

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 of
the Securities Exchange Act of 1934

For the month of May 2024

Commission File Number: 001-38283

InflaRx N.V.

Winzerlaer Str. 2
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(Address of principal executive offices)

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 ☐

INCORPORATION BY REFERENCE

On May 21, 2024, InflaRx N.V. issued a press release titled, “InflaRx Presents New Analysis of PANAMO Phase III Trial in Severe COVID-19 at ATS 2024 Showing Potential Synergy With Vilobelimab When Used in Combination with Other Immunomodulators.” A copy of the press release is attached hereto as Exhibit 99.1, which shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

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EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated May 21, 2024

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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: May 21, 2024

By: /s/ Niels Riedemann

Name: Niels Riedemann

Title: Chief Executive Officer



InflaRx Presents New Analysis of PANAMO Phase III Trial in Severe COVID-19 at ATS 2024 Showing Potential Synergy With Vilobelimab When Used in Combination with Other Immunomodulators

Jena, Germany, May 21, 2024 – InflaRx N.V. (Nasdaq: IFRX), a biopharmaceutical company pioneering anti-inflammatory therapeutics by targeting the complement system, announced data presented at the American Thoracic Society (ATS) 2024 International Conference that is being held from May 17-22, 2024 in San Diego.

InflaRx is presenting a poster at the thematic poster session at the ATS conference today from 11:30 AM PT / 2:30 PM ET to 1:15 PM PT / 4:15 PM ET. The poster is titled, “Vilobelimab in Combination with Tocilizumab or Baricitinib Dramatically Improves Mortality in Critically Ill COVID-19 Patients” and is being presented during the “ARDS and Acute Respiratory Failure: Mechanism, Risk, and Outcomes” thematic poster session.

The data being presented is derived from a post-hoc subgroup analysis of the PANAMO Phase III global study, one of the largest 1:1 randomized, double-blind placebo-controlled trials in invasively mechanically ventilated (IMV) COVID-19 patients in intensive care units in adult critically ill COVID-19 patients. Tocilizumab, an anti-IL6R antibody, and baricitinib, a JAK inhibitor, are immunomodulators used in some patients as part of the standard of care treatment in this trial. PANAMO included a total of 369 patients and was used to support the emergency use authorization (EUA) granted by the U.S. Food and Drug Administration (FDA) in April 2023 for GOHIBIC (vilobelimab) for the treatment of critically ill COVID-19 patients.

The analysis presented at ATS 2024 is comprised of 71 patients from PANAMO that assessed 28- and 60-day all-cause mortality in the subgroup of patients taking the combination of vilobelimab plus tocilizumab or baricitinib versus patients on placebo plus tocilizumab or baricitinib. All patients received standard of care. Safety was also assessed.

The point estimate for 28-day all-cause mortality was 6.3% in the vilobelimab plus tocilizumab or baricitinib arm, and 40.9% in the placebo plus tocilizumab or baricitinib arm: this is a significant relative reduction of 84.6% (HR 0.13; 95% CI:0.03-0.56, p=0.006) between the two arms. Day 60 all-cause mortality was 16.4% and 49.3%, respectively (HR 0.25; 95% CI:0.09-0.68, p=0.006), a significant relative reduction.

The co-administration of vilobelimab with baricitinib or tocilizumab was not associated with safety concerns. In addition, demographics of these subgroups were generally well-balanced and comparable to the overall study population.

Camilla Chong, MD, Chief Medical Officer of InflaRx, commented: “I am thrilled that we can share this additional data from the PANAMO study, which will provide further scientific insights into the utility of vilobelimab when used with tocilizumab and baricitinib in critically ill hospitalized COVID-19 patients. We believe this analysis further supports the life-saving potential of vilobelimab in the acute care setting and indicates our continued commitment to these patients.”

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.

Important Information about GOHIBIC (vilobelimab)

Vilobelimab has been granted an EUA for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV or extracorporeal membrane oxygenation.



The emergency use of GOHIBIC (vilobelimab) is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization revoked sooner.

Vilobelimab is an investigational drug that has not been approved by the FDA for any indication including for the treatment of COVID-19. There is limited information known about the safety and effectiveness of using GOHIBIC (vilobelimab) to treat people in the hospital with COVID-19. Please see additional information in the Fact Sheet for Healthcare Providers, Fact Sheet for Patients and Parents/Caregivers and FDA Letter of Authorization on the GOHIBIC (vilobelimab) website (www.GOHIBIC.com).

Important Safety Information about GOHIBIC (vilobelimab)

There is limited clinical data available for GOHIBIC (vilobelimab). Serious and unexpected adverse events (AEs) may occur that have not been previously reported with GOHIBIC (vilobelimab) use.

GOHIBIC (vilobelimab) has been associated with an increase of serious infections. In patients with COVID-19, monitor for signs and symptoms of new infections during and after treatment with GOHIBIC (vilobelimab). Hypersensitivity reactions have been observed with GOHIBIC (vilobelimab). If a severe hypersensitivity reaction occurs, administration of GOHIBIC (vilobelimab) should be discontinued and appropriate therapy initiated.

The most common adverse reactions (incidence $\geq 3\%$) are pneumonia, sepsis, delirium, pulmonary embolism, hypertension, pneumothorax, deep vein thrombosis, herpes simplex, enterococcal infection, bronchopulmonary aspergillosis, hepatic enzyme increased, urinary tract infection, hypoxia, thrombocytopenia, pneumomediastinum, respiratory tract infection, supraventricular tachycardia, constipation, and rash.

Healthcare providers and/or their designee are responsible for mandatory FDA MedWatch reporting of all medication errors and serious AEs or deaths occurring during GOHIBIC (vilobelimab) treatment and considered to be potentially attributable to GOHIBIC (vilobelimab).

Report side effects to the FDA at 1-800-FDA-1088 or www.FDA.gov/medwatch. In addition, side effects can be reported to InflaRx at: pvusa@inflarx.de

For the full prescribing information and additional important safety information, please visit www.GOHIBIC.com

About InflaRx N.V.:

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

InflaRx (Nasdaq: IFRX) is a biopharmaceutical 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 is also developing INF904, an orally administered small molecule inhibitor of C5a-induced signaling via the C5a receptor. 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.de.

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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 U.S. or elsewhere; our ability to successfully implement The InflaRx Commitment Program, 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, including INF904, 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 Marketing Authorization Application 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 European Medicines Agency 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 oversight; 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.