an important part of the patient's immune system, ultimately results in the cleavage of a protein called C5, which leads to the generation of the cleavage products C5a and C5b. 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 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 that specifically target C5a. In order to achieve this goal, we have developed vilobelimab, an antibody drug that selectively inhibits C5a, which we are developing in several disease indications. Key elements of our business strategy include to:

- rapidly advance the development of our clinical stage product candidates, including vilobelimab for the treatment of neutrophil-induced inflammatory diseases such as severe Covid-19, hidradenitis suppurativa (HS), ANCA-associated vasculitis (AAV), pyoderma gangraenosum (PG) and PD-1/PD-L1 resistant or refractory cutaneous squamous cell carcinoma (sSCC);
- establish R&D and commercialization capabilities in the US and Europe;
- utilize our technology platform and intellectual property portfolio to continue building our development product portfolio, including our follow-on product IFX-2;
- establish manufacturing capabilities to provide vilobelimab in sufficient quantities to conduct our clinical trials and to provide commercial quantities in cGMP compliant manner;
- establish collaborations with companies in our industry to develop and commercialize our product candidates.

In executing our strategy, the Board fulfills a critical role in and is committed to (i) continuing to develop and lead the strategic direction of the Company, (ii) the growth and creation of shareholder and other stakeholder value, (iii) the performance of the Company, (iv) the anticipated future challenges and opportunities facing the Company and (v) sustainable long-term value creation for the benefit of our shareholders, while also serving the interests of our other stakeholders.

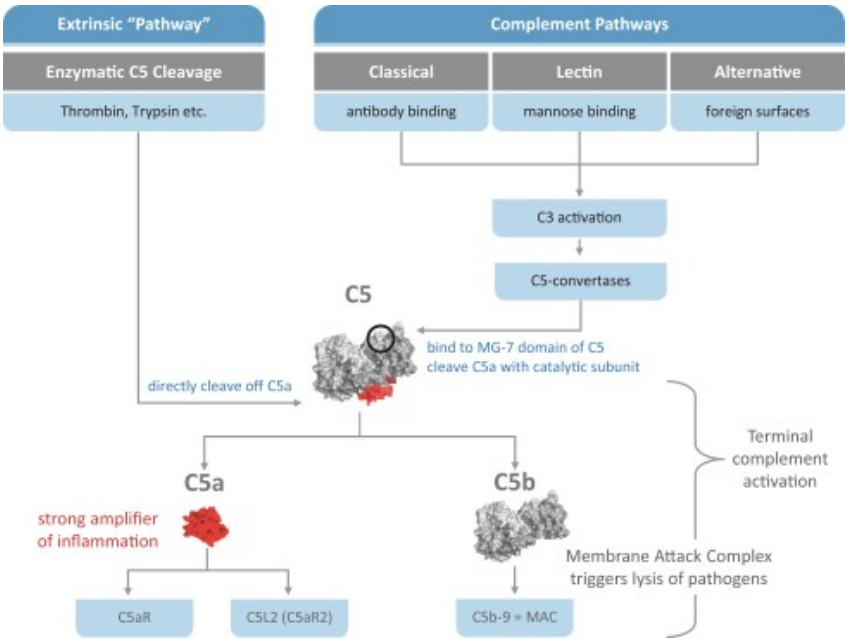
The complement system and role of C5a

The complement system: overview and terminal complement activation

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 classical pathway, the mannose binding lectin, or MBL, pathway and the alternative pathway. Activation of any pathway 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 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.



Functional importance of the complement system and the need for control

Overview of critical functions

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 Membrane Attack Complex.** 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 over the last 18 years 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.

In a recently published article in Clinical Immunology, 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 elicited by uncontrolled C5a. Importantly, various other complement activation products such as C3a, C3a-desArg, C4a etc. 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.

In the inflammatory response, C5a is an accelerator or "booster" of inflammation. This role of C5a extends to a broad variety of responses that include, but are not limited to, 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.
- 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. 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.

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. Multiple international research groups have demonstrated 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 C5a in cancer growth and metastatic disease

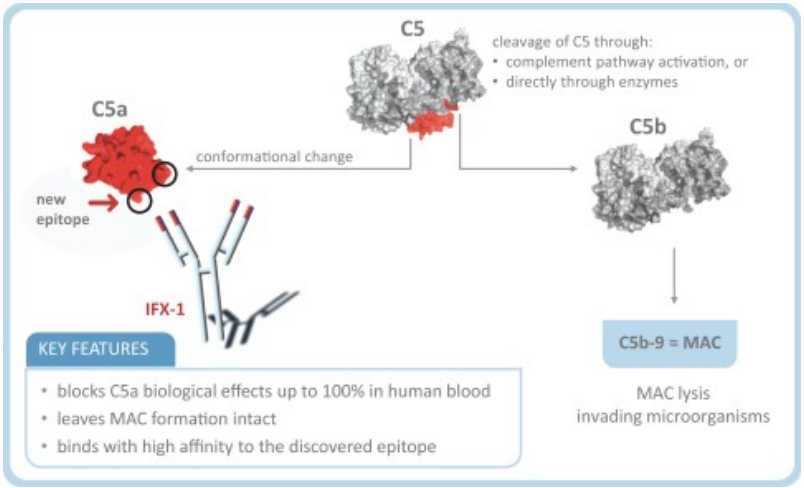
Different cancer cells have been found to generate their own C5a when cultured in vitro in the absence of any other complement factors or intact complement pathways. This result is possible because cancer cells produce C5, together with enzymes to directly cleave C5, thereby generating functionally active C5a. Recent research suggests that C5a contributes to cancer growth and metastatic disease, with multiple mechanisms proposed in the literature to explain this phenomenon. C5a appears to be associated with the recruitment and activation of myeloid-derived suppressor cells, also referred to as MDSCs, in tumors. Activating MDSCs suppresses the important T-cell-mediated mechanisms that usually inhibit tumor growth. Recently published findings in Cancer Cell in 2018 confirmed this mode of action that has been suggested in earlier published work. It has also been documented that C5a generates a microenvironment favorable for tumor growth by increasing angiogenesis and enhancing the expression of the checkpoint molecule PDL1, as well as other mediators that enable tumor growth. These and other existing data may explain why combined therapy of anti-PD-1/PD-L1 and C5a blockade has been shown to effectively reduce tumor growth and metastasis in a pre-clinical mouse model.

Our proprietary anti-C5a technology and product candidates

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.

Our anti-C5a technology

When targeting C5a with a drug, the challenge is to fully control and block C5a while leaving MAC formation intact. We believe our discovery of a new conformational epitope, a binding site that can be detected by antibodies, on C5a has allowed us to solve this challenge. 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 HS and AAV.



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 up-regulated 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 of these features are necessary for a drug targeting C5a to achieve clinically meaningful pharmacological performance for the treatment of C5a-driven diseases such as HS, AAV or 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:

- **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; and

- **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 which 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 are currently evaluating vilobelimab in various disease indications. In our lead indication HS, we have completed an international Phase IIb and an open-label Phase IIa study including a follow-on observational analysis. We have also completed one placebo-controlled, single-center Phase I study of vilobelimab in healthy volunteers and completed two double-blind, placebo-controlled, multi-center Phase IIa studies in two other acute care indications, early septic organ dysfunction and complex cardiac surgery. In all completed studies, vilobelimab was observed to be well tolerated. The placebo-controlled, multi-center Phase IIa studies in the two acute care indications demonstrated that the occurrence of adverse events was comparable between treatment groups and placebo group. The results of these studies also demonstrated that vilobelimab blocked C5a with high statistical significance (p-values < 0.001) and that MAC formation, as demonstrated by a CH50 assay 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 anti-drug antibody detection assay conducted in connection with our Phase IIb clinical trial in HS, 10% of patients had anti-drug antibodies (ADA) 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.

In addition to HS, we are developing vilobelimab as a therapy for AAV given C5a's well-established disease promoting role in AAV, as well as in PG, a well characterized neutrophilic dermatosis, in which we have initiated a Phase II clinical development. We plan to advance development of vilobelimab in other disease settings where we believe an anti-C5a antibody could be successfully developed into a marketed therapy.

Additional clinical and pre-clinical development for vilobelimab

Beyond HS, severe COVID-19, AAV, PG and cSCC, the indications we described in the above sections, we plan to advance the clinical development of vilobelimab in additional inflammatory and chronic complement-mediated autoimmune disease indications for which a good pre-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, are identified.

Additional clinical and pre-clinical development for vilobelimab

We have also completed one Phase I clinical trial of vilobelimab in healthy volunteers and two Phase II clinical trials in patients with septic organ dysfunction and complex cardiac surgery, respectively.

Phase I: Placebo controlled dose escalation study in healthy human volunteers

We have completed a Phase I randomized, double-blind, placebo controlled clinical trial of vilobelimab in healthy volunteers to assess the safety, tolerability, PK and PD of vilobelimab following escalated single-dose IV administration. Five dosing groups were assessed with doses of 0.02 mg, 0.1 mg, 0.5 mg, 2 mg and 4 mg per kg of bodyweight, and each dose group was accompanied by placebo dosed patients. Each subject received a single IV administration of the study medication or placebo. The first subject was screened on March 23, 2011 and the last patient's last visit was on October 11, 2011. Out of 26 total patients, 24 patients completed the study as planned (one subject receiving the placebo was withdrawn due to protocol deviations and another subject withdrew his consent). Of those patients, 15 were treated with vilobelimab and the other patients were treated with a placebo. To be included in the clinical trial, patients had to be healthy male Caucasian subjects, aged between 18 and 40 years, with specified body mass index and bodyweight parameters. The study was sponsored by us and conducted in Neuss, Germany.

In all dose groups, we observed that single intravenous doses of vilobelimab were well tolerated in healthy volunteers. No clinically significant changes were observed in vital signs, physical examination or clinical laboratory parameters, including hematology, blood chemistry, coagulation, urinalysis and ECGs. Local tolerability was positive, and no serious adverse events occurred.

Ex vivo performance of vilobelimab was assessed in a secondary PD analysis in fresh human whole blood with vilobelimab samples from the two high dose groups. This assessment resulted in a mean *ex vivo* effect of vilobelimab for blocking C5a-induced neutrophil activation (CD11b upregulation) of approximately 100%.

Previously completed Phase IIa clinical trials with vilobelimab

We have completed clinical Phase IIa studies in two acute care indications, early septic organ dysfunction and complex cardiac surgery. The purpose of both trials was to evaluate the safety and tolerability of vilobelimab, assess pharmacokinetics, or PK, and pharmacodynamics, or PD, as well as various clinical and surrogate endpoints. Neither trial was powered for statistical significance with respect to clinical endpoints.

SCIENS Phase IIa clinical trial: Placebo controlled multi-center dose escalation study in patients suffering from early septic organ dysfunction

We completed a multi-center, double-blind, placebo-controlled Phase IIa study in 72 patients with early septic organ dysfunction (SCIENS). The study was conducted to assess the occurrence of adverse events, tolerability, PK and PD of vilobelimab at different dose regimens. It was sponsored by us and conducted at 17 study centers in Germany. Eligible patients suffered from early, newly developing organ dysfunction and were diagnosed with either abdominal or pulmonary infection as cause of sepsis. vilobelimab was administered to patients within 3 hours after screening in three dose groups: three doses of 4 mg/kg of bodyweight over 72 hours (high dose), two doses of 4 mg/kg of bodyweight over 24 hours (medium dose) or 2 mg/kg of bodyweight over 12 hours (low dose), or placebo. The first patient entered the study on April 25, 2014, and the last patient was treated on December 3, 2015.

In all dose groups, we observed that vilobelimab was well tolerated, with levels of adverse events or serious adverse events in treatment groups comparable to those in the control group. No relevant differences between placebo and treated patients were observed with respect to clinical laboratory parameters, ECGs or local tolerability. No anti-drug antibodies were detected during the 28 days of observation.

The study demonstrated that vilobelimab reduced elevated C5a levels in these patients with statistical significance in a dose dependent manner. Mean C5a concentrations were decreased in the different dose groups with high statistical significance ($p < 0.01$) starting at the first blood sampling two hours after the start of vilobelimab infusion. The duration of statistically significant decrease of C5a compared to placebo was 24 hours for the low dose group, 5 days for the medium dose group and 13

days for the high dose group (with $p < 0.01$ at all time points except for the last time point at day 13 in the high dose group, for which $p = 0.039$).

Ex vivo secondary PD analysis with plasma samples from treated patients added to fresh human whole blood in which recombinant C5a was added showed *ex vivo* vilobelimab was fully active in blocking C5a-induced neutrophil activation.

Although we were encouraged by our observations from SCIENS, we have determined that focusing on HS and AAV would provide more efficient clinical and regulatory paths forward, due to the historically increased risk and uncertainty relating to clinical development for product candidates within the sepsis indication.

CARDIAC Phase IIa clinical trial: Placebo controlled multi-center dose escalation study in patients undergoing complex cardiac surgery

We have also completed a multi-center, double-blind, placebo-controlled Phase IIa study in 116 patients electively undergoing pre-specified complex cardiac surgery (CARDIAC). vilobelimab or placebo was administered to patients prior to the start of surgery. The primary objective was to evaluate safety and tolerability of vilobelimab, as well as assess the effect of vilobelimab on peak IL-6 levels. It was sponsored by us and conducted at 10 sites in Germany. Four dosing groups were assessed with vilobelimab doses of 1 mg, 2 mg, 4 mg and 8 mg per kg of bodyweight, and each dose group was accompanied by placebo-dosed patients. The first patient was dosed on June 6, 2016, and the last patient's last visit was on January 24, 2017.

In all dose groups we observed, vilobelimab was well tolerated, and adverse events detected were comparable to those from the control group. No relevant differences between placebo and treated patients were observed with respect to clinical laboratory parameters, ECGs or local tolerability. C5a plasma levels were decreased with high statistical significance ($p < 0.001$) and in a dose-dependent manner. In all dose groups, MAC formation as assessed by the CH50 test was intact.

However, we observed a high level of variability in the patient population across the placebo and treatment arms. For example, IL-6 levels were more variable than estimated in advance based on literature, and vilobelimab did not affect IL-6 levels with statistical significance. In addition, the overall mortality in this study was 1.9%, significantly below the levels in the published literature and the estimations conducted with the principle investigator, which were in the range of 12% to 18%. As a result, we have decided to discontinue development of vilobelimab for complex cardiac surgery.

Pre-clinical studies involving vilobelimab

We established pre-clinical proof of concept for vilobelimab in various different pre-clinical settings and studies in monkeys. Collectively, these studies demonstrated that vilobelimab is highly effective in blocking C5a-induced biological effects while leaving MAC formation intact and that vilobelimab administration showed strong initial clinical evidence of disease-modifying effect in reducing neutrophil-driven organ damage in monkeys.

Vilobelimab improves outcome in pre-clinical disease model in monkeys

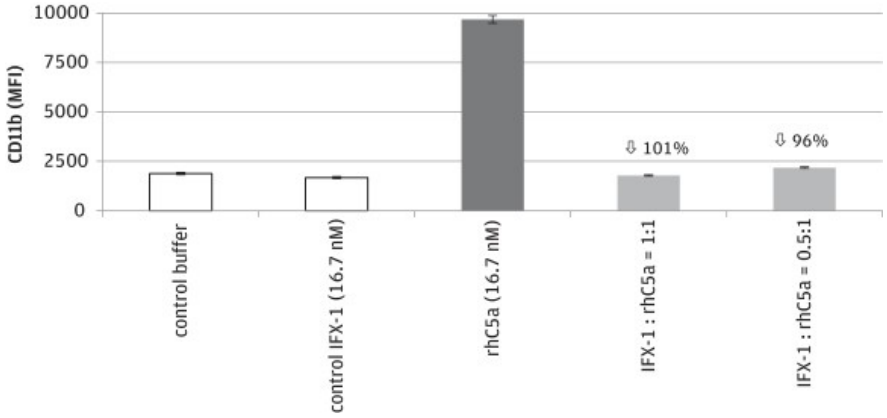
Vilobelimab was tested in an African green monkey model of acute lung injury, or ALI, induced by the new avian flu virus, H7N9, that exhibits clinical features comparable to H7N9 viral pneumonia in humans. In the absence of vilobelimab, extensive complement activation accompanied by severe lung structural damage was detected in infected monkeys. Twelve two- to four-year-old African green monkeys were used in this study. Ten monkeys were inoculated intratracheally with 10^6 50% tissue culture infective dose of H7N9 while two monkeys were mock-infected. Four of the 10 virus-infected monkeys were treated intravenously with 5 mg/kg of vilobelimab and the remaining six monkeys received a sham intravenous treatment. Treatment with vilobelimab resulted in: greatly attenuated lung damage in histological analysis, reduced viral replication within the lungs, significantly lowered levels

of inflammatory mediators, including IL-1ß, IP-10, MCP-1, IL-6, TNF-alpha and INF-gamma, and significantly fewer inflammatory infiltrating cells, especially neutrophils, in the lung.

The study was performed in 2014 at the State Key Laboratory of Pathogen and Biosecurity, Beijing Institute of Microbiology and Epidemiology, in Beijing, China. The primary goal of this study was to evaluate if vilobelimab treatment could reduce H7N9-induced lung tissue damage as expressed by the histopathological, or HE, score and decrease cytokine levels. The results demonstrated that treatment with vilobelimab significantly reduces HE score post-H7N9 infection ($p < 0.001$) and strongly reduced the levels of cytokines including IL-1ß, MCP-1, IL-6, TNF-alpha and INF-gamma ($p < 0.001$), suggesting a beneficial effect of vilobelimab on this viral-induced lung injury.

Vilobelimab fully blocks C5a-induced effects on neutrophils in human whole blood

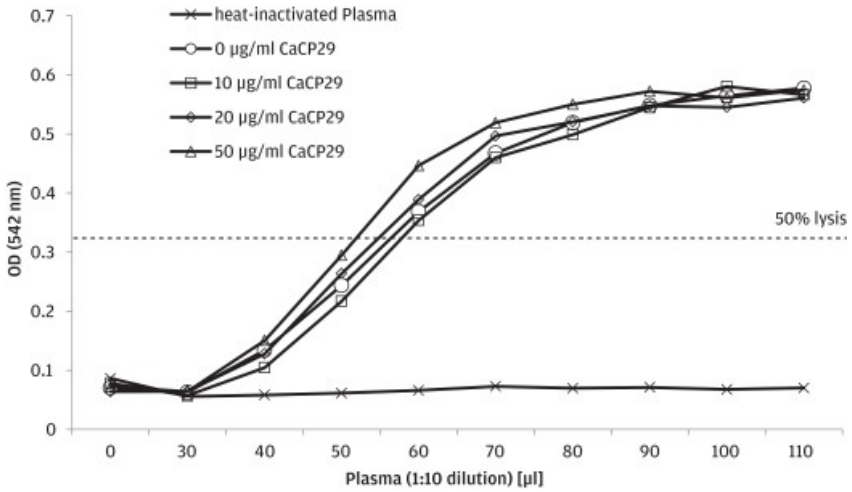
To assess vilobelimab's ability to block C5a-induced biological effects on neutrophils in human blood, fresh human whole blood from voluntary blood donors was used, with the activation of neutrophils assessed using flow cytometric measurement of the known marker CD11b. This marker is expressed on neutrophil surfaces at low levels in non-activated neutrophils in the blood of healthy humans (controls in the figure below) and is strongly upregulated when neutrophils are activated, such as by recombinant human C5a (represented by the bar denoted as rhC5a (16.7 nM) in the figure below). Upon C5a stimulation, Cd11b expression was significantly upregulated ($p < 0.0001$). When vilobelimab was added together with recombinant C5a, CD11b upregulation was completely abolished with statistical significance ($p < 0.0001$).



vilobelimab (IFX-1) blocks rhC5a-induced CD11b expression on human neutrophils: CD11b expression on neutrophils was assessed by flow cytometer analysis and was up-regulated by recombinant human C5a. vilobelimab was capable of strikingly reducing the CD-11b upregulation on neutrophils.

