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 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 September 8, 2022, InflaRx N.V. issued a press release titled “InflaRx Announces Vilobelimab Phase III Results in Critically Ill COVID-19 Patients Published in The Lancet Respiratory Medicine.” 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: September 8, 2022

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated September 8, 2022

Exhibit 99.1

InflaRx Announces Vilobelimab Phase III Results in Critically Ill COVID-19 Patients Published in The Lancet Respiratory Medicine

- The Lancet Respiratory Medicine, a peer-reviewed journal, published the results of the PANAMO trial, one of the largest, global, 1:1 randomized, placebo-controlled Phase III studies conducted in invasively mechanically ventilated, critically ill COVID-19 patients

- In-depth statistical analysis confirms robustness of clinical survival benefit of vilobelimab treatment on 28-day and 60-day all-cause mortality

- Vilobelimab targets the inflammatory immune response evoked by SARS-CoV-2 infection that causes viral sepsis leading to organ failure

Jena, Germany, September 08, 2022 – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, today announced that the previously reported results from its Phase III trial of vilobelimab to treat critically ill, invasively mechanically ventilated COVID-19 patients have been published in the peer-reviewed journal, The Lancet Respiratory Medicine. The publication can be accessed free of charge on The Lancet's website.

Professor Dr. Martin Witzenrath, Co-chair of the Department of Infectious Diseases and Respiratory Medicine, Charité Universitätsmedizin Berlin, Germany, and investigator of the PANAMO study, commented: "We remain in urgent need of treatments that can help the most severely affected critically ill and invasively ventilated COVID-19 patients who suffer from a viral sepsis induced lung failure and who still show high mortality rates in the range of 40% despite the applied standard of care. The results of the PANAMO trial demonstrate a robust signal for improved survival with C5a inhibition in these highly vulnerable patients."

The article describes the results from the Phase III, multicenter, randomized, double-blind, placebo-controlled PANAMO study. The PANAMO study is one of the largest 1:1 randomized, double-blind placebo-controlled trials that was powered to show a mortality difference as primary outcome measure in invasively mechanically ventilated COVID-19 patients in the intensive care unit. A total of 369 patients with COVID-19 on invasive mechanical ventilation were randomly assigned (1:1) to the vilobelimab treatment (six 800-mg infusions) or placebo group on top of standard of care, which included treatment with anti-coagulants, dexamethasone and immunomodulators. The published data show that vilobelimab treatment improved survival with a relative reduction in 28-day all-cause mortality of 23.9% compared to placebo in the global data set.

In-depth statistical analysis confirms robustness of clinical survival benefit

The primary statistical analysis of the primary outcome 28-day mortality pre-specified in the statistical analysis plan (SAP) yielded a p-value of 0.0941 and, thus, missed the significance level. However, the original per-protocol planned method (p=0.0266), as well as multiple other comparable pre-specified or post-hoc analyses, yielded p-values of <0.05 or <0.01. In depth analyses of this discrepancy suggest that the reported statistical p-value difference could be explained by the fact that, in the SAP defined model (site-stratified Cox regression), 61 patients from smaller sites with no occurring deaths or single patient sites regardless of outcome (alive or dead) made no factual contribution to the analysis (to the p-value) because of the statistical algorithm applied when including site stratification in the analysis.

All comparable statistical analysis methods applied (different other Cox regression without site stratification) to which all 368 randomized patients in the trial contributed to the p-value, and multiple other pre-specified and post-hoc analyses resulted in p-values below 0.05 or 0.01, confirming a robust signal for the observed survival benefit under vilobelimab treatment when compared to placebo (as shown in the table below).

