

InflaRx Reports Second Quarter 2023 Financial Results & Operating Update

- Quarter highlighted by the Emergency Use Authorization (EUA) and commercial launch of Gohibic (vilobelimab) in the United States
- Oral C5aR inhibitor INF904 progressing in single ascending dose (SAD) and multiple ascending dose (MAD) Phase I trial
- Progress in clinical development of vilobelimab in other indications, including cutaneous squamous cell carcinoma (cSCC) and pyoderma gangrenosum (PG)
- Strong addition to management team as Camilla Chong, M.D., joins as Chief Medical Officer
- Cash, cash equivalents and marketable securities of €115.2 million, expected to fund operations at least into 2026

Jena, Germany, August 10, 2023 – InflaRx N.V. (Nasdaq: IFRX), a clinical-stage biopharmaceutical company developing and commercializing anti-inflammatory therapeutics by targeting the complement system, announced today financial results for the three and six months ended June 30, 2023 and provided an operating update.

"It was truly thrilling to launch Gohibic (vilobelimab) for the treatment of certain critically ill COVID-19 patients in the United States and to be in the position of making our drug available for patients in U.S. hospitals," said Prof. Niels C. Riedemann, Chief Executive Officer and Founder of InflaRx. "Our development work in other disease areas where C5a and C5aR may play a significant role is progressing well as we strive to make Gohibic (vilobelimab) available to other patients who may benefit from it and to further our C5aR inhibitor INF904 into research in additional disease areas. Today, we also announced first data from an ongoing clinical trial in cutaneous squamous cell carcinoma." He continued: "With all the important work ahead, I am very pleased that Dr. Camilla Chong has joined the team to drive our future clinical development work with both vilobelimab and our oral C5aR inhibitor INF904. With her impressive background in the pharmaceutical industry, including her experience in launching new pharmaceutical products, she will be instrumental in advancing our complement-targeting therapies through the clinic and ultimately into the market."



Recent Highlights and Business Update

Camilla Chong, M.D. joins InflaRx as Chief Medical Officer:

Dr. Camilla Chong was appointed as Chief Medical Officer, effective July 1, 2023. She is a medical doctor with 25 years of experience in the global pharmaceutical industry. Dr. Chong has successfully led clinical development, medical affairs, clinical operations, regulatory and pharmacovigilance teams and has managed global clinical development programs. She has extensive experience in the launch of many new pharmaceutical products in multiple geographies. She joined InflaRx from Kyowa Kirin Corporation, where she was Vice President and Global Medical Affairs Therapy Area Head - Immunology. Dr. Chong is leading all clinical development activities at InflaRx.

Commercial Launch of Gohibic (vilobelimab) for the Treatment of Critically ill COVID-19 Patients following the EUA in the United States:

In April 2023, the U.S. Food and Drug Administration (FDA) issued an EUA for Gohibic (vilobelimab) for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO). Gohibic (vilobelimab) has been commercially available to hospitals across the United States since late Q2.

InflaRx is building an experienced and highly focused commercial team to support the drug's launch and distribution to hospitals. At the same time, the Company has set up a robust supply chain to allow for uninterrupted supply of Gohibic to the U.S. market. Lastly, InflaRx is raising awareness for this treatment option in the medical community through dedicated medical information campaigns.

Further, the Company is continuing discussions with the FDA related to the submission of a Biologics License Application (BLA) for a potential future full approval of Gohibic (vilobelimab) in the United States. InflaRx has also completed encouraging meetings with the rapporteur and co-rapporteur member state teams of the European Committee for Medicinal Products for Human Use (CHMP) related to a planned Marketing Authorization Application with the European Medicines Agency (EMA). The Company will provide updates on the status of regulatory submissions in the United States and elsewhere once available.

Development of Vilobelimab in Pyoderma Gangrenosum (PG):

In January 2023, InflaRx presented details related to the design of its planned pivotal Phase III study with vilobelimab in ulcerative PG, following compelling Phase II results for the treatment



of this rare neutrophilic and inflammatory skin disease with destructive, painful cutaneous ulcers. The multi-national, randomized, double-blind, placebo-controlled trial has an adaptive design with an interim analysis that will determine the planned total patient number. InflaRx submitted a Phase III clinical trial protocol to the FDA, initiated the preparatory activities and expects the first patient to be enrolled in Q3 2023.

