InflaRx N.V.

Dutch statutory board report and financial statements

for the fiscal year ended December 31, 2017

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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 fiscal year ended December 31, 2017 and, unless explicitly stated otherwise, information presented in this report is as at December 31, 2017.

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, 2017 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.

In connection with our initial public offering in the fourth quarter of 2017, or intial public offering, InflaRx executed a corporate reorganization whereby InflaRx N.V. became the holding company for InflaRx GmbH, which 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 each became a party to a notarial deed of issue pursuant to which they subscribed for 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. We refer to these transactions in this report as the "corporate reorganization." The Consolidated Financial Statements and the Company Financial Statements are a continuation of the respective financial statements of InflaRx GmbH.

1.2 Forward-looking statements[1]

This 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", "estimate", "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 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

[1] Source: 20-F, FLS.

forward-looking statements include, without limitation, statements about the following:

- the timing, progress and results of clinical trials of 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 of any submission of filings for regulatory approval of IFX-1 or any other product candidate, and the timing of and our ability to obtain and maintain regulatory approval of IFX-1 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 and enforce our intellectual property protection for IFX-1 and any other product candidates, and the scope of such protection;
- whether the FDA, 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 IFX-1 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 IFX-1 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 for our planned future clinical trials;
- 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 IFX-1;
- 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 IFX-1 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 2.2 of this 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 report will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. You should, however, review the factors and risks and other information we describe in the reports we will file from time to time with the U.S. Securities and Exchange Commission after the date of this 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.

Risks related to our financial position and need for additional capital

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

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 unproven and we may not be able to successfully develop and commercialize any product candidates.
- We are heavily dependent on the success of IFX-1, our lead product candidate, and if IFX-1 does not receive regulatory approval or is not successfully commercialized, our business will be harmed.
- 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.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do, and reducing or eliminating our commercial opportunity.

Risks related to our dependence on third parties

- We are subject to manufacturing risks, and use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates, products, or necessary quantities at an acceptable cost.

Risks related to our intellectual property

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

- Our patents covering our proprietary anti-C5a technology may be subject to challenge, narrowing, circumvention and invalidation by third parties.
- It is difficult and costly to protect our intellectual property and our proprietary anti-C5a technologies, and we may not be able to ensure their protection.
- We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Risks related to employee matters and managing growth

- We only have a limited number of employees to manage and operate our business.
- We depend heavily on our executive officers and directors, and the loss of their services would materially harm our business.

2.2 Risk factors[2]

You should carefully consider the risks and uncertainties described below and the other information in this 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 report also contains forward-looking statements that involve risks and uncertainties. See chapter 1.2 of this report. 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

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

We incurred net losses of €8.9 million and €24.2 million for the years ended December 31, 2016 and 2017, respectively. In addition, our accumulated deficit as of December 31, 2017 was €51.3 million. We expect our net losses to increase as we advance IFX-1 into larger and later stage clinical trials, including our Phase IIb clinical trial of IFX in HS that commenced in the first quarter of 2018. To date, we have not commercialized any products or generated any revenues from the sale of products, and absent the realization of sufficient revenues from product sales, we may never attain profitability. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials. Our net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our shareholders' equity and working capital.

We anticipate that our expenses will increase substantially if and as we:

- continue to develop and conduct clinical trials with respect to our lead product candidate, IFX-1, including in connection with the initiation of our planned Phase II clinical trials of IFX-1 for HS and AAV;
- initiate and continue research, preclinical and clinical development efforts for any future product candidates, including IFX-2;
- seek to identify additional product candidates;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials, if any;

[2] Source: 20-F, Item 3.D.

- establish sales, marketing, distribution and other commercial infrastructure in the future to commercialize various products for which we may obtain marketing approval, if any;
- require the manufacture of larger quantities of product candidates for clinical development and, potentially, commercialization;
- collaborate with strategic partners to optimize the manufacturing process for IFX-1 and IFX-2;
- maintain, expand and protect our intellectual property portfolio;
- hire and retain additional personnel, such as clinical, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and help us comply with our obligations as a public company.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue unless and until we are, or any future collaborator is, able to obtain marketing approval for, and successfully commercialize, one or more of our product candidates. Successful commercialization will require achievement of key milestones, including completing clinical trials of IFX-1 and any other product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products for which we, or any of our future collaborators, may obtain marketing approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately predict the timing and amount of revenues, and if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we do, or any future collaborators do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

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

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

We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or 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, 2016 and December 31, 2017, we used €5.0 million and €12.2 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 if and as we commence Phase II clinical trials of IFX-1 in HS, including our Phase IIb trial in HS that commenced in the first quarter of 2018, and AAV and potentially clinical trials in other indications. 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 clinical development of IFX-1 for the treatments of HS and AAV, and of other indications and for working capital and other general corporate purposes. We will be required to expend significant funds in order to advance the development of IFX-1, which remains in the early stages of clinical development, as well as other product candidates we may seek to develop, including IFX-2. While we intend to focus on developing IFX-1 for HS and AAV, we are also evaluating IFX-1 for a number of additional medical indications. As a result, although we may make substantial expenditures on IFX-1 for such indications, we may cease development efforts on some or all of such indications prior to approval, if any. However, any future development activities for our pipeline product candidates will depend heavily on the clinical and marketing success of IFX-1 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 IFX-1 or any of our other product candidates or potentially discontinue operations altogether. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements 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 IFX-1;
- 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 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.

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

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

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

We 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, IFX-1. We have not yet demonstrated an ability to successfully conduct 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 or abandonment of the euro currency 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. In addition, the abandonment of the euro by one or more members of the European Union could lead to the reintroduction of individual currencies in one or more EU member states, or in more extreme circumstances, the dissolution of the European Union. The effects on our business of the abandonment of the euro as a currency, the exit of one or more EU member states from the European Union or a potential dissolution of the European Union, are impossible to predict with certainty, and any such events could have a material adverse effect on our business, financial condition and results of operations.

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 unproven and we may not be able to successfully develop and commercialize any product candidates.

IFX-1 is a novel therapeutic antibody and its potential therapeutic benefit is unproven. There is no approved therapy inhibiting C5a activation and, as a result, the regulatory pathway for IFX-1 may present novel issues that could cause delays in development or approval. Our product candidates may not demonstrate in patients any or all of the pharmacological benefits we believe they may possess. We have not yet succeeded and may never succeed in demonstrating efficacy and safety for these or any other product candidates in pivotal clinical trials or in obtaining marketing approval thereafter. For example, although we have evaluated IFX-1 in preclinical studies and in early-stage clinical trials, we have not yet advanced IFX-1 into Phase III clinical development, nor have we obtained regulatory approval to sell any product based on our therapeutic approaches. Positive results from our early-stage clinical trials are not necessarily predictive of the results of our ongoing Phase IIb clinical trial of IFX-1 for HS. If we cannot replicate the positive results from our Phase I and Phase IIa clinical trials in our Phase IIb and Phase III clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize IFX-1 for HS.

C5a inhibition to treat complement-mediated autoimmune and inflammatory diseases has not been validated. This is an unproven approach to the treatment of HS, which is our lead indication for IFX-1, and of AAV. Accordingly, our focus on treating these diseases may not result in the development of commercially viable products. In addition, our proprietary anti-C5a technology and focus on exploring C5a inhibition may fail to result in the identification of viable additional product candidates in any 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 IFX-1, our lead product candidate, and if IFX-1 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 IFX-1, 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 IFX-1. We cannot be certain that IFX-1 will receive regulatory approval or be successfully commercialized even if we receive regulatory approval for any indication, due in part because IFX-1 remains in early stages of clinical development, and it may be years before we are in a position to seek regulatory approval for IFX-1 in any indication. Moreover, we may not be successful in our efforts to expand the approval, if any, of IFX-1 for other indications. If we

were required to discontinue development of IFX-1 for any indication or if IFX-1 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 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, while we have recently observed positive final results from our Phase IIa clinical trial for IFX-1 in 12 HS patients, such results may not be replicated with statistical significance in future clinical trials, such as our Phase IIb trial for IFX-1 in HS, that include larger numbers of patients with potentially different trial protocols and endpoints. 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.

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

The development and commercialization of new products is highly competitive. We expect that we, and any future collaborators, will face significant competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to any of our product candidates that we, or any future collaborators, may seek to develop or commercialize in the future. For example, other pharmaceutical companies may commence development efforts for product candidates targeting the same indications as IFX-1, including HS or AAV, or any other indications we may target. See "Item 4. Information on the Company—B. Business overview—Competition." Although we have tested and expect to further test IFX-1 in HS patients, some of whom have not responded to adalimumab, the current standard of care for HS, if IFX-1 proves to be effective and is approved for use in such patients, IFX-1 may compete with adalimumab or any other treatment approach which is currently under development in HS and obtains approval. For example, in the area of HS treatment, IFX-1 may compete with MABp1, a monoclonal antibody being developed by XBiotech Inc. targeting interleukin-1 alpha, for which XBiotech recently completed a Phase II clinical trial, as well as Bimekizumab, a monoclonal antibody blocking interleukin-17AF, for which UCB Pharma recently completed a Phase

II clinical trial. In addition, in the area of AAV treatment and HS treatment, IFX-1 may compete with CCX168, a C5aR inhibitor being developed by Chemocentryx targeting multiple severe and rare inflammatory disorders. Though it acts through a different mechanism of action than IFX-1, CCX168 has demonstrated the potential to induce remission in AAV patients and is currently undergoing Phase III clinical trial development. CCX168 was also granted the EMA's Priority Medicine's designation to expedite its clinical development and the European Medicines Agency recently accepted the conditional marketing authorization application for regulatory review. Chemocentryx recently announced the intention to start development as well in HS. There are additional drugs currently being developed for treatment of AAV which may be approved in the future. If approved for the treatment of AAV, IFX-1 would also face competition from current therapies, including corticosteroids, azathioprine, methotrexate, mycophenolate mofetil or rituximab. In addition, several product candidates in development by other pharmaceutical companies targeting C5a have failed or remain in early stages of development, with future development unclear. As a result, complement-mediated treatments, such as eculizumab, currently remain focused on C5 inhibition. However, as the area of terminal complement activation further develops, particularly if IFX-1 is approved for commercialization, our competitors may seek to develop their own product candidates targeting C5a.

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

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

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. 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, all of our product candidates are in early stages of development or clinical testing. For example, IFX-1, our lead product candidate, has only recently completed an initial Phase IIa trial for HS

and we have only recently commenced a Phase IIb trial for HS. 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 IFX-1 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 expect to enroll in our planned clinical trial of IFX-1 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 IFX-1, such events may create a negative safety perception and adversely impact market acceptance of IFX-1 following any approval. For example, in our most recent Phase IIa clinical trial of IFX-1 for HS, we observed several adverse events, even though they were judged not to be related to IFX-1 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 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 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 IFX-1 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.

Even if we complete the necessary preclinical studies and clinical trials for IFX-1 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 we intend to use HiSCR as the primary endpoint in our planned clinical trials of IFX-1 for HS, which we believe is a clinically-accepted endpoint based on the approval of adalimumab, there is no guarantee that the FDA or comparable foreign regulatory authorities will permit us to do so. Further, the HiSCR response is a subjective endpoint, demonstrated if an investigator determines there has been a 50% or higher reduction of the AN count (without any increase of the abscess or draining fistula count from baseline). As a result, the regulatory pathway for IFX-1 is novel and may present unforeseen issues or delays.

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 submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate's clinical development and may vary among jurisdictions. Any marketing approval 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 IFX-1 for many reasons, including:

- we may not be able to demonstrate that IFX-1 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 IFX-1 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 IFX-1;

- 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 HiSCR in our planned clinical trials of IFX-1 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 IFX-1 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;
- 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 cGMPs; 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 IFX-1, 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 IFX-1 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.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We will be required to identify and enroll a sufficient number of patients with HS and AAV for our planned clinical trials of IFX-1 in these indications. Each of these is a rare disease or indication with a relatively small patient population. Trial participant enrollment could be limited in future trials in HS given that many potential participants may be ineligible because they are already undergoing treatment with adalimumab, particularly in the United States where we intend to seek orphan drug designation. We may not be able to initiate or continue clinical trials required by the FDA, EMA or other foreign regulatory agencies for IFX-1 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.

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.

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 IFX-1 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. Physicians are often reluctant to switch their patients from existing therapies (such as adalimumab 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 products 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 IFX-1 for the treatment of HS, we may not be able to successfully convince physicians or patients to switch from adalimumab to IFX-1. 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, IFX-1 may not be accepted by physicians or patients if we cannot demonstrate, or if IFX-1 is perceived as not having, strong duration of effect, including compared to existing treatments for HS. The duration of effect of IFX-1 has only been studied 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. Further, the potential patient populations for our initial targeted indications, including HS and AAV, are relatively small. This could affect the rate of adoption and as a result, market acceptance of our product candidates, if approved, could be much slower than anticipated.

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 IFX-1 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 IFX-1 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 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.

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

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

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

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

We 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 IFX-1. 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 and AAV for IFX-1, each of which is a rare disease 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 IFX-1 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.

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

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

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

Clinical development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of IFX-1 or any future product candidate we may develop.

The risk of failure for IFX-1 and any other future product candidates we may develop is high. It is impossible to predict when or if IFX-1 will prove to be effective and safe in humans or will receive regulatory approval for the treatment of HS or AAV. Additionally, before regulatory authorities grant marketing approval for IFX-1, 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. 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 IFX-1 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 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 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 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 plan to seek orphan drug designation for IFX-1 in HS, but we may be unable to obtain such designation or to maintain the benefits associated with orphan drug status, including market exclusivity, even if that designation is granted.

We plan to seek orphan drug designation from the FDA for IFX-1 in HS and potentially in other orphan indications in which there is a medically plausible basis for its use, and we may seek orphan drug designation for other preclinical product candidates in our pipeline or that we may develop. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the FDA review and approval process. Although we intend to seek orphan drug designation for IFX-1 in HS from the FDA, we may never receive such designation. Moreover, obtaining orphan drug designation for IFX-1 in HS does not mean we will be able to obtain such designation for another indication. We do not plan to seek orphan drug designation for IFX-1 in HS in the European Union because we do not expect that the population criterion would be satisfied.

If a product that has orphan drug designation from the FDA subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same drug for the same indication for seven years, except in limited circumstances such as if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Similarly, the FDA can subsequently approve a drug with the same active moiety for the same condition during the exclusivity period if the FDA concludes that the later drug is clinically superior, meaning the later drug is safer, more effective, or makes a major contribution to patient care. Even if we were to obtain orphan drug designation for IFX-1 from the FDA, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products, and thus approval of IFX-1 could be blocked for seven years if another company obtains approval and orphan drug exclusivity for the same drug and same condition before us. If we do obtain exclusive marketing rights in the United States, they may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of the relevant patients. Further, exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition, the same drugs can be approved for different indications and might then be used off-label in our approved indication, and different drugs for the same condition may already be approved and commercially available.

