InflaRx Reports Third Quarter 2024 Financial Results and Provides Business Update

- *Achieved 30-patient recruitment milestone in Phase 3 vilobelimab trial in pyoderma gangrenosum (PG) to enable interim analysis, with guidance for trial size adaptation or futility expected by the end of 2Q 2025*
- *InflaRx pipeline highlighted at multiple medical congresses, including vilobelimab in COVID-19 and hidradenitis suppurativa (HS) and INF904*
- *Phase 2a trial for INF904 expected to initiate by year-end 2024, with first data readout expected in summer 2025*
- *European Committee for Medicinal Products for Human Use (CHMP) review of vilobelimab continues, with discussions ongoing and a CHMP opinion anticipated around mid-November*
- *Cash, cash equivalents and marketable securities of €62.0 million, expected to fund operations into 2026*

Jena, Germany, November 8, 2024 – InflaRx N.V. (Nasdaq: IFRX), a biopharmaceutical company pioneering anti-inflammatory therapeutics targeting the complement system, today announced financial results for the three and nine months ended September 30, 2024, and provided an operating update.

Prof. Niels C. Riedemann, Chief Executive Officer and Founder of InflaRx, commented: *"The start of the second half of 2024 has been a time of considerable momentum for the Company, and our leadership position in complement inhibition continues to strengthen. As we consider the remainder of the year, we remain well positioned to start our Phase 2a trial in two immuno-dermatology indications with INF904. We are excited about upcoming expected milestones looking into 2025, including the interim analysis of the vilobelimab Phase 3 trial in pyoderma gangrenosum and the first Phase 2a data readout from INF904."*

Guggenheim Securities Inaugural Healthcare Innovation Conference on November 11 - 13, 2024

InflaRx will participate in the Guggenheim Securities Inaugural Healthcare Innovation Conference on November 11, 2024, at 11:00 AM ET / 5:00 PM CET. A link to register for the fireside chat live stream and its replay is available here.

RECENT HIGHLIGHTS AND BUSINESS UPDATE

Oral C5aR inhibitor INF904

In March 2024, InflaRx announced it will pursue two initial immuno-dermatology indications with INF904 in a single Phase 2a basket trial that is expected to begin by the end of 2024, with initial data anticipated in summer 2025. The trial will be a multi-center, open-label study involving 75 patients and evaluating multiple INF904 dosing regimens over 4 weeks of treatment in patients with moderate-to-severe chronic spontaneous urticaria (CSU) and moderate-to-severe HS, both highly debilitating skin conditions. The objective of this Phase 2a trial is to generate additional safety and pharmacokinetic (PK) data and provide signs of clinical benefit, and to inform the design of a Phase 2b trial that InflaRx has a goal to initiate in late 2025.

InflaRx believes CSU and HS both have potential addressable markets of $1 billion or more for INF904. The Company also believes INF904 could address meaningful opportunities in additional immuno-dermatology and immuno-inflammatory indications, including in nephrology, neurology and hematology. While InflaRx intends to focus its resources on its immediate goals addressing CSU and HS, the Company continues to assess and monitor the value of pursuing additional areas and applications via potential future collaborations with partners.

New preclinical findings for INF904 presented at the 19th European Meeting on Complement in Human Diseases (EMCHD)

InflaRx presented two posters on INF904 at the EMCHD. InflaRx believes the collective data presented provided strong evidence of INF904's significant anti-inflammatory and strong PK properties, further supporting the Company's belief that INF904 may have differentiating advantages and best-in-class potential as a member of the C5aR inhibitor drug class.

Vilobelimab in PG – Pivotal Phase 3 trial interim analysis expected by the end of 2Q 2025

Given recent progress in enrollment, InflaRx expects the results of the interim analysis for its ongoing Phase 3 trial of vilobelimab in PG in the second quarter of 2025. The study dosed its first patient in November 2023 and has an adaptive design with an interim analysis blinded for the sponsor and investigators (but unblinded for the independent data safety monitoring committee), which is planned when approximately 30 patients randomized 1:1 to the two arms have completed treatment. The interim analysis with a set of predefined rules will take into account the then-observed difference in complete target ulcer closure between the two arms and will then determine whether the trial sample size will be adapted or whether the trial should

be stopped due to futility. The enrollment period is projected to last at least two years, and its overall period will depend on the total trial size after sample size adaptation.

