

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 March 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):

INFLARX N.V.

On March 24, 2022, InflaRx N.V. issued a press release. 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: March 24, 2022

By: /s/ Niels Riedemann

Name: Niels Riedemann

Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit	Description
No.	
99.1	Press Release, dated March 24, 2022



InflaRx Reports Full Year 2021 Financial and Operating Results

- Company received corrected FDA advice letter for Phase III trial with vilobelimab in hidradenitis suppurativa
- Positive Phase IIa data reported with vilobelimab in pyoderma gangrenosum; data being presented as late-breaker oral presentation at AAD Annual Meeting
- Topline data in vilobelimab Phase III trial in severe COVID-19 expected by end of March
- Both US and EU Phase II trials with vilobelimab in AAV met their objectives
- Phase II trial with vilobelimab in cSCC enrolling with first efficacy data expected later this year
- New program, INF904 oral small molecule inhibitor of C5aR, recently introduced
- Year-end cash and cash equivalents of approximately €26.2 million and financial assets of approximately €84.4 million

Jena, Germany, March 24, 2022 – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing anti-inflammatory therapeutics by targeting the complement system, announced today financial and operating results for the year ended December 31, 2021.

Prof. Niels C. Riedemann, Chief Executive Officer and Founder of InflaRx, commented: “We have made important progress in broadening and advancing our development activities over the course of 2021 and into 2022. This includes introducing a new program, the oral small molecule C5aR inhibitor, INF904, and moving vilobelimab into a new indication, cutaneous small cell carcinoma. In addition, we reported promising results with vilobelimab in pyoderma gangrenosum and ANCA-associated vasculitis, and we now await the Phase III topline results in our COVID-19 trial. We are hopeful for a positive outcome but, either way, we believe the results will help to further the overall understanding of this devastating disease.”

He continued, “We are thankful for the corrected advice letter from the FDA related to vilobelimab development in hidradenitis suppurativa and will clarify our path forward in this debilitating disease in the coming months. We expect a busy year ahead as we work towards our goal of developing treatments to control inflammation and improve the lives of patients suffering from neutrophil-driven diseases.”



Recent Highlights and R&D Update

Vilobelimab for Hidradenitis Suppurativa (HS)

In February 2022, the Company received an advice letter from the FDA related to its Phase III program and its IND. The feedback to the clinical protocol indicated that the FDA recommends using the Hidradenitis Suppurativa Clinical Response Score (“HiSCR”) as the primary endpoint in the Phase III trial. This FDA advice contrasted with the FDA advice provided to the Company in a Type A meeting held in the third quarter of 2021.

In the minutes from that Type A meeting, FDA provided advice on how to implement, name and validate the meaningfulness of the modified HiSCR, a new primary endpoint suggested by the Company, which would measure the reduction of all three types of inflammatory lesions in HS—inflammatory nodules, abscesses and draining tunnels. A reduction in draining tunnels is not captured by the HiSCR. In these minutes, the FDA did not recommend the traditional HiSCR as the primary endpoint measure. Based on the advice received in the Type A meeting, InflaRx announced in January 2022, the initiation of a Phase III program designed to study patients with moderate to severe HS suffering from actively draining tunnels. Because of the letter, InflaRx paused activities related to the Phase III trial.

In March 2022, the Company received a corrected advice letter from the FDA. The corrected letter states that the FDA advice received by the Company in February 2022 “contains errors.” In this corrected letter, the FDA no longer recommends that the Company use the HiSCR as the primary endpoint for the chosen patient population but gives recommendations related to implementation of the modified HiSCR.

In light of this corrected advice from FDA, InflaRx believes that further development in HS is feasible. InflaRx is now evaluating next steps for the program, as the Phase III trial activities remain on hold while InflaRx evaluates next steps for the program.

Vilobelimab in Pyoderma Gangrenosum (PG)

InflaRx previously initiated an open label, multi-center Phase IIa exploratory study enrolling patients with moderate to severe PG in Canada, the United States and Poland. The study evaluated the safety and efficacy of vilobelimab in patients with PG.