Even if we obtain FDA approval of IFX-1 or any of our other product candidates, we may never obtain approval or commercialize our products outside of the United States.

In order to market any approved products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding clinical trial design, safety and efficacy. If approved by the relevant governmental authorities, we expect to market IFX-1 for the treatment of HS in Europe and jurisdictions outside the United States, in part due to the relatively larger patient population that exists in Europe as compared to that in the United States. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming and could delay or prevent introduction of IFX-1 or any of our other product candidates in those countries. In addition, we expect to be subject to a variety of risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- foreign reimbursement, pricing and insurance regimes;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

If we or our partners fail to comply with regulatory requirements or to obtain and maintain required approvals, our target market will be reduced, including if we are unable to market IFX-1 for the treatment of HS in Europe, and our ability to realize the full market potential of our product candidates will be harmed.

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

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

Obtaining FDA, EMA or other regulatory agency 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. 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.

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

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with health care professionals, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal civil False Claims Act, that may constrain the business or financial arrangements and relationships through which we conduct clinical research, sell, market and distribute any drugs for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include the following:

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

- federal civil and criminal false claims laws, including, without limitation, the federal civil False Claims Act (that can be enforced through civil whistleblower or qui tam actions), and the civil monetary penalties law, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

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

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

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

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

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom may recommend, purchase or prescribe IFX-1, if approved, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize IFX-1 and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of IFX-1, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, President Obama signed into law the Affordable Care Act, a sweeping law intended to broaden

access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the Affordable Care Act of importance to our potential product candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;

- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, which include, among other things, new government investigative powers and enhanced penalties for non-compliance;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, thereby potentially increasing manufacturers' Medicaid rebate liability;

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- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, thereby potentially increasing manufacturers' Medicaid rebate liability;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- the new requirements under the federal open payments program and its implementing regulations;

- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Some of the provisions of the Affordable Care Act have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 includes a provision

repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called ‘‘Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Congress may consider other legislation to repeal or replace elements of the Affordable Care Act. Although we cannot predict the ultimate content, timing or effect of any changes to the Affordable Care Act or other federal and state reform efforts, we continue to evaluate the effect that the Affordable Care Act, as amended or replaced, will have on our business. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our drug candidate.

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

We expect that the Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. In addition, there have been several recent Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for drugs. At the federal level, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of IFX-1, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent drug labeling and post-marketing testing and other requirements.

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

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any future collaborators, must therefore comply with requirements concerning advertising and promotion for any of our product candidates for which we or they obtain marketing approval. Promotional communications with respect to

prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we and any future collaborators will not be able to promote any products we develop for indications or uses for which they are not approved.

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

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

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

Outside of the United States, international operations are generally subject to extensive governmental price controls and other market regulations. In many countries, such as countries of the European Union, the pricing of prescription pharmaceuticals is subject to varying price control mechanisms, often as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we, or any future collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates, and we believe the increasing emphasis on cost-containment initiatives in the Europe Union has and will continue to put pressure on the pricing and usage of our product candidates. As a result, given the relatively smaller target markets for HS and AAV, our initial indications for IFX-1, in the Europe Union and elsewhere outside the United States, any reduced reimbursement for such product candidates may be insufficient for us to generate commercially reasonable revenue and profits and would adversely affect our financial condition and results of operations.

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

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

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

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

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

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, 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 Good Clinical Practices, or GCPs, 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 GCPs 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 GCPs, 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 GCPs. 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. 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.

We are subject to manufacturing risks, and use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates, products, or necessary quantities at an acceptable cost.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. As a result, we currently rely on third parties for supply of IFX-1. Our current strategy is to outsource all manufacturing of our product candidates and products to third parties while conducting certain quality control tests within our in-house manufacturing processes.

The process of manufacturing our products is complex, highly regulated and subject to several risks. The process of manufacturing biologics, such as IFX-1, is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Further, our product candidates that have been

produced and are stored for later use may degrade, become contaminated or suffer other quality defects, which may cause the affected product candidates to no longer be suitable for their intended use in clinical trials or other development activities. If the defective product candidates cannot be replaced in a timely fashion, we may incur significant delays in our development programs that could adversely affect the value of such product candidates.

We currently engage third-party manufacturers to provide the final drug product formulation of IFX-1 that is being used in our clinical trials. Although we believe that there are several potential alternative manufacturers who could manufacture IFX-1, we may incur added costs and delays in identifying and qualifying any such replacement. We recently engaged a new manufacturer for clinical supply of IFX-1. There is no assurance that we will be able to timely secure needed alternative supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or, to commercialize them, if approved. There may be difficulties in scaling up to commercial quantities or optimization of processes and formulation of IFX-1 and the costs of manufacturing could be prohibitive.

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

- reliance on third-parties for manufacturing process development, regulatory compliance and quality assurance;
- costs and validation of new equipment and facilities required for additional scale-up or optimization of processes;
- failure to comply with cGMP and similar foreign standards;
- limitations on supply availability resulting from capacity and scheduling constraints of third-parties;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- the possible breach of manufacturing agreements by third-parties because of factors beyond our control; and
- the possible termination or non-renewal of the manufacturing agreements by the third-party, at a time that is costly or inconvenient to us, and our ability to obtain alternative supply.

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

We participate in the manufacturing process with crucial quality control testing within our own laboratories, and we hold the manufacturer license for, and therefore oversee, the overall manufacturing process, and we are responsible for ensuring that this part of our business also operates according to

GMP standards. Additionally, we currently hold an importing license. We therefore employ key personnel within the manufacturing process such as a head of quality assurance, a head of manufacturing, and a qualified person.

Thus, our laboratories and our quality control system and related documentation and personnel, are also subject to frequent governmental inspections to assure adherence to GMP guidelines and to maintain our manufacturing and importing license. Related to these activities, there are risks which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects, including but not being limited to the following risks:

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

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

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

Our third-party manufacturers or we may not be able to comply with the cGMP regulatory requirements applicable to IFX-1 and biologics, including applicable provisions of the FDA's drug cGMP regulations, device cGMP requirements embodied in the Quality System Regulation, or QSR, or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. In addition, our third-party manufacturers and suppliers and we are subject to FDA and other local regulatory authority inspection from time to time. Failure by our third-party manufacturers and suppliers or us to pass such inspections and otherwise satisfactorily complete the FDA approval regimen with respect to our product candidate may result in regulatory actions such as the issuance of FDA Form 483 notices of observations, warning letters or injunctions or the loss of operating licenses. In addition, we and our third-party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of the regulatory action, our clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could have a material adverse effect on our business, including our clinical research activities and our ability to develop our product candidates and market our products following approval, if any.

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

In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of IFX-1 or any of our other product candidates in our pipeline or that we may develop, our third party manufacturers will be required to increase their production and optimize their manufacturing processes while maintaining the quality of the product. The transition to larger scale production could prove difficult or costly. Further, any claims in our manufacturing process as a result of scaling up or optimization of the manufacturing, supply and fill process may result in the need to obtain regulatory approvals. If our third party manufacturers are not able to optimize manufacturing process to increase the product yield for our product candidates, or are unable to produce increased amounts of our product candidates while maintaining the quality of the product, then we may not be

able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits. Difficulty in achieving commercial scale-up production or production optimization or the need for additional regulatory approvals as a result could have a material adverse impact on our business and results of operations.

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

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

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

Collaborations are complex and time-consuming to negotiate and document. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have may resulted in a reduced number of potential future collaborators. Any collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations or to otherwise develop specified product candidates. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

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

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

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs, based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, including trade secrets and intellectual property rights, contract interpretation, or the preferred course of development might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours is involved in a business combination, it could decide to delay, diminish or terminate the development or commercialization of any product candidate licensed to it by us.

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 and maintain patent, trade secret and other intellectual property protection in the United States and other countries with respect to IFX-1 and other proprietary product candidates. If we do not adequately protect our intellectual property rights, competitors may be able to erode, negate or preempt any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our novel product candidates 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 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 marketplace 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 and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek 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 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, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we would need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Furthermore, we, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Any of our patents may be challenged, narrowed, circumvented, or invalidated by third parties. The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and

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

In addition, our competitors and other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to IFX-1 or other product candidates but that uses a technology that falls outside the scope of our patent protection. Our competitors may also seek approval to market generic versions of any approved products and in connection with seeking such approval may claim that our patents are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

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

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

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;

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

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

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

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

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

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

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

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

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

The ultimate determination by the USPTO or by a court or other trier of fact in the United States, or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. Although our C5a inhibitor portfolio consists of three families of patent applications that we own directed to C5a inhibitors and related methods of use, we cannot predict the

breadth of claims that may be allowed or enforced in our patents or patent applications, in our licensed patents or patent applications or in third-party patents.

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

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

- we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs, including our HS program;
- it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent(s) will be insufficient to protect our technology, provide us with a basis for commercially viable products or provide us with any competitive advantages;
- if our pending applications issue as patents, they may be challenged by third parties as not infringed, invalid or unenforceable under United States or foreign laws; or
- if issued, the patents under which we hold rights may not be valid or enforceable.

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

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

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

In addition, it is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If

any of our present or future partners, collaborators, licensees, or licensors, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments and similar legislation in the EU. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. In Europe, a maximum of five and a half years of supplementary protection can be achieved for an active ingredient or combinations of active ingredients of a medicinal product protected by a basic patent, if a valid marketing authorization exists (which must be the first authorization to place the product on the market as a medicinal product) and if the product has not already been the subject of supplementary protection. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the United States, including the Leahy-Smith America Invents Act, or the America Invents Act, could increase those uncertainties and costs. The America Invents Act was signed into law on September 16, 2011, and many of the substantive changes became effective on March 16, 2013. The America Invents Act reforms United States patent law in part by changing the U.S. patent system from a "first to invent" system to a "first inventor to file" system, expanding the definition of prior art, and developing a post-grant review system. This legislation changed United States patent law in a way that may weaken our ability to obtain patent protection in the United States for those applications filed after March 16, 2013.

Further, the America Invents Act created new procedures to challenge the validity of issued patents in the United States, including post-grant review and *inter partes* review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent with an effective filing date of March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine month window from issuance of the patent. A petition for *inter partes* review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. A petition for *inter partes* review can be filed after the nine month period for filing a post-grant review petition has expired for a patent with an effective filing date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of invalidity, whereas *inter partes* review proceedings can only raise an invalidity challenge based on published prior art and patents. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts, and use a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent invalidated in a USPTO post-grant review or *inter partes* review proceeding than invalidated in a litigation in a U.S. federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we or our licensors or collaborators will be successful in defending the patent, which would result in a loss of the challenged patent right to us.

In addition, recent court rulings in cases such as Association for Molecular Pathology v. Myriad Genetics, Inc., BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litigation, Promega Corp. v. Life Technologies Corp. and Abbvie Deutschland GmbH v. Janssen Biotech, Inc. have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Any changes to patent law in the U.S. or other jurisdictions that impairs our ability to protect IFX-1 and other product candidates could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and market their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products

may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Moreover, such proceedings could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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 licensors', patents or other proprietary or 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 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 intellectual property. If we become involved in any litigation, it could consume a substantial portion of our resources, and 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 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 violation 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 intellectual property and other proprietary 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 marketing 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 confidential information or trade secrets of third parties could have a similar negative impact on our business. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Many of our current and former employees and our licensors' current and former employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including some which may be competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a

license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

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

Competitors may infringe, misappropriate, or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving one or more of our patents could limit our ability to assert those patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we were to assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of our common shares. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Any such litigation could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

We may be reliant upon licenses to certain patent rights and proprietary anti-C5a technology form third parties that are important or necessary to the development of our product candidates. These

and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses. Our licensors may have relied on third party consultants or collaborators or funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-license. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under current and any future collaborative development relationships;
- our diligence obligations under any license agreement and what activities satisfy such obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our license counterparties and us and our partners; and
- the priority of invention of patented technology.

In spite of our best efforts, our license counterparties might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, which may remove our ability to develop and commercialize the product candidates and technology covered by these license agreements. If any in-licenses are terminated, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. It is possible that we may be unable to obtain any additional licenses that we require at a reasonable cost or on reasonable terms, if at all. In

that event, we may be required to expend significant time and resources to redesign our product candidates, technology, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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

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

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

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Certain of our employees and patents are subject to German law.

A number of our personnel, including our directors, work in Germany and are subject to German employment law. Inventions which may be the subject of a patent or of protection as a utility model as well as technical improvement proposals for other technical innovations that may not be the subject of a patent or of protection as a utility model made by such employees are subject to the provisions of the German Act on Employees' Inventions (*Gesetz über Arbeitnehmererfindungen*), which regulates the ownership of, and compensation for, inventions made by employees. We face the risk that disputes may occur between us and our current or past employees pertaining to the sufficiency of compensation paid by us, allocation of rights to inventions under this act or alleged non-adherence to the provisions of this act, any of which may be costly to resolve and take up our management's time and efforts whether we prevail or fail in such dispute. In addition, under the German Act on Employees' Inventions, certain

employees retain rights to patents they invented or co-invented and disclosed to us prior to October 1, 2009. While we believe that all of our current and past German employee inventors have subsequently assigned to us their interest in patents they invented or co-invented, there can be no assurance that all such assignments are fully effective. Even if we lawfully own all inventions of our employee inventors who are subject to the German Act on Employees' Inventions, we are required under German law to reasonably compensate such employees for the use of the patents. If we are required to pay increased compensation or face other disputes under the German Act on Employees' Inventions, our results of operations could be adversely affected.

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

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, 2017, we had 21 full-time or part-time employees. Our focus on the development of IFX-1 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 IFX-1 or run our operations or to accomplish all of 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, Arnd Christ, our Chief Financial Officer and Dr. Othmar Zenker, our Chief Medical Officer. In addition, we have established relationships with universities and research institutions which have historically provided, and continue to provide, us with access to research laboratories, clinical trials, facilities and patients. 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.

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.

Risks related to our common shares and our status as a public company

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

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

- the timing, enrollment and results of clinical trials of IFX-1 and any other product candidates;
- regulatory actions with respect to IFX-1, our other product candidates or our competitors' products and product candidates;
- the success of existing or new competitive products or technologies;
- any delay in our development or regulatory filings for IFX-1 or any future product candidate and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- commencement or termination of collaborations for our development programs;
- failure or discontinuation of any of our development programs;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;

- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results or development timelines;
- announcement or expectation of additional financing efforts;
- sales of our common shares by us, our insiders or other shareholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our shares;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this chapter 2.2.

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

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

Future sales of a substantial number of our common shares, or the perception that such sales will occur, could cause a decline in the market price of our common shares. We had a total of 23,812,100 common shares outstanding as of December 31, 2017. If our existing shareholders sell substantial amounts of common shares in the public market, or the market perceives that such sales may occur, the market price of our common shares and our ability to raise capital through an issue of equity securities in the future could be adversely affected.