Vilobelimab leaves MAC formation intact in human whole blood

Vilobelimab was added to plasma samples from healthy human individuals (voluntary blood donors) and tested for potential disturbance of the ability of intact human plasma to generate MAC formation. This is assessed with the CH50 assay. In this test, intact MAC formation leads to the lysis of red blood cells, which is also referred to as the hemolytic activity and which is assessed indirectly by optical measurement of hemoglobin in the sample being released from lysed red blood cells. When vilobelimab was added to this test, the hemolytic activity curves from plasma alone and plasma plus vilobelimab were substantially similar, indicating that vilobelimab in the dose range of zero to 50 µg/mL had no influence on C5 cleavage and MAC formation (C5b-9).



vilobelimab does not influence the hemolytic activity curves in intact human plasma and therefore leaves C5 cleavage and formation of C5b-9 (MAC) intact. Hemolytic activity is assessed with the optical density (OD)

IFX-2 as follow-on anti-C5a monoclonal antibody

To expand the breadth of our anti-C5a technology, we are developing IFX-2, a follow-on anti-C5a monoclonal antibody for the treatment of chronic inflammatory applications. IFX-2 shares the same mechanism of action as vilobelimab in its potential to block C5a with high specificity but is designed with a dosing regimen that may be more suitable for chronic therapy. We are optimizing IFX-2 to provide a prolonged half-life and potentially to be administered subcutaneously or intravenously. IFX-2 will keep the performance relevant properties to fully block C5a-induced biological effects while leaving MAC formation intact. We believe that IFX-2 holds the potential to treat various chronic inflammatory diseases that may be T-cell driven and could benefit from a dosing regimen more suitable for chronic therapy. IFX-2 is in pre-clinical development.

Intellectual property

We aim to protect our product candidates and other commercially important proprietary anti-C5a technology 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. 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 “Risk factors—Risks related to intellectual property” for additional information.

As of December 31, 2020, we owned three issued U.S. patents, five pending U.S. non-provisional patent applications, 14 issued foreign patents, one Eurasian Patent validated in 9 countries, as well as one European patent validated in 37 countries, 32 pending foreign patent applications and two pending applications filed under the Patent Cooperation Treaty (PCT). These patents include claims relating to C5a inhibitors and associated methods of use.

Our patent portfolio relating to vilobelimab and IFX-2, as of December 31, 2020, is summarized below.

As of December 31, 2020, 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 15 issued foreign patents, six pending foreign patent applications one pending European patent application, one Eurasian Patent validated in nine countries, as well as two European patents validated in 74 countries 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 patent applications would be expected to expire in 2030, excluding any additional term for patent term adjustments or patent term extensions.

As of December 31, 2020, we owned two granted U.S. patents covering the use of certain binding moieties, such as antibodies, that inhibit C5a for the treatment of viral pneumonia. In addition, we owned one issued foreign patent, two pending foreign patent applications, as well as one European patent validated in 3 countries covering the use of certain binding moieties, such as antibodies, that inhibit C5a for the treatment of viral pneumonia. If issued, U.S. and foreign patents are expected to expire in 2035, excluding any additional term for patent term adjustments or patent term extensions.

As of December 31, 2020, we owned one granted US patent, three pending U.S. non-provisional patent applications, two granted foreign patent applications, 28 pending foreign patent applications, and one pending European patent application 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, 2020, we owned one pending U.S. non-provisional patent application and one patent application under the PCT covering inhibitors of C5aR.

As of December 31, 2020, we owned one European application covering an improved C5a specific antibody.

As of December 31, 2020, we owned one pending application under the PCT covering the use of inhibitor of C5a activity, for example vilobelimab, for treating Corona viral diseases.

Collaboration agreements

On December 28, 2015, we entered into a co-development agreement with Beijing Defengrei Biotechnology Co. Ltd., or BDB, ("Co-Development Agreement") for the use of the vilobelimab 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-1 and BDB-2, as well as molecules that bind or interact with certain specified targets ("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-1 or BDB-2. We retain the right to develop and manufacture vilobelimab and IFX-2 in China solely for the purpose of commercializing products outside of China and to use the vilobelimab cell line and IFX-2 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 IFX-2 for an indication, and BDB does not pursue regulatory approval for BDB-1 or BDB-2 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-1. BDB-1 may only be commercialized in China (PRC) by BDB, and InflaRx is not directly involved in the BDB-1 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-1. To support BDB's development of BDB-1, in 2020, InflaRx allowed BDB to conduct clinical studies with BDB-1 in Spain, India, Indonesia and Bangladesh. However, InflaRx remains the sole owner of all commercial rights to BDB-1 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-1 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-1.

In addition, we reserve the right to commercialize products containing BDB-1 and BDB-2 outside of China in indications for which we elect not to commercialize vilobelimab or IFX-2. 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.

The agreement continues 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. Moreover, we may terminate the agreement if BDB has not established a GMP standard manufacturing process or initiated any approved toxicology program by 2020.

On March 20, 2020, we entered into a clinical trial collaboration and supply agreement with Merck (known as MSD outside the US and Canada) to evaluate the combination of vilobelimab and Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in patients with cSCC. Under the terms of the agreement, we will conduct a Phase IIa clinical study with two vilobelimab arms including one with KEYTRUDA®[2]. The first patient is expected to be dosed in the first half of 2021.

Sales and marketing

Subject to receiving marketing approval, we intend to independently pursue the commercialization of vilobelimab for HS in the United States and Europe, when approved by the applicable regulators, by employing a targeted commercial infrastructure to promote access to vilobelimab through centers-of-excellence that treat HS 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

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

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 HS and any other relevant fields of medicine.

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 third-party contract manufacturers to produce our products and intend to recruit 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 expect to engage third-party manufacturers in the United States for sales of any of our approved products in the United States. We hold the manufacturer and importing license and participate in the drug product release procedure by running a key immunological release assay in-house, allowing us to release only antibody batches that demonstrate 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 biotechnologies, 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.

The only approved product to treat HS in the United States and Europe is adalimumab (Humira), an inhibitor of TNF-alpha. Humira is marketed by AbbVie Inc. (AbbVie). A number of additional companies are developing product candidates to treat HS with varying mechanisms of action. These companies include Novartis AG, UCB Pharma GmbH (UCB), Janssen Research and Development LLC (Janssen), Incyte Corporate, ChemoCentryx Inc (ChemoCentryx), Eli Lilly and Company (Eli Lilly) and Pfizer Inc. (Pfizer).

Janssen has initiated a randomized, double-blind, placebo-controlled Phase II clinical study evaluating bermekimab, a monoclonal antibody targeting interleukin-1 alpha, in patients with moderate to severe HS. The multi-center, international study will enroll approximately 144 patients into three groups: two bermekimab dosing regimens versus a placebo arm over 16 weeks of therapy. The study's primary endpoint is the percentage of subjects achieving HiSCR at week 12 (secondary endpoint is HiSCR at week 16). Janssen previously completed a multicenter, open-label Phase II clinical trial for a subcutaneously administered bermekimab in HS. The rights to bermekimab were acquired by Janssen Biotech in 2019. Results of the study demonstrated that weekly treatment with bermekimab was associated with statistically significant improvement in HS, using HiSCR. In the study, 61% of patients with no prior biological therapy achieved positive HiSCR at 12 weeks, while 63% of patients who had failed previous biological therapy also achieved a positive HiSCR. An earlier single-center placebo-controlled trial as an intravenous formulation demonstrated significant improvement in the treatment arm as well (involving ten placebo and ten patients on therapy who previously failed to respond to adalimumab with the same compound). In 2016, Novartis completed a Phase II clinical trial for CJM112, a monoclonal antibody targeting interleukin-17 alpha, in moderate to severe HS patients. A limited amount of data presented within a conference poster presentation suggested certain benefits. Novartis has since launched a large Phase III clinical development program involving the marketed anti-IL17A monoclonal antibody, secukinumab, to be studied in two Phase III trials with a goal of enrolling over 900 patients combined. This compound has not recently been studied by Novartis in HS before, but 2 smaller investigator-initiated trials have recently been completed as detailed in the paragraph below. Also, Novartis has initiated a Phase II clinical study in moderate to severe HS with iscalimab, an Anti-Cd40 monoclonal antibody and LYS006 a small molecule, in 90 patients including two

active and two placebo arms. The primary endpoint for each investigational drug is the proportion of patients achieving a HiSCR after 16 weeks of treatment. In addition, UCB Pharma has completed a Phase II clinical trial in moderate to severe HS patients for bimekizumab, a monoclonal antibody blocking interleukin-17AF. The study enrolled 157 patients that received bimekizumab for 12 weeks and were evaluated using the HiSCR as the primary endpoint. The study results have not been published. UCB has initiated two Phase III studies with 490 patients per study. Patients will be enrolled in either 3 dosing arms or placebo with the primary endpoint of HiSCR at Week 16. According to UCB at the JP Morgan Conference in January 2021, topline data will be available in the first half of 2023. Janssen Research and Development has initiated a Phase II study with guselkumab, a monoclonal antibody targeting IL-23 targeting enrollment of 184 patients evaluating the proportion of patients achieving a HiSCR at week 16. In 2020, ChemoCentryx, Inc. has completed a 398 patient, Phase II study in moderate to severe HS in two doses of CCX168, a C5aR inhibitor, using the primary endpoint as the proportion of subjects a HiSCR at Week 12. The study failed to achieve statistical significance on the primary endpoint. In the lower dose of 10mg BID, 40/130 (30.8%) achieved a HiSCR response and in the higher dose group of 30mg BID 47/134 (35.1%) compared to placebo response of 40/130 (30.8%). ChemoCentryx is planning on continuing the program into a Phase III in a smaller subset of patients, the Hurley Stage 3 group. Incyte Corporation has completed a Phase IIa open label study and a Phase II dose-escalation, placebo-controlled study for INCB 54707. The Phase II clinical study is a 35 patient, dose escalating, placebo-controlled study aimed at evaluating the safety of INCB 54707 over an 8-week treatment period in patients with moderate to severe HS. The primary endpoint is the number of treatment emergent adverse events at week 8, with a secondary endpoint using the proportion of patients achieving a HiSCR up to week 16. By week 3, 33%, 56% and 50% of the 30 mg, 60 mg and 90 mg INCB054707 dose groups had AN count of 0 to 2 vs none in the placebo group. However, by week 8, there was no difference between placebo and the active treatment groups in AN count. Still, Incyte has decided to initiate a 200 patient Phase II trial with INCB 54707 using a primary endpoint of mean change from baseline in total AN count by week 16, with a secondary endpoint of HiSCR at week 16. This trial is currently recruiting. AbbVie has also initiated a Phase II, 190 patient study to evaluate the safety and efficacy of 2 dose levels of risankizumab in HS. The primary endpoint will be evaluated at 16 weeks using the HiSCR. In addition, AbbVie has initiated a Phase II, 60 patient study to investigate upadacitinib, a Janus kinase inhibitor, in HS using HiSCR at 12 weeks as the primary endpoint. The trial is currently ongoing. Eli Lily has recently initiated a 52 patient Phase II trial with LY3041658, an antagonist of CXCR1 and CXCR2, using HiSCR at week 16 as the primary endpoint. The trial is currently ongoing. Pfizer has also initiated a 192 patient Phase II study with 3 kinase inhibitors (PF 06650833, PF 06700841 and PF 06826647) in participants with moderate to severe HS. The primary endpoint is HiSCR at week 16.

Additionally, several investigator-initiated trials have been conducted or are in progress in HS:

- An open-label single center trial in the US enrolling 18 out of originally planned 21 patients with moderate to severe HS has recently been concluded with Secukinumab, a monoclonal antibody blocking interleukin-17A and initial conference reports suggested improvement of the HiSCR at last observation carried forward.

- Another open-label trial with Secukinumab enrolling 17 HS patients at a center in France has recently been conducted and reported first results during the European HS foundation meeting in February 2019, suggesting that 13 patients showed a HiSCR response at 4 months of treatment. In this study, two patients developed Crohn´s disease on month four of treatment which remained active after an immediate treatment stop throughout the 14 months trial period. Induction of Crohn´s disease is a known side effect of secukinumab and Crohn´s disease has been reported to be associated with HS disease.

- An open-label trial for Janssen's ustekinumab was recently completed in 12 HS patients. Ustekinumab is a monoclonal antibody directed against IL12 and IL23.

- A small placebo-controlled Phase II study for Swedish Orphan Biovitrum AB's anakinra, as well as an open-label single-center trial in six patients, were completed in HS patients suggesting potential efficacy in a modified intent-to-treat population. Anakinra is an IL-1 receptor antagonist.

- An open-label single center 20 patient study at the Florida Academic Dermatology Centers, sponsored by Ortho Dermatologics (Bausch Health) to evaluate the efficacy of SILIQ™ (brodalumab) for the treatment of moderate HS using the HiSCR for a period of 24 weeks of treatment, followed by an observational four-week post treatment visit.

Finally, a range of surgical procedures, topically applied medicinal products, laser and radiotherapy procedures are being investigated for the treatment of HS.

If approved for treatment of severe COVID-19 patients, vilobelimab would face competition from currently used therapeutics such as corticosteroids, interleukin IL-1, IL-6 inhibitors and anti-thrombotic therapy. Given the nature of the pandemic, many different therapeutic targets are being developed which may be or become relevant competition with vilobelimab, however the most direct competition may come from other therapies targeting the complement system. Other treatments currently under investigation for severe COVID-19 which target the complement system include:

- A Phase III open-label, randomized, controlled study to evaluate the efficacy and safety of intravenously administered ravulizumab compared with best supportive care in patients with COVID-19 severe pneumonia, acute lung injury, or acute respiratory distress syndrome by Alexion Pharmaceuticals. This study has currently been paused.

- A Phase II trial evaluating efficacy and safety of eculizumab (Soliris) in patients with COVID-19 infection, nested in the CORIMUNO-19 cohort by Alexion Pharmaceuticals. Alexion has not initiated additional studies after the data has been published.

- An investigator initiated, double-blind, randomized study versus placebo of avdoralimab (IPH5401), an anti-C5aR antibody, in patients with COVID-19 severe pneumonia by Innate Pharma

- A Phase II Randomized, Double-Blinded, Vehicle-Controlled, Multicenter, Parallel-Group Study of APL-9 in Mild to Moderate Acute Respiratory Distress Syndrome Due to COVID-19 by Apellis Pharmaceuticals, Inc

- A Phase II clinical Trial to Assess the Safety and Efficacy of Complement 3 Inhibitor, AMY-101, in Patients with Acute Respiratory Distress Syndrome Due to COVID-19 (SAVE) by Amyndas Pharmaceuticals S.A.

If approved for the treatment of AAV, vilobelimab would potentially face competition from currently used therapies, including corticosteroids, azathioprine, methotrexate, mycophenolate mofetil and rituximab. The current standard of care to induce remission in acutely ill AAV patients is a combination of either rituximab or azathioprine with high dose corticosteroids. Rituximab is approved and marketed by Genentech for this indication and label extension studies are ongoing. In addition, biosimilars of Ritximab are approved and marketed in Europe. Therapies to maintain remission include low dose corticosteroids, methotrexate, mycophenolate mofetil and rituximab. Nucala (mepolizumab), marketed by GlaxoSmithKline plc, is also FDA approved to treat a type of AAV in adults called eosinophilic granulomatosis with polyangiitis (EGPA).

We are not aware of any C5 or C5a inhibitors under clinical development for the treatment of AAV, except, ChemoCentryx's avacopan, a C5aR inhibitor. Though it acts through a different mecha-

nism of action than vilobelimab, avacopan has demonstrated the potential to induce and maintain remission in AAV patients in a Phase III clinical trial. This global study enrolled a total of 331 patients with acute ANCA vasculitis met both of its primary endpoints, disease remission at 26 weeks and sustained remission at 52 weeks, which was assessed by the Birmingham Vasculitis Activity Score, or BVAS. Remission was defined as a BVAS score of zero and being off glucocorticoid treatment for at least the preceding four weeks. The pre-specified primary endpoints were remission of acute vasculitis activity at week 26 and sustained remission at week 52, where avacopan was statistically non-inferior to glucocorticoid-containing standard of care. BVAS remission was achieved at week 26 in 72.3% of the avacopan treated subjects versus 70.1% of subjects in the glucocorticoid control group ($p<0.0001$ for non-inferiority). Sustained remission at 52 weeks was observed in 65.7% of the avacopan treated patients versus 54.9% in the glucocorticoid control group ($p=0.0066$ for superiority of avacopan). Avacopan treatment also resulted in additional benefits for patients when compared to the glucocorticoid control group such as significant reduction in glucocorticoid-related toxicity, significant improvement in kidney function in patients with renal disease as measured by the glomerular filtration rate at weeks 26 and 52 (statistically significant improvements at both time points), significant improvement in health-related quality of life measures such as the validated quality of life instrument SF-36 at and the EuroQOL-5D-5L instrument (for both at weeks 26 and 52). A completed Phase II trial for avacopan was designed to assess whether high dose chronic steroids used as the standard for induction of remission in severe AAV flares could be reduced or eliminated, without compromising efficacy, by replacement with avacopan. The trial met its primary clinical endpoint, which was based on the Birmingham Vasculitis Score 3, or BVAS 3 at week 12 in patients receiving avacopan treatment, compared to the response of patients receiving the standard of care treatment. ChemoCentryx has filed the NDA for avacopan and the FDA accepted the NDA filing, setting a PDUFA goal date for July 7, 2021. We are encouraged by the published outcome data for avacopan that validates the role of the C5a/C5aR signaling axis in AAV patients and provides evidence that inhibition of the C5a pathway may be beneficial in treatment of AAV.

An additional therapy for AAV in development includes an ongoing investigator-initiated trial, Abatacept, a selective T-cell costimulation modulator from Bristol-Meyers Squibb, being investigated for efficacy to achieve sustained corticosteroid-free remission in a subset of AAV patients with severe GPA. Abatacept is approved in the United States for treatment moderate to severe rheumatoid arthritis. In a large investigator-initiated clinical trial, the efficacy of a plasma exchange procedure has recently been tested in conjunction with corticosteroid treatment with respect to its impact on all-cause mortality and end-stage renal disease but did not reveal an outcome benefit for this treatment. Recently, AstraZeneca initiated a 140 patient, Phase III study with benralizumab, a monoclonal antibody targeting interleukin-5 and interleukin-5R in a type of AAV, eosinophilic granulomatosis with polyangiitis.