Analysis method for 28-day mortality (all Cox regression models are age adjusted)	p-value	Hazard ratio (95% CI) or risk difference for logistic regression	Patient numbers with "factual contribution"	Plan for analysis
Cox regression incl. stratification by site	0.0941	0.728 (0.502; 1.056)	307	Pre-specified primary endpoint analysis method
Cox regression incl. no stratification	0.0266	0.674 (0.476; 0.955)	368	Original protocol-defined analysis method
Cox regression using "Frailty" model (random effect for site)	0.0181	0.648 (0.453; 0.929)	368	Post hoc analysis
Cox regression incl. stratification by country	0.0067	0.613 (0.430; 0.873)	368	Post hoc analysis
Logistic regression (multiple imputation of missing values)	0.0293	-11.0% (-20.8%; -1.2%)	369*	pre-specified sensitivity analysis
Simple log-rank test	0.0407		368	Post hoc analysis

Note: Different analysis methods pre-specified or post-hoc for the primary endpoint 28-day all-cause mortality.
* One patient was randomized in error but is included in the logistic regression sensitivity analysis.

Comparable findings were made when applying the corresponding analysis to the key secondary endpoint, 60-day all-cause mortality, with even lower p-values, for which a maintained relative reduction in mortality by vilobelimab compared to placebo treatment was detected (relative reduction of 22.6% using Kaplan Meier analysis).

A particularly strong relative reduction in 28-day all-cause mortality for vilobelimab treatment over placebo of 43% was reported for the pre-specified Western European region analysis (p-value=0.014). In addition, three pre-specified subgroup analyses for patients of higher severity all showed a reduction in 28-day all-cause mortality with vilobelimab compared to placebo ($p<0.05$ for all three). The need for renal replacement therapy as a secondary endpoint was lower in vilobelimab-treated patients compared to the placebo group ($p<0.05$).

“The results of this Phase III trial show the life-saving potential of vilobelimab in treating these highly vulnerable, invasively mechanically ventilated COVID-19 patients, and we are very happy that the importance of these data has now been recognized through publication by a top research journal after having gone through a rigorous review process,” said Prof. Niels C. Riedemann, CEO and Founder of InflaRx. “Critically ill COVID-19 patients are believed to suffer from a septic inflammatory immune response to SARS-CoV-2 leading to C5a generation. Vilobelimab is therefore ideally positioned to provide a mechanism of action offering benefit to patients suffering from the damaging effects of their own immune response to the virus,” he added.

Following encouraging interactions with the U.S. Food and Drug Administration (FDA) at a recent Type B meeting, the Company recently reported it plans to submit a request for emergency use authorization with the FDA by end of Q3 2022.

About viral sepsis in SARS-CoV-2 infection

Invasively mechanically ventilated patients who have tested positive for COVID-19 fulfill the criteria set by the 3rd international consensus definitions for sepsis and septic shock, which define sepsis as a “life-threatening organ dysfunction caused by a dysregulated host response to infection.” Viral infection-mediated sepsis is believed to be driven by the inflammatory immune response of a patient to the virus. Observational studies have suggested that the inflammatory response, endothelial permeability and coagulopathy observed in severe COVID-19 are associated with complement activation and C5a generation, as part of the human innate immune system and its inflammatory response. By targeting the complement component C5a in critically ill and invasively mechanically ventilated patients, vilobelimab blocks a key mediator of this inflammatory host response induced by severe SARS-CoV-2 infection and thus offers a mechanism of action which may be independent of the viral variant which has caused this response, once initiated.

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 (PG) 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.

The COVID-19 related work described herein was partly funded by the German Federal Government through grant number 16LW0113 (VILO-COVID). All responsibility for the content of this work lies with InflaRx.

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 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.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 InflaRx’s intentions, beliefs, projections, outlook, analyses and current expectations concerning, among other things, the Company’s ongoing and planned pre-clinical development and clinical trials, including the development of vilobelimab in several indications; the Company’s interactions with regulators regarding the results of clinical trials and potential regulatory approval pathways; the Company’s submission of an application to the FDA in the third quarter of 2022 for emergency use authorization for vilobelimab to treat critically ill COVID-19 patients; 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; 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 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.