Moreover, we have entered into a registration rights agreement entitling our existing holders of an aggregate of 16,743,972 common shares to rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other shareholders. In addition, we have registered on a Form S-8 registration statement all common shares that we may issue under our equity incentive plan. As a result, these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements entered into in connection with our initial public offering. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common shares could decline.

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

As of December 31, 2017, we had €123.3 million in cash and cash equivalents. Our management will have broad discretion in the use of such cash and could spend it in ways that do not improve our results of operations or enhance the value of our common shares. You will not have the opportunity to influence our decisions on how to use our cash on hand. The failure by our management to apply these funds effectively could result in financial losses that could harm our business, cause the price of our common shares to decline and delay the development of our product candidates. Pending its use, we may invest our cash on hand in a manner that does not produce income or that loses value.

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

We will report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act, (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their Annual Report on Form 20-F until four months after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their Annual Report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

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

We are a foreign private issuer and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. If in the future we are not a foreign private issuer as of the last day of the second fiscal quarter in any fiscal year, we would be required to comply with all of the periodic disclosure, current reporting requirements and proxy solicitation rules of the Exchange Act applicable to U.S. domestic issuers. In order to maintain our current status as a foreign private issuer, either (a) a majority of our common shares must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our directors and executive officers may not be United States citizens or residents, (ii) more than 50% of our assets cannot be located in the United States and (iii) our business must be administered principally outside the United States. If we were to lose this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and stock exchange rules. The regulatory and compliance costs to us if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the costs we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. These rules and regulations could also make it more difficult for us to attract and retain qualified directors.

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

We are a foreign private issuer. As a result, in accordance with the listing requirements of NASDAQ we rely on home country governance requirements and certain exemptions thereunder rather than relying on the corporate governance requirements of NASDAQ. In accordance with Dutch law and generally accepted business practices, our Articles of Association do not provide quorum requirements generally applicable to general meetings of shareholders. To this extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding

voting stock. Although we must provide shareholders with an agenda and other relevant documents for the general meeting of shareholders, Dutch law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally accepted business practice in the Netherlands; thus, our practice will vary from the requirement of Nasdaq Listing Rule 5620(b). As permitted by the listing requirements of NASDAQ, we have also opted out of the requirements of Nasdaq Listing Rule 5605(d), which requires, among other things, an issuer to have a compensation committee that consists entirely of independent directors and makes determinations regarding the independence of any compensation consultants, Nasdaq Listing Rule 5605(e), which requires independent director oversight of director nominations, and Nasdaq Listing Rule 5605(b)(2), which requires an issuer to have a majority of independent directors on its board. We are also relying rely on the phase-in rules of the SEC and NASDAQ with respect to the independence of our audit committee. These rules require that a majority of our directors must be independent and all members of our audit committee must meet the independence standard for audit committee members within one year of the effectiveness of the registration statement relating to our initial public offering. In addition, we have opted out of shareholder approval requirements, as included in the Nasdaq Listing Rules, for the issuance of securities in connection with certain events such as the acquisition of shares or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us and certain private placements. To this extent, our practice varies from the requirements of Nasdaq Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events. Accordingly, you may not have the same protections afforded to shareholders of companies that are subject to these NASDAQ requirements.

We are an "emerging growth company" and, as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common shares may be less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only three years of audited financial statements with correspondingly reduced disclosure in our Annual Report on Form 20-F;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- not being required to hold a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common shares less attractive because we will rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common shares that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. Given that we currently report and expect to continue to report under IFRS as issued by the IASB, we will not be

able to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required by the IASB.

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

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

We are required to disclose changes made in our internal controls and procedures and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an "emerging growth company" for up to five years after our initial public offering. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

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

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

Concentration of ownership of our common shares among our existing executive officers, directors and principal shareholders may prevent new investors from influencing significant corporate decisions.

Certain of our existing shareholders, including certain of our directors and affiliates of our directors, our executive officers, directors and current beneficial owners of 5% or more of our common shares and their respective affiliates, in the aggregate, beneficially own approximately 80% of our outstanding common shares. As a result, such holders are able to control, and these other persons, acting together, are able to significantly influence all matters requiring shareholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions.

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

The trading market for our common shares depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We do not currently have research coverage, and there can be no assurance that analysts will

cover us, or provide favorable coverage. Securities or industry analysts may elect not to continue to provide research coverage of our common shares, and such lack of research coverage may negatively impact the market price of our common shares. In the event we do have analyst coverage, if one or more analysts downgrade our common shares, change their opinion of our common shares or publish inaccurate or unfavorable research about our business, our share price would likely decline. In addition, if one or more analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

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

Our ability to utilize our net operating losses, or NOLs, is currently limited, and may be limited further, under Section 8c of the *Körperschaftsteuergesetz* (German Corporation Income Tax Act or KStG) and Section 10a of the *Gewerbesteuergesetz* (German Trade Tax Act or GewStG). These limitations apply if a qualified ownership change, as defined by Section 8c KStG, occurs and no exemption is applicable. Generally, a qualified ownership change occurs if more than 25% of the share capital or the voting rights are directly or indirectly transferred to a shareholder or a group of shareholders within a period of five years. A qualified ownership change may also occur in case of a transaction comparable to a transfer of shares or voting rights or in case of an increase in capital leading to a respective change in the shareholding. In the case of such a qualified ownership change tax loss carry forwards, consisting of the NOLs in the same percentage as the ownership change, cannot be utilized. If the percentage of the aforementioned ownership change/change in voting rights exceeds 50%, tax loss carry forwards expire in full. To the extent that the tax loss carry forwards exceed hidden reserves (*stille Reserven*) taxable in Germany, they may be further utilized despite a qualified ownership change. In case of a qualified ownership change within a group, tax loss carry forwards will be preserved if certain conditions are satisfied.

According to a decision of the Federal Constitutional Court dated 29 March 2017–2 BvL 6/11, the present Section 8c para. 1 sentence 1 KStG is not in line with the German constitution. Thus, Section 8c para. 1 sentence 1 KStG needs to be amended. At the moment it is unclear when the German legislature will present a draft bill reflecting the required changes to the present Section 8c paragraph 1, sentence 1 KStG. Furthermore, another appeal has been filed by the fiscal court of Hamburg dated August 29, 2017 – 2 K 245/17 with regard to Section 8c, paragraph 1, sentence 2 KStG— that is, the forfeiture of all tax loss carryforwards in case more than 50% of shares/voting rights will be assigned to a new shareholder. The appeal is still pending. It is unclear when the Federal Constitutional Court will decide this case. According to statements in German legal literature, there are good reasons to believe that the Federal Constitutional Court may come to the conclusion that Section 8, paragraph 1, sentence 2 KStG is not in line with the German constitution

As of December 31, 2017, we had NOL carry forwards for German tax purposes of €34.8 million available. Future changes in share ownership may also trigger an ownership change and, consequently, a Section 8c KStG, or a Section 10a GewStG limitation. Any limitation may result in the expiration of a portion or the complete tax operating loss carry forwards before they can be utilized. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carry forwards to reduce German income tax may be subject to limitations, which could potentially result in increased future cash tax liability to us.

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

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

taxes on income of 2012. However, we may become subject to limited income tax liability in other countries with regard to the income generated in the respective other country, for example, due to the existence of a permanent establishment or a permanent representative.

The applicable tax laws or interpretations thereof may change. Furthermore, whether we have our place of effective management in Germany and are as such tax resident in Germany is largely a question of fact and degree based on all the circumstances, rather than a question of law, which facts and degree may also change. Changes to applicable laws or interpretations thereof and changes to applicable facts and circumstances (for example, a change of board members or the place where board meetings take place), may result in us becoming a tax resident of a jurisdiction other than Germany. As a consequence, our overall effective income tax rate and income tax expense could materially increase, which could have a material adverse effect on our business, results of operations, financial condition and prospects, which could cause our share price and trading volume to decline. However, if there is a double tax treaty between Germany and the respective other country the double taxation of income may be avoided. Thus, the detrimental tax effects should be mitigated by the application of the respective double tax treaty.

Although we do not believe that we were a "passive foreign investment company," or a PFIC, for U.S. federal income tax purposes in 2017, we may be a PFIC in 2018 or one or more future taxable years. If we are a PFIC in 2018 or any future taxable year, U.S. shareholders may be subject to adverse U.S. federal income tax consequences.

Under the Internal Revenue Code of 1986, as amended (the "**Code**"), we will be a PFIC for any taxable year in which, after the application of certain look-through rules with respect to subsidiaries, either (i) 75% or more of our gross income consists of passive income or (ii) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, passive income. Passive income includes, among other things, dividends, interest, certain non-active rents and royalties, and capital gains. Based on our current operations, income, assets and certain estimates and projections, including as to the relative values of our assets and the treatment of our grants received as gross income that is not passive income, we do not believe that we were a PFIC for our 2017 taxable year. However, there can be no assurance that the Internal Revenue Service (the "IRS") will agree with our conclusion. In addition, whether we will be a PFIC in 2018 or any future taxable year is uncertain because, among other things, (i) we currently own a substantial amount of passive assets, including cash, (ii) the valuation of our assets that generate non-passive income for PFIC purposes, including our intangible assets, is uncertain and may vary substantially over time, (iii) the treatment of grants as income for U.S. federal income tax purposes is unclear, and (iv) the composition of our income may vary substantially over time. Accordingly, there can be no assurance that we will not be a PFIC for any taxable year.

If we are a PFIC for any taxable year during which a U.S. investor holds common shares, we would continue to be treated as a PFIC with respect to that U.S. investor for all succeeding years during which the U.S. investor holds common shares, even if we ceased to meet the threshold requirements for PFIC status, unless certain exceptions apply. Such a U.S. investor may be subject to adverse U.S. federal income tax consequences, including (i) the treatment of all or a portion of any gain on disposition as ordinary income, (ii) the application of a deferred interest charge on such gain and the receipt of certain dividends and (iii) compliance with certain reporting requirements. We do not intend to provide the information that would enable investors to make a qualified electing fund election that could mitigate the adverse U.S. federal income tax consequences should we be classified as a PFIC.

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

As an entity incorporated under Dutch law, but with its place of effective management in Germany (and not in the Netherlands), our dividends are generally subject to German dividend withholding tax and not Dutch dividend withholding tax. Dutch dividend withholding tax is required to be withheld from dividends if and when paid to Dutch resident holders of our shares (and non-Dutch resident holders

of our shares that have a permanent establishment in the Netherlands to which their shareholding is attributable). As a result, upon a payment (or deemed payment) of dividends, we will be required to identify our shareholders in order to assess whether there are Dutch residents (or non-Dutch residents with a permanent establishment to which the shares a1re attributable) in respect of which Dutch dividend tax has to be withheld. Such identification may not always be possible in practice. We may approach Dutch Revenue prior to a payment of dividends to apply for a tax ruling confirming that no withholding of any Dutch dividend tax is applicable at all (as the dividend withholding tax can generally be credited against a Dutch resident shareholder's income tax anyway). The outcome of tax ruling requests is uncertain. If a favorable tax ruling cannot be obtained and if the identity of our shareholders cannot be determined, withholding of both German and Dutch dividend tax may occur, upon a payment of dividends.

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

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

The rights of shareholders and the responsibilities of directors may be different from the rights and obligations of shareholders and board members in companies governed by the laws of U.S. jurisdictions. In the performance of its duties, our executive officers and board of directors are required by Dutch law to consider the interests of our company, its shareholders, its employees and other stakeholders, in all cases with due observation of the principles of reasonableness and fairness. It is possible that some of these parties will have interests that are different from, or in addition to, your interests as a shareholder.

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

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

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

The protective foundation's articles of association provide that it will promote and protect the interests of the company, the business connected with the company and the company's stakeholders from time to time, and repressing possible influences which could threaten the strategy, continuity, independence and/or identity of the company or the business connected with it, to such an extent that this could be considered to be damaging to the aforementioned interests. These influences may include a third party acquiring a significant percentage of our 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.

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

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

The DCGC applies to all Dutch companies listed on a government-recognized stock exchange, whether in the Netherlands or elsewhere, including NASDAQ. We do not comply with all the best practice provisions of the DCGC. For a list of the most substantial DCGC best practices that we do not comply with, see chapter 7.1 of this report. This may affect your rights as a shareholder and you may not have the same level of protection as a shareholder in a Dutch company that fully complies with the DCGC.

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

We are incorporated under the laws of the Netherlands, and our headquarters is located in Germany. Substantially all of our assets are located outside the United States. The majority of our directors and executive officers reside outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce against them or us in U.S. courts, including judgments predicated upon the civil liability provisions of the federal securities laws of the United States.

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

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

The United States and Germany currently do not have a treaty providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. Consequently, a final judgment for payment or declaratory judgments given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in Germany. German courts may deny the recognition and enforcement of a judgment rendered by a U.S. court if they consider the U.S. court not to be competent or the decision to be in violation of German public policy principles. For example, judgments awarding punitive damages are generally not enforceable in Germany. A German court may reduce the amount of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages.

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

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

3 INFORMATION ON THE COMPANY[3]

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, 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 IFX-1 for the treatment of Hidradenitis Suppurativa, or HS, a rare and chronic debilitating systemic inflammatory skin disease, for which we initiated a Phase IIb clinical trial in the first quarter of 2018. Beyond HS, we intend to develop IFX-1 and other proprietary antibodies to address a wide array of complement-mediated diseases with significant unmet medical needs, including ANCA-associated vasculitis, or AAV, a rare and life-threatening autoimmune disease.

InflaRx was founded in 2007 as InflaRx GmbH by Professor Niels Riedemann and Professor Renfeng Guo in Jena, Germany. Our offices and laboratories are located in Jena, Germany and Munich, Germany, where we employ 21 employees, nine 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 18 years of complement research experience, having published extensively on C5a and its receptors. Additionally, our Chief Medical Officer, Othmar Zenker, has more than 25 years of experience in clinical drug development, and our Chief Financial Officer, Arnd Christ, has served in the same capacity for various private and public European biotechnology companies over the last 18 years.

3.2 Business overview

Overview

C5a is a central part of the complement system and a critical component of the innate immune system. Its most prominent role 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.

[3] Source: 20-F, Item 4.

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.

IFX-1 is currently being developed for the treatment of HS, a chronic debilitating systemic inflammatory skin disease that has orphan designation in the United States, where we estimate that moderate to severe HS has a prevalence of up to 200,000 patients. 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 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. Based on the final results of our open-label Phase IIa clinical trial, which showed responses based on the same HiSCR endpoint used to support the approval of adalimumab, IFX-1 may have the potential to provide significant clinical benefit to moderate to severe HS patients. Following eight weeks of administration, nine out of the 12 patients (75%) showed a response to IFX-1 based on the Hidradenitis Suppurativa Clinical Response, or HiSCR, and at the end of the 12-week trial observation period, 10 out of the 12 patients (83%) showed a response to IFX-1 based on the HiSCR. We believe that these results are particularly encouraging given the short duration of treatment and the severe disease burden of the patients enrolled in our study. We plan to seek orphan drug designation in the United States.