If approved for the treatment of PG, vilobelimab would potentially face competition from currently used therapies, such as glucocorticoids, cyclosporin or other immunosuppressive therapies. We are also not aware of any other company currently developing a drug in PG for the US or European market. However, Janssen's Remicade (infliximab) has been used several clinical studies in PG. The largest placebo-controlled trial (13 patients received infliximab and 17 patients received placebo) was published in 2005 showing benefit in PG, but no formal clinical development has continued. Janssen completed a Phase II clinical study in 10 patients using bermekimab in 2016 but has not announced any further plans to continue development. In 2015, Novartis completed an 8-patient open label proof of concept study in 2015 with gevokizumab. Novartis has not announced any plans to continue the program in PG. Outside the US and EU in Japan, AbbVie received approval in November 2020 with Humira (adalimumab) from a Phase III open label study with 22 Japanese patients with active ulcers.

There have been previously completed investigator studies in PG along with ongoing studies as stated below:

- The Technical University of Munich has an ongoing Phase II, single arm study in 5 patients with secukinumab (using the PGA five-point scale at week 16 compared to week 0 as the primary endpoint).

- The Ohio State University completed a 5 patient, Phase II open label study with ixekizumab in 2018
- The University of Zurich in 2015 completed an open label study evaluating canakinumab (Ilaris) for treatment of subjects with PG.
- Wake Forest University has currently initiated 6 patient exploratory study with Secukinumab in PG. This trial is currently recruiting.

If approved in PD-1/PD-L1 inhibitor resistant/refractory locally advanced or metastatic Cutaneous Squamous Cell Carcinoma (cSCC), vilobelimab would face competition from currently used therapeutics such as epidermal growth factor inhibitors, cisplatin and 5-fluorouracil (5-FU). PD-1/PD-L1 inhibitors are FDA approved to treat locally advanced or metastatic cSCC. Pembrolizumab (KEYTRUDA®) from Merck & Co is indicated for recurrent or metastatic cSCC that is not curable by surgery or radiation. Cemiplimab-rwlc (LIBTAYO®) from Regeneron is indicated for metastatic cSCC or locally advanced cSCC for those that are not candidates for curative surgery or radiation. Other treatments currently under investigation include for advanced or metastatic cSCC:

- A Phase II study of cetuximab as monotherapy and first line treatment in patients with locally advanced or metastatic squamous cell carcinoma of the skin expressing EGFR by the Centre Hospitalier of Chartres.
- A Phase II randomized trial of avelumab plus cetuximab versus avelumab alone in advanced cSCC by the Alliance for Clinical Trials in Oncology.
- A Phase II, open-label, single-arm, multi-cohort, proof-of-principle study to investigate the efficacy of cobimetinib and atezolizumab in advanced rare tumors including metastatic cSCC by the MD Anderson Cancer Center.
- A Phase II study of nivolumab in patients with locally advanced/ metastatic squamous cell carcinoma of the skin by Salzburger Landeskliniken and Bristol-Myers Squibb.
- A Phase I study of panitumumab (anti-EGFR) and talimogene laherparepvec (a gene-modified virus that may help the body build an effective immune response to kill tumor cells by the National Cancer Institute.
- A Phase I/Ib study of lenvatinib and cetuximab in patients with recurrent/metastatic head and neck squamous cell carcinoma and cutaneous squamous cell carcinoma by Memorial Sloan Kettering Cancer Center.
- A multicenter open-label Phase 1/1b study to evaluate the safety and preliminary efficacy of SO-C101 as monotherapy and in combination with pembrolizumab in patients with selected advanced/metastatic solid tumors including cSCC by Sotio a.s.
- An open-label, investigational study using ASP-1929 photoimmunotherapy in combination with cetuximab anti-PD1 therapy in EGFR expressing advanced solid tumors by Rakuten Medical, Inc.
- A first-in-human study of CDK-002 (exoSTING and innate immune response activator) in subjects with advanced/metastatic, recurrent, injectable solid tumors, with emphasis on squamous cell carcinoma of the head and neck, triple negative breast cancer, anaplastic thyroid carcinoma, and cutaneous squamous cell carcinoma by Codiak BioSciences.

However, we do not yet have FDA approval for PD-1/PD-L1 inhibitor resistant/refractory locally advanced or metastatic cSCC.

More generally, in the terminal complement space, there are currently two approved drugs, Eculizumab (Soliris) and Ravulizumab (Ultomiris), marketed by Alexion Pharmaceuticals, Inc. for the treatment of PNH and typical hemolytic uremic syndrome, or aHUS. However, there are several other companies developing C5 inhibitors for other indications, including Hoffmanm-La Roche AG together in collaborations with Chugai Pharmaceutical Co., Ltd, UCB, Akari Therapeutics Plc, Iveric Bio, Alnylam Pharmaceuticals, Inc., Regeneron Pharmaceuticals, Inc. and Novartis. In addition, Alexion is known to have had a C5a inhibitor under development for graft versus host disease. Clinical stage companies focusing on the inhibition of the C5a receptor C5aR include ChemoCentryx as mentioned above, with its product candidate avacopan, as well as Innate Pharma S.A., with the in-licensed antibody IPH5401, which had recently been developed in collaboration with Astra Zeneca within the oncology field, and I-Mab Biopharma in collaboration with MorphoSys AG that has an ongoing Phase I in patients with relapsed or refractory advanced solid tumors. In addition, there are clinical stage companies targeting complement inhibition upstream from C5, such as C3, factor D and components of the lectin pathway. These approaches will likely also result in a lowering of C5a generation in blood. Companies in this area include Apellis Pharmaceuticals, Inc., Alexion Pharmaceuticals Inc. and Omeros Corporation. Furthermore, there are numerous additional companies developing pre-clinical drug candidates which target terminal complement factors and their receptors.

The key competitive factors affecting the success of our product candidates, if approved, are likely to be their efficacy, safety, dosing convenience, price and degree of market acceptance, as well as our 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 chapter 2.2 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 will 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.

International conference on harmonization (ICH)

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, or the ICH, is a project that brings together the regulatory authorities

of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of pharmaceutical product registration. The purpose of ICH is to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines by recommending ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration. Harmonization would lead to a more economical use of human, animal and material resources, the elimination of unnecessary delay in the global development and availability of new medicines while maintaining safeguards on quality, safety, efficacy and regulatory obligations to protect public health.

ICH guidelines have been adopted as law in several countries but are only used as guidance for the FDA. Nevertheless, in many areas of drug regulation ICH has resulted in comparable requirements, for instance with respect to the Common Technical Document, or the CTD, which has become the core document for filings for market authorization in several jurisdictions. Thus, ICH has facilitated a more efficient path to markets.

FDA approval process

All of our current product candidates are subject to regulation in the United States by the FDA as biological products, or biologics. The FDA subjects biologics to extensive pre- and post-market regulation. The Public Health Service Act (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. 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, 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.

The process required by the FDA before a new biologic may be marketed in the United States is long, expensive, and inherently uncertain. Biologics 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 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 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, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (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 for marketing approval are typically conducted in three sequential phases, but the phases may overlap or be combined. In Phase I, the biologic is initially introduced into healthy human subjects or patients and is tested to assess PK, 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 may be conducted in the intended patient population. Phase II usually involves trials in a limited patient population to determine the effectiveness of the biologic for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to obtain additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites. These Phase III 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 and to provide adequate information for the labeling of the biologic. Trials conducted outside of the US 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 is prepared and submitted to the FDA. FDA review and approval of the BLA is required before marketing of the product may begin in the United States. The BLA 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 must also contain extensive manufacturing information. The cost of preparing and submitting a BLA is substantial. Under federal law, the submission of most BLAs 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 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. Most such applications for standard review biologics 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 biologics, or biologics 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 generally follows such recommendations. Before approving a BLA, 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 biologic is manufactured. The FDA will not approve the product unless it verifies that compliance with cGMP standards is satisfactory and the BLA contains data that provide substantial evidence that the biologic is safe and effective in the indication studied.

After the FDA evaluates the BLA 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, 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 if applicable regulatory criteria are not satisfied.

Under the PHSA, the FDA may approve a BLA 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 biologic with specific prescribing information for specific indications. The approval for a biologic 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 approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the biologic 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 biologic can materially affect the potential market and profitability of the biologic. Moreover, product approval may require, as a condition of approval, substantial post-approval testing and surveillance to monitor the biologic'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 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 biological products. After approval of biologics, manufacturers must address any

safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection.

Fast track

The Fast Track program, a provision of the FDA Modernization Act of 1997, is designed to facilitate interactions between a sponsoring company and the FDA before and during submission of a BLA for an investigational agent that, alone or in combination with one or more other drugs, is intended to treat a serious or life-threatening disease or condition, and which demonstrates the potential to address an unmet medical need for that disease or condition. Under the Fast Track program, the FDA may consider reviewing portions of a marketing application before the sponsor submits the complete application if the FDA determines, after a preliminary evaluation of the clinical data, that a fast track product may be effective. A Fast Track designation provides the opportunity for more frequent interactions with the FDA, and a fast track product could be eligible for priority review if supported by clinical data at the time of submission of the BLA.

Biosimilars

The Patient Protection and Affordable Care Act, which we refer to as the Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009. That Act created an approval pathway authorizing the FDA to approve biosimilars and interchangeable biosimilars. Biosimilars are biological products which are "highly similar" to a previously approved biologic product or "reference product" and for which there are no clinically meaningful differences between the biosimilar product and the reference product in terms of safety, purity, and potency. For FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biosimilar and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation which are still being worked out by the FDA.

A reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product. A biosimilar application may be filed four years after the approval of the reference biologic. Although the patents for the reference biologic may be challenged by an applicant seeking approval of a biosimilar or interchangeable product after submission of its application but before FDA approval pursuant to the BPCIA statutory patent challenge framework, no biosimilar or interchangeable product will be licensed by the FDA until the end of the exclusivity period.

Accelerated approval pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, 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. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a

therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase IV or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Advertising and promotion

Once a BLA is approved, a product will be subject to continuing post-approval regulatory requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Failure to comply with these regulations can result in significant penalties, including the issuance of warning letters directing a company to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and federal and state civil and criminal investigations and prosecutions.

Biologics may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling or manufacturing processes or facilities, require submission and FDA approval of a new BLA or BLA supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs.

Adverse event reporting and cGMP compliance

Adverse event reporting and submission of periodic reports are required following FDA approval of a BLA. The FDA also may require post-marketing testing, known as Phase IV 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. Biologics 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

Under the Orphan Drug Act, the FDA may grant orphan drug designation to biologics intended to treat a rare disease or condition—generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the biologic 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 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 biologic for the same disease or condition, or the same biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee.

Special Protocol Assessment process

A Special Protocol Assessment or *SPA* is a process in which Companies may ask to meet with FDA to reach agreement on the design and size of certain clinical trials, clinical studies, or animal studies ("a Request for SPA" or "Request") to determine if they adequately address scientific and regulatory requirements for a study that could support marketing approval. An SPA agreement indicates concurrence by FDA with the adequacy and acceptability of specific critical elements of overall protocol design (e.g., entry criteria, dose selection, endpoints, and planned analyses) for a study intended to support a future marketing application. These elements are critical to ensuring that the trial conducted under the protocol can be considered an adequate and well-controlled study that can support marketing approval. Feedback on these issues provides the benefit of certainty of adequacy in planning a late-phase development strategy. However, an SPA agreement does not indicate FDA's concurrence on every protocol detail. The existence of an SPA agreement does not guarantee that FDA will file (accept) a BLA or that the results will be adequate to support approval.

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 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 EU 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 (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 Marketing Authorization Application or 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 current Good Manufacturing Practices;
- 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

Pursuant to the Clinical Trials Directive 2001/20/EC, as amended, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, approval must be obtained from the competent national authority of each EU member state in which a study is planned to be conducted. To this end, a CTA is submitted, which must be supported by an investigational medicinal product dossier, or IMPD, and further supporting information prescribed by the Clinical Trials Directive and other applicable guidance documents including, but not limited to, the study protocol. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application in that country. In Germany, CTA is often not granted until after one or more rounds of questions to be answered or requests to be met by the regulatory authority.

Directive 2001/20/EC will be replaced by Regulation (EU) No 536/2014, which became effective on June 16, 2014. The timing of its first application depends, however, on a fully functional EU clinical trials portal and database. The Regulation becomes applicable six months after the European Commission publishes a notice of confirmation that the required functionality is in place. The entry into application of the Regulation is currently estimated to occur in 2019. The Regulation introduces an authorization procedure based on a single submission via a single EU portal, an assessment procedure

leading to a single decision, as well as transparency requirements (the proactive publication of clinical trial data in the EU database). Since October 2016, based on its Policy 0070, the EMA has been publishing clinical data submitted by pharmaceutical companies to support their MAA for human medicines under this centralized procedure.

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 current Good Manufacturing Practices.

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 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 European Commission, which is automatically valid in all EU member states. The other European Economic Area member states (namely Norway, Iceland and Liechtenstein) are also obligated to recognize the Commission decision. The EMA and the European Commission 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 if 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 European Commission, 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.

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.

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 intend to apply for orphan status for the HS indication in the United States for vilobelimab. Depending on the outcome and available data of vilobelimab studies in the AAV indication, we may apply for orphan drug status in the United States as well as in Europe.

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.

International regulation

In addition to regulations in the United States and Europe, a variety of foreign regulations govern clinical trials, commercial sales, and distribution of product candidates. The approval process varies from country to country and the time to approval may be longer or shorter than that required for FDA or European Commission 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 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 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 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 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 product candidates 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 product candidates or products to other available therapies. The conduct of such a clinical trial 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 candidate to currently available therapies. European Union member states may also require approval of a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other 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 entry of new 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.

3.3 Organizational structure

InflaRx N.V. has two direct wholly-owned subsidiaries, InflaRx GmbH and InflaRx Pharmaceuticals, Inc. We primarily operate our business out of our operating subsidiary InflaRx GmbH.

3.4 Property and equipment

Our headquarters are in Jena, Germany, where we occupy approximately 8,000 square feet of office and laboratory space under an extendable lease that expires in December 2022. In addition, we occupy approximately 13,700 square feet of office space in Munich, Germany under a lease that expires in May 2022. Furthermore, we have leased office and laboratory space in Ann Arbor, United States under an extendable lease that expires in April 2021.

3.5 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.

4 OPERATING AND FINANCIAL REVIEW AND PROSPECTS

4.1 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 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 "2.2 Risk factors" and "1.2 Forward-Looking Statements."

Overview

We are a clinical-stage biopharmaceutical company focused on applying our proprietary anti-C5a technology to discover and develop first-in-class, potent and specific inhibitors of the complement activation factor known as C5a. 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.

We have been developing vilobelimab for the treatment of HS, a chronic debilitating systemic inflammatory skin disease. In June 2019, we announced that our Phase IIb clinical trial of vilobelimab in HS did not meet its primary endpoint. We subsequently announced the results of additional analysis and first interim results of the open label extension trial. In light of all available data from the completed Shine study, the Company continues to consider options with respect to the development of vilobelimab for HS, including seeking to engage regulatory authorities in connection with pursuing further clinical trials in HS. We intend to develop vilobelimab and other proprietary antibodies and molecules, and evaluate other technologies as well, to address a wide array of complement-mediated and other diseases with significant unmet needs, including severe COVID-19, AAV, a rare, life-threatening autoimmune disease, PG, a rare inflammatory skin disorder and cSCC and potentially other indications and diseases. Since our inception in December 2007, we have devoted substantially all of our resources to establishing our company, raising capital, developing our proprietary anti-C5a technology, identifying and testing potential product candidates and conducting clinical trials of our lead product candidate, vilobelimab. To date, we have not generated any product revenue and have financed our operations primarily through public offerings, the private placement of our securities and other income from various grants. As of December 31, 2020, we had raised an aggregate of approximately €215.9 million, comprised of €49.2 million in net proceeds from a follow-on public offering in May 2018, €81.8 million in net proceeds from our initial public offering, €74.0 million in gross proceeds from private placements of our securities, €9.0 million in net proceeds from an at-the-market program and €1.9 million in payments in connection with various grants.

On July 8, 2020, the Company filed with the United States Securities and Exchange Commission (SEC) a Form F-3 registration statement with respect to the offer and sale of securities of the Company (Shelf Registration Statement). The Company also filed with the SEC a prospectus supplement (Prospectus Supplement) relating to an at-the-market program providing for the sales of our stock over time of up to $50.0 million of its common shares pursuant to a Sales Agreement with SVB Leerink LLC. As of December 31, 2020, the Company had issued 1,958,186 common shares through this program, resulting in €9.0 million in net proceeds to the Company. Following these issuances, the remaining value authorized for sale under the at-the-market program is $38.8 million. As of December 31, 2020, we had cash and cash equivalents of €26.0 million and €46.7 million in marketable securities.

As of December 31, 2020, we had an accumulated deficit of €168.3 million. We have incurred significant net operating losses in every year since our inception and expect to continue to incur increasing net operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses may increase significantly if, and as we

- evaluate any additional clinical development of vilobelimab in HS;
- continue to advance vilobelimab through clinical development for additional indications, including severe COVID-19, AAV, PG and cSCC;
- initiate and continue research programs and development activities, including development of IFX-2;
- actively seek to identify additional research programs and additional product candidates;
- maintain, expand and protect our intellectual property portfolio;
- hire and retain personnel, such as for business development and others; and
- incur additional costs with operating as a public company, including expanding our operational, finance and management teams.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for a product candidate, which we expect will take a number of years and is subject to significant uncertainty. If we obtain regulatory approval for any product candidate, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we may seek to further fund our operations through public or private equity or debt financings or other sources, including strategic collaborations. We may, however, be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed, could have a negative impact on our financial condition and our ability to develop vilobelimab or any additional product candidates.

Financial operations overview

Revenue

To date, we have not generated any revenue and do not expect to do so in the near future. We expect that our revenue will be less than our expenses for the foreseeable future and that we will experience increasing losses as we continue our development of, and seek regulatory approvals for, vilobelimab and any other product candidates and, if approved, begin to commercialize any approved products. Our ability to generate revenue for each product candidate for which we receive regulatory approval will depend on numerous factors, including level of competition, availability of reimbursement from payers, commercial manufacturing capability, market acceptance and approved use by regulators.

Other income

We have historically earned other income through several grants from the German government, the European Union and other educational institutions on behalf of the German government, primarily with respect to research and development activities related to the development of vilobelimab and IFX-2. These grants generally provide for reimbursement of approved costs incurred as defined in the respective grants. Income in respect of grants also includes contributions towards the costs of research and development. Income is recognized when costs under each grant are incurred in accordance with the terms and conditions of the grant and the collectability of the receivable is reasonably assured. We recognized €0.2 million of other income from grants in 2020, €0.4 million in 2019 and €0.2 million in 2018 respectively.

Research and development expenses

Research and development expenses have consisted principally of:

- expenses incurred under agreements with contract research organizations, or CROs, contract manufacturing organizations, or CMOs, 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.