The Phase 3 trial is a multi-national, randomized, double-blind, placebo-controlled pivotal study assessing the benefit of vilobelimab for treating ulcerative PG, a rare, chronic inflammatory form of neutrophilic dermatosis characterized by accumulation of neutrophils in the affected skin areas. The trial has two arms: (1) vilobelimab plus a low dose of corticosteroids tapered over an 8-week period and (2) placebo plus the same dose of corticosteroids. The primary endpoint of the study is complete closure of the target ulcer at any time up to 26 weeks after initiation of treatment.

Vilobelimab has been granted orphan drug designation for the treatment of PG by both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), as well as fast track designation by the FDA.

Vilobelimab Marketing Authorization Application (MAA) in the European Union (EU)

In July 2023, InflaRx submitted an MAA for SARS-CoV-2 induced septic acute respiratory distress syndrome (ARDS) receiving invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO) to EMA. In October 2024, the Committee for Medicinal Products for Human Use (CHMP) convened to review the MAA; the regulatory process continues with discussions ongoing between the Company and the CHMP, with a CHMP opinion anticipated around the middle of November.

Should vilobelimab be approved in the EU, InflaRx is weighing options for its commercialization, with an expectation that efforts associated with any potential commercialization will not have a meaningfully negative impact on the Company's cash burn.

GOHIBIC (vilobelimab) medical education program

During the second half of 2024, InflaRx continued its medical education efforts for GOHIBIC (vilobelimab) in COVID-19, with data presentations at multiple congresses in the U.S. and Asia. This included the 20th Annual Congress of International Drug Discovery Science & Technology, CHEST 2024, AMCP Nexus 2024, and ID Week. In addition, InflaRx presented a post hoc analysis of the SHINE trial of vilobelimab in HS at the 2024 European Academy of Dermatology and Venereology Congress.

Dr. Thomas Taapken, Chief Financial Officer of InflaRx, said: *"We continue to focus on efficiently utilizing our resources to advance our pipeline of complement inhibitors, with preparations to initiate a Phase 2a trial for INF904 and our continued progress with the ongoing late-stage trial of vilobelimab. InflaRx remains funded into 2026, and we look forward to reaching our next value inflection points."*

FINANCIAL HIGHLIGHTS

Revenue

For the nine months ended September 30, 2024, the Company realized revenues from product sales of GOHIBIC (vilobelimab) in the amount of €166 thousand. Revenues reported are sales to end customers (hospitals). All revenues are attributed to sales made in the United States.

Cost of sales

Cost of sales during the nine months ended September 30, 2024 primarily consisted of write-downs of short-lived inventories.

Sales and marketing expenses

Sales and marketing expenses incurred for the nine months ended September 30, 2024 increased by €3.2 million compared to the nine months ended September 30, 2023. This increase is primarily due to GOHIBIC (vilobelimab). Sales and marketing expenses were incurred for all of the nine months ended September 30, 2024

R&D expenses

R&D expenses incurred for the nine months ended September 30, 2024 decreased by €4.5 million compared to the nine months ended September 30, 2023. This decrease is primarily due to higher third-party expenses incurred during the nine months ended September 30, 2023 in connection with our efforts to develop the commercial manufacturing process and to obtain an EUA for GOHIBIC (vilobelimab). The decrease of third-party expenses is offset by an increase of personnel expenses by €1.3 million. This increase is attributed to higher stock-based compensation expenses.

General and administrative expenses

General and administrative expenses decreased by €0.4 million to €9.6 million for the nine months ended September 30, 2024, from €10.0 million for the nine months ended September 30, 2023.

