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 2023

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 ☐

EXPLANATORY NOTE

On November 6, 2023, InflaRx N.V. issued a press release titled “InflaRx Announces First Patient Dosed in Phase III Trial with Vilobelimab in Pyoderma Gangrenosums.” A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated November 6, 2023

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 6, 2023

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

Exhibit 99.1

InflaRx Announces First Patient Dosed in Phase III Trial with Vilobelimab in Pyoderma Gangrenosum

- Multi-national, randomized, controlled adaptive Phase III study in ulcerative pyoderma gangrenosum (PG) initiated and first patient dosed in the U.S.

- PG is a rare and debilitating autoimmune skin disease characterized by painful ulcers that can rapidly progress

Jena, Germany, November 6, 2023 – InflaRx N.V. (Nasdaq: IFRX), a biotechnology company pioneering anti-inflammatory therapeutics targeting the complement system, announced today that the first patient has been dosed in its Phase III study investigating the efficacy and safety of vilobelimab in ulcerative PG, a rare neutrophilic and inflammatory skin disease characterized by destructive, painful cutaneous ulcers.

“We are pleased that the first patient has been dosed in the U.S. in our pivotal Phase III study with vilobelimab for the treatment of ulcerative pyoderma gangrenosum. There are currently no approved treatments for this debilitating disease in either the U.S. or Europe, and therefore, there remains a high unmet medical need for these patients,” said Dr. Camilla Chong, MD, Chief Medical Officer of InflaRx. “The Phase III study builds on our promising Phase II clinical results, and we look forward to the continual collaboration with external experts with the ultimate goal of helping patients that are suffering from this devastating condition.”

The Phase III clinical study is designed to enroll patients worldwide, including countries such as the U.S., countries in Europe, and Australia. The multi-national, randomized, double-blind, placebo-controlled trial has two arms: one arm receiving vilobelimab (2400mg every other week) plus a low dose of corticosteroids and another arm receiving placebo plus the same low dose of corticosteroids. In both arms, corticosteroid treatment will be initiated on day 1 and will be tapered off within the first 8 weeks of the trial. The primary endpoint of the study is complete closure of the target ulcer at any time up to 26 weeks after initiation of treatment.

The study has an adaptive trial design with an interim analysis blinded for the sponsor and investigators (but unblinded for the independent data safety monitoring committee), which is planned upon enrollment of approximately 30 patients, divided equally between the two aforementioned arms of the study. The interim analysis with a set of predefined rules will take into account the then-observed difference in complete target ulcer closure between the two arms and will then determine whether the trial sample size will be adapted or whether the trial should be stopped due to futility. The enrollment period is projected to last at least two years, and its overall period will depend on the total trial size after sample size adaptation.

The Company has received Fast Track and Orphan Drug (OD) designations by the U.S. Food and Drug Administration (FDA), as well as OD designation by the European Medicines Agency (EMA) for the treatment of PG.

About Pyoderma Gangrenosum

Ulcerative PG is a rare, non-infectious, neutrophilic dermatosis recurrent skin disorder characterized by painful, necrolytic, cutaneous ulcers that can rapidly progress. PG is considered an autoimmune disease of the skin, but the underlying cause of PG is not known in detail. PG lesions are histologically characterized by pronounced infiltration of neutrophils, and activated neutrophils surrounding the ulcers are believed to be disease drivers. PG typically occurs in patients between the ages of 40 and 60, and PG patients often also suffer from other autoimmune disorders, such as inflammatory bowel disease and rheumatoid arthritis. There are currently no approved drugs for the treatment of PG in the U.S. or in Europe, and there is no established standard of care based on controlled studies.

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 of the innate immune system, which is not the case for molecules blocking C5. In pre-clinical studies, vilobelimab has been shown to control the inflammatory response driven tissue and organ damage by specifically blocking C5a as a key “amplifier” of this response. Gohibic (vilobelimab) has been granted an Emergency Use Authorization (EUA) in the U.S. for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO). A Marketing Authorization Application (MAA) for the treatment of adult patients with SARS-CoV-2 induced septic acute respiratory distress syndrome receiving IMV or ECMO is currently under review by the European Committee for Medicinal Products for Human Use. In addition to development in COVID-19, vilobelimab is being developed for other debilitating or life-threatening inflammatory indications, including pyoderma gangrenosum.