Our total research and development expenses in 2020 were lower compared to our expenses in 2019 and 2018 but costs might increase again in 2021 as we initiate the Phase III development of vilobelimab in HS and in other indications. Research and development expenses in 2020 primarily relate to the following key programs:

- **Vilobelimab.** We expect our expenses associated with vilobelimab will increase in 2021 if and once we initiate the Phase III development of vilobelimab in patients with HS, conduct our Phase II clinical program of vilobelimab in patients with AAV and continue our Phase II clinical trial program in patients with PG as well as our currently running Phase III program in severe COVID-19 and initiate our Phase II program in cSCC. We anticipate that our research and development expenses will increase substantially in connection with the commencement of these and any additional clinical trials. In addition, we are also incurring expenses related to the manufacturing of clinical trial material and investigating commercial scale production options.

- ***IFX-2.*** We are continuing preclinical development of IFX-2, expenses for which mainly consist of salaries, costs for preclinical testing conducted by CROs and costs for the production of preclinical material.

- ***Other development programs.*** Our other research and development expenses relate to our preclinical studies of other product candidates and discovery activities, expenses for which mainly consist of salaries, costs for production of preclinical compounds and costs paid to CROs.

In 2020 and 2019, we incurred €25.7 million and €44.6 million of research and development expense, respectively. Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, including due to timing of clinical trial initiation and potential enrollment. Compared to 2020, research and development expenses are expected to increase in 2021 as we advance the clinical development of vilobelimab in several indications and further advance the research and development of our preclinical product candidates.

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 patient enrollment or clinical site activations for services received and efforts expended. Research and development activities are central to our business model. We expect research and development costs to increase significantly for the foreseeable future as our current development programs progress and new programs are added.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from, any of our product candidates. This is due to numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- clinical trials or our product candidates producing negative or inconclusive results, including failure to demonstrate statistical significance;
- the scope, rate of progress, results and cost of our clinical trials, nonclinical testing, and other related activities;
- delays in reaching, or failing to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- the cost of manufacturing clinical supplies and establishing commercial supplies of our product candidates and any products that we may develop;
- third-party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the number and characteristics of product candidates that we pursue;
- undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the cost, timing, and outcomes of regulatory approvals;
- the number of trials required for approval;
- the duration of patient follow-up;
- the cost and timing of establishing sales, marketing, and distribution capabilities; and
- the terms and timing of any collaborative, licensing and other arrangements that we may establish, including any milestone and royalty payments thereunder.

A change in the outcome of any of these variables with respect to the development of vilobelimab, IFX-2 or any other product candidate that we may develop could mean a significant change in the costs and timing associated with the development of such product candidate.

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;

- 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, communication and office expenses.

We expect that our general and administrative expenses will increase in the future as our business expands and we incur additional costs associated with operating as a public company. These public company-related costs relate primarily to additional personnel, additional legal fees, audit fees, directors' and officers' liability insurance premiums and costs associated with investor relations.

Critical judgements and accounting estimates

The preparation of the consolidated financial statements in conformity with IFRS requires management to make judgements, 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 our financial statements, the critical judgements made by management in applying our accounting policies involves the accounting estimates identified in note '2. Risk – (a) Critical estimates and judgements' to our consolidated financial statements included elsewhere in this Annual Report.

New standards and interpretations not yet adopted

The standards, amendments to standards and interpretations that are effective for annual periods beginning after December 31, 2020 and have not been applied in preparing these consolidated financial statements are disclosed in note '4. Other information – (g) Summary of significant accounting policies – 3. New standards and interpretations not yet adopted' to our consolidated financial statements included elsewhere in this Annual Report.

Results of operations

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, 2020 and 2019

	2020	2019	Change
		(in €)	
Research and development expenses	(25,684,140)	(44,582,136)	18,897,996
General and administrative expenses	(8,467,203)	(12,501,048)	4,033,845
Other income and expenses (net)	208,539	315,011	(106,485)
Loss before interest and income taxes	**(33,942,804)**	**(56,768,173)**	**22,825,369**
Net financial result	(40,810)	3,513,355	(3,554,165)
Loss before tax	**(33,983,614)**	**(53,254,817)**	**19,271,203**
Income tax expense	—	—	—
Loss for the period	**(33,983,614)**	**(53,254,817)**	**19,271,203**
Exchange differences on translating operations in foreign currency	(5,954,019)	2,177,033	(8,131,052)
Total comprehensive loss	**(39,937,633)**	**(51,077,785)**	**11,140,152**

Research and development expenses

	2020	2019	Change
		(in €)	
Third-party expenses	19,886,693	36,783,223	(16,896,530)
Personnel expenses	4,480,890	6,231,812	(1,750,922)
Other expenses	1,316,557	1,567,101	(250,544)
Total	**25,684,140**	**44,582,136**	**(18,897,996)**

Research and development expenses decreased by €18.9 million in the year ended December 31, 2020 compared to the year ended December 31, 2019.

This decrease is attributable to lower CRO and CMO costs from clinical trials in the amount of €16.9 million. The conclusion of the Phase IIb for HS in 2019 could not be fully compensated in 2020 by costs associated with the new Phase II/III clinical trial in patients with COVID (2020: €4.9 million, 2019: nil) or other running trials like Phase II clinical program in patients with AAV, the Phase II clinical program in patients with PG, the preparation of a Phase II clinical program in patients cSCC or ongoing manufacturing activities for clinical trial related materials.

In addition there was a €1.8 million decrease in employee-related costs mainly caused by a €2.0 million decrease in expenses from non-cash share-based compensation.

General and administrative expenses

	2020	2019	Change
		(in €)	
Personnel expenses	3,880,349	7,534,073	(3,653,724)
Legal, consulting and audit fees	1,603,711	2,199,640	(595,929)
Other expenses	2,983,144	2,767,335	215,809
Total	**8,467,203**	**12,501,048**	**(4,033,845)**

General and administrative expenses decreased by €4.0 million to €8.5 million for the year ended December 31, 2020, from €12.5 million for the year ended December 31, 2019. This decrease is primarily attributable to a €3.8 million decrease in expenses from non-cash share-based compensation. Legal, consulting and audit fees and other expenses decreased by €0.6 million to €1.6 million for the year ended December 31, 2020, from €2.2 million for the year ended December 31, 2019, which decrease is mainly attributable to lower consulting and travel costs. The increase of other expenses by €0.2 million is primarily related to higher Directors and officers liability insurance cost.

Net financial result

	2020	2019	Change
		(in €)	
Foreign exchange gain	3,491,727	3,379,643	112,084
Interest and other income	887,702	2,840,676	(1,952,974)
Total finance costs	**4,379,429**	**6,220,320**	**(1,840,891)**
Foreign exchange loss	4,268,240	2,684,699	1,583,541
Other finance costs	144,689	22,265	135,189
Total finance costs	**4,420,240**	**2,706,964**	**1,713,276**
Net financial result	**(40,810)**	**3,513,355**	**(3,554,165)**

Net financial result decreased by €3.6 million in the year ended December 31, 2020 compared to the year ended December 31, 2019. This decrease is mainly attributable to (a) higher foreign exchange losses, which increased by €1.6 million and (b) lower interest on marketable securities, which decreased by €2.0 million. Foreign exchange income and expense is mainly derived from the translation of our U.S. dollar dominated cash, cash equivalents and marketable securities held by InflaRx GmbH. These amounts are translated into euros at the exchange rates prevailing on the reporting date. Any resulting translation differences are recognized in profit and loss.

4.2 Liquidity and capital resources

Overview on Cash Requirements and Sources of Liquidity

Since inception, we have incurred significant operating losses due to our R&D activities and G&A costs. For the years ended December 31, 2020 and 2019, we incurred net losses of €34.0 million and €53.3 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 secondary placement of shares. Historically, we have been able to fund our capital needs with cash from financing rounds and placement of shares. In 2020 we have raised €9.0 million in net proceeds from an at-the-market transaction (2019: nil), this program further extends into 2021. Besides our working capital doesn`t have any indebtedness in 2020 (2019 also nil).

Our cash and cash equivalents were €26.0 million as of December 31, 2020 (2019: €33.1 million).We also had marketable securities valued at €55.4 million (2019: €82.6 million) as of December 31, 2020. Our cash and cash equivalents primarily consist of cash and bank deposit accounts. Our marketable securities consist of quoted debt securities issued by financial institutions with investment grade credit ratings (A- to AAA). Our cash is deposited at banks with equally high credit ratings as assed by agencies such as S&P Global.

We expect to finance our operations and working capital needs in the near future from our cash, cash equivalents and marketable securities.

Cash flows - Comparison of the years ended December 31, 2020 and 2019

The table below summarizes our consolidated statement of cash flows for the years ended December 31, 2020 and 2019:

	December 31, 2020	December 31, 2019
	(in €)	(in €)
Net cash used in operating activities	(37,353,608)	(43,204,492)
Net cash from investing activities	22,187,929	20,341,554
Net cash provided by/ (used in) financing activities	9,171,893	(294,344)
Cash and cash equivalents at the beginning of the period	33,131,280	55,386,240
Exchange (losses)/gains on cash and cash equivalents	**(1,168,813)**	**902,321**
Cash and cash equivalents at the end of the period	**25,968,681**	**33,131,280**

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 decreased to €37.4 million in the year ended December 31, 2020, from €43.2 million in the year ended December 31, 2019, mainly due to the decrease of research and development expenditures and lower personnel costs, excluding stock-based compensation.

Net cash from investing activities

Net cash from investing activities decreased by €1.8 million in the year ended December 31, 2020 mainly due to lower investments in marketable securities in 2020.

Net cash provided by/ (used in) financing activities

Net cash generated from financing activities in 2020 mainly relates to €9.0 million net proceeds from the issuance of common shares under an at-the-market program and the exercise of share options, resulting in proceeds to the Company in the amount of €0.5 million. These effects were compensated only to a small part by annual repayments of leasing debt (2020: €0.4 million; 2019: €0.3 million).

Contractual obligations and commitments

The table below sets forth our capital expenditure from contractual obligations as of December 31, 2020.

	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 commitments and other contractual obligations under operating contracts or services:	19,944,695	17,443,538	2,501,158	—	—
Contractual lease obligations (incl. capitalized leases)	601,460	352,261	249,199	—	—
Total	**20,546,155**	**17,795,799**	**2,750,356**	—	—

Contingencies

We enter 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 commenced. In the table above, the amounts for unavoidable contractual obligations assumes that the contracts were terminated on December 31, 2020 and will then continue to run for approximately 30 to 180 days.

Contractual lease obligations

Contractual lease obligations mainly consist of payments pursuant to non-cancellable lease agreements relating to our leases of office space. The lease term of our premises in Jena, Germany expires in December 2022. The lease term of our premises in Planegg-Martinsried, Germany expires in May 2022. The lease term of our premises in Ann Arbor, United States expires in April 2021.

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 24 months.

We anticipate that our expenses will increase in the next years in connection with our ongoing activities. In particular, we anticipate that we will continue and complete Phase II clinical trials in AAV and PG, initiate Phase II clinical development in cSCC, and we will continue to conduct the Phase III part of the clinical trial in severe COVID-19. Additionally, we may pursue additional indications as well. We also plan to continue preclinical development of IFX-2. We plan to initiate new research and preclinical development efforts and we may seek marketing approval for any product candidates that we successfully develop. If we initiate a Phase III clinical development program with vilobelimab in HS, additional costs in connection with such development will be incurred. 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 product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, royalty-based financings, future collaborations, strategic alliances, and licensing arrangements. 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 a common 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.

5 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 “2.2 Risk factors.”

6 CONTROLS AND PROCEDURES

6.1 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 (ii) the effectiveness of the Company's internal control over financial reporting.

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, 2019, 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.

On June 1, 2019, we replaced our DATEV accounting system and introduced an ERP system (enterprise resource planning) called ‘Microsoft Dynamics NAV 2018’. There have been no further changes in our internal control over financial reporting during the period covered by this annual report that have materially affected or reasonably likely to materially affect our internal control over financial reporting.

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.

Currently, no improvements to the risk management system are planned.

February 25, 2020

/s/ Nicolas Fulpius

Chairman of the Board of Directors

/s/ Prof. Dr. Niels Riedemann

Executive member of the Board and CEO

7 CORPORATE GOVERNANCE

7.1 Dutch Corporate Governance Code (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.

Internal audit function (best practice provisions 1.3.1 and 1.3.2)

The DCGC recommends the establishment of an internal audit function. The Company has not established an internal audit department. Our board of directors is of the opinion that adequate alternative measures have been taken in the form of the Company's risk management and control systems, as outlined elsewhere in this report, and that it is presently not necessary to establish an internal audit function. The internal audit activities are performed by management and the audit committee under supervision of the non-executive directors.

Committee chairmanship (best practice provision 2.3.4)

The DCGC recommends that the audit comittee or the remuneration committee should not be chaired by thechairman of the board o by a fer 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. 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 (as required by 2.3.7). 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)

In the first quarter of 2019, Mr. Jason Marks has been appointed as company secretary. He left the Company in the third quarter of 2020. The Company is currently considering re-appoitning a new company secretary. In the meantime, meeting minutes and other typical company secretary tasks are performed within the Board.

Compensation (best practice provisions 3.1.2, 3.2.3, 3.3.2, 3.3.3 and 3.4.1)

Consistent with market practice in the United States, and for as longs as that is the trading jurisdiction of our common 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;

- though individual and Company performance are considered when granting any variable pay, no pre-defined measurable performance criteria apply, and no scenario analyses have been performed in relation to variable pay;
- our directors may generally sell our common 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.

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.

7.2 Code of conduct 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. The text of the Company's code of ethics can be accessed at http://www.inflarx.de/Home/Investors/Corporate-Governance.html. The Company does not voluntarily apply other formal codes of conduct or corporate governance practices.

7.3 Risk management and control systems

See chapters 2.3 and 6.1 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.

7.4 General meeting of shareholders

7.4.1 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.

7.4.2 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.

7.4.3 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 chapter 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.

7.5 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 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.

As at December 31, 2020, 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
Nicolas Fulpius (47)**	Male	Swiss	8 November 2017	2022 AGM	100%
Niels Riedemann (49)*	Male	German	6 June 2017	2022 AGM	100%
Katrin Uschmann (55)**	Female	German	8 November 2017	2021 AGM	86%
Mark Kubler (46)**	Male	Swiss	8 November 2017	2021 AGM	100%
Lina Ma (44)**	Female	Chinese	8 November 2017	2021 AGM	86%
Renfeng Guo (50)*	Male	American	8 November 2017	2022 AGM	100%
Richard Brudnick (64) **	Male	American	23 May 2019	2022 AGM	100%

* Executive director
** Non-executive director

Nicolas Fulpius, Chairman. Mr. Fulpius is one of our co-founders and has served as a director and chairman of our Board since 2007. He has served as Chief Digital Officer for Swisscom Cloud Lab and for Swisscom Schweiz AG since 2015 and is member of the Venture Investment Committee of the Swisscom Venture Funds. Previously he was Chief Executive Officer and Shareholder of Veltigroup SA from 2010 to 2015. Prior to that role, he was a partner and shareholder in Affentrager Associates

from 2006 to 2010, Investment Director and shareholder in Ultreia Capital from 2002 to 2006 and an Investment Manager at Lombard Odier from 1998 to 2002 for the Immunology Fund. He has served as chairman of the board of Idros S.A. and Baszanger SA since 2016 and as a member of the boards of Anaroll Holding S.A. since 2014, BRS Immobilier S.A. since 2013, Affentrager Associates AG since 2006 and CIMA Corporate Investment Management Affentrager Holding AG since 2006. He previously served on the boards of Swisscom Digital Technology S.A., Akenes S.A., Skwich Holding S.A., Veltigroup S.A., LANexpert S.A., insentia S.A., ITS Information Technologie Services S.A., epyx S.A. and Veltigroup Consulting S.A., among others. He holds an M.S. in Management Science and Engineering from Stanford University and the Swiss equivalent of an MBA from St. Gall University.

Katrin Uschmann. Ms. Uschmann joined our board as a director and deputy chairwoman in 2007. She has served as an Investment Manager at beteiligungsmanagement thüringen gmbh since 1999. Prior to joining beteiligungsmanagement thüringen gmbh, Ms. Uschmann served in various roles at several banks, such as Credit Analyst and Corporate Relationship Manager at Bayerische Vereinsbank AG and at Thüringer Aufbaubank, and taught Economics at Fachhochschule in Gotha, Germany. She has served on the boards of eZono AG since 2007, where she was the board's deputy chairwoman from 2009 to 2010, and has served as the chairwoman since 2010, and of Preventicus GmbH since 2014 and of JenaCell GmbH since 2017. She holds a skilled worker degree and an MBA from Fachhochschule für Finanzen (University of Applied Financial Sciences), as well as a degree in project management from GPM Deutsche Gesellschaft für Projektmanagement.

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.

Lina Ma. Ms. Ma has been a director on our board since September 2016. Ms. Ma has been the Vice President and Secretary of the board of Staidson (Beijing) BioPharmaceuticals Co., Ltd. since June 2012 and a director since September 2018, the chairman of the board of Beijing Defengrei Biotechnology Co. Ltd since September 2015, the Company Secretary of Staidson BioPharma Inc., in California, since 2013 and the Chief Executive Officer of Staidson Hong Kong Investment Company Limited, in Hong Kong, since 2015. In previous roles, she has served as the General Manager and Securities Affair Representative of Staidson (Beijing) BioPharmaceuticals Co., Ltd. from 2009 to 2012, in JOINN Laboratories (Beijing) from 2002 to 2009, and in the China Medical Association Telemedicine Consultation Center from 2000 to 2001. Ms. Ma holds a bachelor's degree from Hunan Medical University in China and an MBA from HKU SPACE Community College.

Richard Brudnick. Mr. Brudnick has been a director on our board since 2019. Mr. Brudnick currently serves as Chief Business Officer and Head of Strategy for Codiak BioSciences, a leader in the field of exosome therapeutics since June 2018. Prior to joining Codiak, Mr. Brudnick was Executive Vice President of Business Development and Alliance Management at Bioverativ, Inc., a company he helped found in 2016. From 2001 to 2016, Mr. Brudnick held various roles of increasing responsibility at Biogen, Inc. including Senior Vice President of Corporate Development. Mr. Brudnick graduated from Massachusetts Institute of Technology with an SB and he also graduated from the Sloan School of Management with an MBA.

Niels Riedemann, Chief Executive Officer. Professor Riedemann is one of our co-founders and has served as our Chief Executive Officer since 2007. He is specialized as an intensive care physician and was the Vice Director of Intensive Care Medicine at the Friedrich Schiller University in Jena, Germany from 2008 to 2015. He spent several years working in basic science at the University of Michigan in the field of complement immunology and inflammation before completing his board certification as General Surgeon at the Hannover Medical School where he holds an adjunct Professorship for Experimental Surgery. He has served as a member of the scientific advisory board of

the Center for Innovation Competence Septomics, a large scientific governmental program, since 2015 and served on the board of directors of the Center for Sepsis Control and Care in Jena, Germany, from 2014 to 2015. Professor Riedemann received his medical training at the Albert-Ludwig University in Freiburg, Germany and Stanford University in the United States and graduated from Albert-Ludwig University in 1998.

Renfeng Guo, Chief Scientific Officer. Professor Guo is one of our co-founders and has served as our Chief Scientific Officer since 2007. Prior to joining us, he served as a faculty member of the University of Michigan since 2001, where he holds a position as Adjunct Research Associate Professor. He holds an Adjunct Professorship at the Beijing Institute of Microbiology and Epidemiology, since 2008. Professor Guo received his medical degree from Norman Bethune Medical School in China and he did his post-doctoral training in immunology at University of Michigan.

