

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 November 2024

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

EXPLANATORY NOTE

Exhibits 99.1 and 99.2 to this report on Form 6-K (the “Report”) shall be deemed to be incorporated by reference into (i) the registration statements on Form S-8 (File No. 333-221656 and 333-240185) and (ii) the registration statement on Form F-3 (File No. 333-273058) of InflaRx N.V. and to be a part thereof from the date on which this Report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

Exhibit 99.3 to this Report shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, 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.

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	InflaRx N.V. Unaudited Condensed Consolidated Financial Statements as of and for the Three and Nine Months Ended September 30, 2024
99.2	InflaRx N.V. Management's Discussion and Analysis of Financial Condition and Results of Operations
99.3	InflaRx N.V. Press Release dated November 8, 2024

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: November 8, 2024

By: /s/ Niels Riedemann

Name: Niels Riedemann

Title: Chief Executive Officer

INFLARX N.V.

UNAUDITED CONDENSED CONSOLIDATED

FINANCIAL STATEMENTS – SEPTEMBER 30, 2024

These unaudited condensed financial statements are consolidated financial statements for the group consisting of InflaRx N.V. and its wholly owned subsidiaries InflaRx GmbH, Jena, Germany, and InflaRx Pharmaceuticals Inc., Ann Arbor, Michigan, United States (together, the “Group”). The financial statements are presented in euros (€).

InflaRx N.V. is a company limited by shares, incorporated and domiciled in Amsterdam, The Netherlands.
Its registered office and principal place of business is in Germany, Jena, Winzerlaer Str. 2.

Index to unaudited condensed consolidated financial statements
for the three and nine months ended September 30, 2024

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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

	Note	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	2	123,819	60,803	166,212	60,803
Cost of sales	3	72,555	(255,116)	(496,119)	(255,116)
Gross profit (loss)		196,374	(194,313)	(329,907)	(194,313)
Sales and marketing expenses	4	(1,707,748)	(1,562,473)	(4,995,915)	(1,838,524)
Research and development expenses	5	(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	6	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	7	768,326	1,189,826	2,522,475	2,732,873
Finance expenses	7	(5,032)	(4,897)	(15,876)	(15,476)
Foreign exchange result	7	(2,847,692)	2,292,938	(311,905)	1,923,274
Other financial result	7	—	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)

The accompanying notes are an integral part of these condensed consolidated financial statements.

InflaRx N.V. and subsidiaries

Unaudited condensed consolidated statements of financial position as of September 30, 2024 and December 31, 2023

	Note	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	8	217,491	257,267
Financial assets	11	4,694,199	9,052,741
Total non-current assets		<u>6,065,762</u>	<u>10,740,069</u>
Current assets			
Inventories	8	9,718,882	11,367,807
Other assets	9	3,714,912	4,036,650
Trade receivables	11	87,571	—
Tax receivables	10	2,211,455	3,791,564
Financial assets	11	31,683,244	77,504,518
Cash and cash equivalents	13	26,205,938	12,767,943
Total current assets		<u>73,622,003</u>	<u>109,468,483</u>
TOTAL ASSETS		<u><u>79,687,764</u></u>	<u><u>120,208,552</u></u>
EQUITY AND LIABILITIES			
Equity			
Issued capital	14	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		<u>65,282,425</u>	<u>102,581,730</u>
Non-current liabilities			
Lease liabilities		498,928	745,716
Other liabilities	12	36,877	36,877
Total non-current liabilities		<u>535,805</u>	<u>782,593</u>
Current liabilities			
Trade and other payables	11	11,719,795	11,974,362
Lease liabilities		398,979	374,329
Employee benefits		1,514,478	1,609,766
Other liabilities	12	236,284	2,885,772
Total current liabilities		<u>13,869,535</u>	<u>16,844,229</u>
Total Liabilities		<u>14,405,340</u>	<u>17,626,822</u>
TOTAL EQUITY AND LIABILITIES		<u><u>79,687,764</u></u>	<u><u>120,208,552</u></u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