In October 2021, InflaRx announced preliminary results from the third dosing cohort. At 2400mg biweekly, six of the seven patients achieved clinical remission with a PGA score of ≤ 1 , which reflects a closure of the target ulcer. All patients in the third dosing cohort had elevated C5a levels at baseline that were continuously suppressed after initiation of vilobelimab.

In August 2021, InflaRx also reported data for ten evaluable patients in the first two dose cohorts at day 99. The patient in the second dosing cohort demonstrating complete target ulcer closure had been increased from the 1600mg dose group to the highest dose of 2400mg dose on day 57 of the study, and the ulcer closed after the dose escalation.

Final data will be presented as a late-breaker oral presentation on March 26th at the American Academy of Dermatology Association (AAD) Annual Meeting.

InflaRx plans to meet with the FDA this year to discuss the design for a pivotal study.

Vilobelimab for Severe COVID-19

In October 2021, InflaRx announced full enrollment in the Phase III part of the global Phase II/III trial evaluating vilobelimab in mechanically ventilated patients with COVID-19. A total of 369 patients across several countries, including in Europe, South America and other regions, were enrolled. Topline data for the 28-day mortality primary endpoint is expected to be available by the end of March 2022. The results from this Phase III trial will heavily influence our decision with respect to any future development of vilobelimab in COVID-19 and the larger strategic focus of the Company.

In October 2021, InflaRx announced that it had received a grant of up to €43.7 million from the German Ministry of Education and Research and the German Ministry of Health to support the Company's development of vilobelimab for the treatment of severe COVID-19 patients. The initial tranche amounts to €25.8 million (approximately \$29.9 million) and is structured as reimbursement of 80% of certain pre-specified expenses related to the clinical development and manufacturing of vilobelimab. The remainder of the grant will be awarded in three additional subsequent tranches, each conditional on reaching agreed-upon development and manufacturing-related milestones for the preceding tranche and structured as reimbursement for Company expenses. Individual tranches will not be paid if the preceding milestone of a tranche is not met. As of December 31, 2021, InflaRx had received €8.3 million of this grant funding.



Vilobelimab for ANCA-associated Vasculitis (AAV)

In May 2021, InflaRx reported topline data from the U.S. IXPLORE Phase II study of vilobelimab in AAV. The results indicated that vilobelimab, when added to the current standard of care, was well tolerated.

In November 2021, InflaRx reported topline data from the European Phase II IXCHANGE study of vilobelimab in AAV. The study achieved its principal objective, demonstrating comparable clinical response of vilobelimab to standard of care, while significantly reducing the need for glucocorticoid treatment in this life-threatening indication.

The Company plans to discuss the data from the U.S. and EU studies with regulatory authorities to determine next steps with this program.

Vilobelimab for Cutaneous Squamous Cell Carcinoma (cSCC)

InflaRx is developing vilobelimab for the treatment of PD-1/PD-L1 inhibitor resistant/refractory locally advanced or metastatic cSCC. InflaRx previously initiated an open label, non-comparative, two-stage, Phase II trial (NCT04812535) at sites in Europe, the United States and elsewhere. The study is investigating two independent arms: vilobelimab alone (Arm A) and vilobelimab in combination with pembrolizumab (Arm B). The trial is expected to enroll a total of approximately 70 patients.

In February 2022, the Company announced the start of the second dosing cohort of Arm B. The interim analysis in this arm, which is required to move to the second stage of the Phase II trial, is expected after ten patients have been treated and are evaluable for response assessment at the recommended Phase II dose level, which will be selected based on data from the safety run-in phase of the study. These data are expected to be available in the first quarter of 2023.

In parallel, enrollment continues in the monotherapy Arm A. Six patients are now enrolled in this arm. The interim analysis in Arm A required to proceed to the second stage is expected to be available after ten patients are evaluable for response assessment. These data are expected to be available in the third quarter of 2022.



INF904

InflaRx announced in January 2022 a new pipeline program, INF904, an oral small molecule inhibitor of C5aR. InflaRx has been granted a composition of matter patent for INF904 and associated compounds by the U.S. Patent and Trademark Office and has completed IND-enabling (preclinical) studies that demonstrated no obvious toxicological findings even in the highest dose groups in required GLP toxicity analyses.