All of our non-executive directors are independent within the meaning of the DCGC.

7.6 Committees

7.6.1 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, 2020, 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	12* (100%)	2* (100%)	1* (100%)
Mark Kubler	2** (67%)	2 (100%)	1 (100%)
Richard Brudnick	12 (100%)		

* Chairman **since his nomination to the Committee

7.6.2 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 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;
- 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, including the effectiveness of the design and operation of our internal controls;
- reviewing the operation of and our compliance with our code of ethics; and
- 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 eight 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 & risk management of R&D projects and external auditor report & engagement.

7.6.3 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;
- 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 twice 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.

7.6.4 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 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; and
- submitting proposals for the appointment or reappointment 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 and to the periodic review and adjustments of governance rules.

7.7 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. 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.

7.8 Diversity

The Company has a diversity policy with respect to the composition of our board of directors. The Company is committed to supporting, valuing and leveraging the value of diversity. However, the importance of diversity, in and of itself, should not set aside the overriding principle that someone should be recommended, nominated and appointed for being "the right person for the job". Although the Company has not set specific targets with respect to particular elements of diversity, 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. Under the Company's diversity policy, to the extent possible and practicable, the Company intends for the composition of our board of directors to be such that at least 30% of the Directors are men and at least 30% of them are women, consistent with applicable Dutch law. In addition to age and gender, the Company recognises 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 policy.

The Company believes that the composition of its board of directors is such, that the Company's diversity objectives, as outlined above, have been achieved in the financial year to which this board report relates. As at 31 December 2020, the composition of the board of directors does not meet the Company's diversity targets in term of gender (presently, 29% of our directors are women). This is primarily due to the selection of the current members of our board of directors based on the required profile and their backgrounds, experiences, qualifications, knowledge, abilities and viewpoints without positive or negative bias on gender. In the future, this will continue to be the Company's basis for selection of new members of our board of directors.

7.9 Corporate values and code of conduct

We have adopted a code of ethics (see chapter 7.2 of this report), implementing our main corporate values, being honesty, accountability, integrity, professionalism and fairness. 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.

8 COMPENSATION REPORT

8.1 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 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 long-term objectives while keeping with the Company's risk profile.

8.2 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, 2020, for services in all capacities was EUR 2,488,333. In 2020, we did not grant options to purchase common shares to our senior management.

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, 2020, we have no amounts set aside or accrued to provide pension, retirement or similar benefits to our directors, and in 2020, our non-executive directors received EUR 284,349 in total compensation, including benefits in kind, from us for services in such capacity. In 2020, we did not grant options to purchase common shares to our non-executive directors under the Plan.

Pay Ratio

According to the methodology used in SEC`s Item 402 of Regulation S-K we have determined a pay ratio of 9.8 as of December 31, 2020 (9.3 as of December 2019). We have used the SEC guidance for pay ratio determination as we are listed on Nasdaq. The increase in the pay ratio is due to a higher variable payment to the CEO in 2020 compared to 2019.

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 it`s 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 2020 and

2019 with annual total compensation of €82.4 thousand. This annual total compensation includes the annual base salary and 3% voluntary retirement benefit.

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. 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 common 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 common 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 common shares available for issuance under equity incentive awards granted pursuant to the 2017 Plan equals 2,341,097 common shares. On January 1, 2021 and on January 1 of each calendar year thereafter, an additional number of shares equal to 3% of the total outstanding common 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").

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 common 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.

9 Related Party Transactions

Since January 1, 2020 we did not enter in related party transactions with any of our officers, directors and the holders of more than 5% of our common shares.

10 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 common shares, the announcement of an unsolicited public offer for our common shares, shareholder activism, other concentration of control over our common 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 common 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 common shares and thus can be used as a defensive measure. These preferred shares will have both a liquidation and dividend preference over our common 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.

APPENDIX A - INFLARX N.V. CONSOLIDATED FINANCIAL STATEMENTS

INFLARX N.V.

CONSOLIDATED FINANCIAL STATEMENTS

FOR THE FINANCIAL YEAR ENDED DECEMBER 31, 2020

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

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Audited Annual Consolidated Financial Statements

InflaRx N.V. and subsidiaries

Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2020, 2019 and 2018

	Note	2020	2019	2018
		(in €, except for share information)		
Operating Expenses				
Research and development expenses	3.1	(25,684,140)	(44,582,136)	(25,028,554)
General and administrative expenses	3.2	(8,467,203)	(12,501,048)	(12,786,869)
Total Operating Expenses		**(34,151,343)**	**(57,083,184)**	**(37,815,422)**
Other income		221,748	400,253	303,860
Other expenses		(13,209)	(85,242)	(4,802)
Operating Result		**(33,942,804)**	**(56,768,173)**	**(37,516,364)**
Finance income	3.4.1	887,702	2,840,676	2,182,842
Finance expenses	3.4.1	(26,000)	(22,265)	—
Foreign exchange result	3.4.2	(776,512)	694,944	5,626,071
Other financial result	3.4.3	(126,000)	—	(107,182)
Loss for the Period		**(33,983,614)**	**(53,254,817)**	**(29,814,634)**
Share Information	4.9			
Weighted average number of shares outstanding		27,064,902	26,004,519	25,095,027
Loss per share (basic/diluted)		(1.26)	(2.05)	(1.19)
Loss for the Period		**(33,983,614)**	**(53,254,817)**	**(29,814,634)**
Other comprehensive income (loss) that may be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of foreign currency		(5,954,019)	2,177,033	50,196
Total Comprehensive Loss		**(39,937,633)**	**(51,077,785)**	**(29,764,438)**

The accompanying notes are an integral part of these financial statements.

InflaRx N.V. and subsidiaries

Consolidated Statements of Financial Position as December 31, 2020 and 2019

	Note	2020	2019
		(in €)	
ASSETS			
Non-current assets			
Property, plant and equipment*	4.1	408,263	576,373
Right-of-use assets*	4.2	546,694	836,924
Intangible assets	4.3	350,184	452,400
Other assets	4.5	353,522	452,217
Financial assets	0	272,268	272,614
Total non-current assets		**1,930,931**	**2,590,528**
Current assets			
Current other assets*	4.5	3,734,700	2,365,916
Income tax receivable*	4.6.3	1,419,490	1,134,968
Financial assets	0	55,162,033	82,353,867
Cash and cash equivalents	4.8	25,968,681	33,131,280
Total current assets		**86,284,904**	**118,986,031**
TOTAL ASSETS		**88,215,834**	**121,576,558**
EQUITY AND LIABILITIES			
Equity			
Issued capital	4.9.1	3,387,410	3,132,631
Share premium	4.9.3	220,289,876	211,006,606
Other capital reserves	4.9.3	26,259,004	25,142,213
Accumulated deficit	4.9.3	(168,345,620)	(134,362,006)
Other components of equity	4.9.3	(3,726,791)	2,227,228
Total equity		**77,863,880**	**107,146,673**
Non-current liabilities			
Lease liabilities	4.4	220,525	330,745
Other liabilities		33,323	39,013
Total non-current liabilities		**253,847**	**369,758**
Current liabilities			
Trade and other payables	4.10	8,258,133	12,413,662
Lease liabilities	4.4	338,516	515,203
Employee benefits		1,368,731	975,629
Other liabilities		117,727	105,634
Provisions		15,000	50,000
Total current liabilities		**10,098,107**	**14,060,128**
Total Liabilities		**10,351,954**	**14,429,886**
TOTAL EQUITY AND LIABILITIES		**88,215,834**	**121,576,558**

The accompanying notes are an integral part of these financial statements.

* Please refer to Note 2.1 regarding certain presentational reclassifications

InflaRx N.V. and subsidiaries

Consolidated Statements of Changes in Shareholders' Equity for the Years Ended December 31, 2020, 2019 and 2018

	Note	Shares outstanding	Issued capital	Share premium
			(in €)	
Balance as of January 1, 2018		**23,812,100**	**2,857,452**	**161,638,566**
Loss for the Period		—	—	—
Exchange differences on translation of foreign currency		—	—	—
Total Comprehensive Loss		**—**	—	—
Issuance of common shares	4.9	1,850,000	222,000	52,768,733
Transaction costs		—	—	(3,801,265)
Equity-settled share-based payments	3.6	—	—	—
Share options exercised		302,279	36,273	415,801
Balance as of December 31, 2018		**25,964,379**	**3,115,725**	**211,021,835**
Loss for the Period		—	—	—
Exchange differences on translation of foreign currency		—	—	—
Total Comprehensive Loss		**—**	**—**	**—**
Equity-settled share-based payments	3.6	—	—	—
Share options exercised		140,876	16,905	(15,229)
Balance as of December 31, 2019		**26,105,255**	**3,132,631**	**211,006,606**
Loss for the Period		—	—	—
Exchange differences on translation of foreign currency		—	—	—
Total Comprehensive Loss		**—**	**—**	**—**
Issuance of common shares	4.9	1,958,186	234,982	9,535,961
Transaction costs		—	—	(729.840)
Equity-settled share-based payments	3.6	—	—	—
Share options exercised		164,974	19,797	477,149
Balance as of December 31, 2020		**28,228,415**	**3,387,410**	**220,289,876**

The accompanying notes are an integral part of these financial statements.

InflaRx N.V. and subsidiaries
Consolidated Statements of Changes in Shareholders' Equity for the Years Ended December 31, 2020, 2019 and 2018 – continued

	Note	Other capital reserves	Accumulated deficit	Other components of equity	Total equity
			(in €)		
Balance as of January 1, 2018		**6,225,353**	**(51,292,555)**	**—**	**119,428,816**
Loss for the Period		—	(29,814,634)	—	(29,814,634)
Exchange differences on translation of foreign currency		—	—	50,196	50,196
Total Comprehensive Loss		**—**	**(29,814,634)**	**50,196**	**(29,764,438)**
Issuance of common shares	4.9	—	—	—	52,990,733
Transaction costs		—	—	—	(3,801,265)
Equity-settled share-based payments	3.6	12,084,651	—	—	12,084,651
Share options exercised		—	—	—	452,075
Balance as of December 31, 2018		**18,310,003**	**(81,107,188)**	**50,196**	**151,390,571**
Loss for the Period		—	(53,254,817)	—	(53,254,817)
Exchange differences on translation of foreign currency		—	—	2,177,033	2,177,033
Total Comprehensive Loss		**—**	**(53,254,817)**	**2,177,033**	**(51,077,784)**
Equity-settled share-based payments	3.6	6,832,210	—	—	6,832,210
Share options exercised		—	—	—	1,676
Balance as of December 31, 2019		**25,142,213**	**(134,362,006)**	**2,227,228**	**107,146,673**
Loss for the Period		—	(33,983,614)	—	(33,983,614)
Exchange differences on translation of foreign currency		—	—	(5,954,019)	(5,954,019)
Total Comprehensive Loss		**—**	**(33,983,614)**	**(5,954,019)**	**(39,937,633)**
Issuance of common shares		—	—	—	9,770,943
Transaction costs		—	—	—	(729.740)
Equity-settled share-based payments	3.6	1,116,791	—	—	1,116,791
Share options exercised		—	—	—	496,946
Balance as of December 31, 2020		**26,259,004**	**(168,345,620)**	**(3,726,791)**	**77,863,880**

The accompanying notes are an integral part of these financial statements.

InflaRx N.V. and subsidiaries

Consolidated Statements of Cash Flows for the Years ended December 31, 2020, 2019 and 2018

	Note	2020	2019	2018
			(in €)	
Operating activities				
Loss for the Period		(33,983,614)	(53,254,817)	(29,814,634)
Adjustments for:				
Depreciation & amortization of property, plant, equipment, right-of-use assets and intangible assets		712,713	663,166	173,630
Net finance income	0	40,810	(3,513,355)	(7,701,731)
Share-based payment expense	0	1,116,791	6,832,210	12,084,651
Net foreign exchange differences		(247,323)	(368,477)	(17,257)
Other non-cash adjustments		3,436	60,628	213,956
Changes in:				
Other assets		(1,554,611)	(2,364,399)	(893,602)
Current financial assets		—	—	(316,112)
Employee benefits		355,545	235,500	494,837
Other liabilities		8,960	(209,948)	304,627
Trade and other payables		(4,155,529)	5,734,795	2,243,137
Interest received		1,201,547	3,001,109	1,679,250
Interest paid		(26,387)	(20,903)	—
Net cash used in operating activities		**(36,527,661)**	**(43,204,492)**	**(21,549,248)**
Investing activities				
Purchase of intangible assets and property, plant and equipment		(94,189)	(594,889)	(806,531)
Purchase of non-current other financial assets		—	(75,543)	(209,705)
Proceeds from the disposal of non-current other financial assets		—	—	21,811
Purchase of current financial assets		(101,600,176)	(82,547,409)	(106,445,120)
Proceeds from the maturity of current financial assets		123,056,346	103,559,395	7,990,204
Net cash from/ (used in) investing activities		**21,361,982**	**20,341,554**	**(99,449,341)**
Financing activities				
Proceeds from issuance of common shares	4.9	9,770,944	—	52,990,733
Transaction costs from issuance of common shares		(729,841)	—	(3,801,265)
Proceeds from exercise of share options	0	496,946	1,676	452,075
Repayment of lease liabilities		(366,156)	(296,020)	—
Net cash from/ (used in) financing activities		**9,171,893**	**(294,344)**	**49,641,542**
Net increase/(decrease) in cash and cash equivalents		**(5,993,786)**	**(23,157,282)**	**(71,357,047)**
Effect of exchange rate changes on cash and cash equivalents		(1,168,813)	902,321	3,461,399
Cash and cash equivalents at beginning of period		33,131,280	55,386,240	123,281,888
Cash and cash equivalents at end of period	4.8	**25,968,681**	**33,131,280**	**55,386,240**

The accompanying notes are an integral part of these financial statements.

InflaRx N.V. and subsidiaries
3 Notes to the Consolidated Financial StatementsCorporate Information

The consolidated financial statements of InflaRx N.V. and its subsidiaries (collectively, the Group) for the year ended December 31, 2020 were authorized for issue in accordance with a resolution of the board of directors on March 24, 2021. InflaRx N.V. (the Company or the parent) 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, InflaRx N.V.'s common shares have been listed on The NASDAQ Global Select Market under the symbol "IFRX".

InflaRx is a clinical-stage biopharmaceutical Group focused on applying its proprietary anti-C5a technology to discover and develop first-in-class, potent and specific inhibitors of the complement activation factor known as C5a.

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 principal subsidiaries at December 31, 2020 are set out below. Unless otherwise stated, they have share capital consisting solely of common shares that are held directly by the Group, and the proportion of ownership interests held equals the voting rights held by the Group.

Name	Place of business/ country of incorporation	Functional currency	Ownership interest held by the Group 2020	2019	Principal activities
InflaRx GmbH	Germany	EUR	100%	100%	Principal operating subsidiary, biopharmaceutical company
InflaRx Pharmaceutical Inc.	U.S.	USD	100%	100%	Subsidiary for basic research

InflaRx GmbH is a clinical-stage biopharmaceutical company founded in 2008. In 2017, InflaRx N.V. became the sole shareholder of InflaRx GmbH through the contribution of the subsidiary's shares to InflaRx N.V. by its existing shareholders in exchange of new shares issued by InflaRx N.V.

InflaRx Pharmaceutical Inc., a Delaware corporation, was founded on January 5, 2018 by InflaRx N.V.

4 Significant accounting policies

4.3 Basis of preparation

The consolidated financial statements of the Company are part of the statutory financial statements of the Company.

The consolidated financial statements of the Group have been prepared in accordance with International Financial Reporting Standards (herein 'IFRS'). The financial statements comply with IFRS as adopted by the European Union (IFRS) and with Section 2:362(9) of the Netherlands Civil Code. We have developed our disclosures and tables in this document. In this context, we have adapted the presentation of tables and the structure of this document. The composition of figures or subtotals may differ from the presentation in the previous year. However, there have been no changes content-wise compared to previous year.

The financial statements have been prepared on a historical cost basis. Certain prior year amounts have been reclassified for consistency with the current year presentation. 'Right-of-use assets' have been presented separately from in 'Property and equipment' and 'Income tax receivable' has been presented separately from 'Current other non-financial assets' in the statements of financial position. These reclassifications had no effect on the reported results of operations.

These consolidated financial statements of the Group comprise the Company and its wholly-owned subsidiaries InflaRx GmbH, and InflaRx Pharmaceutical Inc. The consolidated financial statements are presented in Euro (€). USD ($) is also the functional currency of InflaRx N.V.. Effective January 1, 2019, the functional currency of InflaRx N.V. has changed to U.S. Dollars from €, as most of the income and expenses of InflaRx N.V. occur in U.S. Dollar. The presentation currency of the Group did not change and continues to be €, as the functional currency of the largest operating company InflaRx GmbH continues to be the €. The functional currency of InflaRx Pharmaceutical Inc is USD.

These financial statements were issued under the going concern assumption, i.e. valuation and capitalization of assets and liabilities was based on the going concern assumption. Based on the monetary funds of the Company and the intended business development, management expects going concern for at least the next fifteen months after the release of these financial statements.

4.4 Summary of significant accounting policies

This section describes significant 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.

4.4.1 New and amended standards adopted by the Group

The below listed amendments and interpretations apply for the first time in 2020, but do not have a material impact on the consolidated financial statements of the Group:

- Conceptual Framework Amendments, References to the Conceptual Framework in IFRS Standards (IFRS 2 Share-Based Payment, IFRS 3 Business Combinations, IAS 1 Presentation of Financial Statements, IAS 8 Accounting Policies, IAS 34 Interim Financial Reporting, IAS 37 Provisions, Contingent Liabilities and Contingent Assets, IFRIC 12 Service Concession Arrangements, IFRIC 19 Extinguishing Financial Liabilities with Equity Instruments IFRIC 22 Foreign Currency Transactions and Advance Consideration, SIC 32 Intangible Assets — Web Site Costs,), effective as of January 1, 2020
- IFRS 3 Business Combinations, Definition of a business, effective January 1, 2020
- IAS 39 Financial Instruments: Recognition and Measurement, IFRS 7 Financial Instruments Disclosures, IFRS 9 Financial Instruments, Interest Rate Benchmark Reform — Phase 1, effective January 1, 2020,
- IAS 1 Presentation of Financial Statements, IAS 8 Accounting Policies, Definition of Material, as of January 1, 2020

4.4.2 2.3.2 New standard not yet adopted

The following amendments will be adopted effective January 1, 2021 and are not expected to have a material impact on the consolidated financial statements of the Group:

- Interest Rate Benchmark Reform — Phase 2, Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16
- COVID-19-related Rent Concessions, Amendment to IFRS 16

The following standards issued will be adopted in a future period and the potential impact, if any, they will have on the Group's consolidated financial statements is being assessed:

- Amendments to IFRS 4 Insurance Contracts
- IFRS 17 Insurance Contracts, including Amendments to IFRS 17
- Amendments to IAS 1 Presentation of Financial Statements: Classification of Liabilities as Current or Non-current and Classification of Liabilities as Current or Non-current
- Amendments to IFRS 3 Business Combinations; IAS 16 Property, Plant and Equipment; IAS 37 Provisions, Contingent Liabilities and Contingent Assets; Annual Improvements 2018-2020
- Amendments to IAS 1 Presentation of Financial Statements and IFRS Practice Statement 2: Disclosure of Accounting policies
- Amendments to IAS 8 Accounting policies, Changes in Accounting Estimates and Errors: Definition of Accounting Estimates
-

4.4.3 Current and non-current distinction

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 twelve 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.