In January 2018, the U.S. Food and Drug Administration, or FDA, accepted our previously submitted IND application which allowed us to commence a larger multi-center international Phase IIb study to determine the efficacy and safety of IFX-1 in HS patients. The trial is a randomized, double-blind and placebo-controlled multicenter study being conducted at approximately 50 sites in several countries. We commenced enrollment in February 2018 and expect to enroll approximately 175 patients in the trial, divided equally into five dose groups, including a placebo group, and have commenced the enrollment process. After a placebo-controlled double-blind period of 16 weeks, the study will be extended to a 28 week open-label extension phase to assess long-term efficacy and safety. The main objective of the study is the evaluation of a dose response signal assessed by the HiSCR score at week 16 as the primary endpoint. Secondary objectives include evaluation of safety and tolerability of IFX-1 as well as assessment of additional efficacy and patient-reported outcome parameters.

We are also developing IFX-1 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. We intend to initiate the clinical phase II development with IFX-1 in AAV patients in the second or thirtd quarter of 2018, and we plan to seek orphan drug designation for AAV in the United States and Europe. We also intend to develop IFX-1 in various other inflammatory conditions, with a focus on complement-mediated diseases. Finally, we intend to explore the potential of IFX-1 for inhibiting cancer progression and metastatic disease given the emerging scientific evidence of the role of C5a in these indications.

To expand the breadth of our anti-C5a technology, we are developing IFX-2 for the treatment of chronic inflammatory indiciations. IFX-2 shares the same mechanism of action as IFX-1, blocking C5a with high specificity, but is designed with a dosing regimen that may be more suitable for chronic therapy. IFX-2 is in early pre-clinical development.

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:

PROGRAM	PRECLINICAL	PHASE I	PHASE II	PHASE III	MARKETED	CURRENT STATUS	NEXT MILESTONE
IFX-1	Hidradenitis Suppurativa (HS)					Undergoing Phase IIb trial	Complete Phase IIb in second half of 2018
	ANCA-associated Vasculitis (AAV)					Preparing Phase II studies - U.S. and Europe	Initiate Phase II in second half of 2018
	Other chronic / Autoimmune disease					Selecting indications for target product profile development	Initiate Phase IIa in second half of 2018
IFX-2		Chronic inflammation and autoimmune diseases				Developing as injectable with longer half-life than IFX-1	Enter clinic for chronic inflammatory disease

Our programs

IFX-1 for Hidradenitis Suppurativa

Our lead product candidate, IFX-1, is a novel intravenously delivered anti-C5a monoclonal antibody in development for HS, 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 disease is characterized by painful inflammatory nodules, boils and abscesses, as well as draining fistulas, often requiring the use of bandages and diapers to absorb the constant flow of pus, thus adversely affecting quality of life. The target patient population for IFX-1 is HS patients displaying a moderate to severe form of the disease. In the United States, this disease has orphan designation, where we estimate that moderate to severe HS has a prevalence of up to 200,000 patients.

The standard of care for HS patients includes topical, oral and intravenous antibiotics, as well as surgery, which at best only provide symptomatic relief. Currently, the only approved drug to treat HS in the United States and in Europe is adalimumab, an inhibitor of TNF-alpha. 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 Hidradenitis Suppurativa clinical response score, or 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. The HiSCR is the primary endpoint that was used to support regulatory approval by the FDA, and the Euro-

pean Medicines Agency, or EMA, of adalimumab for the treatment of HS patients. Patients are considered to be HiSCR responders when they achieve a 50% or higher reduction of the combined abscess and nodule, or AN, count from baseline, but at the same time show no increase of the abscess or draining fistula count from baseline. Despite having demonstrated a clinical benefit, approximately 50% or more of the patients with moderate to severe HS do not respond to adalimumab, thus a high unmet need remains.

We have demonstrated that HS patients have significant complement activation, with C5a playing a key disease promoting role. Based on final results from our open-label Phase IIa clinical trial which showed responses based on the same HiSCR endpoint, IFX-1 may have the potential to provide significant clinical benefit to moderate to severe HS patients. In this trial, IFX-1 was evaluated in a 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. 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. Patients received weekly intravenous injections of IFX-1 for eight consecutive weeks and were subject to follow up for three months thereafter. Final 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. While IFX-1 is a novel antibody whose potential therapeutic benefit is unproven, we believe our results in these very ill, refractory HS patients highlight the novel mechanism of action and the commercial potential of IFX-1, if approved.

In addition, the final results from the trial revealed that weekly injections of IFX-1 resulted in significantly reduced C5a levels at 22 days and 50 days following the start of treatment while leaving MAC formation intact. The final results also demonstrated that IFX-1 administration was well tolerated, with no drug-related adverse events detected.

Based on these results, we are currently planning to submit an application for an orphan drug designation with the FDA. In January 2018, the FDA accepted our previously submitted IND application which allowed us to commence a larger multi-center international Phase IIb study to determine the efficacy and safety of IFX-1 in HS patients, and we commenced enrolling patients in February 2018.

IFX-1 for ANCA-associated Vasculitis

We are also developing IFX-1 for AAV, a rare life threatening autoimmune disease that affects approximately 40,000 and 75,000 patients in the United States and Europe, respectively. A recently conducted study of Chemocentryx, Inc.'s CCX168, an antagonist to the C5a receptor, or C5aR, demonstrated a proof of concept for the role of the C5a/C5aR signaling axis in AAV patients, providing evidence that inhibition of the C5a pathway may be beneficial in treatment of the disease. See "Item 4. Information on the company—B. Business overview—Additional indications for IFX-1—ANCA-associated Vasculitis." We intend to initiate the clinical phase II development with IFX-1 in AAV patients in the second or third quarter of 2018, and we plan to seek orphan drug designation in the United States and Europe.

Our strategy

Our goal is to maintain and further advance our leadership position within the anti-C5a complement space, delivering first-in-class autoimmune and anti-inflammatory therapies to market. To achieve this goal, we are executing on the following strategies:

- **Advance our lead program IFX-1 for HS to commercialization.** We have conducted an initial open-label Phase IIa clinical trial in 12 late-stage HS patients who previously failed all other treatments, including adalimumab. The final results from the trial showed that, following eight weeks of administration with IFX-1, nine out of 12 patients (75%), and at the end of the 12-

week trial observation period, 10 out of 12 patients (83%), showed a HiSCR response, an endpoint that supported the approval of adalimumab. We intend to seek orphan drug designation in the United States. In January 2018, the FDA accepted our previously submitted IND application which allowed us to commence a larger multi-center international Phase IIb study to determine the efficacy and safety of IFX-1 in HS patients, and we commenced enrolling patients in February 2018.

- **Commence Phase II clinical development of IFX-1 for AAV and other complement-mediated autoimmune and inflammatory diseases.** We are developing IFX-1 for the treatment of AAV, and we intend to initiate the clinical phase II development with IFX-1 in AAV patients in the second or third quarter of 2018. We plan to seek orphan drug designation for AAV in the United States and Europe. In addition, we plan to study the potential of IFX-1 in other complement-mediated autoimmune and inflammatory diseases, as well as in oncology settings for which an increasing amount of literature suggests a role for C5a.

- **Pursue the clinical development of IFX-2 and continue to expand the breadth of our anti-C5a technology.** We are developing IFX-2 as an injectable with a longer half-life than IFX-1, making it suitable for chronic inflammatory indications with less severe flares or closer to the onset of disease. IFX-2 shares the same features as IFX-1 with respect to its mechanism of action, covered binding epitope and selectivity. The pre-clinical development of IFX-2 is supported by a grant from the German government. We believe IFX-2 holds the potential to treat various chronic inflammatory diseases that could benefit from a dosing regimen more suitable for chronic therapy.

- **Commercialize IFX-1, if approved, either independently or in collaboration with a partner.** We intend to independently pursue the approval and commercialization of IFX-1 for HS in the United States and Europe. We plan to employ a small, targeted commercial infrastructure to promote access to IFX-1 through centers-of-excellence that treat HS in these core markets. Outside of the United States and Europe, we may pursue the approval and commercialization of IFX-1 for HS either independently or in collaboration with others. For other indications, we intend to develop and commercialize IFX-1 either independently or through collaborations with other parties.

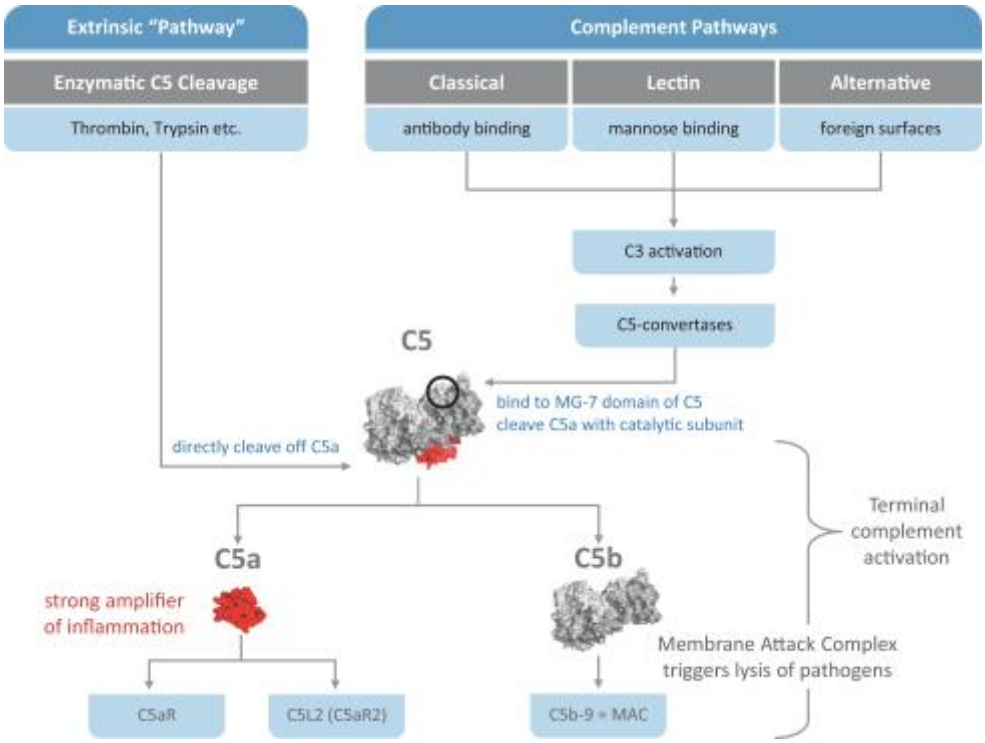
- **Solidify our leadership position in the anti-C5a space by leveraging the full potential of our proprietary anti-C5a technology and expertise in complement and inflammation.** We intend to continue to discover and develop treatments that have the potential to address a broad spectrum of complement-mediated or immune response mediated indications with significant unmet need, either internally or in collaboration with a partner. To accomplish this, we plan to supplement our research and development activities with an additional discovery unit as well as build business development capabilities.

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 17 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.

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

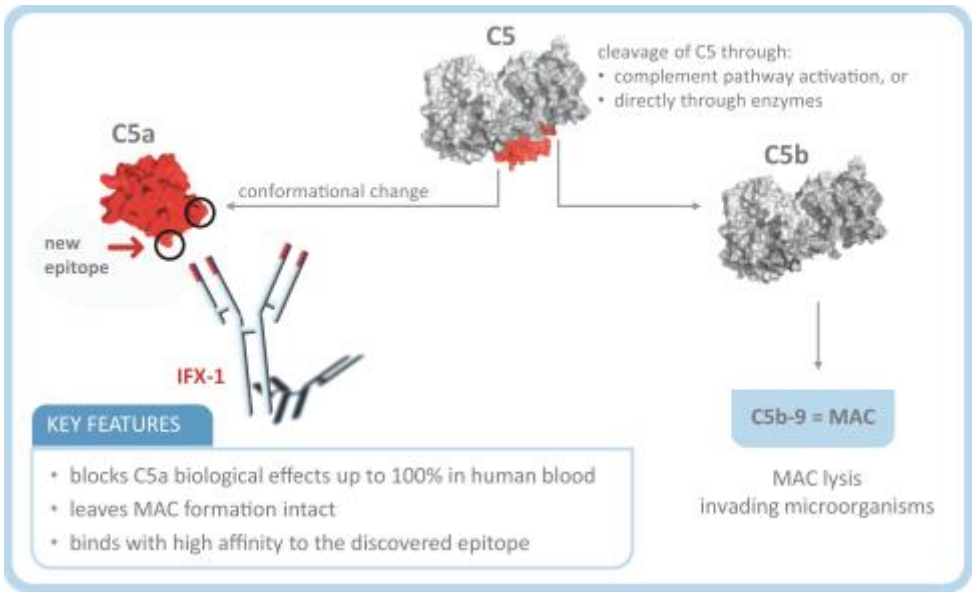
Different cancer cells have been found to generate their own C5a when cultured in vitro in the absence of any other complement factors or intact complement pathways. This result is possible because cancer cells produce C5, together with enzymes to directly cleave C5, thereby generating functionally active 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. 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 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 or AAV. 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.

IFX-1 as first-in-class anti-C5a monoclonal antibody

Our lead product candidate, IFX-1, 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. IFX-1 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 IFX-1 in various disease indications. Our lead indication is HS, for which we have completed enrollment and dosing in our open-label, single-center Phase IIa study. We have also successfully completed one placebo-controlled, single-center Phase I study of IFX-1 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, IFX-1 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 IFX-1 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 IFX-1 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 prospectus.

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 IFX-1 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 IFX-1 *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 IFX-1 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 IIa clinical trial in HS patients (measured pre-dose (day 1) and post-treatment (day 50 and day 134)), anti-drug antibodies were detected in only one participant on day 134 (end of the trial observation period).

In addition, we are developing IFX-1 as a therapy for AAV given C5a's well-established disease promoting role in AAV. We plan to advance development of IFX-1 in other disease settings where we believe an anti-C5a antibody could be successfully developed into a marketed therapy.

Hidradenitis Suppurativa, the lead indication for IFX-1

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.

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 IFX-1 is HS patients displaying a moderate to severe form of the disease. In the United States, this disease has orphan designation, where we estimate that moderate to severe HS has a prevalence of up to 200,000 patients.