About InflaRx

InflaRx GmbH (Germany) and InflaRx Pharmaceuticals Inc. (USA) are wholly owned subsidiaries of InflaRx N.V. (together, InflaRx).

InflaRx (Nasdaq: IFRX) is a biotechnology company pioneering anti-inflammatory therapeutics by applying its proprietary anti-C5a and anti-C5aR technologies to discover, develop and commercialize highly potent and specific inhibitors of the complement activation factor C5a and its receptor C5aR. C5a is a powerful inflammatory mediator involved in the progression of a wide variety of inflammatory diseases. InflaRx's lead product candidate, vilobelimab, is a novel, intravenously delivered, first-in-class, anti-C5a monoclonal antibody that selectively binds to free C5a and has demonstrated disease-modifying clinical activity and tolerability in multiple clinical studies in different indications. 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," "estimate," "believe," "predict," "potential" or "continue," among others. 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, the receptiveness of Gohibic (vilobelimab) as a treatment for COVID-19 by COVID-19 patients and U.S. hospitals and related treatment recommendations by medical/healthcare institutes and other third-party organizations, our ability to successfully commercialize and the receptiveness of Gohibic (vilobelimab) as a treatment for COVID-19 by COVID-19 patients and U.S. hospitals or our other product candidates; our expectations regarding the size of the patient populations for, market opportunity for, coverage and reimbursement for, estimated returns and return accruals for, and clinical utility of Gohibic (vilobelimab) in its approved or authorized indication or for vilobelimab and any other product candidates, under an EUA and in the future if approved for commercial use in the United States or elsewhere; the success of our future clinical trials for vilobelimab's treatment of COVID-19 and other debilitating or life-threatening inflammatory indications, including PG, and any other product candidates and whether such clinical results will reflect results seen in previously conducted pre-clinical studies and clinical trials; the timing, progress and results of pre-clinical studies and clinical trials of our product candidates and statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, the costs of such trials and our research and development programs generally; our interactions with regulators regarding the results of clinical trials and potential regulatory approval pathways, including related to our MAA submission for vilobelimab and our biologics license application submission for Gohibic (vilobelimab), and our ability to obtain and maintain full regulatory approval of vilobelimab or Gohibic (vilobelimab) for any indication; whether the FDA, the EMA or any comparable foreign regulatory authority will accept or agree with the number, design, size, conduct or implementation of our clinical trials, including any proposed primary or secondary endpoints for such trials; our expectations regarding the scope of any approved indication for vilobelimab; our ability to leverage our proprietary anti-C5a and C5aR technologies to discover and develop therapies to treat complement-mediated autoimmune and inflammatory diseases; our ability to protect, maintain and enforce our intellectual property protection for vilobelimab and any other product candidates, and the scope of such protection; our manufacturing capabilities and strategy, including the scalability and cost of our manufacturing methods and processes and the optimization of our manufacturing methods and processes, and our ability to continue to rely on our existing third-party manufacturers and our ability to engage additional third-party manufacturers for our planned future clinical trials and for commercial supply of vilobelimab and for the finished product Gohibic (vilobelimab); our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing; our ability to defend against liability claims resulting from the testing of our product candidates in the clinic or, if approved, any commercial sales; if any of our product candidates obtain regulatory approval, our ability to comply with and satisfy ongoing obligations and continued regulatory overview; our ability to comply with enacted and future legislation in seeking marketing approval and commercialization; our future growth and ability to compete, which depends on our retaining key personnel and recruiting additional qualified personnel; and our competitive position and the development of and projections relating to our competitors in the development of C5a and C5aR inhibitors or our industry; and the risks, uncertainties and other factors described under the heading "Risk Factors" in our periodic filings with the U.S. 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.