INF904 – Low Molecular Weight, Oral C5aR Inhibitor:

InflaRx is currently conducting a single (SAD) and multiple ascending dose (MAD) Phase I clinical trial in healthy volunteers to assess the safety, tolerability and pharmacokinetic / pharmacodynamic properties of InflaRx' new and proprietary low molecular weight C5aR inhibitor INF904. The Company plans to show the effect of INF904 on C5a-induced downstream activity and to generate data in a format comparable with other published data on C5aR inhibitory molecules like avacopan. Results from the SAD part of the study are expected for Q3 2023 and results from the MAD part of the study are expected in Q4 2023. In the future, InflaRx plans to develop INF904 for complement-mediated, chronic autoimmune and inflammatory diseases where oral administration is the preferred choice for patients.

Initial Results for Development of Vilobelimab in Cutaneous Squamous Cell Carcinoma:

InflaRx is conducting an open-label, multicenter Phase II study, evaluating vilobelimab in two study arms - as stand-alone therapy (Arm A) and in combination with pembrolizumab (Arm B) - in patients with programmed cell death protein 1 (PD1) or programmed cell death ligand 1 (PDL1) inhibitor resistant/refractory, locally advanced or metastatic cutaneous squamous cell carcinoma (cSCC). The main objectives of this trial are to assess the safety and antitumor activity of vilobelimab in the monotherapy arm and to assess the maximum tolerated or recommended dose of vilobelimab and the safety and antitumor activity of this drug pair in the combination arm.

An interim analysis of ten evaluable patients in the monotherapy Arm A, which was not powered for significance due to the small number of patients in this cohort, showed first evaluable signals of efficacy: one patient had a complete response and another patient displayed overall stable disease; and a third patient showed stable disease of the target lesion according to "Response Evaluation Criteria In Solid Tumors" (RECIST) criteria. Vilobelimab treatment did not result in signals of concern related to safety or tolerability in these patients with advanced cSCC, who typically are of higher age and frequently suffer from multiple comorbidities.

In Arm B, patients are currently being enrolled and treated in the highest dose cohort. An interim analysis is planned to be performed once ten patients in the highest dose cohort are evaluable



for response assessment. So far, six patients have been enrolled, and the interim results are expected to be available in H1 2024. The decision on whether to progress to stage two of the study in arms A and/or B will be taken once the efficacy analysis in Arm B has been completed.

Although generally, cSCC patients can be effectively treated, some patients become resistant or refractory to current treatment options. Those patients have very high fatality rates and currently no approved treatment options. Based on these first encouraging activity signals in this difficult to treat patient population, the Company will decide on next development steps once more results of the combination arm where patients receive a PD-1 inhibitor in addition to vilobelimab become available.

Financing Activities

In April 2023, the Company issued 3,235,723 ordinary shares under its ATM program, resulting in \in 14.4 million in net proceeds. Also in April 2023, the Company completed an underwritten public offering of an aggregate of 10,823,529 ordinary shares, of which 1,411,764 were sold pursuant to the full exercise of an overallotment option granted to the underwriters. The ordinary shares were sold at a price of \$4.25 per share and have a nominal value of \in 0.12 per share. Aggregate proceeds from these equity offerings amounted to \in 53.5 million after deducting underwriting discounts.

On July 12, 2023, InflaRx filed a shelf registration statement on Form F-3 with the U.S. Securities and Exchange Commission (SEC) in order to replace its expiring shelf registration statement and to authorize the issuance of up to \$250 million in securities in registered offerings.

Dr. Thomas Taapken, Chief Financial Officer of InflaRx, said: "*It is an exciting time for InflaRx* as we evolve into a commercial-stage company and build a strong team to support the commercialization of Gohibic. However, with the lower numbers of severe COVID-19 cases, which we are grateful for, we are expecting moderate demand and first revenues in H2 2023. Thanks to our recent successful financing activities, we are well positioned to invest in the necessary infrastructure to make Gohibic available to hospitals across the United States, in addition to supporting our clinical development activities, including the Phase III trial with vilobelimab in pyoderma gangrenosum and the future development of our promising C5aR inhibitor INF904. Despite a financial market environment that has remained highly challenging, we are well funded to support our operations well into 2026."



Financial Highlights - Q2 2023

Research and Development Expenses

Research and development expenses incurred in H1 2023 increased compared to the corresponding period in 2022 by \in 4.0 million. This increase was primarily due to higher third-party expenses of \in 3.7 million related to manufacturing, development and regulatory activities in conjunction with the EUA application for vilobelimab in COVID-19.

General and Administrative Expenses

General and administrative expenses in H1 2023 decreased by €1.6 million to €7.1 million from €8.7 million in H1 2022. This decrease was primarily attributable to decreasing expenses associated with equity-settled share-based compensation recognized in personnel expenses.