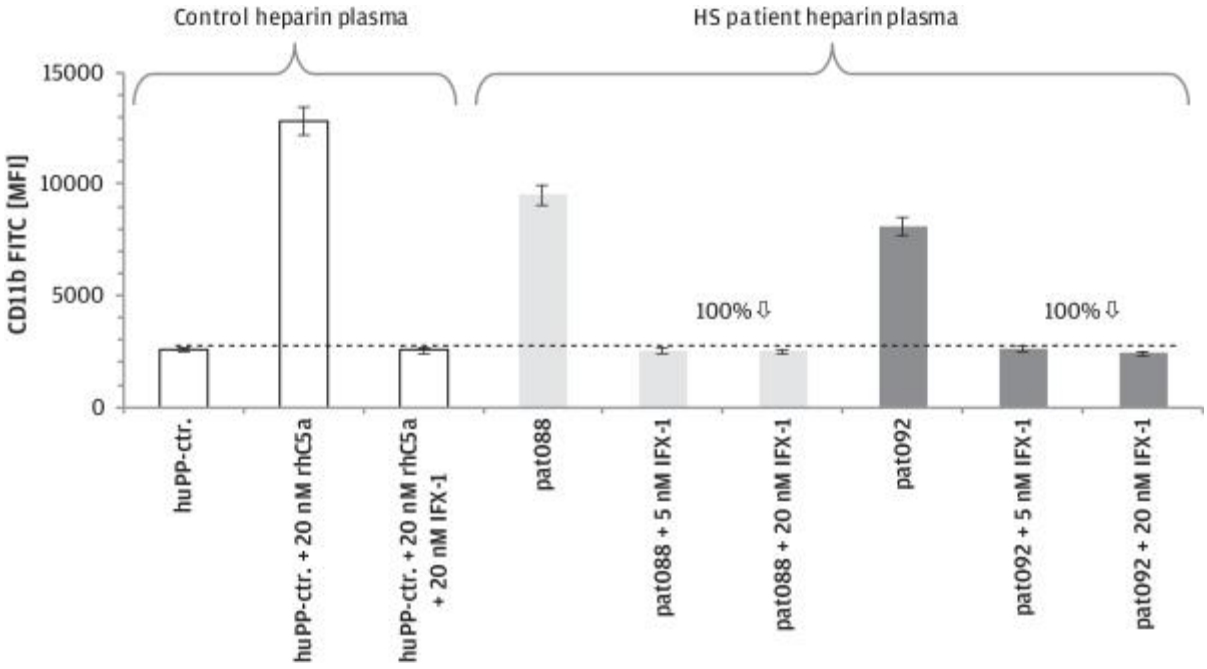
In Europe, the number of affected patients is believed to be greater, with higher prevalence and incidence of HS in countries with warmer climates. The diagnosis and treatment is in most countries

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 and Hurley stage 2 and 3 HS. 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 considered to be 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 IFX-1 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 by us in 2013 and 2014 as part of an investigative project conducted 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. IFX-1, 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 IFX-1 (huPP-ctr + 20 nM rhC5a + 20 nM IFX-1) (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 IFX-1 (middle and darker grey bars) thus implying that C5a in HS patient plasma is the key neutrophil activating factor.

Based on these and other findings, we have recently completed an open-label clinical trial in 12 HS patients. From final results in this trial, we have established first clinical proof of concept, or initial clinical evidence of the disease-modifying mechanism of action, for IFX-1 as a potential future therapy for this disease: at the end of the 8-week dosing period, nine of the 12 HS patients demonstrated a HiSCR response. All 12 of these patients had failed to respond to prior treatment attempts, including adalimumab, to which nine out of the 12 patients failed to respond. At the same time, C5a was significantly inhibited at the pre-specified testing periods, and MAC formation, as demonstrated by a CH50 assay described below, was not influenced through the end of the treatment period. However, early proof of concept data, especially from smaller open-label trials such as this open-label clinical trial in 12 HS patients, must be confirmed in larger clinical studies, and similar results may not be reproduced in future trials with larger patient numbers.

We believe that HS is an attractive lead indication for IFX-1 because of the following important considerations:

- good rationale for the role of C5a and initial clinical data suggesting a strong benefit for the use of IFX-1;
- large market opportunity with potential for orphan drug designation in the United States;
- high unmet medical need;
- path to approval based upon HiSCR response supported by prior FDA approval of adalimumab for the treatment of HS; and

- potential for fast recruitment based on historical enrollment results for the adalimumab pivotal trials.

Phase IIb trial to determine efficacy and safety of IFX-1 in patients suffering from moderate to severe Hidradenitis Suppurativa

In January 2018, the FDA accepted our previously submitted IND application which allowed us to commence a larger multi-center international Phase IIb study to determine the efficacy and safety of IFX-1 in HS patients. The trial is a randomized, double-blind and placebo-controlled multicenter study being conducted at approximately 50 sites in several countries. We commenced enrollment in February 2018 and expect to enroll approximately 175 patients in the trial, divided equally into five dose groups, including a placebo group, and have commenced the enrollment process. After a placebo-controlled double-blind period of 16 weeks, the study will be extended to a 28-week open label extension phase to assess long-term efficacy and safety. The main objective of the study is the evaluation of a dose response signal assessed by the HiSCR score at week 16 as the primary endpoint. Secondary objectives include evaluation of safety and tolerability of IFX-1 as well as assessment of additional efficacy and patient-reported outcome parameters.

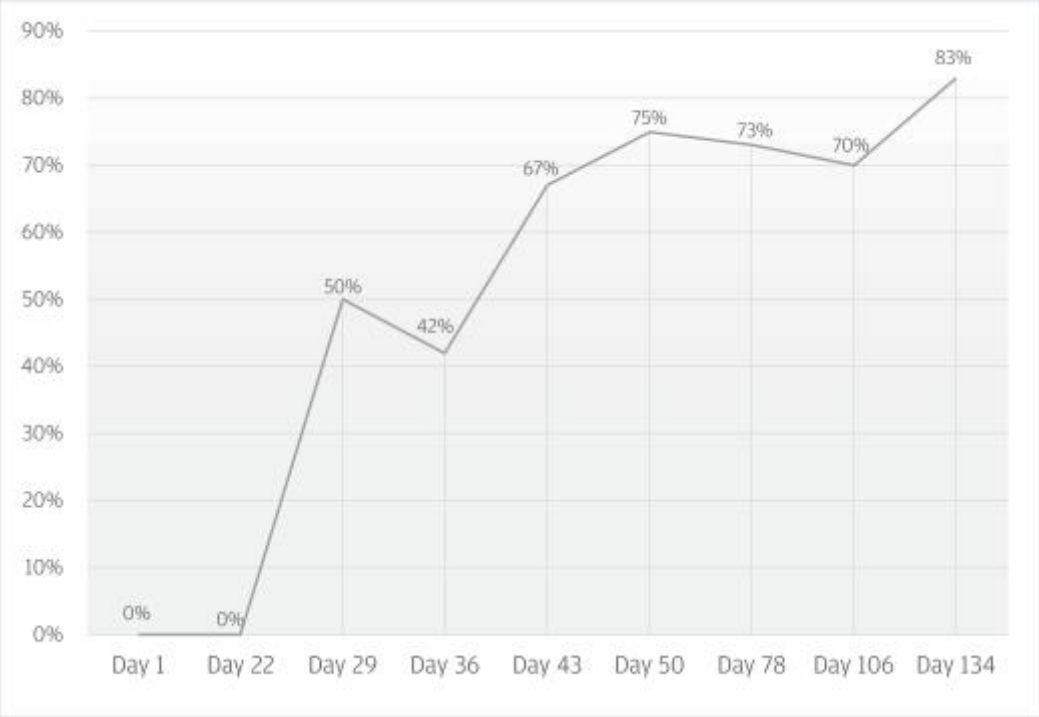
Phase IIa trial exploring IFX-1 in patients suffering from moderate to severe Hidradenitis Suppurativa

We conducted an exploratory Phase IIa study in patients suffering from HS to primarily assess safety and tolerability of IFX-1, as well as efficacy and PK/PD profile as secondary endpoints. This study was a single center open-label trial enrolling adult patients suffering from moderate to severe HS who either experienced a primary or secondary failure to biological treatment or were not eligible for treatment with other biologicals. To participate in the trial, patients also had to have a diagnosis of HS for at least one year, HS lesions in at least two distinct anatomic areas (one of which was Hurley stage 2 or 3), at least three abscesses or inflammatory nodules and a failure to respond to antimicrobial treatment. The trial enrolled 12 such patients who were severely affected by HS, being diagnosed with Hurley stage 3 and who all failed to respond to prior treatment attempts, including adalimumab, to which nine out of the 12 patients failed to respond (four patients were primary treatment failures, meaning those patients did not respond to treatment at 12 weeks of treatment, and five were secondary treatment failures, meaning those patients ceased responding to treatment after 12 weeks of treatment, in each case as determined in the judgment of the clinical investigator). The trial protocol provided that patients would receive weekly intravenous injections of IFX-1 at a dose of 800mg per week for eight consecutive weeks with two infusions in the first week (day 1 and day 4) and would be subject to follow up for three months thereafter. 11 out of the 12 participants received study drug infusions for the eight week period. Study drug infusion was discontinued for one participant after day 29 due to an unrelated adverse event; however such participant was subject to follow up through the end of the 12-week trial observation period. The trial was open-label, was not placebo controlled and did not include a control group. The first patient received treatment on December 15, 2016 and the last patient's last visit was July 4, 2017. The study was sponsored by us and conducted in Greece.

The final results of this trial suggest strong initial clinical evidence of the disease-modifying effect of IFX-1 in HS patients while confirming the advantageous technological properties of IFX-1, leading to a highly specific blockade of C5a while leaving MAC formation intact in the patients' plasma. At the same time, the results revealed that IFX-1 was well tolerated and that no drug-related serious adverse events could be detected.

For clinical disease-modifying effect, we assessed the clinical endpoint HiSCR over the treatment period, at end of treatment and during the follow-up phase. Patients were considered to be HiSCR responders when they achieve a 50% or higher reduction of the combined AN count, but at the same time show no increase of the abscess or draining fistula count from baseline. At the end of treatment (day 50), 75% of the patients, and at the end of the trial observation period (day 134), 83% of the patients, demonstrated a HiSCR response according to this definition, which was previously utilized by FDA and EMA as the basis for approving adalimumab.

HiSCR Response



HiSCR response in treated HS patients during the treatment period from pre-dosing (day 1) through end of treatment (day 50) and through the end of the trial observation period (day 134)

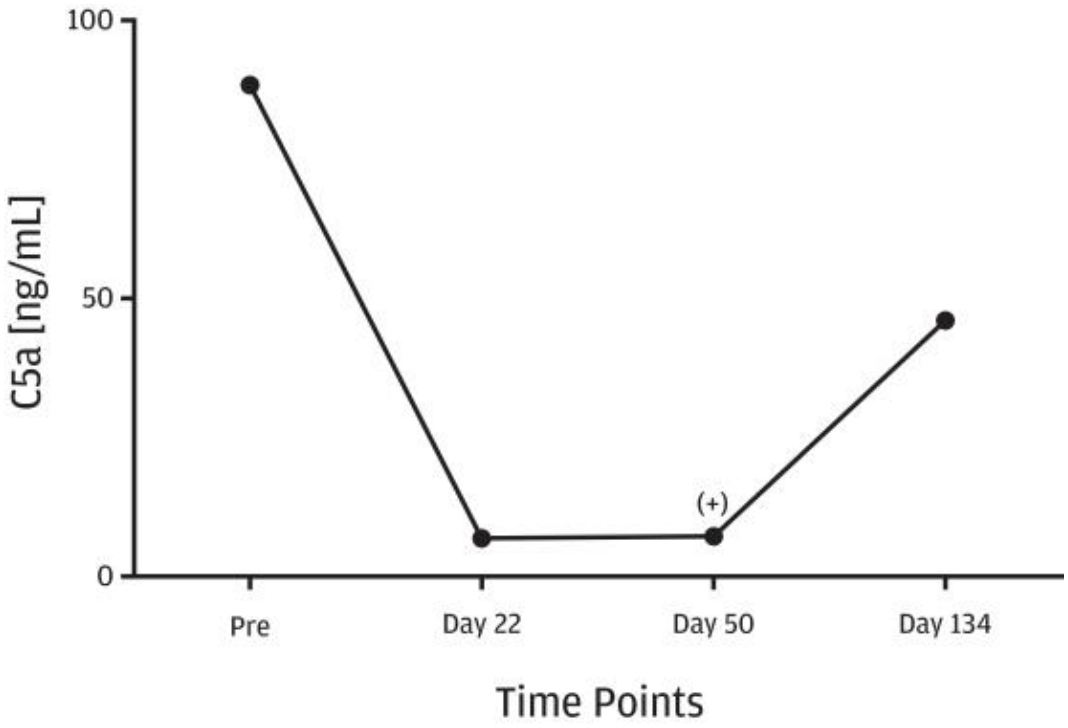
In addition to the HiSCR response, we observed additional trends for the disease-modifying effect of IFX-1 treatment in HS patients. We investigated the absolute and percentage change from day one in the total combined count of abscesses and nodules, or AN count. The median AN count was 6.0 at baseline 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.

We also observed a median dermatology life quality index, or DLQI, total score of 18.5 at baseline, 14.5 on day 22, 17.0 on day 50 and further decreased to a score of 11.0 on day 134 (the end of the trial observation period). The DLQI is a patient reported outcome score which is widely used in dermatological diseases to assess the health-related quality of life. It documents a score of zero to three for each of the 10 defined DLQI questions which are related to disease-specific pain or discomfort and disease-related impact on quality of life, such as the ability to conduct basic daily activities and the impact on relationship with partners and friends. The lower the DLQI score, the lesser the impact the dermatological disease has on the patient's quality of life.

We believe that these data are particularly noteworthy given the patients' treatment history and stage of disease progression, which make them a very difficult to treat patient population. While IFX-1 is a novel antibody whose potential therapeutic benefit is unproven, we believe our results in these very ill, refractory HS patients highlight the novel mechanism of action and commercial potential of IFX-1, if approved.

With respect to confirmation of the biological mechanism of action of IFX-1, the final results revealed that weekly injections of IFX-1 resulted in significantly reduced C5a levels at 22 days and 50

days after start of treatment, demonstrating IFX-1's ability to significantly reduce C5a plasma levels in HS patients:

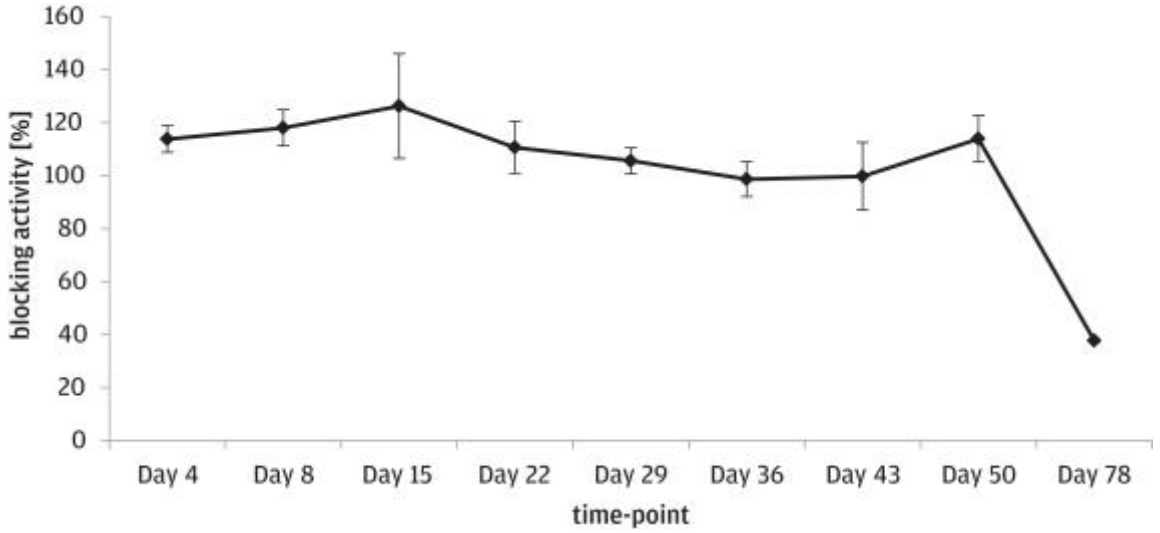


Mean C5a levels (ng / ml) in HS patients at day 1 (pre-dosing), day 22 and day 50 (end of treatment) as well as on day 134 (at the end of the trial observation period). One sample was excluded from this analysis at day 50 (end of treatment) (as indicated with (+) above) from one patient in whom study drug infusion was discontinued prematurely after day 29 due to an unrelated adverse event.