InflaRx expects to initiate a Phase I program in the second half of 2022 and plans to study INF904 in complement-mediated, chronic autoimmune and inflammatory diseases where oral administration is the preferred choice for patients.

2021 Financial Highlights

Research and Development Expenses

InflaRx's research and development expenses increased by €10.0 million in the year ended December 31, 2021 compared to the year ended December 31, 2020.

This increase is attributable to higher contract research organization (CRO) and contract manufacturing organization (CMO) costs from clinical trials in the amount of €8.4 million. This increase was primarily due to higher expense for the Phase III part of our COVID-19 trial and other running trials like Phase II clinical program in patients with AAV, the Phase II clinical program in patients with PG, the preparation of a Phase II clinical program in patients cSCC and ongoing manufacturing activities for clinical trial related materials.

In addition, a €1.5 million increase in employee-related costs was mainly caused by a €1.0 million increase in expenses from share-based compensation.

General and Administrative Expenses

InflaRx's general and administrative expenses increased by €3.5 million to €12.0 million for the year ended December 31, 2021, from €8.5 million for the year ended December 31, 2020. This increase is primarily attributable to a €2.2 million increase in expenses from share-based compensation. Legal, consulting and audit fees and other expenses increased by €0.5 million to €2.1 million for the year ended December 31, 2021, mainly due to higher consulting and legal costs, mainly triggered by SOX implementation. The increase of other expenses by €0.4 million is primarily related to higher D&O insurance cost.



Net Financial Result

InflaRx's net financial result increased by €2.0 million in the year ended December 31, 2021 compared to the year ended December 31, 2020. This net increase is mainly attributable to higher foreign exchange income, which increased by €1.9 million and lower foreign exchange expense, which decreased by €0.8 million. This effect was offset by lower interest income on marketable securities, which decreased by €0.8 million.

Net Loss

InflaRx incurred a net loss of €45.6 million, or €1.10 per common share, in the year ended December 31, 2021 compared to €34.0 million, or €1.3 per common share, in the year ended December 31, 2020. As of December 31, 2021, the Company's total funds available were approximately €110.6 million, composed of €26.2 million of cash and cash equivalents and €84.4 million of financial assets.

Net Cash Used in Operating Activities

InflaRx's net cash used in operating activities increased to €39.9 million in the year ended December 31, 2021, from €36.5 million in the year ended December 31, 2020, mainly due to the increase of research and development expenditures and higher personnel costs.

Additional information regarding these results and other relevant information is included in the notes to the financial statements as of December 31, 2021 in "Item 18. Financial Statements," which are included in InflaRx's most recent annual report on Form 20-F as filed with the U.S. Securities and Exchange Commission.



InflaRx N.V. and subsidiaries

Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2021, 2020 and 2019

in €, except for share information

	<u>2021</u>	<u>2020</u>	<u>2019</u>
Operating Expenses			
Research and development expenses	(35,697,935)	(25,684,140)	(44,582,136)
General and administrative expenses	(11,984,722)	(8,467,203)	(12,501,048)
Total Operating Expenses	<u>(47,682,657)</u>	<u>(34,151,343)</u>	<u>(57,083,184)</u>
Other income	54,221	221,748	400,253
Other expenses	(6,381)	(13,209)	(85,242)
Operating Result	<u>(47,634,816)</u>	<u>(33,942,804)</u>	<u>(56,768,173)</u>
Finance income	109,391	887,702	2,840,676
Finance expenses	(24,769)	(26,000)	(22,265)
Foreign exchange result	1,964,135	(776,512)	694,944
Other financial result	(44,000)	(126,000)	—
Income Taxes	—	—	—
Loss for the Period	<u>(45,630,059)</u>	<u>(33,983,614)</u>	<u>(53,254,817)</u>
Share Information			
Weighted average number of shares outstanding	41,629,974	27,064,902	26,004,519
Loss per share (basic/diluted)	(1.10)	(1.26)	(2.05)
Loss for the Period	<u>(45,630,059)</u>	<u>(33,983,614)</u>	<u>(53,254,817)</u>
Other comprehensive income (loss) that may be re-clas-si-fied to profit or loss in subsequent periods:			
Exchange differences on translation of foreign currency	6,777,061	(5,954,019)	2,177,033
Total Comprehensive Loss	<u>(38,852,998)</u>	<u>(39,937,633)</u>	<u>(51,077,785)</u>