4.4.4 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 foreign currency are translated into Euros at the rate of exchange prevailing at the reporting date and their statements of profit or loss 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.

4.4.5 Notes to the cash flow statement, cash, and cash equivalents

The cash flow statement has been prepared using the indirect method for cash flows from operating activities. The cash disclosed in the cash flow statement 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 month or less. Interest paid and received is included in the cash from operating activities.

4.4.6 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 product, additionally costs are incurred by 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 does not believe 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.

As research expenditure and development expenditure does not meet the recognition criteria they are treated as an expense when incurred.

4.4.7 Employee benefits

4.4.7.1 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 statements of financial position. A liability is recognized, if the Group has a present legal or constructive obligation to pay this amount as a result of past service provided by the employee, and the obligation can be estimated reliably.

4.4.7.2 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 true-up for differences between expected and actual outcomes.

4.4.8 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 security for borrowing purposes. The Group applied IFRS 16 Leases for the first time starting January 1, 2019, previous periods were not adjusted retrospectively. Before the adoption of IFRS 16, the Group classified each of its leases (as lessee) at the inception date as either a finance lease or an operating lease. A lease was classified as a finance lease if it transferred substantially all of the risks and rewards incidental to ownership of the leased asset to the Group; otherwise it was classified as an operating lease. Before January 1, 2019, the Group did not identify any finance leases. For an operating lease, the leased property was not capitalized, and the lease payments were recognized as rent expense in profit or loss on a straight-line basis over the lease term. Any prepaid rent and accrued rent were recognized under prepayments and trade and other payables, respectively.

4.4.8.1 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, 2020 the remaining useful lives of the Company`s right-of-use assets range between four and 33 months. Right-of-use assets are subject to impairment.

4.4.8.2 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 that 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.

4.4.8.3 Short-term leases and leases of low-value assets

The Group applies the short-term lease recognition exemption to its short-term leases of machinery and 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.

4.4.8.4 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 Group would apply 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.

4.4.9 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 Consolidated Statements of Operations and Comprehensive Loss as part of finance income.

4.4.10 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. Software is amortized over three years. The useful lives of intangible assets are reviewed at each reporting date. 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.

4.4.11 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 charged to 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.

4.4.12 Financial assets and liabilities (financial instruments)

4.4.12.1 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).

4.4.12.2 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.

4.4.12.3 Subsequent measurement method

Considering the Group's business model for managing the financial assets, whose objective is 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 Statements of Financial Position by measurement category is disclosed under '4.7 Financial assets and financial liabilities.'

4.4.12.4 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 '3.4 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.

4.4.13 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 which fair values are disclosed (see '4.7 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.

4.4.14 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.

4.4.15 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.

4.4.16 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, 2020 and 2019, based on management's judgment, it was not probable that taxable profit will be available against which the unused tax losses can be utilized, and no deferred tax assets were therefore recognized in the consolidated statement of financial position.

4.5 Significant accounting judgements, estimates and assumptions

The preparation of the consolidated financial statements in conformity with IFRS 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 financial statements, the critical judgments made by management in applying the Group's accounting policies involve the following areas:

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 grant (see Note '3.6.2 Measurement of fair values of share options granted'). In 2020 the Company kept its share price volatility assumption at 135% which has been used for the valuation of all share option grants since June 2019. Although the average volatility has decreased to approximately 130% since June 2019, management believes that an average volatility of 135% is still appropriate as future value inflection points will influence the share price of the Company and consequently will increase the volatility. . 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 must be made based on 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 (see Note 3.6.3 'Change in the accounting estimate of the share options expected to vest').

In measuring R&D expenses for the reporting period, the Company has to estimate the amount of expense to accrue as far as the invoices of the service providers are not yet received (e.g. for pass-through costs charged by the Company's contract research organizations ('CROs')) as the timing of the invoicing of project services by CROs follow contractual billing schedules and can occur several months following a reporting period. This estimation involves determining a percentage-of-completion whereby the estimated progress of the individual project activities contracted from the CRO is assessed by the 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 completed 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 considers resulting increases or decreases in expenses as changes in estimates and reflects such changes in research and development expenses in the period identified.

Following this cut-off procedure, the Company has accrued €5,250,654 as of December 31, 2020 and €8,274,042 as of December 31, 2019 (see Note 4.10 Trade and other payables). At the same time, prepayments were booked for those payments not yet covered by project activities (2020: €1,923,365, 2019: €698,891, see Note 4.5 Other non-financial assets).

5 Material items from Statements of Operations and Comprehensive Loss

5.3 Research and development expenses

Research and development decreased compared to the prior year due to the Company's declining activities in the area of clinical studies and manufacturing. The items below drive research and development expenses.

Research and development expenses	**2020**	**2019**	**2018**
		(in €)	
Third-party services	19,886,693	36,783,223	15,909,366
manufacturing of clinical material	*3,075,347*	*13,479,235*	*4,828,534*
clinical, pre-clinical	*16,811,346*	*23,303,988*	*11,080,832*
Employee benefits expenses	4,480,890	6,231,812	8,037,082
Equity-settled share-based payment expense	*626,833*	*2,580,983*	*5,256,194*
Legal and consulting fees	862,364	668,676	421,041
Other expenses	454,193	898,425	661,065
Total	**25,684,140**	**44,582,136**	**25,028,554**

5.4 General and administrative expenses

General and administrative expenses include the items below. Compared to the prior year the decrease is mainly caused by lower personnel expenses, as well as decline of the Company's business activities and the expense of operating as a public company in the United States.

General and administrative expenses	**2020**	**2019**	**2018**
		(in €)	
Employee benefits expenses	3,880,349	7,534,073	9,146,955
Equity-settled share-based payment expense	*489,958*	*4,251,227*	*6,828,457*
Legal and consulting fees	1,603,711	2,199,640	2,020,447
Insurance expenses	1,311,790	636,035	368,339
Depreciation & amortization expense	556,456	503,683	115,330
Compensation expense for non-executive board directors	283,128	269,030	238,180
Other expenses	831,769	1,358,587	897,618
Total	**8,467,203**	**12,501,048**	**12,786,869**

5.5 Employee benefits expenses

The following table shows the items of employee benefits expenses:

Employee benefits expenses	**2020**	**2019**	**2018**
		(in €)	
Wages and salaries	6,270,757	5,974,807	4,501,840
Social Security contributions (employer's share)	551,804	562,255	350,024
Equity-settled share-based payment expenses (see Note 3.6 Share-based payments)	1,116,791	6,832,210	12,084,651
Other	421,887	396,613	247,522
Total	**8,361,239**	**13,765,885**	**17,184,037**

The number of employees rose to 47.3 full time equivalents (FTE) at the end of 2020 from 43.7 FTE at the end of 2019, respectively 36.8 FTE at the end of 2018 (numbers as of year end, not an average number).

5.6 Net Financial Result

5.6.1 Finance Result

Finance Result	**2020**	**2019**	**2018**
		(in €)	
Finance income			
Interest income	887,702	2,840,676	2,182,842
Finance expenses			
Interest expenses	(18,689)	(9,500)	—
Interest on lease liabilities	(7,311)	(12,765)	—
Total	**861,702**	**2,818,411**	**2,182,842**

5.6.2 Foreign exchange result

Foreign exchange result	**2020**	**2019**	**2018**
		(in €)	
Foreign exchange result			
Foreign exchange income	3,656,922	3,379,644	8,249,853
Foreign exchange expense	(4,433,435)	(2,684,700)	(2,623,782)
Total	**(776,513)**	**694,944**	**5,626,071**

Foreign exchange income and expense is mainly derived from group entities that do not use U.S. dollar as functional currency. Those entities translate U.S. dollar cash, cash equivalents and marketable securities at the exchange rates prevailing on the reporting date. Any resulting translation differences are recognized in profit and loss. These gains and losses are caused by a change in the exchange rates as of the reporting dates and may not ultimately be realized.

5.6.3 Other financial result

	2020	2019	2018
		(in €)	
Other financial result	**(126,000)**	**—**	**(107,182)**

Other finance costs include an expense of €126,000 (nil in 2019 and 2018) due to an adjustment to the expected credit loss allowance in 2020 which is deducted from the Company`s current and non-current financial assets (please also refer to 4.5 'Other non-financial assets').

5.7 Loss per share

Loss per common share is calculated by dividing the loss of the period by the weighted average number of common shares outstanding during the period. The weighted number of common shares outstanding for the financial year 2020 is 27,064,902, for 2019 is 26,004,519 and for 2018 is 25,095,027.

For the period in which the Company is in a loss-making situation, the loss per share diluted and un-diluted is disclosed in the same amount, because the weighted average number of shares to be issued upon the exercise of stock options would produce an anti-dilutive effect.

5.8 Share-based payments

5.8.1 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 common shares of InflaRx N.V. in November 2017:

	2020 number	2020 WAEP	2019 number	2019 WAEP
Outstanding at January 1	148.433	€0.01	289.309	€0.01
Exercised during the year (1)	—	—	(140.876)	€0.01
Outstanding at December 31	**148.433**	€0.01	**148.433**	€0.01
/Exercisable at December 31	148.433	€0.01	148.433	€0.01

(1) The weighted average share price at the date of exercise in 2019 was $3.02/€2.70 (average conversion rates used for one $ in 2019 was $0.8932)

The weighted average remaining contractual life for the share options outstanding as at 31 December 2020 was 2.43 years (2019: 3.43 years).

Under the terms and conditions of the share option plan 2016 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 common shares of InflaRx N.V. in November 2017:

	2020 number	2020 WAEP	2019 number	2019 WAEP
Outstanding at January 1	1.181.484	$3.35/€2.98	1.181.484	€7,81
Exercised during the year (1)	(86,632)	$3.35/€2.94	—	—
Outstanding at December 31	**1,094,852**	$3.35/€2.73	**1.181.484**	$3,35/€2.98*
Exercisable at December 31	1,094,852	$3.35/€2.73	1.181.484	$3,35/€2.98*

(1) The weighted average share price at the date of exercise in 2020 for these options was $8.25/€7.23*.
conversion rates used for one €: December 31, 2020 $0.8149, average rate 2020 $0.8762, January 1, 2020/December 31, 2019 $0.8902, average rate 2019 $0.8932

The weighted average remaining contractual life for the share options outstanding as at 31 December 2020 was 10.93 years (2019: 11,95 years).

In conjunction with the closing of its initial public offering, InflaRx N.V. established a new incentive plan (the "2017 Long-Term Incentive Plan"). The initial maximum number of common shares available for issuance under equity incentive awards granted pursuant to the 2017 Long-Term Incentive Plan equals 2,341,097 common shares:

	2020 number	2020 WAEP	2019 number	2019 WAEP
Outstanding at January 1	2,181,105	$3.44 /€3.06 *	2.051.009	$3,61/€3.16*
Granted during the year	246,188	$4.83 /€4.23 *	242.450	$3,25/€2.91*
Exercised during the year	(78,342)	$3.35 /€2.94 *	—	—
Forfeited during the year	(202,473)	$3.61 /€3.17 *	112.354	$6,17/€5.51*
Outstanding at December 31	**2,146,478**	$3.59 /€2.93*	**2.181.105**	$3,44/€3.06*
Exercisable at December 31	1,863,790	$3.46 /€2.82 *	1.319.548	$3,52/€3.13*

* conversion rates used for one €: December 31, 2020 $0.8149, average rate 2020 $0.8762, January 1, 2020/December 31, 2019 $0.8902, average rate 2019 $0.8932

The weighted average remaining contractual life for the share options outstanding as at 31 December 2020 was 5.38 years (2019: 6.21 years).

The weighted average fair value of options granted during the year was §3.88/€3.40 (2019: $8.16/€7.29). The range of exercise prices for options outstanding at the end of the year was $2.28/€1.86 to $22.75/€18.54 (2019: 2.28/€2.03 to $22.75/€20.25).

On July 3, 2019, the board approved an amendment of the 2016 Share Option Plan and the 2017 Long-Term Incentive Plan. Following the amendment, the exercise 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.

The repricing decision on July 3, 2019 affected the 2016 Plan and the 2017 Long-Term Incentive Plan. 1,181,484 share options from the 2016 plan and 2,105,459 share options from the 2017 long-term incentive plan were affected. The valuation of past grants with the new exercise price of $3.35 resulted in incremental fair values of the outstanding options, i.e. additional compensation expense had to be recognized. Please refer to the table below regarding the measurement of fair values of share options granted.

There were no cancellations or further modifications to the awards in 2020, 2019 or 2018.

5.8.2 Measurement of fair values of share options granted

The fair value of options granted in 2020 under the 2017 long-term incentive plan was determined using the Black-Scholes valuation model. As the Company's common shares are listed on the Nasdaq Global Select Market, the closing price of the common shares at grant date was used.

The modification, resulting from the repricing as described above, increased the fair value of the equity instruments granted under the 2017 Long-Term Incentive Plan and the 2016 Plan. In accordance with IFRS 2.B43, the incremental fair value is recognized over the remaining vesting period, whereas the balance of the grant-date fair value is recognized immediately for fully vested options, or over the remaining original vesting period. The incremental fair value is the difference between the fair value of the modified share-based payment and that of the original share-based payment, both measured at the date of the modification - i.e. July 3, 2019.

Other significant inputs into the model are as follows (weighted average):

Share options granted	**Number**	**Per option**	**FX rate as of grant date**	**Per option**	**Share price at grant date / Exercise price**	**Expected volatility**	**Expected life** (midpoint based)	**Risk-free rate** (interpolated, U.S. sovereign strips curve)
2019								
January 1		$14.45	0.88	€12.69	$26.02	0.65	4.8	3,00%
February 4	18,450	$18.17	0.87	€15.87	$32.63	0.65	4.9	2,60%
May, 14	36,000	$22.54	0.89	€20.08	$41.39	0.65	4.7	2.30%
Repricing, July 3		$0.46-$1.08	0.89	€0.40-€0.96	$3.35	1.35	2.3-4.6	2.30%
October 24	50,000	$1.96	0.90	€1.76	$2.28	1.35	4.7	1,65%
December 16	38,000	$3.07	0.90	€2.75	$3.57	1.35	4.7	1,79%
December 16*	100,000	$3.07	0.90	€2.75	$3.57	1.35	4.7	1,79%
	242,450							
On November 20, 2018 75,000 stock options were awarded subject to a specified condition, which was satisfied on January 1, 2019, therefore, the expense for these share options occurred in 2019.								
* Options granted to the executive management								
2020								
September 18	71,186	$4.16	0.85	€3.52	$4.83	1.35	4.8	0.36%
September 18	25,002	$4.21	0.85	€3.56	$4.83	1.35	5.0	0.39%
October 01	150,000	$3.69	0.85	€3.15	$4.28/$4.83	1.35	5.0	0.36%
	246,188							

Of the options granted in 2020, 200,000 were granted to members of the executive management. For 150,000 options out of those, the grant date, as it is defined by IFRS 2, is determined to be October 1, 2020, as the start of the employment

Expected dividends are nil for all share options listed above.

Expected volatility has been based on the historical volatility of InflaRx' share price. Considering a significant price drop on June 5, 2019, averages were calculated including and excluding said trading day which results in an average volatility of 128% (124% in 2019). For grants after June 2019 the Company has selected a volatility of 135% that accounts for expectations of the management.

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 Long-Term Incentive Plan.

The annual general meeting on July 16, 2020, approved an amendment to the 2017 Long-Term Incentive Plan (LTIP) with effect from January 1, 2021:

- increasing the maximum annual number of common shares in the Company's capital available for issuance under the LTIP, starting on January 1, 2021, to 4% (from 3%) of the Company's outstanding common shares (determined as of December 31 of the immediately preceding year); and

- removing certain restrictions from the LTIP, which will allow the committee administering the LTIP and the Board to (i) lower the exercise price per share of any options and/or share appreciation rights issued under the LTIP or take any other action treated as a 'repricing' of an award and (ii) cancel any option and/or share appreciation rights in exchange for cash or another award granted under the LTIP, in either case, without prior approval of the Company's shareholders.

5.8.3 Change in the accounting estimate of the share options expected to vest

Due to terminations in the third quarter of 2020, effective July 1, 2020, the Company has revised its assumptions about the number of equity instruments that will vest in future quarters. As a result of this change in estimate, the Company recognized a benefit of €64.0 thousand in research and development expenses and a benefit of €72.9 thousand in general and administrative expenses in 2020 and will record €41.5 thousand less expense in research and development expenses and €27.0 thousand less expense in general and administrative expenses from share-based payments in the remaining vesting periods until June 30, 2022. The forfeiture assumptions will be continuously monitored and adjusted when necessary and appropriate.

6 Material items from Statements of Financial Position

6.3 Property and equipment

	Property and equipment	Advance payments	Total
Cost	**(in €)**		
At January 1, 2019	**995,179**	**—**	**995,179**
Additions	259,647	54,338	313,985
Disposals	(142,400)	—	(142,400)
Reclassification	54,408	(54,408)	—
Exchange differences	6,639	70	6,709
At December 31, 2019	**1,173,473**	**—**	**1,173,473**
Additions	66,114	—	66,114
Disposals	(5,298)	—	(5,298)
Exchange differences	(34,750)	—	(34,750)
At December 31, 2020	**1,199,540**	**—**	**1,199,540**
Accumulated depreciation			
At January 1, 2019	**(370,510)**	**—**	**(370,510)**
Depreciation charge for the year	(252,627)	—	(252,627)
Disposals	26,235	—	26,235
Exchange differences	(198)	—	(198)
At December 31, 2019	**(597,101)**	**—**	**(597,101)**
Depreciation charge for the year	(212,733)	—	(212,733)
Disposals	1,793	—	1,793
Exchange differences	16,764	—	16,764
At December 31, 2020	**(791,277)**	**—**	**(791,277)**
Net book value			
At December 31, 2019	**576,372**	**—**	**576,372**
At December 31, 2020	**408,263**	**—**	**408,263**

6.4 Right-of-use assets

	Buildings	Cars	Total
Cost	**(in €)**		
At January 1, 2019	**695,614**	**35,058**	**730.672**
Additions	636,754	—	636,754
Disposals	(266,057)	—	(266,057)
Exchange differences	1,512	—	1,512
At December 31, 2019	**1,067,823**	**35,058**	**1,102,881**
Additions	—	101,993	101,993
Disposals	—	(28,366)	(28,366)
Exchange differences	(7,997)	—	(7,997)
At December 31, 2020	**1,059,826**	**108,685**	**1,168,512**
Accumulated depreciation			
At January 1, 2019	**—**	**—**	**—**
Depreciation charge for the year	(283,350)	(20,831)	(304,181)
Disposals	38,008	—	38,008
Exchange differences	216	—	216
At December 31, 2019	**(245,126)**	**(20,831)**	**(265,957)**
Depreciation charge for the year	(335,608)	(34,410)	(370,017)
Disposals	—	7,880	7,880
Exchange differences	6,277	—	6,277
At December 31, 2020	**(574,457)**	**(47,361)**	**(621,818)**
Net book value			
At December 31, 2019	**822,697**	**14,227**	**836,924**
At December 31, 2020	**485,369**	**61,324**	**546,694**

6.5 Intangible Assets

	Purchased IT-software	Advances paid for soft-ware	Total
Cost		**(in €)**	
At January 1, 2019	**246,351**	**109,852**	**356,204**
Additions	84,449	251,493	335,942
Reclassification	353,155	(353,155)	—
Exchange differences	(64)	—	(64)
At December 31, 2019	**683,891**	**8,190**	**692,081**
Additions	28,075	—	28,075
Reclassification	8,190	(8,190)	—
Exchange differences	(562)	—	(562)
At December 31, 2020	**719,593**	**—**	**719,593**
Accumulated amortization			
At January 1, 2019	**(133,337)**	**—**	**(133,337)**
Amortization charge for the year*	(106,358)	—	(106,358)
Exchange differences	14	—	14
At December 31, 2019	**(239,681)**	**—**	**(239,681)**
Amortization charge for the year	(129,963)	—	(129,963)
Exchange differences	234	—	234
At December 31, 2020	**(369,410)**	**—**	**(369,410)**
Net book value			
At December 31, 2019	**444,210**	**8,190**	**452,400**
At December 31, 2020	**350,184**	**—**	**350,184**

Amortization of intangible assets is included in the line items ‘research and development expenses’ (2020: €27,937, 2019: € 30,662, 2018: €5,841) and ‘general and administrative expenses’ (2020: €102,026, 2019: € 75,696, 2018: € 19,414) in the statements of operations and comprehensive loss.