Furthermore, the results demonstrated that IFX-1 administration left MAC formation intact. Assessment of the hemolytic plasma activity, referred to as the CH50 test, is a conventional method used to determine whether a functionally active MAC can be formed upon activation of the classical complement pathway and resulting cleavage of C5 through complement convertases. Functionally active MAC leads to destruction of red blood cells in the assay, which can be measured by this test. Since IFX-1 binds to C5a, and C5a is a part of C5, it is critical to demonstrate that IFX-1 does not block C5 cleavage, C5b and MAC formation. When MAC formation was tested with patient samples from our HS study, CH50 test results stayed within the normal range of the test assay in all but one patient when measured on day 22, day 50 (end of treatment), and day 134 (end of the trial observation period). The one patient presented with a CH50 value slightly below the normal range at baseline before the start of treatment, which value slightly increased following IFX-1 treatment to be within the normal range at day 50. Therefore, IFX-1 treatment left the ability to form MAC intact in all patients.

The weekly intravenous infusions of IFX-1 were well tolerated. No drug-related adverse events were detected and no infusion-related, allergic or anaphylactic reactions were observed. Anti-drug antibodies were measured pre-dose (day 1) and post-treatment (day 50 and day 134). Anti-drug antibodies were detected in one participant on day 134 (end of the trial observation period). We also designed an assay to evaluate IFX-1's performance in blocking C5a after being injected in humans. Plasma samples from HS patients in our Phase IIa trial following treatment with IFX-1 were added to fresh human whole blood in which additional recombinant C5a was added. The assay determined the activation of neutrophils with the established neutrophil surface marker CD11b. This marker strongly increases on neutrophils when they are activated, in this case by C5a, which activation is believed to play a key disease

promoting role, including in HS. This assessment shows that IFX-1, when functionally active in the HS patient plasma, will strongly inhibit such C5a-induced increase of CD11b, suggesting a significant reduction in neutrophil activation. Specifically, over a 50-day time period, *ex vivo* IFX-1 fully blocked C5a-induced neutrophil activation, as shown by a complete 100% (mean over the period) reduction in CD11b upregulation. The assay was conducted with a fixed amount of added recombinant human C5a leading to robust neutrophil activation in fresh human whole blood prior to addition of the plasma samples containing IFX-1, as indicated by the upregulation of the CD11b marker on neutrophils.



Blocking activity of ex vivo IFX-1 contained in HS patient plasma samples expressed as percentage reduction of the CD11b upregulation on fresh neutrophils in human whole blood when induced by a fixed concentration of recombinant human C5a.

Based on these results, we are currently planning to submit an application for an orphan drug designation with the FDA. In January 2018, the FDA accepted our previously submitted IND application, which allowed us to commence a larger multi-center international Phase IIb study to determine the efficacy and safety of IFX-1 in HS patients, and we commenced enrolling patients in February 2018.

Additional indications for IFX-1—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.

A recently conducted Phase II clinical trial of Chemocentryx's CCX168 designed to assess whether high dose chronic steroids used in the standard of care regimen in AAV could be sharply reduced or eliminated by replacement with CCX168 produced positive top-line data. CCX168 is an antagonist to C5aR currently undergoing Phase III trials for AAV patients by Chemocentryx.

The completed Phase II trial for CCX168 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 CCX168. The trial met its primary clinical endpoint, which was based on the Birmingham Vasculitis Score 3, or BVAS 3, a useful tool in assessing and monitoring disease activity as well as response to treatment, at week 12 in patients receiving CCX168 treatment, compared to the response of patients receiving the standard of care treatment. In the trial, one treatment group that received CCX168 together with a low dose of steroid (one-third of the dose used in the standard of care group) demonstrated a BVAS 3 response of 86% at week 12, compared to 75% for the standard of care. A separate treatment group received CCX168 in the absence of any steroid, and the BVAS 3 response was 81% ($p = 0.02$ for non-inferiority). The standard of care group included a placebo for CCX168. The primary endpoint was prospectively defined as a decrease from baseline of at least 50% in BVAS 3 plus no worsening in any body system. The trial also met several secondary endpoints, including that CCX168 exhibited a more rapid onset of improvement over standard of care treatment. Given that all treatment groups receiving CCX168 in the trial demonstrated a statistically significant ($p = 0.005$) non-inferior clinical efficacy outcome when compared to the standard of care, we believe the trial demonstrates proof of concept for the role of the C5a/C5aR signaling axis in AAV patients. We are encouraged by the published outcome data for CCX168, which provide evidence in patients that inhibition of the C5a/C5aR signaling axis may provide benefit to AAV patients.

We believe that the potential advantages of treatment with IFX-1 in AAV are the following:

- **Rapid onset of action**: IFX-1 has fast onset of action such that after its intravenous administration, IFX-1 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 safety benefits**: IFX-1 is a monoclonal antibody that was well tolerated in one Phase I and three Phase IIa clinical studies, with a total of over 170 treated patients or healthy human volunteers. We believe that the properties of IFX-1, which blocks C5a and not its receptors, may allow IFX-1 to avoid safety concerns arising from potential receptor-related signaling effects or other off-target effects which may be related through binding on the surface of highly active immune competent cells, such as T-cells or dendritic cells.

Our clinical development strategy for IFX-1 in AAV will first focus on acutely ill AAV patients, where we believe IFX-1 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 IFX-1 therapy in AAV patients in February 2017, and based on this, we intend to initiate a US clinical phase II study with IFX-1 in AAV patients in the second or third quarter of 2018 primarily investigating safety and tolerability of IFX-1 in AAV patients as well as exploring efficacy of IFX-1 when added to standard of care therapy. In addition, we

plan to initiate a second phase II study with IFX-1 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 in the second half of 2018. Part of the development strategy will also be submission of an orphan drug application to the FDA and EMA once data from the first AAV trial are available.

Exploratory studies and additional clinical development of IFX-1

We plan to advance the clinical development of IFX-1 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. We also plan to investigate the potential development of IFX-1 for inflammation-driven oncology diseases based on the fact that C5a appears to have a crucial promoting role for the induction of tumor growth. Our plans to explore oncology applications are further supported by the fact that different tumor cells generate C5a in the absence of other complement factors and that there is growing evidence for a crucial role of C5a to promote inflammation and cancer growth through its ability to change the immune-defense cell environment in tumors.

Additional clinical and pre-clinical development for IFX-1

We have also completed one Phase 1 clinical trial of IFX-1 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 IFX-1 in healthy volunteers to assess the safety, tolerability, PK and PD of IFX-1 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 IFX-1 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 IFX-1 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 IFX-1 was assessed in a secondary PD analysis in fresh human whole blood with IFX-1 samples from the two high dose groups. This assessment resulted in a mean ex vivo effect of IFX-1 for blocking C5a-induced neutrophil activation (CD11b upregulation) of approximately 100%.

Previously completed Phase IIa clinical trials with IFX-1

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 IFX-1, 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 IFX-1 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. IFX-1 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 IFX-1 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 IFX-1 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 IFX-1 infusion. The duration of statistical 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* IFX-1 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). IFX-1 or placebo was administered to patients prior to the start of surgery. The primary objective was to evaluate safety and tolerability of IFX-1, as well as assess the effect of IFX-1 on peak IL-6 levels. It was sponsored by us and conducted at 10 sites in Germany. Four dosing groups were assessed with IFX-1 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, IFX-1 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 IFX-1 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 IFX-1 for complex cardiac surgery.

Pre-clinical studies involving IFX-1

We established pre-clinical proof of concept for IFX-1 in various different pre-clinical settings and studies in monkeys. Collectively, these studies demonstrated that IFX-1 is highly effective in blocking C5a-induced biological effects while leaving MAC formation intact and that IFX-1 administration showed strong initial clinical evidence of disease-modifying effect in reducing neutrophil-driven organ damage in monkeys.

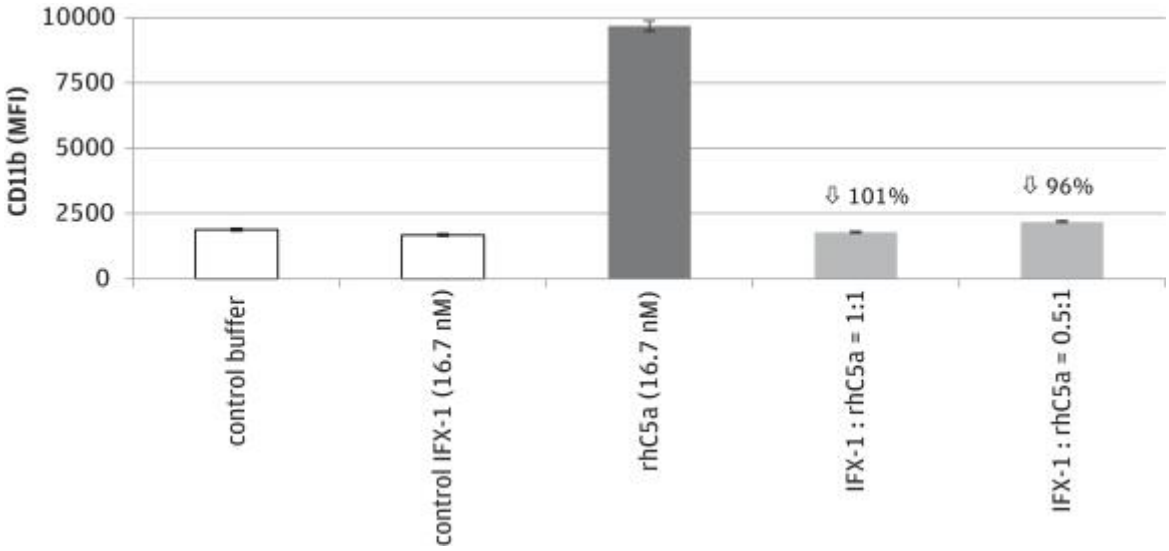
IFX-1 improves outcome in pre-clinical disease model in monkeys

IFX-1 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 IFX-1, 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 106 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 IFX-1 and the remaining six monkeys received a sham intravenous treatment. Treatment with IFX-1 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 IFX-1 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 IFX-1 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 IFX-1 on this viral-induced lung injury.

IFX-1 fully blocks C5a-induced effects on neutrophils in human whole blood

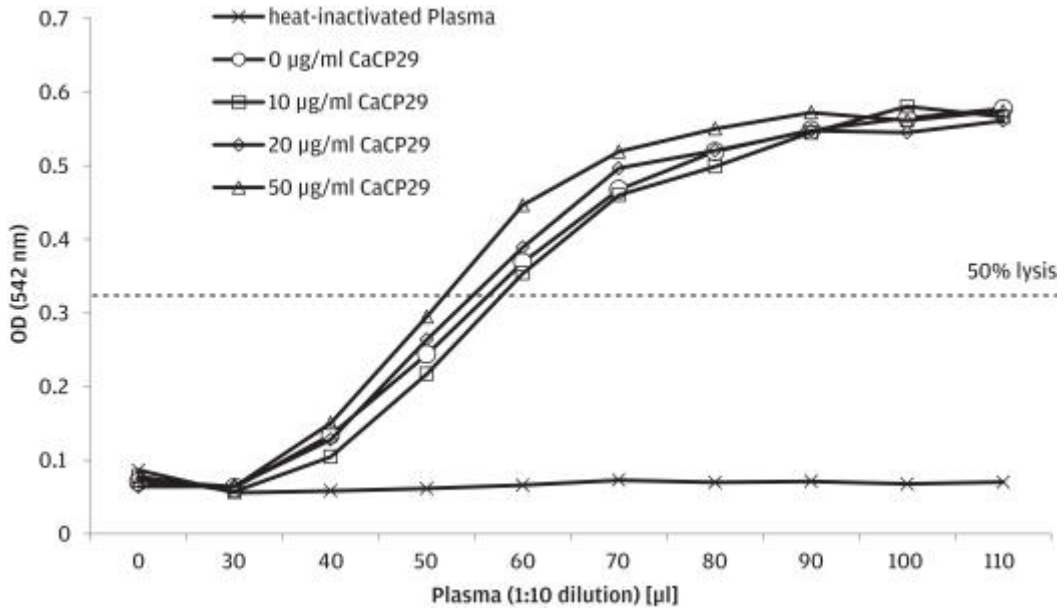
To assess IFX-1's ability to block C5a-induced biological effects on neutrophils in human blood, fresh human whole blood from voluntary blood donors was used, with the activation of neutrophils assessed using flow cytometric measurement of the known marker CD11b. This marker is expressed on neutrophil 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 IFX-1 was added together with recombinant C5a, CD11b upregulation was completely abolished with statistical significance ($p < 0.0001$).



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. IFX-1 was capable of strikingly reducing the CD-11b upregulation on neutrophils.

IFX-1 leaves MAC formation intact in human whole blood

IFX-1 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 IFX-1 was added to this test, the hemolytic activity curves from plasma alone and plasma plus IFX-1 were substantially similar, indicating that IFX-1 in the dose range of zero to 50 µg/mL had no influence on C5 cleavage and MAC formation (C5b-9).



IFX-1 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 IFX-1 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. 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 early 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, and any other inventions that are commercially important to our business. We also rely on trade secrets and know-how 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 or otherwise violating any patents or other intellectual property or proprietary rights of third parties. See the section titled "Risk factors—Risks related to intellectual property" for additional information.

As of December 31, 2017, we owned three issued U.S. patents, two pending U.S. non-provisional patent applications, 7 issued foreign patents, one Eurasian Patent validated in 9 countries, as well as one European patent validated in 37 countries, and 25 pending foreign patent applications. These patents include claims relating to C5a inhibitors and associated methods of use.

