

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 28, 2022, InflaRx N.V. issued a press release titled “InflaRx Provides Update on Development Plans for Vilobelimab in Hidradenitis Suppurativa.” A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

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 28, 2022

By: /s/ Niels Riedemann

Name: Niels Riedemann

Title: Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated February 28, 2022



InflaRx Provides Update on Development Plans for Vilobelimab in Hidradenitis Suppurativa

Jena, Germany, February 28, 2022 – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, today reported that the Company has received an advice letter from the U.S. Food and Drug Administration (FDA) related to its Phase III program with vilobelimab for the treatment of hidradenitis suppurativa (HS). The feedback indicates that the FDA recommends using the Hidradenitis Suppurativa Clinical Response Score (“HiSCR”) as the primary endpoint in the Phase III trial. The FDA advice was provided nearly three months after the Company’s protocol submission and contrasts with the FDA advice provided to the Company in a Type A meeting held in Q3 2021. In the minutes of that meeting, FDA provided advice on how to implement, name and validate the meaningfulness of the modified HiSCR, a new primary endpoint suggested by the Company, that would measure the reduction of all three types of inflammatory lesions in HS – inflammatory nodules, abscesses and draining tunnels. A reduction in draining tunnels is not captured by the HiSCR. Within the Type A written response, FDA did not recommend the traditional HiSCR as the primary endpoint measure. Following the advice received in the Type A meeting, earlier this year, InflaRx announced the initiation of a Phase III trial, designed to study patients with moderate to severe HS disease suffering from actively draining tunnels.

Given the unexpected details of the feedback from the FDA, InflaRx will pause activities related to the Phase III trial. The Company will seek to clarify the advice received and determine next steps, which will be communicated accordingly. The FDA has not issued a clinical hold.

As previously announced, InflaRx completed a Type A meeting with the FDA in Q3 2021 to align on the Phase III HS study design. In this meeting, FDA and InflaRx discussed together a new primary efficacy endpoint for a pivotal study program that focuses on patients with active draining tunnels and includes measuring the reduction of all three types of inflammatory lesions. InflaRx incorporated the FDA’s input and submitted the Phase III protocol to the Agency in late November 2021. The FDA had no comments during the 30-day nor the 60-day review period. In Q1 2022, InflaRx determined it was appropriate to begin study activities, as the Company did not expect any critical protocol review issues to be pending with FDA.



About Vilobelimab

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, and has recently reported positive Phase II results in ANCA-associated vasculitis and pyoderma gangraenosum. Vilobelimab is in Phase III development for the treatment of critically ill COVID-19 patients and in Phase II development for patients suffering from 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.

Contacts:

InflaRx N.V.

Jordan Zwick – Chief Strategy Officer
Jason Stewart – Strategy & Investor Relations
Email: IR@inflarx.de
Tel: +1 917-338-6523

MC Services AG

Katja Arnold, Laurie Doyle, Andreas Jungfer
Email: inflarx@mc-services.eu
Europe: +49 89-210 2280
US: +1-339-832-0752



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, in particular our Phase III trial in HS and related communications with the FDA; 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.