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 €, except for share data)	Note	Shares outstanding	Issued capital	Share premium	Other capital reserves	Accumulated deficit	Other components of equity	Total equity
Balance as of January 1, 2024		58,883,272	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	15	—	—	—	3,725,907	—	—	3,725,907
Balance as of September 30, 2024*		58,883,272	7,065,993	334,211,338	43,775,960	(327,080,450)	7,309,584	65,282,425
Balance as of January 1, 2023		44,703,763	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		14,059,252	1,687,110	54,796,819	—	—	—	56,483,929
Transaction costs		—	—	(3,360,626)	—	—	—	(3,360,626)
Equity-settled share-based payments	15	—	—	—	2,961,491	—	—	2,961,491
Share options exercised		120,257	14,431	222,512	—	—	—	236,943
Balance as of September 30, 2023*		58,883,272	7,065,993	334,211,338	39,597,055	(270,197,663)	7,313,540	117,990,262

*unaudited

The accompanying notes are an integral part of these condensed consolidated financial statements.

InflaRx N.V. and subsidiaries

Unaudited condensed consolidated statements of cash flows for the nine months ended September 30, 2024 and 2023

	Note	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	7	(2,297,978)	(4,864,488)
Share-based payment expense	15	3,725,907	2,961,491
Net foreign exchange differences	7	10,930	(82,574)
Changes in:			
Financial assets from government grants			(431,246)
Inventories	8	1,648,925	(1,639,490)
Trade receivables		(87,571)	—
Other assets	9	1,941,622	4,468,239
Employee benefits		(95,288)	(26,893)
Other liabilities	12	(2,649,488)	2,893,461
Liabilities from government grants received	11		(6,209,266)
Trade and other payables	11	(254,567)	1,011,662
Income taxes paid		(5,217)	—
Interest received	7	1,990,054	1,302,391
Interest paid	7	(16,183)	(15,773)
Net cash used in operating activities		<u>(36,661,890)</u>	<u>(26,937,611)</u>
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		<u>50,407,963</u>	<u>(20,522,621)</u>
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	c)	—	236,943
Repayment of lease liabilities		(290,145)	(279,075)
Net cash from / (used in) financing activities		<u>(290,145)</u>	<u>53,081,170</u>
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	13	<u>26,205,938</u>	<u>21,695,607</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

InflaRx N.V. and subsidiaries

Notes to the unaudited condensed consolidated financial statements

1. Summary of significant accounting policies and other disclosures

a) Reporting entity and the Group's structure

InflaRx N.V. (the "Company" or "InflaRx") is a Dutch public company with limited liability (naamloze vennootschap) with its corporate seat in Amsterdam, the Netherlands, and is registered in the Commercial Register of the Netherlands Chamber of Commerce Business Register under CCI number 68904312. The Company's registered office is at Winzerlaer Straße 2 in 07745 Jena, Germany. Since November 10, 2017, InflaRx N.V.'s ordinary shares have been listed on the Nasdaq Global Select Market under the symbol IFRX.

InflaRx is a biopharmaceutical company pioneering anti-inflammatory therapeutics targeting the complement system by focusing on applying its proprietary anti-C5a and C5aR technologies to discover, develop and commercialize first-in-class, potent and specific inhibitors of the complement activation factor known as C5a and its receptor C5aR. On April 4, 2023, the U.S. Food and Drug Administration issued an Emergency Use Authorization (the "EUA") for GOHIBIC (vilobelimab), for the treatment of COVID-19 in critically ill, invasively mechanically ventilated hospitalized adults. These consolidated financial statements of InflaRx comprise the Group.

b) Basis of preparation

These interim condensed consolidated financial statements for the nine-month reporting period ended September 30, 2024, and 2023 have been prepared in accordance with IAS 34 Interim Financial Reporting. These condensed consolidated financial statements do not include all the information and disclosures required in the annual financial statements. Accordingly, this report is to be read in conjunction with the financial statements in the Company's annual report for the year ended December 31, 2023 on form 20-F.