Sales and Marketing Expenses

During H1 2023, InflaRx reported sales and marketing expenses for the first time, which amounted to $\in 0.3$ million, as a result of the initiation of the commercialization of Gohibic (vilobelimab). These expenses were mainly comprised of $\in 0.1$ million in personnel costs and $\notin 0.1$ million in external distribution services.

Other Income

Other income, which was primarily derived from income from government grants, decreased by €1.8 million to €12.6 million for the first half of 2023, from €14.4 million for the comparable period in 2022. The decrease was primarily due to the absence of a non-recurring catch-up effect of costs incurred in periods before Q2 2022, for which income recognition was deferred until Q3 2022, when the recognition criteria were considered to be met.

Net Financial Result

Net financial result decreased by $\in 1.2$ million to $\in 1.2$ million for the six months ended June 30, 2023, from $\in 2.4$ million in the same period of 2022. This decrease was mainly attributable to lower foreign exchange results which decreased by $\in 2.7$ million, partly compensated by the increase in interest income of $\in 1.4$ million due to increased interest payments from marketable securities.

Net Loss

Net loss in H1 2023 amounted to €19.3 million, compared to €13.5 million in H1 2022.



Net Cash Used in Operating Activities

Net cash used in operating activities in H1 2023 decreased to €21.7 from €25.4 million in H1 2022.

Liquidity and Capital Resources

As of June 30, 2023, the Company's total available funds were approximately €115.2 million, composed of €19.5 million in cash and cash equivalents and €95.7 million in marketable securities. These funds are expected to finance operations at least 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 June 30, 2023, and the three and six months ended June 30, 2023, and 2022, as well as the consolidated financial statements as of and for the year ended December 31, 2022, in "ITEM 18. Financial Statements," in InflaRx's Annual Report on Form 20-F for the year ended December 31, 2022, as filed with the SEC.



Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2023 and 2022

	ended	ree months June 30, 2022	For the six months ended June 30, 2023 2022		
	(unaudited)	(unaudited)	(unaudited)	(unaudited)	
		(in €, except f	or share data)		
	(40.040.505)	(44,400,050)	(05.054.500)	(04.050.004)	
Research and development expenses	(10,919,595)	(11,180,958)	(25,651,503)	(21,652,881)	
General and administrative expenses	(3,540,805)	(4,346,965)	(7,149,359)	(8,734,408)	
Sales and marketing expenses	(276,051)		(276,051)	—	
Other income	4,882,908	14,441,541	12,629,096	14,443,135	
Other expenses	(2,624)	(279)	(3,190)	(844)	
Operating Result	(9,856,168)	(1,086,661)	(20,451,007)	(15,944,999)	
Finance income	1,087,011	82,401	1,543,047	110,362	
Finance expenses	(5,052)	(7,945)	(10,580)	(32,531)	
Foreign exchange result	767,646	1,563,580	(369,664)	2,291,513	
Other financial result	(195,567)	(86,000)	2,241	39,000	
Income Taxes	_	_	_	_	
Income (Loss) for the Period	(8,202,130)	465,376	(19,285,963)	(13,536,654)	
Share Information					
Weighted average number of shares					
outstanding	56,985,734	44,203,763	50,912,459	44,203,763	
Income (Loss) per share (basic/diluted)	(0.14)	0.01	(0.38)	(0.31)	
Other comprehensive income (loss) that may be reclassified to profit or loss in subsequent periods:					
Exchange differences on translation of					
foreign currency	(330)	4,408,940	(17,116)	5,718,815	
Total Comprehensive Income (Loss)	(8,202,460)	4,874,316	(19,303,079)	(7,817,839)	



Unaudited Condensed Consolidated Statements of Financial Position as of June 30, 2023 and December 31, 2022

	June 30, 2023 (unaudited)	December 31, 2022
	(in	€)
ASSETS		
Non-current assets		
Property and equipment	296,382	328,920
Right-of-use assets	1,122,183	1,311,809
Intangible assets	90,789	138,905
Other assets	283,784	308,066
Financial assets	18,951,267	2,900,902
Total non-current assets	20,744,405	4,988,602
Current assets		
Inventories	578,705	—
Current other assets	6,405,867	14,170,510
Current tax assets	2,925,037	1,732,087
Financial assets from government grants	5,193,246	732,971
Other financial assets	77,601,286	64,810,135
Cash and cash equivalents	19,515,959	16,265,355
Total current assets	112,220,100	97,411,058
TOTAL ASSETS	132,964,505	102,399,660
EQUITY AND LIABILITIES Equity		
Issued capital	7,065,993	5,364,452
Share premium	334,211,338	282,552,633
Other capital reserves	38,874,961	36,635,564
Accumulated deficit	(262,746,253)	(243,460,290)
Other components of equity	7,239,965	7,257,081
Total equity	124,646,004	88,349,440
Non-current liabilities		<u>·</u>
Lease liabilities	814,560	987,307
Other liabilities	36,877	36,877
Total non-current liabilities	851,437	1,024,184
Current liabilities		<u>· · · · · · · · · · · · · · · · · </u>
Trade and other payables	5,200,809	4,987,538
Liabilities from government grants	801,632	6,209,266
Lease liabilities	356,099	369,376
Employee benefits	900,474	1,312,248
Other liabilities	208,051	147,608
Total current liabilities	7,467,065	13,026,036
Total Liabilities	8,318,502	14,050,220
TOTAL EQUITY AND LIABILITIES	132,964,505	102,399,660