Other income

Other income for the nine months ended September 30, 2024 amounted to €0.2 million (PY: €13.4 million). There was no income from government grants in 2024 due to the end of the grant period of the German government grant to support the development of vilobelimab or the treatment of critically ill COVID-19 patients on June 30, 2023.

Net financial result

Net financial result decreased by €2.6 million to €2.3 million for the nine months ended September 30, 2024, from €4.9 million for the nine months ended September 30, 2023. This decrease was mainly attributable to a lower foreign exchange result, which decreased by €2.2 million.

Net loss

Net loss for the first nine months of 2024 amounted to €41.0 million, compared to €26.7 million in the first nine months of 2023. This decrease was primarily due to a decrease in other income of € 13.2 million compared to the same period in the prior year, because there was no income from government grants in 2024 due to the end of the grant (i.e. German government grant for the development of vilobelimab for the treatment of critically ill COVID-19 patients) period on June 30, 2023.

Net cash used in operating activities

Net cash used in operating activities for the first nine months of 2024 increased to €36.7 million from €26.9 million for the comparable period in 2023. This increase is related to the decrease in other operating income from the government grant in 2024, as the grant period ended on June 30, 2023.

Liquidity and capital resources

As of September 30, 2024, InflaRx's total available funds amounted to €62.0 million, composed of €26.2 million in cash and cash equivalents and €35.8 million in marketable securities.

From the €26.2 million cash and cash equivalents, €4.2 million are held in EURO and €24.6 million are held in USD, this is equivalent to €22.0 million at an exchange rate of 1.1196 on 30 September 2024. All marketable securities are held in USD and have a nominal value of $40.5 million. These funds are expected to finance operations into 2026.

Additional financial information

Additional information regarding these results and other relevant information is included in the notes to the unaudited interim condensed consolidated financial statements as of September 30, 2024, as well as the consolidated financial statements as of and for the year ended December 31, 2023, in “ITEM 18. Financial Statements,” in InflaRx’s annual report on Form 20-F for the year ended December 31, 2023, as filed with the U.S. Securities and Exchange Commission (SEC) on March 21, 2024.

InflaRx N.V. and subsidiaries

Unaudited condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2024 and 2023

	For the three months ended September 30,		For the nine months ended September 30	
	2024 (unaudited)	2023 (unaudited)	2024 (unaudited)	2023 (unaudited)
	(in €, except for share data)			
Revenues	123,819	60,803	166,212	60,803
Cost of sales	72,555	(255,116)	(496,119)	(255,116)
Gross profit (loss)	**196,374**	**(194,313)**	**(329,907)**	**(194,313)**
Sales and marketing expenses	(1,707,748)	(1,562,473)	(4,995,915)	(1,838,524)
Research and development expenses	(11,140,152)	(7,305,541)	(28,458,832)	(32,957,044)
General and administrative expenses	(2,809,032)	(2,897,732)	(9,614,281)	(10,047,091)
Other income	101,108	808,866	153,839	13,437,963
Other expenses	(589)	339	(297)	(2,851)
Operating result	**(15,360,039)**	**(11,150,854)**	**(43,245,392)**	**(31,601,861)**
Finance income	768,326	1,189,826	2,522,475	2,732,873
Finance expenses	(5,032)	(4,897)	(15,876)	(15,476)
Foreign exchange result	(2,847,692)	2,292,938	(311,905)	1,923,274
Other financial result	—	221,577	103,285	223,818
Income taxes	**(5,217)**	**—**	**(5,217)**	**—**
Income (loss) for the period	**(17,449,654)**	**(7,451,410)**	**(40,952,630)**	**(26,737,373)**
Other comprehensive income (loss) that may be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of foreign currency	(75,418)	73,574	(72,582)	56,459
Total comprehensive income (loss)	**(17,525,072)**	**(7,377,836)**	**(41,025,212)**	**(26,680,914)**
Share information (based on income (loss) for the period)				
Weighted average number of shares outstanding	58,883,272	58,883,272	58,883,272	53,598,594
Income (loss) per share (basic/diluted)	(0.30)	(0.13)	(0.70)	(0.50)