The interim condensed consolidated financial statements were authorized for issue by the board of directors of the Company (the "Board of Directors") on November 7, 2024.

The financial statements are presented in euros (€). The euro is the functional currency of InflaRx N.V. and InflaRx GmbH. The functional currency of InflaRx Pharmaceuticals Inc. is the U.S. dollar.

All financial information presented in euros have been rounded to the nearest euro. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that precede them or may deviate from other tables.

The accounting policies adopted are consistent with those followed in the preparation of the Group's annual consolidated financial statements for the year ended December 31, 2023, except for the adoption of new standards effective as of January 1, 2024, as set out below. The Group has not adopted any other standard, interpretation or amendment that has been issued but is not yet effective early.

The following amendments were adopted effective January 1, 2024, and do not have a material impact on the consolidated financial statements of the Group:

- Amendments to IFRS 16 Leases: Leases on Sale and Leaseback
- Amendments to IAS 1 Presentation of Financial Statements: Classification of Liabilities as Current or Non-current and Non-current Liabilities with Covenants
- Amendments to IAS 7, Statement of Cash Flows and IFRS 7, -Supplier Finance Arrangements

The following standards issued will be adopted in a future period, and the potential impact, if any, they will have on the Group's consolidated financial statements is being assessed:

- Amendments to IAS 21 Effects of Changes in Foreign Exchange Rates: Lack of exchangeability
- IFRS 18 Presentation and Disclosure in Financial Statements

2. Revenues

	For the three months ended September 30,		For the nine months ended September 30,	
	2024 (unaudited)	2023 (unaudited)	2024 (unaudited)	2023 (unaudited)
	(in €)			
Revenues	123,819	60,803	166,212	60,803
Total	123,819	60,803	166,212	60,803

For the three months ended September 30, 2024, the Company realized revenues from the product sales of GOHIBIC (vilobelimab) in the amount of €124 thousand. For the nine months ended September 30, 2024, the Company realized revenues from GOHIBIC (vilobelimab) product sales in the amount of €166 thousand.

Revenues reported are sales to end customers (hospitals). Sales to distributors do not constitute revenue for the Company under IFRS 15. All revenues are attributed to sales made in the United States.

3. Cost of sales

	For the three months ended September 30,		For the nine months ended September 30,	
	2024 (unaudited)	2023 (unaudited)	2024 (unaudited)	2023 (unaudited)
	(in €)			
Cost of sales	(72,555)	255,116	496,119	255,116
Total	(72,555)	255,116	496,119	255,116

The cost of sales during nine months ended September 30, 2024 was primarily related to write-downs of short-lived inventories. The Company adjusts its inventory write-downs on a quarterly basis based on its rolling sales forecast. The € 0.5 million includes both write-downs and reversals of previous write-downs. Cost of sales during the three months ended September 30, 2024 was primarily related to a reversal of a previous write-down in the amount of €75 thousand due to a change in estimate of sales of goods prior to expiry of their shelf life.

4. Sales and marketing expenses

Sales and marketing expenses incurred for the three months ended September 30, 2024 increased by €0.1 million compared to the three months ended September 30, 2023. For the nine months ended September 30, 2024, these expenses increased by €3.2 million compared to the nine months ended September 30, 2023. This increase is primarily due to increased sales and marketing activities incurred during the nine months ended September 30, 2024 in the US, driven primarily by GOHIBIC (vilobelimab).

5. Research and development expenses

Research and development expenses incurred for the three months ended September 30, 2024 increased by €3.8 million compared to the three months ended September 30, 2023. For the nine months ended September 30, 2024 these expenses decreased by €4.5 million compared to the nine months ended September 30, 2023.

The increase for the three months ended September 30, 2024 is primarily due to higher third-party expenses incurred in connection with the company's efforts to develop INF904.

The decrease for the nine months ended September 30, 2024 is primarily due to higher third-party expenses incurred during the first three quarters of 2023 in connection with the company's efforts to develop the commercial manufacturing process, and to obtain an EUA, for GOHIBIC (vilobelimab).