Our patent portfolio relating to IFX-1 and IFX-2, as of December 31, 2017, is summarized below.

As of December 31, 2017, we owned three issued U.S. patents and one pending U.S. non-provisional patent application 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 seven issued foreign patents, nine pending foreign patent applications, one Eurasian Patent validated in nine countries, as well as one European patent validated in 37 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, 2017, we owned one pending U.S. non-provisional patent application and 15 pending foreign patent applications covering the use of certain binding moieties, such as antibodies,

that inhibit C5a for the treatment of viral pneumonia. If granted, the pending U.S. and foreign patent applications would be expected to expire in 2035, excluding any additional term for patent term adjustments or patent term extensions.

As of December 31, 2017, we owned one pending European priority application covering the use of an inhibitor of C5a activity, for example, IFX-1, for treating HS and other cutaneous, neutrophilic inflammatory diseases. We plan to file additional patent applications claiming priority to this European application in the United States and other jurisdictions which, if granted, would be expected to expire in 2038, excluding any additional term for patent term adjustments or patent term extensions.

Collaboration agreement

On December 28, 2015, we entered into a co-development agreement with Beijing Defengrei Biotechnology Co. Ltd., or BDB, for the use of the IFX-1 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 IFX-1 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 IFX-1 and IFX-2 in China solely for the purpose of commercializing products outside of China and to use the IFX-1 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 IFX-1 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.

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 IFX-1 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.

Sales and marketing

Subject to receiving marketing approval, we intend to independently pursue the commercialization of IFX-1 for HS in the United States and Europe, when approved by the applicable regulators, by employing a small, targeted commercial infrastructure to promote access to IFX-1 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 IFX-1 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.

We currently engage three third-party manufacturers to provide clinical supplies of and fill-finish services for IFX-1. To date, two 200L batches in the United States and six 1,000L batches of IFX-1 in Germany have been produced under cGMP regulations for our clinical trials.

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, a global pharmaceutical company. We are not aware of any C5 or C5a inhibitors under development for the treatment of HS. However, a number of additional companies are developing product candidates to treat HS with varying mechanisms of action. These companies include XBiotech Inc., Novartis AG, UCB Pharma GmbH and Chemocentryx, Inc.

XBiotech has recently completed a Phase II clinical trial for MABp1, a monoclonal antibody targeting interleukin-1 alpha, in HS. After 12 weeks of therapy in 20 patients (1:1 randomization to placebo), MABp1 demonstrated significant improvement in the HiSCR for HS patients compared to placebo. In 2016, Novartis completed a Phase II clinical trial for CJM112, a monoclonal antibody targeting interleukin-17 alpha, in moderate to severe HS patients. Clinical trial results have yet to be published. In addition, UCB Pharma has recently initiated a Phase II clinical trial in moderate to severe HS patients for Bimekizumab, a monoclonal antibody blocking interleukin-17AF. Chemocentryx, Inc. has recently announced their plans to initiate clinical development in HS with CCX168, a C5aR inhibitor.

Additionally, a number of investigator-initiated trials have been conducted or are in progress in HS:

- An open-label trial in 21 patients with moderate to severe HS is currently being conducted with Secukinumab, a monoclonal antibody blocking interleukin-17A.

- A short-term open-label trial for Celgene's Apremilast was recently completed to investigate its safety and efficacy in 20 HS patients. Apremilast is an oral small-molecule inhibitor of phosphodiesterase 4. The same drug was assessed in another recently completed 10-patient placebo-controlled study.

- An open-label trial for Janssen-Cilag'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.

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 the treatment of AAV, IFX-1 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.

We are not aware of any C5 or C5a inhibitors under development for the treatment of AAV. However, Chemocentryx, Inc. is developing CCX168, a C5aR inhibitor, in AAV. Though it acts through a different mechanism of action than IFX-1, CCX168 has demonstrated the potential to induce remission in AAV patients and is currently undergoing Phase III clinical trial development. CCX168 was also granted the EMA's Priority Medicine's designation to expedite its clinical development and the EMA recently accepted the conditional marketing authorization application for regulatory review. In an ongoing investigator-initiated trial, Abatacept, a selective T-cell costimulation modulator from Bristol-Meyers Squibb, is 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 another investigator-initiated clinical trial, the efficacy of a plasma exchange procedure is tested in conjunction with corticosteroid treatment with respect to its impact on all-cause mortality and end-stage renal disease.

More generally, in the terminal complement space, there is currently one approved drug, Eculizumab, 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 Ra Pharmaceuticals, Inc., Akari Therapeutics Plc, Ophthotech Corporation, Alnylam Pharmaceuticals 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 CCX168, as well as Innate Pharma S.A., with the in-licensed antibody IPH5401. 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., Achillion 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 "Item 3. Key Information—D. Risk factors—Risks related to the discovery, development and commercialization of our product candidates—Even if one of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable."

Government regulation and product approval

Government authorities in all major pharmaceutical markets extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing and import and export of pharmaceutical products such as those we are developing. Although our initial focus will be on the United States and Europe, we 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.

Other healthcare laws and compliance requirements

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

EU approval process

The European Medicines Agency, or EMA, is a decentralized scientific agency of the European Union. It coordinates the evaluation and monitoring of centrally-authorized medicinal products. It is responsible for the scientific evaluation of applications for 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 likewise 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 being 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:

(a)(i) 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;

(a)(ii) 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

(b) 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 IFX-1. Depending on the outcome and available data of IFX-1 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. (since January 2, 2018). We primarily operate our business out of our operating subsidiary InflaRx GmbH.

3.4 Property, plant and equipment

Our headquarters are in Jena, Germany, where we occupy approximately 6,700 square feet of office and laboratory space under an extendable lease that expires in December 2019. In addition, we occupy approximately 4,240 square feet of office space in Munich, Germany under a lease that expires in June 2022.

4 OPERATING AND FINANCIAL REVIEW AND PROSPECTS[4]

[4] Source: 20-F, Item 5.

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 chapters 1.2 and 2.2 of this report.

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, 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 IFX-1 for the treatment of HS, a chronic debilitating systemic inflammatory skin disease, for which we have commenced a Phase IIb clinical trial in the first quarter of 2018. Beyond HS, we intend to develop IFX-1 and other proprietary antibodies to address a wide array of complement-mediated diseases with significant unmet needs, including AAV, a rare, life-threatening autoimmune disease.

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, IFX-1. To date, we have not generated any product revenue and have financed our operations primarily through our initial public offering, the private placement of our securities and other income from various grants. As of December 31, 2017, we had raised an aggregate of approximately €157.0 milion, comprised of €81.8 million in net proceeds from our initial public offering, €74.0 million in gross proceeds from private placements of our securities and €1.2 million in payments in connection with various grants. As of December 31, 2017, we had cash and cash equivalents of €123.3 million.

As of December 31, 2017, we had an accumulated deficit of €51.3 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 will increase significantly if, and as we

- progress a Phase IIb clinical trial of IFX-1 in HS;
- continue to advance our lead product candidate, IFX-1, through additional clinical development, including by conducting a Phase II clinical trial program of IFX-1 in AAV;
- initiate and continue our current research programs and development activities, including development of IFX-2;
- seek to identify additional research programs and additional product candidates;
- maintain, expand and protect our intellectual property portfolio;
- hire and retain additional personnel, such as clinical quality control and scientific personnel; and

- incur additional costs associated 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, would have a negative impact on our financial condition and our ability to develop IFX-1 or any additional product candidates.

Our financial statements were materially affected by the corporate reorganization conducted in connection with our initial public offering (see Note 1 to our Consolidated Financial Statements).

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, IFX-1 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 IFX-1 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 €0.1 million and €0.2 million of other income from grants in 2017 and 2016 respectively.

Research and development expenses

Research and development expenses have consisted principally of:

- employee-related expenses, including salaries, benefits and stock-based compensation expense based upon employees' role within the organization;

- professional fees for lawyers related to the protection and maintenance of our intellectual property; and

- 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.

We expect that our total research and development expenses in 2018 will be significantly higher compared to our expenses 2016 and 2017. Such increased research and development expenses primarily relate to the following key programs:

- ***IFX-1***. In 2017, we completed enrollment and dosing in our Phase IIa clinical trial of IFX-1 in patients with HS. In the first quarter of 2018, we commenced our Phase IIb clinical trial of IFX-1 in patients with HS. We expect our expenses associated with IFX-1 will further increase as we conduct our Phase IIb clinical trial program of IFX-1 in patients with HS and prepare to commence a Phase II clinical trial in patients with AAV. 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 2016 and 2017, we incurred €5.3 million and €14.4 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. Research and development expenses are expected to increase as we advance the clinical development of IFX-1 and IFX-2 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 IFX-1, 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 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 expenses include costs of additional personnel, additional legal fees, audit fees, directors' and officers' liability insurance premiums and costs associated with investor relations.

Critical judgments and accounting estimates

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 our financial statements, the critical judgments made by management in applying our accounting policies involves the accounting estimates identified in Notes 3, 13 and 14 to our Consolidated Financial Statements.

New standards and interpretations not yet adopted

The standards, amendments to standards and interpretations that are effective for annual periods beginning after December 31, 2017, and have not been applied in preparing the Consolidated Financial Statements are disclosed in Note 3 to our Consolidated Financial Statements.

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 the Consolidated Financial Statements, and it is qualified in its entirety by reference to them.

Comparison of the years ended December 31, 2016 and 2017

	Year ended December 31,		
	2016	2017	Change
	(in thousands of €)		
Other income and expenses (net)	231	108	(123)
Research and development expenses	(5,278)	(14,415)	(9,137)
General and administrative expenses	(1,844)	(5,138)	(3,294)
Loss before interest and income taxes	(6,891)	(19,445)	(12,554)
Finance costs (net)	(2,048)	(4,793)	(2,745)
Loss before tax	(8,939)	(24,238)	(15,299)
Income tax expense	—	—	—
Loss for the period	(8,939)	(24,238)	(15,299)
Exchange differences on translating foreign operations	1	—	(1)
Total comprehensive loss	**(8,938)**	**(24,238)**	**(15,300)**

Other income and expenses (net)

Other income and expenses (net) decreased by €0.1 million in the year ended December 31, 2017 compared to the year ended December 31, 2016. This decrease is attributable to a €0.1 million decrease in government grants.

Research and development expenses

	Year ended December 31,		
	2016	2017	Change
	(in thousands of €)		
Third party expenses	3,757	8,856	5,099
Personnel expenses	1,293	4,681	3,388
Other expenses	228	878	650
Total	**5,278**	**14,415**	**9,137**

Research and development expenses increased by €9.1 million in the year ended December 31, 2017 compared to the year ended December 31, 2016. This increase is primarily attributable to a €5.1 million increase in CRO and CMO expenses for IFX-1 in connection with the preparation to commence the clinical trial Phase IIb in patients with HS and the Phase II in patients with AAV as well as with the ongoing manufacturing activities for clinical trial material for these clinical trials with IFX-1 and to a €3.4 million increase in employee-related costs associated with salaries, bonus, benefits and non-cash

share-based compensation, which is primarily attributable to the effect of accelerated vesting of our equity awards outstanding upon our IPO and partially attributable to grants under our current equity incentive plans.

General and administrative expenses

	Year ended December 31,		
	2016	2017	Change
	(in thousands of €)		
General and administrative expense:			
Personnel expenses	1,134	2,948	1,814
Legal, consulting and audit fees	394	1,478	1,088
Other expenses	316	712	392
Total	**1,844**	**5,138**	**3,294**

General and administrative expenses increased by €3.3 million to €5.1 million for the year ended December 31, 2017, from €1.8 million for the year ended December 31, 2016. This increase is primarily attributable to a €1.8 million increase in employee-related costs associated with salaries, bonus, benefits and non-cash share-based compensation, which is primarily attributable the effect of accelerated vesting of our equity awards outstanding upon our IPO and partially attributable to grants under our current equity incentive plans. Legal, consulting and audit fees and other expenses increased by €1.5 million to €2.2 million for the year ended December 31, 2017, from €0.7 million for the year ended December 31, 2016, which increase is mainly attributable to operating expenses incurred in connection with the IPO and our NASDAQ listing.

Finance costs-net

	Year ended December 31,		
	2016	2017	Change
	(in thousands of €)		
Finance income	1	130	129
Interest on preferred shares	(1,836)	(2,229)	(393)
Preferred shares issuance costs	(193)	(345)	(152)
Unrealized foreign exchange loss	(3)	(2,358)	(2,355)
Other finance costs	(17)	10	27
Total finance costs	(2,049)	(4,923)	(2,874)
Finance costs (net)	**(2,048)**	**(4,793)**	**(2,745)**

Finance costs (net) increased by €2.7 million to €4.8 million for the year ended December 31, 2017, from €2.0 million for the year ended December 31, 2016. This increase is mainly attributable to (a) interest expense on our outstanding preferred shares issued in the Series C financing, which increased by €0.4 million to €2.2 million for the year ended December 31, 2017, from €1.8 million for the year ended December 31, 2016, and (b) unrealized foreign exchanges losses, which increased by €2.4 million to 2.4 million for the year ended December 31, 2017, recognized on the net proceeds received from our initial public offering.

Comparison of the years ended December 31, 2015 and 2016

	Year ended December 31,		
	2015	2016	Change
	(in thousands of €)		
Other income and expenses (net)	134	231	97
Research and development expenses	(3,478)	(5,278)	(1,800)

	Year ended December 31,		
	2015	2016	Change
	(in thousands of €)		
General and administrative expenses	(438)	(1,844)	(1,406)
Loss before interest and income taxes	**(3,782)**	**(6,891)**	**(3,109)**
Finance costs (net)	(1,135)	(2,048)	(913)
Loss before tax	**(4,917)**	**(8,939)**	**(4,022)**
Income tax expense	—	—	—
Loss for the period	**(4,917)**	**(8,939)**	**(4,022)**
Exchange differences on translating foreign operations	2	1	(1)
Total comprehensive loss	**(4,915)**	**(8,938)**	**(4,023)**

Other income and expenses (net)

Other income and expenses (net) increased by €0.1 million in the year ended December 31, 2016 compared to the year ended December 31, 2015. This decrease is primarily attributable to a €0.1 million increase in government grants.

Research and development expenses

	Year ended December 31,		
	2015	2016	Change
	(in thousands of €)		
Third party expenses	1,960	3,757	1,797
Personnel expenses	1,153	1,293	140
Other expenses	365	228	(137)
Total	**3,478**	**5,278**	**1,800**

We use our employee and infrastructure resources across multiple research and development programs directed toward developing IFX-1 and IFX-2. We manage certain activities such as contract research and manufacturing of IFX-1 and our discovery programs through our third-party vendors. We did not track the costs of these activities on a program-by-program basis until 2017.

Research and development expenses increased by €1.8 million to €5.3 million for the year ended December 31, 2016, from €3.5 million for the year ended December 31, 2015. This increase is primarily attributable to a €1.8 million increase in CRO and CMO expenses in connection with our preclinical studies and clinical trial for IFX-1.