InflaRx N.V. and subsidiaries
Consolidated Statements of Financial Position as December 31, 2021 and 2020

in €	2021	2020
ASSETS		
Non-current assets		
Property and equipment*	274,373	408,263
Right-of-use assets*	1,408,078	546,694
Intangible assets	235,216	350,183
Other assets	336,566	353,522
Financial assets	27,206,990	272,268
Total non-current assets	<u>29,461,224</u>	<u>1,930,930</u>
Current assets		
Current other assets*	10,983,458	3,734,700
Income tax receivable*	1,282,177	1,419,490
Financial assets	57,162,266	55,162,033
Cash and cash equivalents	26,249,995	25,968,681
Total current assets	<u>95,677,896</u>	<u>86,284,904</u>
TOTAL ASSETS	<u><u>125,139,120</u></u>	<u><u>88,215,834</u></u>
EQUITY AND LIABILITIES		
Equity		
Issued capital	5,304,452	3,387,410
Share premium	280,310,744	220,289,876
Other capital reserves	30,591,209	26,259,004
Accumulated deficit	(213,975,679)	(168,345,620)
Other components of equity	3,050,270	(3,726,791)
Total equity	<u>105,280,996</u>	<u>77,863,880</u>
Non-current liabilities		
Lease liabilities	1,066,354	220,525
Other liabilities	35,019	33,323
Total non-current liabilities	<u>1,101,373</u>	<u>253,847</u>
Current liabilities		
Trade and other payables	8,574,244	8,258,133
Liabilities from government grants received	8,300,000	—
Lease liabilities	366,171	338,516
Employee benefits	1,378,130	1,368,731
Other liabilities	138,206	117,727
Provisions	—	15,000
Total current liabilities	<u>18,756,751</u>	<u>10,098,107</u>
Total Liabilities	<u>19,858,124</u>	<u>10,351,954</u>
TOTAL EQUITY AND LIABILITIES	<u><u>125,139,120</u></u>	<u><u>88,215,834</u></u>



InflaRx N.V. and subsidiaries

Consolidated Statements of Changes in Shareholders' Equity for the Years Ended December 31, 2021, 2020 and 2019

in €	Issued capital	Share premium	Other capital reserves	Accumulated deficit	Other components of equity	Total equity
Balance as of January 1, 2019	3,115,725	211,021,835	18,310,003	(81,107,188)	50,196	151,390,571
Loss for the Period	—	—	—	(53,254,817)	—	(53,254,817)
Exchange differences on translation of foreign currency	—	—	—	—	2,177,033	2,177,033
Total Comprehensive Loss	—	—	—	(53,254,817)	2,177,033	(51,077,784)
Equity-settled share-based payments	—	—	6,832,210	—	—	6,832,210
Share options exercised	16,905	(15,229)	—	—	—	1,676
Balance as of December 31, 2019	3,132,631	211,006,606	25,142,213	(134,362,006)	2,227,228	107,146,673
Loss for the Period	—	—	—	(33,983,614)	—	(33,983,614)
Exchange differences on translation of foreign currency	—	—	—	—	(5,954,019)	(5,954,019)
Total Comprehensive Loss	—	—	—	(33,983,614)	(5,954,019)	(39,937,633)
Issuance of common shares	234,982	9,535,961	—	—	—	9,770,943
Transaction costs	—	(729,840)	—	—	—	(729,840)
Equity-settled share-based payments	—	—	1,116,791	—	—	1,116,791
Share options exercised	19,797	477,149	—	—	—	496,946
Balance as of December 31, 2020	3,387,410	220,289,876	26,259,004	(168,345,620)	(3,726,791)	77,863,880
Loss for the Period	—	—	—	(45,630,059)	—	(45,630,059)
Exchange differences on translation of foreign currency	—	—	—	—	6,777,061	6,777,061
Total Comprehensive Loss	—	—	—	(45,630,059)	6,777,061	(38,852,998)
Issuance of common shares	1,873,203	63,269,346	—	—	—	65,142,549
Transaction costs	—	(4,219,222)	—	—	—	(4,219,222)
Equity-settled share-based payments	—	—	4,332,205	—	—	4,332,205
Share options exercised	43,839	970,744	—	—	—	1,014,583
Balance as of December 31, 2021	5,304,452	280,310,744	30,591,209	(213,975,679)	3,050,270	105,280,996