6. Other income

	For the three months ended September 30,		For the nine months ended September 30	
	2024 (unaudited)	2023 (unaudited)	2024 (unaudited)	2023 (unaudited)
	(in €)			
Other income				
Income from government grants	—	772,604	—	13,382,393
Other	101,108	36,262	153,839	55,570
Total	101,108	808,866	153,839	13,437,963

Other income for the three months ended September 30, 2024 amounted to €0.1 million (2023: €0.8 million) and for the nine months ended September 30, 2024 amounted to €0.2 million (2023: €13.4 million). 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.

7. Net financial result

	For the three months ended September 30,		For the nine months ended September 30	
	2024 (unaudited)	2023 (unaudited)	2024 (unaudited)	2023 (unaudited)
	(in €)			
Interest income	768,326	1,189,826	2,522,475	2,732,873
Interest expenses	(321)	(327)	(297)	(1,108)
Interest on lease liabilities	(4,711)	(4,570)	(15,580)	(14,368)
Financial result	763,294	1,184,929	2,506,599	2,717,397
Foreign exchange income	319,442	4,007,995	4,123,268	6,389,514
Foreign exchange expense	(3,167,134)	(1,715,057)	(4,435,173)	(4,466,240)
Foreign exchange result	(2,847,692)	2,292,938	(311,905)	1,923,274
Other financial result	—	221,577	103,285	223,818
Net financial result	(2,084,398)	3,699,444	2,297,978	4,864,488

Net financial result decreased by €5.8 million to a loss of €2.1 million for the three months ended September 30, 2024 from a gain of €3.7 million for the three months ended September 30, 2023. This decrease is mainly attributable to a decrease of the foreign exchange result by €5.1 million due to the weakening of the U.S. dollar during the three months ended September 30, 2024 and a decrease of interest income on marketable securities by €0.4 million, in each case, compared to the three months ended September 30, 2023.

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

8. Inventory

	As of September 30, 2024 (unaudited)	As of December 31, 2023
	(in €)	
Raw material and supplies	138,414	423,560
Unfinished goods	9,459,267	10,614,159
Finished goods	121,200	330,087
Total	<u>9,718,882</u>	<u>11,367,807</u>

As of September 30, 2024, inventory amounted to €9.7 million compared to €11.4 million as of December 31, 2023. As of September 30, 2024 the Group recorded in total write downs of raw materials and supplies of €0.3 million and write downs of finished goods of €0.4 million. These write-downs were due to the expected expiry of the shelf life of GOHIBIC (vilobelimab) related inventories. For more information we refer to Note 3 “cost of sales”. Additionally, during the nine months ended September 30, 2024, unfinished inventory decreased as €1.2 million was recorded as research and development expense for use in clinical studies.

9. Other assets

	As of September 30, 2024 (unaudited)	As of December 31, 2023
	(in €)	
Non-current other assets		
Prepaid expenses	217,491	257,267
Total	<u>217,491</u>	<u>257,267</u>
Current other assets		
Prepayments on research & development projects	2,784,071	3,670,167
Prepaid expenses	751,953	272,999
Others	178,888	93,482
Total	<u>3,714,912</u>	<u>4,036,648</u>
Total other assets	<u>3,932,403</u>	<u>4,293,915</u>

As of September 30, 2024, prepayments on research and development projects amounted to €2.8 million compared to €3.7 million as of December 31, 2023, and consist of prepayments on clinical contracts, primarily for INF904.

Prepaid expenses consist mainly of prepaid D&O insurance expense for the year 2024, which will be recognized into general and administrative expenses pro rata over the year.

The category “others” primarily relate to prepayments on commercial production.

10. Tax receivables

As of September 30, 2024, tax receivables amounted to €2.2 million compared to €3.8 million as of December 31, 2023. The decrease is mainly attributable to VAT refunds for Q2 2023 and Q3 2023 received during the nine months ended September 30, 2024.

