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 August 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 June 28, 2023, InflaRx N.V. issued a press release titled “InflaRx’s Marketing Authorization Application (MAA) for Vilobelimab for Treatment of Critically Ill COVID-19 Patients under review by European Medicines Agency (EMA).” 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 August 30, 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: August 30, 2023

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

Exhibit 99.1

InflaRx's Marketing Authorization Application (MAA) for Vilobelimab for Treatment of Critically Ill COVID-19 Patients under Review by European Medicines Agency (EMA)

- MAA for vilobelimab was submitted in July
- MAA has been validated by EMA and is now under review
- Regulatory submission based on pivotal data from PANAMO Phase III trial
- Company announces attendance at upcoming scientific and investor events

Jena, Germany, August 30, 2023 – InflaRx N.V. (Nasdaq: IFRX), a biotechnology company pioneering anti-inflammatory therapeutics targeting the complement system, announced today that the Company has submitted a Marketing Authorization Application (MAA) for the treatment of adult patients with SARS-CoV-2 induced septic acute respiratory distress syndrome (ARDS) receiving invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO) and that the European Medicines Agency (EMA) has validated the MAA. This means that the application is now under regulatory review by the European Committee for Medicinal Products for Human Use (CHMP) under the centralized procedure, which applies to all 27 member states of the European Union (EU).

InflaRx submitted the MAA to EMA in July 2023 following interactions with the rapporteur and co-rapporteur teams of the CHMP. The MAA submission is based on the previously announced results of the multicenter Phase III PANAMO trial, one of the largest 1:1 randomized, double-blind placebo-controlled trials in invasively mechanically ventilated COVID-19 patients in intensive care units. The results showed 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. The data were published in The Lancet Respiratory Medicine.

"We are pleased that EMA has accepted our MAA submission and that it is now under review. By targeting the complement component C5a, vilobelimab blocks what is believed to be a key mediator of the tissue damaging inflammatory host response induced by severe SARS-CoV-2 infection. Based on the data from our Phase III trial, we believe that our treatment approach can make a meaningful difference for critically ill COVID-19 patients who are invasively mechanically ventilated," said Dr. Camilla Chong, Chief Medical Officer of InflaRx.

"We look forward to continuing to work closely with EMA throughout the MAA review process, which is another important step toward our goal of bringing a potential treatment option to certain critically ill COVID-19 patients in Europe after having recently received an Emergency Use Authorization (EUA) in the United States," added Derval O`Carroll, Senior Vice President and Global Head of Regulatory Affairs & Compliance at InflaRx.

Gohibic (vilobelimab) has received an EUA in the U.S. for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV or ECMO. The Company is continuing discussions with the Food and Drug Administration (FDA) related to the submission of a Biologics License Application (BLA) for a potential future full approval of Gohibic (vilobelimab) in the United States. For additional information related to the EUA, please visit www.Gohibic.com

Upcoming scientific and investor events

InflaRx's management will participate in the following conferences in the coming weeks:

World Antimicrobial Resistance Congress

September 7-8, 2023, Philadelphia, PA, USA

- Panel discussion, September 7, 11:20 am EDT with Prof. Niels C. Riedemann, CEO

H.C. Wainwright 25th Annual Global Investment Conference

September 11-13, 2023, New York, NY, USA

- Company presentation on September 11th

7th Annual Complement-Based Drug Development Summit

September 11-13, 2023, Boston, MA, USA

- Presentation "The Life-Saving Anti-Inflammatory Potential of Blocking the C5a / C5aR Signaling Pathway", by Prof. Riedemann, September 12th, 5:10 pm EDT
- Panel "What are the Future Applications of Complement Therapeutics; What Will the Landscape Look Like in 5 Years' Time?" September 13th, 4:30 pm EDT

BioPharm America 2023

September 11-13, 2023, Research Triangle Park, USA

- Scheduled corporate and investor meetings

Guggenheim Securities 5th Annual Inflammation & Immunology (I&I) Conference

November 6-7, 2023, New York, NY, USA

BIO-Europe®

November 6-8, 2023, Munich, Germany

- Company presentation and scheduled corporate and investor meetings

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 current third international consensus definitions for sepsis, 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 strong complement activation and C5a generation as part of the human innate immune response. By targeting the complement component C5a in critically ill and invasively mechanically ventilated COVID-19 patients, vilobelimab is believed to block a key mediator of this inflammatory host response induced by severe SARS-CoV-2 infection and, thus, potentially offers a mechanism of action that may be independent of the viral variant that has caused such inflammatory response. Inhibition of the C5a / C5aR pathway has been demonstrated to be beneficial or lifesaving in various pre-clinical models of viral lung injury and viral sepsis, including models investigating influenza and corona viruses.

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. In addition to development in COVID-19, vilobelimab is also being developed for various debilitating or life-threatening inflammatory indications, including pyoderma gangrenosum and cutaneous squamous cell carcinoma.

The COVID-19 related work described herein is 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

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 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 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 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 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 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.