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 July 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 July 6, 2022, InflaRx N.V. issued a press release titled “InflaRx Receives FDA Fast Track Designation for Treatment of Ulcerative Pyoderma Gangrenosum.” 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: July 6, 2022

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated July 6, 2022

Exhibit 99.1

InflaRx Receives FDA Fast Track Designation for Treatment of Ulcerative Pyoderma Gangrenosum

- US Food and Drug Administration awards Fast Track designation for the treatment of ulcerative pyoderma gangrenosum
- Fast track follows recently reported orphan drug designation by both US FDA and EMA

Jena, Germany, July 6, 2022 – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, today announced that the US Food and Drug Administration (FDA) granted a Fast Track designation to the development of its first-in-class anti-C5a monoclonal antibody vilobelimab for the treatment of ulcerative pyoderma gangrenosum (PG). The Company had submitted a request for Fast Track designation to the FDA on the positive outcome data in PG from its Phase IIa open-label dose-escalation study.

As previously announced, in the multi-center, proof-of-concept Phase IIa study a total of 19 patients were enrolled. Over a treatment period of 26 weeks, patients were treated biweekly with vilobelimab 800mg, 1600mg or 2400mg, after an initial run-in phase with three doses of 800mg on days 1, 4 and 8, followed by a two-month observation period. Efficacy was assessed with the physician global assessment score (PGA), and 6 out of 7 patients (85.7%) in the high dose cohort demonstrated complete target ulcer closure and treatment response correlated with suppression of C5a levels in patients' plasma over time.

The Company had previously announced that vilobelimab was granted orphan drug designation for the treatment of PG by both the FDA in the US and the European Medicines Agency (EMA) in Europe and that the Company had held a productive End-of-Phase II meeting with the Division of Dermatology with the FDA related to its Phase III development plans in PG.

"We are pleased that our development in pyoderma gangrenosum has been designated Fast Track by the FDA shortly after receiving the Orphan Drug designation, recognizing PG as serious condition with high unmet medical need and vilobelimab as promising potential future treatment option," said Prof. Niels C. Riedemann, CEO and Founder of InflaRx. "The Fast Track designation will further facilitate our interactions with the FDA related to our development in PG and will also allow for faster review and approval upon successful completion of a Phase III development program," he added.

About Fast Track[1]

Fast track is a process designed by the FDA to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. According to the FDA, the purpose is to get important new drugs to the patient earlier. A drug that receives Fast Track designation is eligible for some or all of the following:

- more frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval;
- more frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers;
- eligibility for Accelerated Approval and Priority Review, if relevant criteria are met; and
- Rolling Review, which means that a drug company can submit completed sections of its Biologic License Application (BLA) or New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed.

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. Vilobelimab has been shown to be well tolerated within clinical trials in different disease settings. Vilobelimab is currently being developed for various indications, including pyoderma gangrenosum and severe COVID-19. The Company has recently reported positive Phase IIa results in PG and encouraging Phase III results in mechanically ventilated COVID-19 patients. Vilobelimab is also in Phase II development for patients suffering from cutaneous squamous cell carcinoma.

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1 See U.S. Food and Drug Administration, “Fast Track,” available online.

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, including the development of vilobelimab to treat pyoderma gangrenosum (PG) and severe COVID-19; the impact of the COVID-19 pandemic on us; 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; our status as a foreign private issuer; 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.