11. Financial assets and financial liabilities

Set out below is an overview of financial assets and liabilities, other than cash and cash equivalents, held by the Group as of September 30, 2024 and December 31, 2023:

	As of September 30, 2024 (unaudited)	As of December 31, 2023
	(in €)	
Financial assets at amortized cost		
Trade receivables	87,571	—
Non-current financial assets	4,694,199	9,052,741
Thereof marketable securities	4,456,632	8,815,120
Current financial assets	31,683,244	77,504,518
Thereof marketable securities	31,340,790	76,912,342
Financial liabilities at amortized cost		
Trade and other payables	11,719,583	14,716,441

As of September 30, 2024, the fair value of current and non-current financial assets (primarily quoted debt securities) amounted to €36.1 million (Level 1). The Group's debt instruments at amortized cost consist solely of quoted securities that are graded highly by credit rating agencies such as S&P Global and, therefore, are considered low credit risk investments.

As of September 30, 2024, current and non-current financial assets decreased by €50.2 million to €36.4 million compared to €86.6 million as of December 31, 2023. The decrease is mainly due to the maturity of financial assets, and their subsequent reinvestment into interest bearing bank deposits, which are accounted for as part of cash and cash equivalents.

As of September 30, 2024, trade and other payables decreased by €3.0 million to €11.7 million compared to €14.7 million as of December 31, 2023. As of December 31, 2023 the Company temporarily had higher trade payables from CDMO's, that arose in connection with the manufacturing of commercial products.

Trade receivables arose from GOHIBIC (vilobelimab) product deliveries to end customers (hospitals) through a subsidiary of Cencora, which acts as the U.S. distributor for the Company.

12. Other liabilities

	As of September 30, 2024 (unaudited)	As of December 31, 2023
	(in €)	
Liabilities to commercial partner	—	2,784,231
Miscellaneous other liabilities	236,284	101,542
Total	236,284	2,885,773

As of September 30, 2024, a subsidiary of Cencora which acts as the U.S. distributor for the Company, returned products to the Company and the Company repaid funds previously paid by Cencora, thereby extinguishing liabilities to commercial partners.

In accordance with IFRS 15, InflaRx recognizes revenue when control of product is transferred to end customers (hospitals). Therefore, InflaRx recognizes an amount in liabilities to commercial partner, when the product is in the distributor's warehouse until the product is sold to an end customer.

13. Cash and cash equivalents

	As of September 30, 2024 (unaudited)	As of December 31, 2023
	(in €)	
Short-term deposits		
Deposits held in U.S. dollars	18,615,418	4,120,951
Deposits held in euros	2,510,000	1,020,000
Total	21,125,418	5,140,951
Cash at banks		
Cash held in U.S. dollars	3,360,900	5,041,802
Cash held in euros	1,719,620	2,585,190
Total	5,080,521	7,626,991
Total cash and cash equivalents	26,205,938	12,767,942

As of September 30, 2024, cash and cash equivalents increased by €13.4 million to €26.2 million compared to €12.8 million as of December 31, 2023. The increase is mainly due to certain financial assets having reached their maturity, and the subsequent reinvestment into interest bearing bank deposits, which are classified as cash and cash equivalents.

14. Equity

On June 30, 2023, the Company filed a form F-3 with the United States Securities and Exchange Commission (the “SEC”) with respect to the offer and sale of up to \$250.0 million of securities of the Company.

On June 28, 2024, the Company entered into a Sales Agreement with Leerink Partners LLC, or Leerink, to sell ordinary shares of the Company from time to time through an at-the-market, or ATM, equity offering program of up to \$75.0 million under which Leerink will act as sales agent. As of the date of this report, the Company had not issued any ordinary shares under such ATM program.

