

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, 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 September 8, 2021, InflaRx N.V. (the “Company”) issued a press release titled “InflaRx to Proceed with Pivotal Development for Vilobelimab in Hidradenitis Suppurativa with New Primary Endpoint.” A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The Company has seen the press release issued by German Federal Research Minister Anja Karliczek and Federal Health Minister Jens Spahn regarding their support for a program pursuant to which the Company applied for funding for the development of vilobelimab for the treatment of COVID-19. The Company has not received any official notice from the German government in response to its application.

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, 2021

By: /s/ Niels Riedemann

Name: Niels Riedemann

Title: Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated September 8, 2021

InflaRx to Proceed with Pivotal Development for Vilobelimab in Hidradenitis Suppurativa with New Primary Endpoint

- InflaRx received feedback from FDA within its Type A meeting which is supportive of a new primary endpoint measuring reductions in all three inflammatory HS lesions – including reductions of draining tunnels (previously referred to as draining fistulas)
- InflaRx will focus its pivotal development program on patients suffering from moderate to severe HS with active draining disease, as supported by the FDA
- InflaRx will incorporate FDA feedback in the study protocol for its pivotal program and submit the protocol in Q4 2021 with study activities to begin upon approval by FDA

Jena, Germany, September 8, 2021 – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, announces its plan to proceed with a pivotal development program for vilobelimab in Hidradenitis Suppurativa (HS) after a successful Type A meeting with the US Food and Drug Administration (FDA) and receipt of the official meeting minutes.

InflaRx had submitted the Type A meeting request to the FDA in July to align on the Phase III HS study design. The meeting discussion focused on reaching consensus on the overall study population and the primary endpoint measure. The FDA agreed that pain and draining from HS lesions, including draining tunnels (also previously referred to as draining fistulas) may interfere with a patient’s daily life. They also agreed that controlling these disease manifestations would represent a clinically meaningful outcome to patients. The FDA response was supportive of a pivotal study program that focuses on patients with active draining tunnels and a new primary efficacy endpoint that will include measuring the reduction of all three lesions - inflammatory nodules, abscesses and draining tunnels.

“Introducing the reduction of draining tunnels, being the most chronic burdensome lesion type in HS, in a new primary efficacy endpoint and the recognition of the importance of capturing the reduction of these lesions by regulatory agencies, marks an important milestone for drug development in the HS field,” commented Christopher Sayed, MD, Associate Professor of Dermatology, University of North Carolina School of Medicine, Chapel Hill, NC, USA. “With only one drug approved, there is a large medical need for new drugs with new mechanisms for patients, especially for the treatment of draining tunnels. I therefore look forward to the future development of vilobelimab as a potential new treatment option for patients suffering from HS and from actively draining tunnels, which is scientifically supported by its mode of action and the data generated in recent trials,” he added.

“Our team is very happy and proud that we were able to work out a path forward for the further development of vilobelimab in Hidradenitis Suppurativa, upon detailed and productive discussions with the FDA,” said Prof. Niels C. Riedemann, Chief Executive Officer and Founder of InflaRx. “We are grateful to the Agency for the constructive interaction, and we are now adapting our pivotal trial protocol according to their suggestions. We look forward to submitting the protocol in Q4 2021 and starting our study activities upon approval by the FDA.”

InflaRx is still in active dialogue with the FDA on the final details of the pivotal study design. The company also plans to include various secondary and exploratory endpoints to validate the new primary efficacy measure which thus far has not been used in prospective randomized trials. Once the protocol is approved by the Agency, the Company will provide more details about the study, including the primary endpoint.

About Hidradenitis Suppurativa (HS):

HS is a chronic debilitating systemic skin disease which results in painful inflammation of the hair follicles, typically in the armpit, groin and genitalia regions. HS patients suffer from pain driven by inflamed nodules, abscess and draining tunnel formation and significant discomfort resulting from the constant formation of pus, particularly in the areas described above, leading to social isolation. HS is typically present after adolescence and often develops into a life-long debilitating chronic disease. In the United States, up to 200,000 patients are affected annually with moderate to severe disease (Hurley stages II to III), with a current increase in recognition and diagnoses being expected and discussed amongst key opinion leaders. In Europe, the number of affected patients is considered to be higher, with a trend of more cases of HS in countries with overall warmer climates. The standard of care for HS patients includes antibiotic treatment, which often only provides temporary symptomatic relief. In some cases, patients also undergo surgery. The only approved biological drug in this indication for moderate to severe HS patients is an anti-TNF-alpha monoclonal antibody.

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 severe 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 pre-clinical development and clinical trials, including the ultimate design and timing of our planned trial of vilobelimab in HS, as well as future interactions with the FDA related thereto; 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.