General and administrative expenses

	Year ended December 31,		
	2015	2016	Change
	(in thousands of €)		
General and administrative expense:			
Personnel expenses	309	1,134	825
Legal, consulting and audit fees	86	394	308
Other expenses	43	316	273
Total	**438**	**1,844**	**1,406**

General and administrative expenses increased by €1.4 million to €1.8 million for the year ended December 31, 2016, from €0.4 million for the year ended December 31, 2015. This increase is primarily attributable to a €0.8 million increase in employee-related costs associated with salaries, bonus, benefits and non-cash stock-based compensation, which is mainly in connection with the grants under the 2016

Plan, a €0.3 million increase in legal, consulting and audit fees and a €0.3 million increase in other expenses.

Finance costs-net

Finance costs for year ended December 31, 2016 mainly consisted of interest expense on our outstanding preferred shares of €2.0 million, an 80% increase over the €1.1 million incurred in the year ended December 31, 2015 due to the increase of outstanding preferred shares issued in the Series C financing.

4.2 Liquidity and capital resources

Since inception, we have incurred significant operating losses. For the years ended December 31, 2016 and 2017, we incurred net losses of €8.9 million and €24.2 million, respectively. To date, we have financed our operations primarily through the sale of our securities including in our initial public offering. As of December 31, 2017, we had cash and cash equivalents of €123.3 million.

Our cash and cash equivalents primarily consist of bank deposit accounts and a money market investment fund.

Cash flows

Comparison of the years ended December 31, 2016 and 2017

The table below summarizes our consolidated statement of cash flows for the years ended December 31, 2016 and 2017:

	Year ended December 31,	
	2016	**2017**
	(in thousands of €)	
Cash used in operating activities	(4,992)	(12,152)
Net cash used in investing activities	(53)	(167)
Net cash from financing activities	30860	108,801
Cash and cash equivalents at the beginning of the period	3,302	29,117
Exchange gains/losses on cash and cash equivalents	**1**	**(2,317)**
Cash and cash equivalents at the end of the period	**29,117**	**123,282**

Net cash used in operating activities

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

Net cash used in operating activities increased from €5.0 million in the year ended December 31, 2016 to €12.2 million in the year ended December 31, 2017, mainly due to the increase of cash expenses, such as third-party expenses for manufacturing and clinical trials attributable to our lead program IFX-1 and our personnel expenses.

Net cash used in investing activities

Net cash used for investing activities increased by €0.1 million in the year ended December 31, 2017 due to investments in software and office equipment.

Net cash provided by financing activities

Net cash generated from financing activities increased by €78.0 million to €108.9 million in the year ended December 31, 2017, compared to €30.9 million in the year ended December 31, 2016 and relates to the cash contributions received from the sale of Series C and Series D preferred shares and to our initial public offering.

Comparison of the years ended December 31, 2015 and 2016

The table below summarizes our consolidated statement of cash flows for the years ended December 31, 2015 and 2016:

	Year ended December 31,	
	2015	2016
	(in thousands of €)	
Cash used in operating activities	(3,308)	(4,992)
Net cash used in investing activities	(13)	(53)
Net cash from financing activities	0	30,860
Cash and cash equivalents at the beginning of the period	6,622	3,302
Exchange gains on cash and cash equivalents	**1**	**1**
Cash and cash equivalents at the end of the period	**3,302**	**29,117**

Net cash used in operating activities

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

Net cash used in operating activities increased by 51% from €3.3 million in the year ended December 31, 2015 to €5.0 million in the year ended December 31, 2016 mainly due to the increase of cash expenses, such as third-party expenses for manufacturing and clinical trials in connection with our lead program IFX-1 and our own personnel expenses.

Net cash used in investing activities

Net cash used for investing activities increased from €0 million in the year ended December 31, 2015 to €0.01 million in the year ended December 31, 2016.

Net cash provided by financing activities

Net cash generated from financing activities of €30.9 million in the year ended December 31, 2016 relates to our Series C preferred share financing.

Funding requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct Phase II clinical trials of IFX-1 in patients with HS and AAV, continue preclinical development of IFX-2, initiate new research and preclinical development efforts and seek marketing approval for any product candidates that we successfully develop and receive approval for. If our ongoing Phase IIb trial of HS is successful, we plan to commence a Phase III program of IFX-1 in HS and currently anticipate that the cost of such program could be in the range of €40 to €50 million. 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. Furthermore, we expect to incur 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 would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts. We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least the next 24 months.

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, your ownership interest 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 valuable 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[5]

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. See chapter 2.2 of this report.

6 CONTROLS AND PROCEDURES[6]

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 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 appetite. 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, 2017, 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.

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

[5] Source: 20-F, Item 8.A.
[6] Source: 20-F, Item 15.

required disclosures.

On the basis of reports and information provided to our board of directors, 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, 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.

Any material failings in, material changes to, and/or material improvements of the Company's risk management and control systems which have been observed, made and/or planned, respectively, during the fiscal year to which this report relates, have been discussed with our audit committee and with our non-executive directors.

7 CORPORATE GOVERNANCE

7.1 Dutch Corporate Governance Code

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 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.

Committee chairmanship (best practice provision 2.3.4)

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)

Given the current organization of the Company, our board of directors has not appointed a vice chairman. Our board of directors is of the opinion that the tasks and duties of the chairman will sufficiently be done by the other non-exective directors.

Company secretary (best practice provision 2.3.10)

Given the current organization of the Company, our board of directors has not appointed a company secretary. Our board of directors is of the opinion that it receives sufficient support from our employees and officers and from external advisors in order to properly fulfil their duties.

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, 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;
- 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.

Also, given the current organization of the Company and its recent transformation into a listed company, our board of directors has not yet determined the pay ratios within the Company.

Majority requirements for dismissal and overruling binding nominations (best practice provision 4.3.3)

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 our 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. 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 chapter 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 subsidaries 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 car-

ries 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

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. 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, 2017, 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 (44)**	Male	Swiss	8 November 2017	2022 AGM	100%
Niels Riedemann (46)*	Male	German	6 June 2017	2022 AGM	100%
Katrin Uschmann (53)**	Female	German	8 November 2017	2021 AGM	0%
Mark Kubler (42)**	Male	Swiss	8 November 2017	2021 AGM	100%
Lina Ma (40)**	Female	Chinese	8 November 2017	2021 AGM	0%
Renfeng Guo (48)*	Male	American	8 November 2017	2022 AGM	100%

* Executive director
** Non-executive director

The participation rates for Ms. Uschmann and Ms. Ma are not representative of their efforts on our board of directors, but are due to the fact that there was only one formal meeting of our board of directors after our initial public offering, which they could not attend.

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 the Head of Digital Enterprise Solutions at Swisscom Schweiz AG since 2015 and 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. He has served as chairman of the board of Idros S.A. 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 Sapphire Innovation AG, a predictive analytics software firm, as well as 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, 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.

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 Associate Professor. Professor Guo holds an Honorary Professorship at the Beijing Institute of Basic Sciences. Professor Guo received his medical degree from Norman Bethune Medical School in China.

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, 2017, the committees were composed as follows:

Name	Audit committee (and participation rate)	Compensation committee (and participation rate)	Nomination and corporate governance committee (no meetings in 2017)
Nicolas Fulpius	X* (100% participation)	X* (100% participation)	X*
Katrin Uschmann	X		
Mark Kubler	X (100% participation)	X (100% participation)	X

* Chairman

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 twice in order to carry out its responsibilities. The main items discussed at those meetings related to quarterly financial statements and external auditor 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 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, as of the establishment of our audit committee on 8 November 2017, no meetings of our nomination and corporate governance committee were held.

7.7 Evaluation

Because our initial public offering occurred shortly before the end of the financial year to which this report pertains, the annual evaluation by our board of directors of its own functioning, the functioning of the committees of our board of directors and the functioning of the individual directors was not performed in the financial year 2017 and shall be performed during the financial year 2018.

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 under review. Currently, the composition of the board of directors does not exactly meet the Company's diversity targets in term of gender (presently, approximately 28% 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. In the financial year under review, 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

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[7]

The aggregate compensation, including benefits in kind, accrued or paid to our senior management with respect to the year ended December 31, 2017, for services in all capacities was €5,174 thousand. In 2017, we granted options to purchase 1,591,848 common shares to our senior management.

As of December 31, 2017, we have no amounts set aside or accrued to provide pension, retirement or similar benefits to our directors, and in 2017, our non-executive directors received €124 thousand in total compensation, including benefits in kind, from us for services in such capacity. In 2017, we granted options to purchase 137,856 of our common shares to our directors under our 2017 equity

[7] Source: 20-F, Item 6.B.

incentive plan (see chapter 8.3 of this report).

See Note 16 (*Compensation*) to the Consolidated Financial Statements for further information concerning the implementation of the Compensation Policy in the fiscal year to which this report relates. In determining the level and structure of the compensation of the directors in the fiscal year to which this report relates relevant scenario analyses carried out in advance have been considered.

8.3 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.

9 RELATED PARTY TRANSACTIONS[8]

[8] Source: 20-F, Item 7.B.

The following is a description of related party transactions we have entered into since January 1, 2017 with any of our officers, directors and the holders of more than 5% of our common shares.

Series D preferred financing

On October 12, 2017, InflaRx GmbH and its shareholders entered into an investment and adherence agreement with entities affiliated with RA Capital Management, LLC, Bain Capital Life Sciences Investors, LLC and Cormorant Asset Management LLC and certain funds and accounts managed or advised by subsidiaries of BlackRock, Inc. (the "BlackRock Funds"), which we refer to collectively as the Series D investors, pursuant to which InflaRx GmbH issued and sold in a private placement an aggregate of 2,314,620 Series D preferred shares to the Series D investors at a price per share of €11.05 (in each case giving effect to the corporate reorganization), for aggregate net cash proceeds to InflaRx GmbH of approximately €25.6 million. In addition, the Series D investors purchased 1,928,946 Series A preferred shares and Series B preferred shares at a price per share of €11.05 (in each case giving effect to the corporate reorganization) from entities affiliated with Private Equity Thüringen GmbH & Co. and KfW (which we refer to as the Secondary Placement). Such Series A preferred shares and Series B preferred shares converted into Series D preferred shares upon the closing of the Series D financing (which we refer to as the Conversion). The Series D financing closed in the second half of October 2017. We refer to the transactions described above collectively as the Series D financing.

The table below sets forth the number of Series D preferred shares issued to and the price paid for such shares by each Series D investor, including in the Secondary Placement, after giving effect to the corporate reorganization.

	Series D preferred shares issued for cash	Aggregate cash purchase price for Series D preferred shares	Series D preferred shares received in the conversion	Aggregate cash purchase price paid in the secondary placement
Entities affiliated with RA Capital Management, LLC	925,848	€10,227,534.24	617,232	€6,818,356.16
BCLS Investco, L.P.	925,848	€10,227,534.24	617,232	€6,818,356.16
Entities affiliated with Cormorant Asset Management LLC	462,924	€5,113,767.12	308,616	€3,409,178.08
BlackRock Funds	—	—	385,896	€4,262,864.48

Investment and shareholders agreement

InflaRx GmbH and its shareholders entered into an investment and shareholders agreement, dated July 21, 2016 (referred to as the Shareholders Agreement). The Shareholders Agreement provides for certain restrictions on the shareholders party thereto, including restrictions on transfer of the Series C preferred shares, as well as certain co-sale rights, drag-along rights and rights of first refusal. On October 12, 2017, the Series D investors entered into an investment and adherence agreement with InflaRx GmbH and its shareholders pursuant to which the Series D investors agreed to accede to the Shareholders Agreement on substantially the same terms and conditions as applicable to the shareholders party thereto. The Shareholders Agreement terminated upon the closing of our initial public offering.

Management and director service agreements

We entered into management and director service agreements with our executive officers and our directors in connection with our initial public offering. See "Item 6. Directors, Senior Management and Employees—B. Compensation—Management and director service agreements."

Indemnification agreements

We entered into indemnification agreements with our directors and senior management. The indemnification agreements and our Articles of Association require us to indemnify our directors to the fullest extent permitted by law.

Registration rights agreement

We entered into a registration rights agreement with certain of our existing shareholders in connection with our initial public offering pursuant to which we granted them the rights set forth below.

Demand registration rights. Certain of our shareholders that are party to the Registration Rights Agreement (the "RRA Shareholders") are entitled to request that we effect up to an aggregate of six demand registrations under the Registration Rights Agreement, and no more than one demand registration within any six-month period, covering the RRA Shareholders' common shares that are subject to transfer restrictions under Rule 144 ("registrable securities"). The demand registration rights are subject to certain customary conditions and limitations, including customary underwriter cutback rights and deferral rights. No demand registration rights exist while a shelf registration is in effect.

Piggyback registration rights. If we propose to register any common shares (other than in a shelf registration or on a registration statement on Form S-4 or S-8), the RRA Shareholders are entitled to notice of such registration and to include their registrable securities in that registration. The registration of RRA Shareholders' registrable securities pursuant to a piggyback registration does not relieve us of the obligation to effect a demand registration. The managing underwriter has the right to limit the number of registrable securities included in a piggyback registration if the managing underwriter believes it would interfere with the successful marketing of the common shares.

Form F-3 registration rights. When we are eligible to use Form F-3, one or more RRA Shareholders have the right to request that we file a registration statement on Form F-3. RRA Shareholders will have the right to cause us to undertake underwritten offerings from the shelf registration, but no more than one underwritten offering in a six-month period. Each underwritten takedown constitutes a demand registration for purposes of the maximum number of demand registrations we are obligated to effectuate.

Subject to limited exceptions, the Registration Rights Agreement provides that we must pay all registration expenses in connection with a demand, piggyback or shelf registration. The Registration Rights Agreement contains customary indemnification and contribution provisions.

For further information on related party transactions, see Note 16 (*Related party disclosures*) to the Consolidated Financial Statements.

Where applicable, best practice provisions 2.7.3, 2.7.4 and 2.7.5 of the DCGC have been observed with respect to the transactions referenced above in this chapter 9.

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.

11 OTHER INFORMATION

11.1 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:

a. 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;

b. 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;

c. 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;

d. following those distributions, our board of directors shall determine which part of the remaining profits shall be added to the Company's reserves; and

e. 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.

11.2 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 2017, no preferred shares in the Company's capital were issued.

11.3 Material subsequent events

There were no subsequent events which might influence the Company's outlook.

11.4 Branches

The Company has no branch offices.

Signature page to the Dutch statutory board report of InflaRx N.V. for the fiscal year ended December 31, 2017.

By signing this signature page, the Dutch statutory board report of InflaRx N.V. for the fiscal year ended December 31, 2017, the InflaRx N.V. 2017 consolidated financial statements and the InflaRx N.V. 2017 company financial statements (appendices A and B, respectively) are approved.

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

Appendix A - InflaRx N.V. Consolidated Financial Statements

Appendix B - InflaRx N.V. Company Financial Statements