6.6 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 expires in the next 24 months: Jena, Germany December 2022, Martinsried, Germany May 2022 and Ann Arbor, United States April 2021.

Set out below, are the carrying amounts and the movements of the Group's lease liabilities:

Lease liabilities	**2020**	**2019**
As of January 1	**845,948**	**730,672**
Additions	101,993	636,754
Derecognition	(20,555)	(228,547)
Re-payments	(366,156)	(296,020)
Short-term liability for accrued interest expense	(388)	1,362
Foreign exchange difference	(1,802)	1,727
As of December 31	**559,041**	**845,948**

The following are the amounts recognized in profit or loss:

	December 31, 2020	**December 31, 2019**
	(in €)	
Depreciation expense of right-of-use assets (see Note 4.2)	362,137	265,957
Interest expense on lease liabilities	7,311	12,765
Rental expense from leases	6,275	70,451
short-term leases (included in administrative expenses)	*937*	*65,348*
leases of low-value assets (included in administrative expenses)	*5,338*	*5,103*
Total amounts recognized in profit or loss	**375,723**	**349,173**

The Group had total cash outflows for leases of €374,698 in 2020 (€378,035 in 2019).

6.7 Other non-financial assets

Other non-financial assets	**December 31, 2020**	**December 31, 2019**
	(in €)	
Non-current other assets		
Prepaid expense	353,522	452,217
Total	**353,522**	**452,217**
Current other assets		
Prepayments on research & development projects	2,340,643	698,891
Prepaid expense	1,295,682	1,467,936
Other	98,374	199,088
Total	**3,734,699**	**2,365,915**
Total other non-financial assets	**4,088,221**	**2,818,132**

Prepayments on research & development projects consists of prepayments on lCRO and manufacturingcontracts. Prepaid expense mainly consists of prepaid insurance expense.

6.8 Income tax

6.8.1 Income tax reconciliation

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	**2020**	**2019**	**2018**
		(in €)	
Loss for the Period (accounting profit before income tax)	(33,983,614)	(53,254,817)	(29,814,634)
Tax rate	28.7%	29.6%	29.1%
Tax benefits at tax rate	9,761,910	15,815,083	8,715,116
Tax losses for which no deferred tax asset was recognized	(9,761,910)	(15,815,083)	(8,715,116)
Current income tax	—	—	—

The tax rate applied above represents the weighted average of the statutory tax rates in Germany and the USA. In Germany InflaRx N.V. and its German subsidiary InflaRx GmbH are subject to corporate income tax (2020/2019/2018: 15%), a solidarity surcharge (2020/2019/2018: 0.8%) and trade taxes (2020: 13.0%, 2019: 13.9%, 2018: 13.4%). This equals an average total tax rate of 28.9% in 2020 (2019: 29.7%, 2018: 29.2%). InflaRx Pharmaceutical Inc., Ann Arbor, Michigan, USA is subject an average total tax rate of 27.0% in 2020 (2019 and 2018: 27.0%), which is made up of U.S. federal tax (2020, 2019, 2018: 21%) and state tax (2020, 2019, 2018: 6%).

6.8.2 Tax losses carried forward

The Group has total tax loss carryforwards of €148.9 million (2019: €114.4 million) from three areas that cannot be utilized outside these areas:

- As of December 31, 2020 the Group has €107,188,000 (2019: €75,767,524) 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 (€34,787,000) are frozen from 2018 onwards due to the 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 €6,971,000 (2019: 3,816,023) from the operations of InflaRx Pharmaceutical Inc. which can also only be utilized there, generally do not expire, but are generally limited to 80% of taxable income.

As of December 31, 2020 and 2019, no deferred tax assets were recognized for the carryforward of unused tax losses.

6.8.3 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 (2020: €1,026,494, 2019: €1,134,968). The Company is reimbursed for the payments after filing a tax return.

6.9 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, 2020 and December 31, 2019:

Financial assets and financial liabilities	December 31, 2020	December 31, 2019
	(in €)	
Financial assets at amortized cost		
Non-current financial assets	272,268	272,614
Current financial assets	47,138,738	82,353,867
Financial liabilities at amortized cost		
Trade and other payables	8,375,005	12,413,662

The fair value of current and non-current financial assets amounted to €47,392 thousand (level 1). The Group's financial assets at amortized cost consist mainly of quoted debt securities with fixed interest rates that are graded in the top investment category (AAA) by credit rating agencies such as S&P Global and, therefore, are considered low credit risk investments.

The maturities of all securities as of December 31, 20220 are between three and eleven months (2019: between one and eleven months), they bear nominal fixed interest in the range of 1.4% to 3.1% (2019: 1.5% to 2.1%).

6.10 Cash and cash equivalents

Cash and cash equivalents	December 31, 2020	December 31, 2019
	(in €)	
Short-term deposits		
Deposits held in U.S. dollars (3 months original maturity and less)	22,616,767	27,803,153
Deposits held in EURO (3 months original maturity and less)	1,800,000	—
Total	**24,416,767**	**27,803,153**
Cash at banks		
Cash held in Euro	1,189,126	1,211,478
Cash held in U.S. dollars	362,788	4,116,649
Total	**1,551,914**	**5,328,127**
Total cash and cash equivalents	**25,968,681**	**33,131,280**

6.11 Equity

6.11.1 Issued capital

In connection with InflaRx N.V.'s initial public offering in the fourth quarter of 2017, whereby 7,068,128 common shares were issued against gross proceeds of €90,903,488, the Company executed a corporate reorganization whereby InflaRx N.V. became the holding company for InflaRx GmbH, which was previously the Group's parent company and remains the principal operating subsidiary of InflaRx N.V. In the initial step of the corporate reorganization, the existing preferred and common shareholders of InflaRx GmbH became a party to a notarial deed of issue pursuant to which they subscribed for 16,743,972 new common shares of Fireman B.V., a newly incorporated Dutch private company with limited liability, and agreed to contribute and transfer their shares in InflaRx GmbH to Fireman B.V. in consideration therefor. Upon consummation of the contribution and transfer, Fireman B.V. became the sole shareholder of InflaRx GmbH. In the final step of the corporate reorganization, the legal form of Fireman B.V. was converted from a Dutch private company with limited liability to a Dutch public company with limited liability. The conversion resulted in a name change from Fireman B.V. to InflaRx N.V. The preferred and common shares of InflaRx GmbH were exchanged on a one-to-84 basis. The conversion of outstanding option awards into awards exercisable for common shares of InflaRx N.V. also occurred on a one-to-84 basis.

On May 8, 2018, a public offering of common shares was completed pursuant to which the Company sold an aggregate of 1,850,000 common shares with a nominal value of €0.12 per share, resulting in gross proceeds from the sale of common shares of €52,990,733. Directly attributable transaction costs of €3,801,265 were incurred and paid in connection with the sale of these common shares and deducted from capital reserves.

As of December 31, 2020, the issued capital of the Company is divided into 28,228,415 common shares (2019: 26,105,255). 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 July 7, 2020, the Company filed with the United States Securities and Exchange Commission (SEC) a Form F-3 with respect to the offer and sale of securities of the Company (Registration Statement). The Company also filed with the SEC a prospectus supplement (Prospectus Supplement) relating to an at-the-market program providing for the sales over time of up to $50 million of its common shares pursuant a Sales Agreement with SVB Leerink LLC.

As of December 31, 2020, the Company had issued 1,958,186 common shares resulting in €9.0 million in net proceeds to the Company. Following these issuances, the remaining value authorized for sale under the at-the-market program is $38.8 million.

6.11.2 Authorized capital

According to the articles of association of the Company, up to 55,000,000 common shares and up to 55,000,000 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 us 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 common 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. The Company is of the opinion that the call option does not represent a significant fair value based on a level 3 valuation, since the preference shares are restricted in use and can be cancelled by us as stated above.

As of December 31, 2020, the Company expensed €60,000 of ongoing costs to reimburse expenses incurred by the protective foundation.

6.11.3 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.
- The *other capital reserves* solely contain the expense resulting from the issue of share options.
- *Accumulated deficit* contains the losses of previous periods.
- *Other components of equity* exclusively contain currency reserves from the conversion of financial statements in foreign currencies

-

6.12 Trade and other payables

Trade and other Payables	December 31, 2020	December 31, 2019
	(in €)	
Accrued liabilities from R&D projects	5,250,654	8,274,042
Accounts payable	1,741,251	3,351,100
Other accrued liabilities and payables	1,266,228	788,520
Total trade and other payables	**8,258,133**	**12,413,662**

Accrued liabilities from R&D projects capture the services from the Company`s ongoing projects that have not yet been invoiced to the Company as of the reporting date.

7 Risk

7.3 Financial risk management

7.3.1 Financial risk management objectives and policies

The Group's risk management is predominantly controlled by central treasury activities under the Investment Policy approved by the Board of Directors. Those treasury activities identify, evaluate and hedge financial risks consistently with the Group's operating needs. The board 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).

Hedge accounting 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 and not worth hedging.

The Group's principal financial assets comprise quoted debt securities with credit ratings range from AA- to AAA. 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

7.3.2 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 U.S. dollars and Euro. The currencies in which these transactions and financial assets are primarily denominated are U.S. dollars and Euro. The Group is exposed to the exchange rate between the Euro and the U.S. dollars. Due to the initial public offering in 2017 and public offering in 2018, the Group has a significant U.S. dollar amount on its statements of financial position. 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 2020 the Group recognized significant foreign exchange gains and losses as the natural hedge is not yet achieved and the functional currency for 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 GmbH.

In 2020, if the Euro had weakened/strengthened by 10% against the U.S. dollars with all other variables held constant, the Group`s loss would have been €3 million higher/€3 million lower, mainly as a result of foreign exchange on translation of U.S. dollars-denominated assets of InflaRx GmbH.

Cash, cash equivalents and financial assets denominated in USD that belong to InflaRx GmbH	**December 31, 2020**	**December 31, 2019**
	(in €)	**(in €)**
Current financial assets (securities and accrued interest)	8,333,240	32,947,491
Cash and cash equivalents	22,530,687	4,123,532
Total assets exposed to the risk	**30,863,927**	**37,071,023**
Conversion rate EUR/USD at reporting date 1/1.2271		

Sensitivity analysis:	**Conversion rate**	**Profit/(loss)**	**carrying amount**
		(in €)	
Euro weakens against U.S. dollars	1.2500	(2,805,812)	28,058,115
Euro strengths against U.S. dollars	1.0500	3,429,325	34,293,252

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 1.0500 and 1.2500 could be reasonably possible. Compared to the exchange rate on the balance sheet date (EUR/USD at reporting date is 1/1.2271), these rates could have a material impact on the Company`s total loss of the period.

7.3.3 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 that fall under the credit limits approved by the investment policy. For short-term investments in Euro or USD debt securities, a AAA credit rating is required. Only for short-term investments in cash and cash equivalents with the Company`s principal banks, their lower credit ratings are accepted (credit ratings varying between A and BBB). Complex financial products as well as other investments denominated in currencies other than USD or Euro 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 €81.4 million at December 31, 2020 (December 31, 2019: €115.8 million). This amount equals the carrying amount at year end of cash and cash equivalents (2020: €26.0 million; 2019: €33.1 million) plus financial assets (2020: €55.4 million; 2019: €82.6 million).

7.3.4 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 debt under '6 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.

In November 2017, May 2018, and July/August 2020, InflaRx raised significant funding that it estimates will enable the Group to fund operating expenses and capital expenditure requirements for at least the 24 months from December 31, 2020. 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, 2020**	**December 31, 2019**
	(in €)	
Short-term deposits	24,416,767	27,803,153
Cash at banks	1,551,914	5,328,127
Marketable Securities (current)	54,752,700	81,895,377
Other (non-current portion)	272,268	272,614
Other (current)	409,333	458,491
Total funds available	**81,402,982**	**115,757,762**

The remaining contractual maturities of financial assets at the reporting period is less than one year in amount of €81,402,982 (2019: €115,757,762). The amounts are gross and undiscounted.

7.4 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 debt, besides trade and other payables or leasing liabilities.

No changes were made in the objectives, policies or processes for managing capital during the year.

8 Commitments

8.3 Operating contracts or services

The Group enters 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 commenced.

During 2020, the Group did not enter contracts to purchase property, plant and equipment or patents and trademarks (respectively nil in 2019).

8.4 Lease obligations

The maturity analysis of lease liabilities is disclosed in the following table:

Maturity analysis for capitalized leases	Contractual minimum lease obligations	Effect of discounting	Lease liabilities
		(in €)	
Within one year	346,000	7,485	338,516
After one year but not more than five years	231,715	11,190	220,525
More than five years	—	—	—
Total	**577,715**	**18,675**	**559,040**

Anticipated future lease expenses were converted with the exchange rate as of December 31, 2020, 1 Euro = 1.2271 USD.

Maturity analysis for all lease obligations in 2020	Total	Low value leases	Short-term leases	Capitalized leases
		(in €)		
Within one year	352,261	6,261	—	346,000
After one year but not more than five years	249,199	17,484	—	231,715
More than five years	—	—	—	—
Total	**601,460**	**23,745**	—	**577,715**

Anticipated future lease expenses were converted with the exchange rate as of December 31, 2020, 1 Euro = 1.2271 USD.

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.

Maturity analysis for all lease obligations in 2019	Total	Low value leases	Short-term leases	Capitalized leases
		(in €)		
Within one year	371,105	5,387	10,841	354,878
After one year but not more than five years	532,845	12,779	20,005	500,062
More than five years	—	—	—	—
Total	**903,951**	**18,166**	**30,845**	**854,940**

Anticipated future lease expenses were converted with the exchange rate as of December 31, 2019, 1 Euro = 1.1234 USD.

9 Other information

9.3 Segment reporting

The Group has one Segment. The Group is a clinical-stage biopharmaceutical group focused on applying its proprietary anti-C5a technology. These activities are conducted as own project development. The Executive 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. No revenues were generated in 2020, 2019 and 2018. The geographic location of the Group's non-current assets are as follows:

- 31 December 2020: €1,712 thousand in Germany and €219 thousand in the United States,
- 31 December 2019: €2,217 thousand in Germany and €374 thousand in the United States.

None of the non-current assets are in the country where the Company is incorporated (the Netherlands).

9.4 Related party transactions

The compensation of the Group's executive management comprises the following for the twelve months ending December 31:

Board Compensation	**2020**	**2019**	**2018**
		(in €)	
Executive Management			
Short-term employee benefits	1,995,292	2,793,529	2,524,202
Share-based payments	1,139,286	5,218,324	9,801,454
Total	**3,134,578**	**8,011,853**	**12,325,656**
Non-executive Board of Directors			
Short-term employee benefits	283,127	269,031	238,180
Share-based payments	69,938	710,611	1,085,917
Total	**353,065**	**979,642**	**1,324,098**
Total Compensation	**3,487,643**	**8,991,495**	**13,649,754**

Executive Management comprises executive directors of the board and members from the C-Level of the Company.

The table above discloses short-term employee benefits that were contractually agreed for the board and executive management. At the balance sheet €1,152,416 were not paid but accrued (2019: €868,848) for executive management and €209,990 (2019: €103,040) for the Company`s non-executive board of directors..

Remuneration of InflaRx'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 us 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.

9.4.1 COVID-19 Pandemic

The COVID-19 pandemic, which began in December 2019 has spread worldwide and continues to cause many governments to maintain measures to slow the spread of the outbreak through quarantines, travel restrictions, closure of borders and requiring maintenance of physical distance between individuals.

Since the second quarter of 2020 the Company's employees have been able to work from their home offices or return to the Company's offices. The Company's service providers also resumed full operations in the second quarter of 2020. As the Company is currently devoting significant resources to the development of a severe COVID-19 therapy, which is currently recruiting patients in the Phase III part of a randomized, double-blind, placebo-controlled Phase II/III study, such development may impair the ability to timely progress other product candidates in clinical trials. In addition, enrollment in other programs may be delayed as a result of the COVID-19 pandemic. However, the recruitment of patients and opening of new clinical trial sites continued in the third and fourth quarter of 2020. We have taken measures to counter the negative impact of the pandemic with respect to recruitment speed, including opening of additional sites in different countries. The rapid development and fluidity of the situation presents uncertainty and risk with respect to the Company, its performance and its financial results.

9.5 Significant events after the reporting date

9.5.1 At the Market Transaction - Offering of Common Shares

Following December 31, 2020, the Company issued, under its at-the-market program (refer to '4.9.1 Issued capital'), 610,022 common shares resulting in €2.8 million in net proceeds to the Company. Following these issuances, the remaining value authorized for sale under the Sales Agreement was $35.2 million.

9.5.2 Issue of common shares and accompanying warrants

On February 25, 2021, the Company sold an aggregate of 15,000,000 common shares through a public offering. The common shares were sold at a price of $5.00 per share and have a nominal value of €0.12 per share. For each common share purchased, an investor also received a warrant to purchase a common share at an exercise price of $5.80. The warrants are exercisable immediately and have a term of up to one year. The gross offering proceeds to the Group from this offering were $75.0 million (€62.2 million), before deducting $4.5 million (€3.7 million) in underwriting discounts and other offering expenses of $0.5 million (€0.5 million) and excluding the exercise of any warrants. The aforementioned Euro amounts were calculated using the exchange rate as of March 01, 2021 (1 USD = 0.8297 EUR).

