UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13A-16 OR 15D-16 UNDER
THE SECURITIES EXCHANGE ACT OF 1934

For the month of February, 2022

Commission File Number: 001-38283

InflaRx N.V.

(Translation of registrant's name into English)

Winzerlaer Str. 2
07745 Jena, Germany
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☐ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

INFLARX N.V.

On February 16, 2022, InflaRx N.V. (the "Company") issued a press release titled "InflaRx Reports Progress in Ongoing Phase II Clinical Trial with Vilobelimab in Cutaneous Squamous Cell Carcinoma"

On February 16, 2022, the Company announced progress made in the ongoing open label, non-comparative, two-stage, Phase II trial with vilobelimab in cutaneous squamous cell carcinoma and that there are no safety concerns on either arm of the study to date. A copy of the press release is attached hereto as Exhibit 99.1 and is being furnished and shall not be deemed filed or incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such a filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INFLARX N.V.

Date: February 16, 2022

By: /s/ Niels Riedemann
Name: Niels Riedemann
Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated February 16, 2022

Exhibit 99.1

InflaRx Reports Progress in Ongoing Phase II Clinical Trial with Vilobelimab in Cutaneous Squamous Cell Carcinoma

- In vilobelimab and pembrolizumab combination arm, the three patients enrolled in the first dosing cohort have been treated for 36 days with no safety concerns
- Steering Committee unanimously voted to continue study as planned and open enrollment for second dosing cohort
- Enrollment is also ongoing in vilobelimab monotherapy arm, with no safety concerns identified

Jena, Germany, February 16, 2022 – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, today announced the start of the second dosing cohort of the vilobelimab and PD-1 checkpoint inhibitor, pembrolizumab, combination arm of the Phase II clinical trial in cutaneous squamous cell carcinoma (cSCC).

The open label, non-comparative, two-stage, Phase II trial (NCT04812535) is ongoing at sites in Europe, the U.S. and elsewhere. The study is investigating two independent arms: vilobelimab alone (Arm A) and vilobelimab in combination with pembrolizumab (Arm B). The main objectives of the trial are to assess the safety and antitumor activity of vilobelimab monotherapy and to determine the maximum tolerated or recommended dose, safety and antitumor activity in the combination arm. The trial is expected to enroll a total of approximately 70 patients.

“We are pleased to see the progress in our first oncology study with vilobelimab and that there are to date no safety concerns in either arm,” said Dr. Korinna Pilz, Global Head of Clinical Research and Development at InflaRx. “Scientific data suggest C5a involvement in tumor formation and progression, as well as in immunosuppression, and there is pre-clinical evidence of synergies between PD-1 and C5a/C5aR inhibitors in inducing anti-tumor responses. While there are PD-1 checkpoint inhibitors approved for the treatment of advanced cSCC, there currently are no treatment options for patients who are PD-1 checkpoint inhibitor resistant or refractory. We look forward to continuing to advance the development of vilobelimab with the hope of bringing a new therapy to treat the advanced stages of this potentially deadly skin cancer.”

In the combination Arm B, three patients have been treated for at least 36 days in the first dosing cohort of the study, receiving intravenous infusions of 400 mg of vilobelimab on Days 1, 4, 8, and 15 and from Day 22 onwards, 800 mg every two weeks. Patients are also receiving 400 mg of pembrolizumab starting on Day 8 of the first cycle and every six weeks thereafter. The data from the first 36 days of treatment have been reviewed by the Steering Committee and no safety concerns were raised. The Steering Committee recommended to continue the study as planned and to open enrollment for the second dosing cohort with 1200 mg vilobelimab every two weeks after administration of 600 mg vilobelimab on Days 1,4, 8 and 15. The interim analysis in Arm B required to move to the second stage of the Phase II trial is expected after ten patients have been treated and are evaluable for response assessment at the recommended Phase II dose level, which will be selected based on data from the safety run-in phase of the study. These data are expected to be available in the first quarter of 2023.

In parallel, enrollment continues in the monotherapy Arm A. In this arm, patients are receiving a dose of 800 mg vilobelimab on Days 1, 4, 8, and 15 of the first cycle, followed by a dose of 1600 mg vilobelimab every two weeks starting on Day 22. Six patients are now enrolled in this arm. The interim analysis in Arm A required to proceed to the second stage is expected to be available after ten patients are evaluable for response assessment. These data are expected to be available in the third quarter of 2022.

About Cutaneous Squamous Cell Carcinoma (cSCC)
cSCC is the second most common form of skin cancer and, if caught early, it is generally curable. In the U.S. alone, according to the Skin Cancer Foundation, an estimated 1.8 million cases are diagnosed each year, which translates to about 205 cases diagnosed every hour. The incidence of cSCC has increased up to 200% in the past three decades. Approximately 5% of patients with cSCC develop locally advanced or metastatic disease. These forms of cSCC have a poor prognosis with low survival rates. Over 15,000 people in the U.S. die each year from this disease.

About Vilobelimab (IFX-1)
Vilobelimab is a first-in-class monoclonal anti-human complement factor C5a antibody, which highly and effectively blocks the biological activity of C5a and demonstrates high selectivity towards its target in human blood. Thus, vilobelimab leaves the formation of the membrane attack complex (C5b-9) intact as an important defense mechanism, which is not the case for molecules blocking the cleavage of C5. Vilobelimab has been demonstrated in pre-clinical studies to control the inflammatory response driven tissue and organ damage by specifically blocking C5a as a key “amplifier” of this response. Vilobelimab is believed to be the first monoclonal anti-C5a antibody introduced into clinical development. Over 300 people have been treated with vilobelimab in completed clinical trials, and the antibody has been shown to be well tolerated. Vilobelimab is currently being developed for various indications, including hidradenitis suppurativa, ANCA-associated vasculitis and pyoderma gangraenosum, as well as other areas, such as critical COVID-19 and cutaneous squamous cell carcinoma (cSCC).

About InflaRx N.V.

InflaRx (Nasdaq: IFRX) is a clinical-stage biopharmaceutical company focused on applying its proprietary technology to discover and develop first-in-class or best-in-class, potent and specific inhibitors of C5a and C5aR. Complement C5a and C5aR are powerful inflammatory mediators involved in the progression of a wide variety of autoimmune and other inflammatory diseases. InflaRx was founded in 2007, and the group has offices and subsidiaries in Jena and Munich, Germany, as well as Ann Arbor, MI, USA. For further information, please visit www.inflarx.com.

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FORWARD-LOOKING STATEMENTS
This press release contains forward-looking statements. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “believe,” “estimate,” “predict,” “potential” or “continue” and similar expressions. Forward-looking statements appear in a number of places throughout this release and may include statements regarding our intentions, beliefs, projections, outlook, analyses and current expectations concerning, among other things, our ongoing and planned pre-clinical development and clinical trials; the impact of the COVID-19 pandemic on the Company; the timing and our ability to commence and conduct clinical trials; potential results from current or potential future collaborations; our ability to make regulatory filings, obtain positive guidance from regulators, and obtain and maintain regulatory approvals for our product candidates; our intellectual property position; our ability to develop commercial functions; expectations regarding clinical trial data; our results of operations, cash needs, financial condition, liquidity, prospects, future transactions, growth and strategies; the industry in which we operate; the trends that may affect the industry or us and the risks, uncertainties and other factors described under the heading “Risk Factors” in InflaRx’s periodic filings with the Securities and Exchange Commission. These statements speak only as of the date of this press release 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. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, and we assume no obligation to update these forward-looking statements, even if new information becomes available in the future, except as required by law.