InflaRx N.V. and subsidiaries

Consolidated Statements of Cash Flows for the Years ended December 31, 2021, 2020 and 2019

in €	2021	2020	2019
Operating activities			
Loss for the Period	(45,630,059)	(33,983,614)	(53,254,817)
Adjustments for:			
Depreciation & amortization of property and equipment, right-of-use assets and intangible assets	669,434	712,713	663,166
Net finance income	(2,004,757)	40,810	(3,513,355)
Share-based payment expense	4,332,205	1,116,791	6,832,210
Net foreign exchange differences	111,606	(247,322)	(368,477)
Other non-cash adjustments	—	3,436	60,628
Changes in:			
Other assets	(7,094,467)	(1,554,611)	(2,364,399)
Employee benefits	(3,290)	355,545	235,500
Other liabilities	19,863	8,960	(209,948)
Liabilities from government grants received	8,300,000	—	—
Trade and other payables	316,112	(4,155,529)	5,734,795
Interest received	1,070,235	1,201,547	3,001,109
Interest paid	(23,633)	(26,387)	(20,903)
Net cash used in operating activities	<u>(39,936,750)</u>	<u>(36,527,661)</u>	<u>(43,204,492)</u>
Investing activities			
Purchase of intangible assets and property and equipment	(37,778)	(94,189)	(594,889)
Purchase of non-current other financial assets	—	—	(75,543)
Purchase of current and non current financial assets	(97,516,417)	(101,600,176)	(82,547,409)
Proceeds from the maturity of current financial assets	71,603,310	123,056,347	103,559,395
Net cash from/ (used in) investing activities	<u>(25,950,885)</u>	<u>21,361,982</u>	<u>20,341,554</u>
Financing activities			
Proceeds from issuance of common shares	65,142,549	9,770,944	—
Transaction costs from issuance of common shares	(4,219,222)	(729,841)	—
Proceeds from exercise of share options	1,014,583	496,946	1,676
Repayment of lease liabilities	(360,644)	(366,156)	(296,020)
Net cash from/ (used in) financing activities	<u>61,577,266</u>	<u>9,171,893</u>	<u>(294,344)</u>
Net increase/(decrease) in cash and cash equivalents	(4,310,369)	(5,993,786)	(23,157,282)
Effect of exchange rate changes on cash and cash equivalents	4,591,683	(1,168,813)	902,321
Cash and cash equivalents at beginning of period	<u>25,968,681</u>	<u>33,131,280</u>	<u>55,386,240</u>
Cash and cash equivalents at end of period	<u>26,249,995</u>	<u>25,968,681</u>	<u>33,131,280</u>



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 clinical trials, and the antibody has been shown to be well tolerated. Vilobelimab is being developed for various indications, including hidradenitis suppurativa, ANCA-associated vasculitis and pyoderma gangrenosum, as well as 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.de.

Contacts:

InflaRx N.V.

Jordan Zwick – Chief Strategy Officer

Email: IR@inflarx.de

Tel: +1 917-338-6523

MC Services AG

Katja Arnold, Laurie Doyle, Andreas Jungfer

Email: inflarx@mc-services.eu

Europe: +49 89-210 2280

US: +1-339-832-0752



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, in particular our Phase III trial in HS and related communications with the FDA, in particular addressing the FDA’s advice in various communications to us regarding the primary endpoint for the Phase III 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 most recent annual report on Form 20-F filed 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.
