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 November 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): ☐

On November 9, 2022, InflaRx N.V. issued a press release titled “InflaRx Initiates First-in-Human Study with Small Molecule C5aR Inhibitor INF904.” 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: November 9, 2022

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

EXHIBIT INDEX

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press Release, dated November 9, 2022 |

Exhibit 99.1

InflaRx Initiates First-in-Human Study with Small Molecule
C5aR Inhibitor INF904

- Randomized, double-blind, placebo-controlled Phase I trial of orally administered complement inhibitor INF904 initiated
- Study designed as single ascending dose to determine safety, tolerability and pharmacokinetics in healthy volunteers
- Future development in complement-mediated chronic diseases

Jena, Germany, November 9, 2022 – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, today announced that it has dosed its first healthy volunteer in a randomized, double-blind, placebo-controlled Phase I trial of orally administered, small molecule C5aR inhibitor INF904. This single ascending dose Phase I trial aims to evaluate the safety, tolerability and pharmacokinetics of INF904 in healthy volunteers.

“Our preclinical studies with our new orally administered, small molecule C5aR inhibitor INF904 have shown potential for INF904 to inhibit C5a-induced signaling through its receptor C5aR. We are excited to enter clinical development of this new drug candidate,” said Renfeng Guo, M.D., Chief Scientific Officer and Founder of InflaRx. “INF904 is a promising addition to our pipeline of candidates controlling the terminal complement C5a / C5aR pathway. As an orally administered compound, we plan to study if INF904 is especially suitable for patients suffering from complement-mediated chronic autoimmune and inflammatory diseases requiring ongoing long-term treatment,” he added.

In the Phase I first-in-human trial, InflaRx plans to initially enroll approximately 62 healthy volunteers who will be randomly assigned to receive INF904 or placebo. The study will assess single ascending doses under fasted conditions. The main objective of the trial is to assess safety and tolerability. Secondary endpoints include several pharmacokinetic parameters. The effect of INF904 on C5a-induced downstream activity will also be explored.

As reported in January 2022, INF904 showed anti-inflammatory therapeutic effects in several preclinical disease models and there were no obvious toxicological findings in investigational new drug (IND)-enabling (preclinical) studies, including required good laboratory practice (GLP) toxicity analyses. In these preclinical studies, oral INF904 showed higher plasma exposure in animals, including non-human primates, and improved neutrophil-inhibitory activity in a hamster model compared to a marketed C5aR inhibitor. Further, in contrast to the marketed C5aR inhibitor, in vitro experiments demonstrated that INF904 has substantially less inhibition of the cytochrome P450 3A4/5 (CYP3A4/5) enzymes, which play an important role in the metabolism of a variety of metabolites and drugs, including glucocorticoids. InflaRx plans to study INF904 for the treatment of complement-mediated, chronic autoimmune and inflammatory diseases where oral administration is the preferred choice for patients.

About InflaRx N.V.:

InflaRx (Nasdaq: IFRX) is a clinical-stage biopharmaceutical company focused on applying its proprietary anti-C5a and C5aR technologies to discover and develop first-in-class or best-in-class, potent and specific inhibitors of the complement activation factor known as C5a and its receptor known as C5aR. Complement C5a and its receptor 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.de.

Contacts:

InflaRx N.V.

e-mail: IR@inflarx.de

MC Services AG

Katja Arnold, Laurie Doyle, Dr. Regina Lutz
e-mail: 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 InflaRx’s intentions, beliefs, projections, outlook, analyses and current expectations concerning, among other things, the Company’s ongoing and planned preclinical development and clinical trials, including the planned clinical trial of INF904 and the safety, tolerability and efficacy thereof; the Company’s interactions with regulators regarding the results of clinical trials and potential regulatory approval pathways; the impact of the COVID-19 pandemic on the Company; the timing and its ability to commence and conduct clinical trials; potential results from current or potential future collaborations; its ability to make regulatory filings, obtain positive guidance from regulators, and obtain and maintain regulatory approvals for its product candidates; its intellectual property position; its ability to develop commercial functions; expectations regarding clinical trial data; decisions regarding the strategic direction of the Company; its results of operations, cash needs, financial condition, liquidity, prospects, future transactions, growth and strategies; the industry in which the Company operates; the trends that may affect the industry or the Company’s business; and the risks, uncertainties and other factors described under the heading “Risk Factors” in InflaRx’s periodic filings with the SEC. 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 the Company’s 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 InflaRx assumes no obligation to update these forward-looking statements, even if new information becomes available in the future, except as required by law.