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 October, 2021

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): ☐

INFLARX N.V.

On October 12, 2021, InflaRx N.V. (the "Company") issued a press release titled "InflaRx Completes Enrollment of Vilobelimab Phase III Study in Severe COVID-19."

The Company announced today the completion of enrollment of the Phase III part of the Phase II/III vilobelimab study in severe COVID-19 patients. The randomized, double-blind and placebo-controlled Phase III part of the Phase II/III study enrolled 369 mechanically ventilated patients with COVID-19 across sites in the EU, South America and other regions. Patients were randomized 1:1 to receive either vilobelimab or placebo; all patients received standard of care. The primary endpoint is 28-day all-cause mortality; key secondary endpoints include assessment of organ support and disease improvement. Treatment is still ongoing and topline results are expected to be available in Q1 2022.

The Phase II part of the study evaluated vilobelimab treatment plus best supportive care compared to best supportive care alone for up to 28 days. The Phase II part was randomized, open label and enrolled a total of 30 patients. The 28-day all-cause mortality rate was 13% (n = 2 of 15) in the vilobelimab treatment arm compared to 27% (n = 4 of 15) in the best supportive care arm. All deaths in the best supportive care arm occurred due to COVID-19-induced multi-organ failure. In the vilobelimab treatment arm, fewer patients experienced renal impairment assessed by estimated glomerular filtration rates compared to best supportive care alone, and more patients showed reversal of blood lymphocytopenia and a greater lowering of lactate dehydrogenase concentrations, a sign of reduction in tissue damage. A temporary, but statistically significant, increase in D-dimer levels in the first days following vilobelimab administration was noted, a potential signal for induction of blood clot lysis. No statistically significant group differences in the primary endpoint of relative change (%) from baseline to day 5 in oxygenation index (defined as PaO2/FiO2 ratio) were detected.

A copy of the press release is attached hereto as Exhibit 99.1 and is being furnished and shall not be deemed filed or incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such a filing.

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: October 12, 2021

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated October 12, 2021

Exhibit 99.1

InflaRx Completes Enrollment of Vilobelimab Phase III Study in Severe COVID-19

- Study has enrolled 369 patients across 9 countries
- Topline results expected to be available in Q1 2022

Jena, Germany, October 12, 2021 – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, announced today the completion of enrollment of the Phase III part of the Phase II/III vilobelimab study in severe COVID-19 patients.

The randomized, double-blind and placebo-controlled Phase III part of the Phase II/III study enrolled 369 mechanically ventilated patients with COVID-19 across sites in the EU, South America and other regions. Patients were randomized 1:1 to receive either vilobelimab or placebo; all patients received standard of care. The primary endpoint is 28-day all-cause mortality; key secondary endpoints include assessment of organ support and disease improvement. Treatment is still ongoing and topline results are expected to be available in Q1 2022.

Dr. Korinna Pilz, Chief Clinical Development Officer, said: “There remains an urgent need for treatments for critically ill patients with severe COVID-19, and we are pleased that enrollment has completed in this trial. Based on our current expectations regarding when we will be able to lock the database and complete the data analyses, we expect to report topline results in Q1 2022. We are hopeful that vilobelimab can make a meaningful difference for COVID-19 patients. Should the data so warrant, we would then discuss with regulatory authorities the next steps.”

The Phase II part of the study evaluated vilobelimab treatment plus best supportive care compared to best supportive care alone for up to 28 days. The Phase II part was randomized, open label and enrolled a total of 30 patients. The 28-day all-cause mortality rate was 13% (n = 2 of 15) in the vilobelimab treatment arm compared to 27% (n = 4 of 15) in the best supportive care arm. All deaths in the best supportive care arm occurred due to COVID-19-induced multi-organ failure. In the vilobelimab treatment arm, fewer patients experienced renal impairment assessed by estimated glomerular filtration rates compared to best supportive care alone, and more patients showed reversal of blood lymphocytopenia and a greater lowering of lactate dehydrogenase concentrations, a sign of reduction in tissue damage. A temporary, but statistically significant, increase in D-dimer levels in the first days following vilobelimab administration was noted, a potential signal for induction of blood clot lysis. No statistically significant group differences in the primary endpoint of relative change (%) from baseline to day 5 in oxygenation index (defined as PaO2/FiO2 ratio) were detected.

The data from the Phase II part of the study have been published in the peer-reviewed journal, The Lancet Rheumatology.

About vilobelimab (IFX-1):
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 to control the inflammatory response driven tissue and organ damage by specifically blocking C5a as a key "amplifier" of this response in pre-clinical studies. Vilobelimab is believed to be the first monoclonal anti-C5a antibody introduced into clinical development. Over 300 people have been treated with vilobelimab in completed clinical trials, and the antibody has been shown to be well tolerated. Vilobelimab is currently being developed for various indications, including hidradenitis suppurativa, ANCA-associated vasculitis and pyoderma gangraenosum, as well as other areas, including critical COVID-19 and cutaneous squamous cell carcinoma (cSCC).

About InflaRx N.V.:
InflaRx (Nasdaq: IFRX) is a clinical-stage biopharmaceutical company focused on applying its proprietary anti-C5a technology to discover and develop first-in-class, potent and specific inhibitors of C5a. Complement C5a is a powerful inflammatory mediator 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 preclinical development and clinical trials, including when we expect to report topline data from our clinical trial of vilobelimab in COVID-19, as well as the safety and efficacy results of the trial; the impact of the COVID-19 pandemic on the Company; 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 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.