Unaudited Condensed Consolidated Statements of Changes in Shareholders' Equity for the six months ended June 30, 2023 and 2022

(in €)	Issued capital	Share premium	Other capital reserves	Accumulated deficit	Other components of equity	Total equity
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				(19,285,963)		(19,285,963)
Exchange differences on translation of foreign currency Total comprehensive loss				 (19,285,963)	(17,116) (17,116)	(17,116) (19,303,079)
Issuance of common shares Transaction costs	1,687,110 —	54,796,819 (3,360,626)	=	_	_	56,483,929 (3,360,626)
Equity-settled share-based payments Share options exercised	 14,431		2,239,397	<u> </u>		2,239,397 236,943
Balance as of June 30, 2023	7,065,993	334,211,338	38,874,961	(262,746,253)	7,239,965	124,646,004
Balance as of January 1, 2022 Loss for the period	<u>5,304,452</u> —	280,310,744	<u> </u>	(213,975,679) (13,536,654)	3,050,271	105,280,996 (13,536,654)
Exchange differences on translation of foreign currency Total comprehensive loss				 (13,536,654)	5,718,815 5,718,815	5,718,815 (7,817,839)
Equity-settled share-based payments Balance as of June 30, 2022			4,668,481 35,259,689	(227,512,333)	 8,769,086	4,668,481 102,131,638



Unaudited Condensed Consolidated Statements of Cash Flows for the six months ended

June 30, 2023 and 2022

	For the six months ended June 30,		
	2023 (unaudited)	2022 (unaudited)	
	(ir	(€)	
Operating activities			
Loss for the period	(19,285,963)	(13,536,654)	
Adjustments for:			
Depreciation & amortization of property and equipment,			
right-of-use assets and intangible assets	293,328	300,870	
Net finance income	(1,165,044)	(2,408,345)	
Share-based payment expense	2,239,397	4,668,481	
Net foreign exchange differences	(23,953)	130,347	
Changes in:			
Financial assets from government grants	(4,460,274)	(8,260,503)	
Other assets	6,295,975	611,843	
Employee benefits	(411,774)	(640,112)	
Other liabilities	60,443	(7,869)	
Liabilities from government grants received	(5,407,634)	(6,154,865)	
Trade and other payables	213,270	(661,741)	
Inventories	(578,705)	—	
Interest received	556,068	631,504	
Interest paid	(10,777)	(32,039)	
Net cash used in operating activities	(21,685,642)	(25,359,081)	
Investing activities			
Purchase of intangible assets, property and equipment	(24,673)	(9,728)	
Purchase of current financial assets	(83,071,163)	(47,031,216)	
Proceeds from the maturity of financial assets	55,202,491	59,595,044	
Net cash from/(used in) investing activities	(27,893,346)	12,554,101	
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	(184,791)	(182,014)	
Net cash from/(used in) financing activities	53,175,455	(182,014)	
Net increase/(decrease) in cash and cash equivalents	3,596,467	(12,986,995)	
Effect of exchange rate changes on cash and cash	0,000,101	(12,000,000)	
equivalents	(345,862)	2,153,152	
Cash and cash equivalents at beginning of period	16,265,355	26,249,995	
	19,515,959	15,416,152	
Cash and cash equivalents at end of period	13,313,333	13,410,132	



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 biopharmaceutical company focused on applying its proprietary anti-C5a and C5aR technologies to discover and develop and commercialize first-in-class, potent and specific inhibitors of the complement activation factor known as C5a and its receptor known as C5aR. C5a is a powerful inflammatory mediator involved in the progression of a wide variety of autoimmune and other inflammatory diseases. InflaRx' 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 settings. 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 <u>www.inflarx.de</u>.

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.

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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 preclinical 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 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 gualified 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.