InflaRx N.V. and subsidiaries
Unaudited condensed consolidated statements of financial position
as of September 30, 2024 and December 31, 2023

	September 30, 2024 (unaudited)	December 31, 2023
	(in €)	
ASSETS		
Non-current assets		
Property and equipment	260,240	289,577
Right-of-use assets	850,001	1,071,666
Intangible assets	43,831	68,818
Other assets	217,491	257,267
Financial assets	4,694,199	9,052,741
Total non-current assets	**6,065,762**	**10,740,069**
Current assets		
Inventories	9,718,882	11,367,807
Other assets	3,714,912	4,036,650
Trade receivables	87,571	—
Tax receivables	2,211,455	3,791,564
Financial assets	31,683,244	77,504,518
Cash and cash equivalents	26,205,938	12,767,943
Total current assets	**73,622,003**	**109,468,483**
TOTAL ASSETS	**79,687,764**	**120,208,552**
EQUITY AND LIABILITIES		
Equity		
Issued capital	7,065,993	7,065,993
Share premium	334,211,338	334,211,338
Other capital reserves	43,775,960	40,050,053
Accumulated deficit	(327,080,450)	(286,127,819)
Other components of equity	7,309,584	7,382,166
Total equity	**65,282,425**	**102,581,730**
Non-current liabilities		
Lease liabilities	498,928	745,716
Other liabilities	36,877	36,877
Total non-current liabilities	**535,805**	**782,593**
Current liabilities		
Trade and other payables	11,719,795	11,974,362
Lease liabilities	398,979	374,329
Employee benefits	1,514,478	1,609,766
Other liabilities	236,284	2,885,772
Total current liabilities	**13,869,535**	**16,844,229**
Total Liabilities	**14,405,340**	**17,626,822**
TOTAL EQUITY AND LIABILITIES	**79,687,764**	**120,208,552**

InflaRx N.V. and subsidiaries
Unaudited condensed consolidated statements of changes in shareholders' equity for the nine months ended September 30, 2024 and 2023

(in €)	Issued capital	Share premium	Other capital reserves	Accumulated deficit	Other components of equity	Total equity
Balance as of January 1, 2024	**7,065,993**	**334,211,338**	**40,050,053**	**(286,127,819)**	**7,382,166**	**102,581,730**
Loss for the period	—	—	—	(40,952,630)	—	(40,952,630)
Exchange differences on translation of foreign currency	—	—	—	—	(72,582)	(72,582)
Total comprehensive loss	**—**	**—**	**—**	**(40,952,630)**	**(72,582)**	**(41,025,212)**
Equity-settled share-based payments	—	—	3,725,907	—	—	3,725,907
Balance as of September 30, 2024	**7,065,993**	**334,211,338**	**43,775,960**	**(327,080,450)**	**7,309,584**	**65,282,425**
Balance as of January 1, 2023	**5,364,452**	**282,552,633**	**36,635,564**	**(243,460,290)**	**7,257,081**	**88,349,440**
Loss for the period	—	—	—	(26,737,373)	—	(26,737,373)
Exchange differences on translation of foreign currency	—	—	—	—	56,459	56,459
Total comprehensive loss	**—**	**—**	**—**	**(26,737,373)**	**56,459**	**(26,680,914)**
Issuance of common shares	1,687,110	54,796,819	—	—	—	56,483,929
Transaction costs	—	(3,360,626)	—	—	—	(3,360,626)
Equity-settled share-based payments	—	—	2,961,491	—	—	2,961,491
Share options exercised	14,431	222,512	—	—	—	236,943
Balance as of September 30, 2023	**7,065,993**	**334,211,338**	**39,597,055**	**(270,197,663)**	**7,313,540**	**117,990,262**

InflaRx N.V. and subsidiaries
Unaudited condensed consolidated statements of cash flows
for the nine months ended September 30, 2024 and 2023