APPENDIX B - INFLARX N.V. COMPANY FINANCIAL STATEMENTS

Appendix B - InflaRx N.V. Separate Financial Statements

Balance sheet as at 31 December 2020

(before appropriation of result)

EUR	Note	2020		2019	
Non-current assets					
Intangible Fixed Assets		3,213		5,729	
Tangible Fixed Assets		14,245		18,434	
Financial fixed assets	6.	12,665,923		841,944	
Other assets	7.	353,522		432,989	
Total non-current assets			13,036,903		1,299,096
Current assets					
Other receivables and prepaid expenses	7.	17,643,495		30,741,905	
Securities	8.	38,328,032		48,969,537	
Cash and cash equivalents	9.	9,789,627		27,170,443	
Total current assets			65,761,154		106,881,884
Total assets			**78,798,057**		**108,180,980**
Shareholders' equity	10.				
Issued capital		3,387,410		3,132,631	
Share premium reserve		181,247,437		171,964,167	
Other legal reserve		(3,726,791)		2,227,228	
Other reserves		(69,060,562)		(16,922,536)	
Net Result for the period		(33,983,614)		(53,254,817)	
			77,863,880		107,146,673
Current liabilities	11.		934,177		1,034,307
Total equity and liabilities			**78,798,057**		**108,180,980**

Company only profit and loss account for the year ended 31 December 2020

EUR	Note	2020	2019
Share of result of participating interests after tax	5.	(29,053,382)	(43,104,952)
Other result, after tax	13.	(4,930,232)	(10,149,865)
Net loss		**(33,983,614)**	**(53,254,817)**

Notes to the 2020 Company only financial statements

1. 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.

2. Financial reporting period

The Company financial statements cover the year 2020, which ended at the balance sheet date of December 31, 2020. These are the fourth year's financial statements of the Company and the comparative period relates to the year 2019, which ended at the balance sheet date of December 31, 2019.

3. 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.

The functional currency of InflaRx N.V. is U.S. Dollars, as the majority of income and expenses of InflaRx N.V. occurs in U.S. Dollar, whereas the presentation currency is the Euro.

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.

4. 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 recognised from the date on which control is obtained by the Company and derecognised 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.

5. 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.

6. Financial fixed assets

Financial assets include the 100% investment of the Company in its fully owned subsidiary InflaRx GmbH, with statutory seat in Jena, Germany, and its fully owned subsidiary InflaRx Pharmaceutical Inc., a Delaware corporation, US. The latter was established on January 5, 2018 by the Company. On July 1, 2020 and on December 1, 2020, capital contributions of €892,857 (USD 1.000.000) respectively €835,562 (USD 1.000.000) were conducted.

A summary of the movement in the value of the investments is given below:

(EUR)	InflaRx GmbH	InflaRx Pharmaceutical Inc.	**Total Investments**
Net asset value at December 31, 2019	—	841,944	841,944
Contribution InflaRx GmbH (settlement 2019 result)	40,922,418	—	40,922,418
Contribution InflaRx Pharmaceutical Inc.	—	1,728,419	1,728,419
Repayments by InflaRx Pharmaceutical Inc.	—	(1,067)	(1,067)
Exchange difference on translating foreign operations	—	(6,242)	(6,242)
Share in result subsidiaries	(26,594,173)	(2,459,209)	(29,053,382)
Reversal of last year`s presentation negative net asset value deducted from InflaRx GmbH's intercompany receivable	(1,766,167)	—	(1,766,167)
Net asset value at December 31, 2020	12,562,078	103,845	**12,665,923**

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.

As a result of InflaRx GmbH`s loss in 2019 and past losses, the Company's investment in InflaRx GmbH were fully written off in 2019. An excess part (€1,766,167) over the investment balance of zero was deducted from the outstanding receivable as of December 31, 2019, with InflaRx GmbH (see note 7). In 2020 the investment InflaRx GmbH has made a loss of €26,594,173, but this loss was over compensated by the capital contribution as a result of the settlement of the aforementioned loss transfer agreement (2020: €40,922,418, 2019: €20,393,879). Accordingly, the impairment of the outstanding receivable as of December 31, 2019 (€1,766,167), with InflaRx GmbH was reversed in 2020.

Following the loan agreement from 2018 between InflaRx N.V. and InflaRx Pharmaceutical Inc. an interest payment of €1,067 occurred in 2020 (2019: €91,277). The loan was fully repaid in 2020.

7. Other receivables and prepaid expenses

(EUR)	**December 31, 2020**	**December 31, 2019**
Receivables group parties	14,971,002	28,113,181
Prepaid expense (current & non-current)	1,460,890	1,603,321
Corporate income tax	820,665	853,229
Accrued interest on securities	351,465	436,838
VAT receivables	392,995	168,324
Net asset value at December 31, 2020	**17,997,017**	**31,174,893**

The receivable with group companies covers short-term lending to InflaRx GmbH (2020: €14,971,002; 2019: 27,943,474) and InflaRx Pharmaceutical Inc. (2020: €0; 2019: €169,707). These receivables bear no interest with the following exception. A short-term loan that InflaRx Pharmaceutical Inc. repaid in 2020 (2020: nil; 2019: €169,708) bore an interest rate of 6% per annum.

The Company`s investment in InflaRx GmbH has been fully written off in 2019 because of the losses in 2019 and preceding years. The excess part of the 2019 loss was deducted from the outstanding receivable with InflaRx GmbH (see note 6.). In 2020 this deduction was fully reversed, after the settlement of the loss compensation following the loss transfer agreement with InflaRx GmbH.

Prepaid expense mainly consists of accrued insurance expense for D&O and insurance expenses. The proportion that continues for more than 1 year is €353,522 (2019: €432,989).

All receivables are due within one year.

8. Securities

The securities relate to listed debt securities (with credit ratings ranging from AA- to AAA) measured at amortized cost using the effective interest rate method. The market value of these securities amounts to €38,435,001 at 31 December 2020 (€81,929,426 at 31 December 2019). Acquisition costs of securities disclosed at December 31, 2020 were €38,649,114 (€48,980,312 at 31 December 2019). None of the securities have been pledged.

The maturities of all securities are less than one year and their nominal interests ranges between 1.4% and 3.1%.

9. 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.

10. Shareholders' equity

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	Unappropriated result	Total equity
January 1, 2019	**3,115,725**	**171,979,396**	**50,196**	**6,059,888**	**(29,814,634)**	**151,390,571**
Changes in the financial year 2019:						
Appropriation of the result	—	—	—	(29,814,634)	29,814,634	—
Equity-settled share-based payment	—	—	—	6,832,210	—	6,832,210
Share options exercised	16,905	(15,229)	—	—-	—	1,676
Net Loss for the period	—	—	—	—	(53,254,817)	(53,254,817)
Exchange differences on translation in presentation currency	—	—	2,177,033	—	—	2,177,033
December 31, 2019	**3,132,631**	**171,964,167**	**2,227,228**	**(16,922,536)**	**(53,254,817)**	**107,146,673**
Changes in the financial year 2020:						
Appropriation of the result	—	—	—	(53,254,817)	53,254,817	—
Issue of ordinary shares	234,982	9,535,961	—	—	—	9,770,943
Transaction costs	—	(729,840)	—	—	—	(729,840)
Equity-settled share-based payment	—	—	—	1,116,791	—	1,116,791
Share options exercised	19,797	477,149	—	—	—	496,946
Net Loss for the period	—	—	—	—	(33,983,614)	(33,983,614)
Exchange differences on translation in presentation currency	—	—	(5,954,019)	—	—	(5,954,019)
December 31, 2020	**3,387,410**	**181,247,437**	**(3,726,791)**	**(69,060,562)**	**(33,983,614)**	**77,863,880**

Common and preferred shares

According to the articles of association of the Company, up to 55,000,000 common shares and up to 55,000,000 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, 2020, following the at-the-market-transaction (see below) in the third quarter of 2020 and the exercise of stock options in 2019 and the second quarter of 2020, the issued capital of the Company is divided into 28,228,415 common shares (December 31, 2019: 26,105,255 common shares) with a par value of €0.12 (€12 cent) per share. All issued shares are fully paid. No preferred shares have been issued.

The Company`s general meeting of shareholders approved the right of an independent foundation under Dutch law, or protective foundation, to acquire 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 common 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 2020, no preferred shares in the Company's capital were issued.

Issued capital and share premium

On July 8, 2020, the Company filed with the United States Securities and Exchange Commission (SEC) a Form F-3 with respect to the offer and sale of securities of the Company (Registration Statement). The Company also filed with the SEC a prospectus supplement (Prospectus Supplement) relating to an at-the-market program providing for the sales of our stock over time of up to €40.7 million ($50.0 million) of its common shares pursuant to a Sales Agreement with SVB Leerink LLC. In 2020, the Company issued 1,958,186 common shares resulting in €9.0 million in net proceeds to the Company under this program. Following these issuances, the remaining value authorized for sale under the at-the-market program is €31.6 million ($38.8 million).

Other legal reserve

Besides the minimum amount of share capital to be held under Dutch law and the translation reserve (2020: €(3,726,791), 2019: €2,227,228), there are no distribution restrictions applicable to equity of the Company.

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 common shares of the Company (note 4d 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.

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 common 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 3,389,763 share options were outstanding as of December 31, 2020 (2019: 3,511,022). Further details to options are disclosed in the table below and in Appendix A of this report under ‘share-based payments.’

Share options outstanding 2020	January 1, 2020	Granted in 2020	Exercised in 2020	Forfeited in 2020	December 31, 2020
Plans prior to 2016	148,433	-	-	-	148,433
thereof exercisable					*148,433*
2016 Plan	1.181,484	-	(86,632)	-	1,094,852
thereof exercisable					*1,094,852*
2017 Long-Term Incentive Plan	2,181,105	246,188	(78,342)	(202,473)	2,146,478
thereof exercisable					*1,863,790*
	3,511,022	**246,188**	**(164,974)**	**(202,473)**	**3,389,763**

Share options outstanding 2019	January 1, 2019	Granted in 2019	Exercised in 2019	Forfeited in 2019	December 31, 2019
Plans prior to 2016	289,309	-	(140,876)	-	148,433
thereof exercisable					*148,433*
2016 Plan	1,181,484	-	-	-	1,181,484
thereof exercisable					*1,181,484*
2017 Long-Term Incentive Plan	2,051,009	242,450	-	(112,354)	2,181,105
thereof exercisable					*1,319,548*
	3,521,802	**242,450**	**(140,876)**	**(112,354)**	**3,511,022**

Unappropriated result

Appropriation of result of 2019:

The financial statements for the reporting year 2019 have been adopted by the General Meeting on June 26, 2020. The General Meeting has adopted the appropriation of the result after tax as proposed by the Board of Management.

Proposal for result appropriation:

The General Meeting will be proposed to carry forward the loss after tax for 2020 and deduct €33,983,614 from the other reserves.

The result after tax for 2020 is included in the item unappropriated result within equity.

11. Current liabilities

(EUR)	December 31, 2020	December 31, 2019
Accounts payable	11,925	209,096
Salaries	265,131	336,283
Liabilities to affiliated companies	12,839	-
Other liabilities	644,282	488,928
Total	**934,177**	**1,034,307**

Liabilities to affiliated companies resulted mainly from the charging of personnel expenses between the Company and its subsidiary InflaRx Pharmaceutical Inc. The liability is non-interest bearing.

Other liabilities include €533,183 accrued liabilities, for services rendered but not yet invoiced (2019: €429,780), €83,391 German income taxes on salaries and board compensation withheld by the Company (2019: €28,902) and accruals for statutory archive requirements (2020: €27,708, 2019: €30,265).

All current liabilities are due within one year.

12. Financial instruments

The Company's principal financial assets comprise securities and short-term deposits at commercial banks with a maturity on inception of three months or less. The main purpose of these financial instruments is to provide

funds for the subsidiary's 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.

13. Other result, after tax

Other result, after tax includes the following income and expenses related to transactions with InflaRx GmbH or InflaRx Pharmaceutical Inc.:

(EUR)	December 31, 2020	December 31, 2019
Expenses from intercompany charges	(1,142,902)	(1,114,333)
FX-gains on intercompany receivables and liabilities	216,197	307,044
FX-losses on intercompany receivables and liabilities	(2,622)	(183,740)
Total	**(929,327)**	**(991,029)**

Expenses from intercompany charges are dominated by expenses charged from InflaRx Pharmaceutical Inc. to the Company. The Company reimburses its subsidiary for cost related to employees that are predominantly working for the Company, like corporate legal services or business development services for the group.

14. 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.

2020 Board of Directors' remuneration

In 2020 no 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**
Executive directors				
Prof. Niels C. Riedemann, CEO	536,091	24,000	247,000	542,383
Prof. Renfeng Guo, CSO	431,094	12,267	204,770	490,728
Non-executive directors				
Nicolas Fulpius, Chairman, and Chairman of the Audit Committee	115,500	-	-	27,120
Jens Holstein, Member of the Audit Committee (until July 16, 2020)	23,588	-	-	***(58,693)
Richard Brudnick, Member of the Audit Committee	42,082	-	-	20,150
Mark Kübler, Member of the Audit Committee (since July 29, 2020)	43,179	-	-	27,120
Katrin Uschmann	30,000	-	-	27,120
Lina Ma	30,000	-	-	27,120
Total	**1,251,534**	**36,267**	**451,770**	**1,103,048**

** variable compensation is not based on pre-determined and measurable performance targets*
*** this includes 2017 Long-Term Incentive plan*
**** 7,686 options forfeited in 2020*

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 4c of the consolidated financial statements.

Share options not exercised 2020	Share options exercised in 2020	Share options outstanding as of January 1, 2020	Share options outstanding as of December 31, 2020	weighted average exercise price in €	weighted average remaining contractual life
Executive directors					
Prof. Niels C. Riedemann, CEO	-	1,224,707	1,224,707	2,45	6,6
Prof. Renfeng Guo, CSO	-	965,691	965,691	2,73	7,0
Non-executive directors					
Nicolas Fulpius, Chairman, and Chairman of the Audit Committee	-	34,464	34,464	2,73	5,0
Jens Holstein, Member of the Audit Committee (until July 16, 2020)	-	18,452	10,764	2.73	5.7
Richard Brudnick, Member of the Audit Committee	-	18,450	18,450	2.73	6.1
Mark Kübler, Member of the Audit Committee (since July 29, 2020)	-	41,772	41,772	2.25	5.1
Katrin Uschmann	-	49,584	49,584	1.90	5.1
Lina Ma	-	34,464	34,464	2.73	5.0
	-	**2,387,584**	**2,379,896**		

2019 Board of Directors' remuneration

In 2019 no stock options were granted to the Board of Directors under the 2017 Equity Incentive Plan, but on July 3, 2019, the board approved an amendment of the 2016 Stock Option Plan and the 2017 Long-Term 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. The valuation of past grants with the new strike price of $3.35 resulted in incremental fair values of the outstanding options, i.e. additional compensation expense had to be recognized which is included in the last column of the table below.

(EUR)	Periodically paid compensation	Retirement benefit expenses	Variable compensation*	Share based expense**
Executive directors				
Prof. Niels C. Riedemann, CEO	539,970	24,000	208,000	2,112,833
Prof. Renfeng Guo, CSO	432,647	19,344	175,308	1,899,858
Non-executive directors				-
Nicolas Fulpius, Chairman, and Chairman of the Audit Committee	88,000	-	-	96,443
Jens Holstein, Member of the Audit Committee	37,500	-	-	196,241
Richard Brudnick, Member of the Audit Committee (since May 23, 2019)	26,713			189,924
Anthony Gibney (until June 11, 2019)	13,646	-	-	*** (61,327)
Mark Kübler	40,000	-	-	96,443
Katrin Uschmann	30,000	-	-	96,443
Lina Ma	30,000	-	-	96,443
Total	1,238,477	43,344	383,308	4,723,301

** variable compensation is not based on pre-determined and measurable performance targets*
*** this includes 2017 Long-Term Incentive plan as well as the expense following the repricing of options on July 3, 2019*
**** 16,335 options forfeited in 2019*

For further details and other information with regard to related-party transactions as well as the Executive and Non-executive directors' compensation, reference is made to note 4c of the consolidated financial statements.

Share options not exercised 2019	Share options exercised in 2019	Share options outstanding as of January 1, 2019	Share options outstanding as of December 31, 2019	weighted average exercise price in €	weighted average remaining contractual life
Executive directors					
Prof. Niels C. Riedemann, CEO	-	1,224,707	1,224,707	2.68	7.6
Prof. Renfeng Guo, CSO	140,876*	1,106,567	965,691	2.98	8.0
Non-executive directors					
Nicolas Fulpius, Chairman, and Chairman of the Audit Committee	-	34,464	34,464	2.98	6.0
Jens Holstein, Member of the Audit Committee	-	18,452	18,452	2.98	6.7
Richard Brudnick, Member of the Audit Committee (since May 23, 2019)	-	-	18,450	2.98	7.1
Anthony Gibney (until June 11, 2019)	-	28,002	11,667	20.25	8.1
Mark Kübler	-	41,772	41,772	2.48	6.1
Katrin Uschmann	-	49,584	49,584	2.08	6.1
Lina Ma	-	34,464	34,464	2.98	6.0
	140,876	**2,538,012**	**2,399,251**		

** exercise price was €0.01 per share*

15. Employees

In addition to the board of directors the Company employed one employee in 2020, as well as in 2019.

16. 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)	Ernst & Young Accountants LLP 2020	Other EY network 2020	Total EY 2020
Audit of the financial statements	85,000	355,000	440,000
Other audit engagements	-	48,000	48,000
Tax-related advisory services	-	-	-
Other non-audit services	-	-	-
	85,000	403,000	488,000

There are no comparative figures for 2019, as Ernst & Young was appointed as new auditor in 2020 for the first time.

(EUR)	KPMG Accountants N.V. 2020	Other KPMG network 2020	Total KPMG 2020
Audit of the financial statements	-	15,750	15,750
Other audit engagements	-	65,000	65,000
Tax-related advisory services	-	-	-
Other non-audit services	-	-	-
	-	80,750	80,750

(EUR)	KPMG Accountants N.V. 2019	Other KPMG network 2019	Total KPMG 2019
Audit of the financial statements	81,315	166,739	248,054
Other audit engagements	-	-	-
Tax-related advisory services	-	-	-
Other non-audit services	-	-	-
	81,315	166,739	248,054

17. 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.

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 €107,188,000 (2019: €75,767,524).

18. Subsequent events

We refer to Appendix A, InflaRx N.V. Consolidated Financial Statements, 7.3 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, 2020.

By signing this signature page, the Dutch statutory board report of InflaRx N.V. for the fiscal year ended December 31, 2020, the InflaRx N.V. 2020 consolidated financial statements and the InflaRx N.V. 2020 company financial statements (appendices A and B, respectively) are approved.

_____	_____
N.C. Riedemann	R. Guo
_____	_____
N.F. Fulpius	M. Kubler
_____	_____
K. Uschmann	L. Ma
_____	
R. Brudnick	

OTHER INFORMATION

1.1 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 common shares.

1.2 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 2020, no preferred shares in the Company's capital were issued.

1.3 Material subsequent events

We refer to Note ‘7.3 Significant events after the reporting date ‘ in Appendix A – InflaRx N.V. Consolidated Financial Statements.

1.4 Branches

The Company has a branch registered in the commercial register of Jena, Germany.