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 September 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 September 11, 2023, InflaRx N.V. issued a press release titled “InflaRx Announces Positive Topline Results from the Single Ascending Dose (SAD) Phase I Study with C5aR Inhibitor INF904.” 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 September 11, 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: September 11, 2023

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

Exhibit 99.1

InflaRx Announces Positive Topline Results from the Single Ascending Dose (SAD) Phase I Study with C5aR Inhibitor INF904

- SAD data confirm best-in-class potential for INF904 as orally administered C5aR inhibitor:
    - Safety and tolerability with no signals of concern over entire dose range
    - Pharmacokinetics (PK): favorable dose-proportional systemic exposure with overall PK profile confirming pre-clinical data
    - Desired blocking activity (>90%) of C5a-induced neutrophil activation at disease relevant C5a levels 24 hours post administration for doses of 30 mg to 240 mg
    - INF904 can be formulated with drug strength of 30 mg per capsule
- Data from the ongoing multiple ascending dose (MAD) part of the study to be presented in early 2024
- Company to host a conference call today, September 11, 2023 at 8:30 am EDT/14:30 CEST

Jena, Germany, September 11, 2023 – InflaRx N.V. (Nasdaq: IFRX), a biotechnology company pioneering anti-inflammatory therapeutics targeting the complement system, announced today its topline results from the single ascending dose (SAD) part of its randomized, double-blind, placebo-controlled Phase I trial of the orally administered, low molecular weight C5aR inhibitor INF904. In the SAD part of the study, INF904 demonstrated an excellent safety and tolerability profile as well as a very favorable pharmacokinetic (PK) and pharmacodynamic (PD) profile, confirming INF904´s best-in-class potential.

The SAD part of the Phase I first-in-human trial enrolled 62 healthy volunteers within six different dosing groups from 3 mg to 240 mg who were randomly assigned to receive INF904 or a placebo. Different drug concentrations were tested for the 60 mg dosing group. The main objectives were to assess safety and tolerability of single ascending doses under fasting conditions. Secondary endpoints included several PK parameters, and the effect of INF904 on C5a-induced neutrophil activation in blood samples from treated volunteers ex vivo also was explored.

“Our team has spent several years developing an orally administered inhibitor of the terminal complement C5a / C5aR pathway with optimized PD and PK properties primarily for the long-term treatment of patients with chronic inflammatory conditions in need of improved therapeutic options. We are very pleased that the results announced today confirm our pre-clinical studies with INF904, which did not reveal any safety concerns and demonstrated favorable PK and PD profiles. We look forward to seeing the results from the MAD part of the study and advancing INF904 in development,” commented Renfeng Guo, M.D., Chief Scientific Officer and Founder of InflaRx.

The results show that INF904 was well tolerated in treated patients and resulted in no safety signals of concern in single doses ranging from 3 mg to 240 mg. The overall percentage of adverse events (AEs) was lower in the INF904 treated patients compared to the placebo group, and no serious or severe AEs were observed at any dosing level. No related AEs were reported in conjunction with INF904 dosing.

Analysis of INF904 PK in subject plasma samples revealed sustained exposure to INF904 with six hours to maximum concentration (t_{max}). INF904 plasma levels were dose proportional for systemic exposure (AUC_{last}) and nearly dose proportional for maximum concentration (C_{max}) over the dose range used in the study. With the 30 mg dose, INF904 reached a C_{max} of 289 ng/ml with an AUC_{last} of 5197 h.ng/ml, which are approximately 3-fold and 10-fold, respectively, higher than the published Phase I data from the only marketed comparator[1].

Single doses of 30 mg or higher of INF904 achieved ≥90% blocking of C5a induced up-regulation of the activation marker CD11b on neutrophils in plasma samples from subjects ex vivo at 24 hours post dosing. This inhibition was achieved when 12.6 nM recombinant C5a was added as stimulus in this assay, a C5a concentration which can be observed in patients with severe inflammatory conditions such as the immuno-dermatological disease, hidradenitis suppurativa, or during life-threatening inflammation (e.g., in critically ill COVID-19 patients or septic patients). Thus, INF904 inhibition of C5a-induced neutrophil activation in human plasma achieved the set goal for effective C5aR control at disease relevant C5a levels.

“We are excited about the results we have seen to date in this Phase 1 trial, which support the best-in-class potential of our orally administered C5aR inhibitor INF904,” said Prof. Niels C. Riedemann, Chief Executive Officer and Founder of InflaRx. “Based on these promising results, we are initiating necessary steps to prepare for the future clinical evaluation of INF904. We plan to develop INF904 primarily for complement-mediated, chronic autoimmune and inflammatory diseases where oral administration is the preferred choice for patients,” he added.

The MAD part of the Phase 1 trial is ongoing, and the Company expects to present results from the approximately 24 healthy volunteers at the beginning of 2024. InflaRx is currently preparing to initiate additional required pre-clinical studies, including chronic toxicology studies, for the future clinical development of INF904 in chronic inflammatory diseases. In parallel, the Company is evaluating select potential indications for future development.

[1] InflaRx has not conducted a head-to-head comparison of the marketed C5aR inhibitor to INF904 in a clinical study. Without such head-to-head data, InflaRx is unable to make comparative claims between INF904 and the marketed C5aR inhibitor.

Conference call scheduled for today, September 11, 2023

InflaRx will host a conference call today, September 11, 2023 at 8:30 am EDT (14:30 CEST) to provide more details about the announced topline results of the SAD part of its Phase I study of INF904 in healthy human subjects. To participate in the conference call, participants may pre-register here and will receive a dedicated link and dial-in details to easily and quickly access the call. A replay will be available on the InflaRx website in the Investors – Events & Presentations section after the live conference call has concluded.

About INF904

INF904 is an orally administered small molecule inhibitor of C5a-induced signaling via the receptor C5aR. INF904 showed anti-inflammatory therapeutic effects in several pre-clinical disease models, and there were no obvious toxicological findings in investigational new drug (IND)-enabling studies, including required good laboratory practice (GLP) toxicity analyses. 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. Reported results from the single ascending dose part of an ongoing first-in-humans study demonstrated that INF904 is well tolerated in treated subjects and exhibits no safety signals of concern in single doses ranging from 3 mg to 240 mg. 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

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 first-in-class, 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, our ability to 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 emergency use authorization (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 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, including the MAD part of the Phase 1 trial with C5aR inhibitor INF904, 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 marketing authorization application (MAA) submission for vilobelimab and our biologics license application (BLA) submission for Gohibic (vilobelimab), and our ability to obtain and maintain full regulatory approval of vilobelimab or Gohibic (vilobelimab) for any indication; whether the U.S. Food and Drug Administration (FDA), the European Medicines Agency (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 (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 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.