	For the nine months ended September 30,	
	2024 (unaudited)	**2023 (unaudited)**
	(in €)	
Operating activities		
Loss for the period	(40,952,630)	(26,737,373)
Adjustments for:		
Depreciation & amortization of property and equipment, right-of-use assets and intangible assets	374,377	432,248
Net finance income	(2,297,978)	(4,864,488)
Share-based payment expense	3,725,907	2,961,491
Net foreign exchange differences	10,930	(82,574)
Changes in:		
Financial assets from government grants		(431,246)
Inventories	1,648,925	(1,639,490)
Trade receivables	(87,571)	—
Other assets	1,941,622	4,468,239
Employee benefits	(95,288)	(26,893)
Other liabilities	(2,649,488)	2,893,461
Liabilities from government grants received		(6,209,266)
Trade and other payables	(254,567)	1,011,662
Income taxes paid	(5,217)	—
Interest received	1,990,054	1,302,391
Interest paid	(16,183)	(15,773)
Net cash used in operating activities	**(36,661,890)**	**(26,937,611)**
Investing activities		
Purchase of intangible assets, property and equipment	(29,992)	(45,942)
Purchase of current financial assets	(27,835,062)	(91,590,134)
Proceeds from the maturity of financial assets	78,273,017	71,113,455
Net cash from / (used in) investing activities	**50,407,963**	**(20,522,621)**
Financing activities		
Proceeds from issuance of common shares	—	56,483,929
Transaction costs from issuance of common shares	—	(3,360,626)
Proceeds from exercise of share options	—	236,943
Repayment of lease liabilities	(290,145)	(279,075)
Net cash from / (used in) financing activities	**(290,145)**	**53,081,170**
Net increase in cash and cash equivalents	13,455,929	5,620,938
Effect of exchange rate changes on cash and cash equivalents	(17,934)	(190,686)
Cash and cash equivalents at beginning of period	12,767,943	16,265,355
Cash and cash equivalents at end of period	**26,205,938**	**21,695,607**

About GOHIBIC (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 April 2023, the FDA issued the EUA for GOHIBIC (vilobelimab) for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of IMV or ECMO. In January 2024, InflaRx announced the launch of The InflaRx Commitment Program, pursuant to which the cost of GOHIBIC (vilobelimab) will be refunded for up to six (6) administered inpatient doses (the full treatment course) to institutions that meet the eligibility requirements, for patients who were administered GOHIBIC (vilobelimab) in line with its EUA and who died due to COVID-19 in the intensive care unit. The MAA for the treatment of adult patients with SARS-CoV-2 induced septic ARDS receiving IMV or ECMO is under regulatory review by the European Committee for Medicinal Products for Human Use under the centralized procedure, which applies to all 27 member states of the European Union.

In addition to development in COVID-19, vilobelimab is also being developed for various debilitating or life-threatening inflammatory indications, including PG. Vilobelimab has been granted orphan drug designation for the treatment of PG by both the FDA and EMA, as well as fast track designation by the FDA.

About INF904

INF904 is an orally administered, small molecule inhibitor of the C5a receptor that has shown anti-inflammatory therapeutic effects in several pre-clinical disease models. Further, in contrast to the marketed C5aR inhibitor, in vitro experiments demonstrated that INF904 has minimal inhibition of the cytochrome P450 3A4/5 (CYP3A4/5) enzymes, which play an important role in the metabolism of a variety of metabolites and drugs, including glucocorticoids. Reported results from a first-in-human study demonstrated that INF904 is well tolerated in treated subjects and exhibits no safety signals of concern in single doses ranging from 3 mg to 240 mg or multiple doses ranging from 30 mg once per day (QD) to 90 mg twice per day (BID) for 14 days.

PK / pharmacodynamic data support the best-in-class potential of INF904 with a ≥90% blockade of C5a-induced neutrophil activation achieved over the 14-day dosing period.

About 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 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.com.

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

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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, current expectations and the risks, uncertainties and other factors described under the headings, "Risk factors" and "Cautionary statement regarding forward looking statements", 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.