

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 March, 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 March 17, 2022, InflaRx N.V. (the “Company”) issued a press release titled “InflaRx Receives Corrected Advice Letter from FDA Related to Phase III Program for Vilobelimab in Hidradenitis Suppurativa.”

The Company announced today that it received a corrected 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). In the corrected letter, the FDA no longer recommends that the Company use the Hidradenitis Suppurativa Clinical Response Score (“HiSCR”) as the primary endpoint for the chosen patient population but gives recommendations related to implementation of the modified HiSCR (m-HiSCR). The written advice letter received in February 2022 had stated that the FDA recommended using the HiSCR as the primary endpoint in the Phase III trial, which was inconsistent with the minutes from a Type A advice meeting held between the Company and the FDA in the third quarter of 2021.

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: March 17, 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 March 17, 2022



InflaRx Receives Corrected Advice Letter from FDA Related to Phase III Program for Vilobelimab in Hidradenitis Suppurativa

Jena, Germany, March 17, 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 a corrected 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). In this corrected letter, FDA no longer recommends that the Company use the Hidradenitis Suppurativa Clinical Response Score (“HiSCR”) as the primary endpoint for the chosen patient population but gives recommendations related to implementation of the modified HiSCR (m-HiSCR).¹ The written advice letter received in February 2022 had stated that the Agency recommended using the HiSCR as the primary endpoint in the Phase III trial, which was inconsistent with the minutes from a Type A advice meeting held between InflaRx and the FDA in the third quarter of 2021.

“We appreciate the prompt feedback from the FDA clarifying the advice received in February,” stated Dr. Korinna Pilz, Chief Clinical Development Officer.

In light of this corrected advice from FDA, InflaRx believes that further development in HS is feasible. Given the additional financing needs for a full Phase III HS program and the recent promising data in another immuno-dermatological disease, pyoderma gangrenosum, InflaRx is currently evaluating its strategic options on how to most efficiently develop vilobelimab in this disease space.

¹ m-HiSCR is defined as achieving both i) total body inflammatory lesion count (ANdT) reduction from Baseline of at least 50% and ii) a draining tunnel (dT) count reduction from Baseline of at least 50% at the end of Week 16.



The Company plans to update the markets on its pipeline development strategy in the second quarter of 2022.

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 Phase IIa results in pyoderma gangrenosum. 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.

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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, in particular our Phase III trial in HS and related communications with the FDA, in particular addressing the FDA’s advice in various communications to us regarding the primary endpoint for the Phase III trial; 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.