15. Share-based payments

a) Equity settled share-based payment arrangements

InflaRx GmbH granted options under the 2012 Stock Option Plan. Those InflaRx GmbH options were converted into options for ordinary shares of InflaRx N.V. at the time of its IPO in November 2017:

Number of share options	2024	2023
Outstanding as of January 1,	148,433	148,433
Exercised during the nine months ended September 30	—	—
Outstanding as of September 30, thereof vested / exercisable	148,433 148,433	148,433 148,433

Under the terms and conditions of the share option plan 2016, InflaRx GmbH granted rights to subscribe for InflaRx GmbH’s ordinary shares to directors, senior management, and key employees. Those InflaRx GmbH options were converted into options for ordinary shares of InflaRx N.V. at the time of its IPO in November 2017:

Number of share options	2024	2023
Outstanding as of January 1,	888,632	888,632
Exercised during the nine months ended September 30	—	—
Outstanding as of September 30, thereof vested / exercisable	888,632 888,632	888,632 888,632

InflaRx also granted share options under the 2017 LTIP subsequently to its IPO in November 2017. The total number of share options granted during the nine months ended September 30, 2024 under the 2017 LTIP was as follows:

Number of share options	2024	2023
Outstanding as of January 1,	6,584,946	4,985,523
Granted during the nine months ended September 30,	2,275,000	1,735,750
Exercised during the nine months ended September 30,	-	(105,327)
Forfeited during the nine months ended September 30,	(7,000)	(26,000)
Outstanding as of September 30,	8,852,946	6,589,946
thereof vested / exercisable	7,196,446	5,170,321

The number of share options granted during the nine months ended September 30, 2024 under the 2017 LTIP was as follows:

Share options granted 2024	Number	Fair value per option	FX rate as of grant date	Fair value per option	Share price at grant date / Exercise price	Expected volatility	Expected life (midpoint based)	Risk-free rate (interpolated, U.S. sovereign strips curve)
January 05	2,245,000	\$ 1.65	0.916 €	1.51	\$ 1.79	1.47	5.30-5.50	4.023%-4.025%
February 21	30,000	\$ 1.40	0.925 €	1.30	\$ 1.51	1.47	5.50	4.308%
	<u>2,275,000</u>							

Of the 2,275,000 options granted in the nine months ended September 30, 2024 (ended September 30, 2023: 1,735,750), 1,615,000 options (September 30, 2023: 1,396,000) were granted to members of the executive management or Board of Directors.

Expected dividends are nil for all share options listed above.

b) Share-based payment expense recognized

For the nine months ended September 30, 2024, the Company has recognized €3.7 million (2023: €3.0 million) of share-based payment expense in the statements of operations and comprehensive loss.

None of the share-based payment awards were dilutive in determining earnings per share due to the Group's loss position.

c) Share options exercised

During the nine months ended September 30, 2024, no shares (2023: 105,327) were issued upon the exercise of share options, resulting in no proceeds to the Company (nine months ended September 30, 2023: €98). All share options exercised in 2023 were granted under the 2017 LTIP.

16. Protective foundation

According to the articles of association of the Company, up to 147,200,000 ordinary shares and up to 147,200,000 preferred shares with a nominal value of €0.12 per share are authorized to be issued. All shares are registered shares. No share certificates shall be issued.

In order to deter acquisition bids, the Company's general meeting of shareholders approved the right of an independent foundation under Dutch law, or protective foundation, to exercise a call option pursuant to the call option agreement, upon which preferred shares will be issued by the Company to the protective foundation of up to 100% of the Company's issued capital held by others than the protective foundation, minus one share. The protective foundation is expected to enter into a finance arrangement with a bank or, subject to applicable restrictions under Dutch law, the protective foundation may request the Company to provide, or cause the Company's subsidiaries to provide, sufficient funding to the protective foundation to enable it to satisfy its payment obligation under the call option agreement.

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These preferred shares will have both a liquidation and dividend preference over the Company's ordinary shares and will accrue cash dividends at a pre-determined rate. The protective foundation would be expected to require the Company to cancel its preferred shares once the perceived threat to the Company and its stakeholders has been removed or sufficiently mitigated or neutralized. The Company believes that the call option does not represent a significant fair value based on a level 3 valuation since the preferred shares are restricted in use and can be cancelled by the Company.

During the nine months ended September 30, 2024, the Company expensed €38 thousand (2023: €60 thousand) of ongoing costs to reimburse expenses incurred by the protective foundation.

MANAGEMENT'S DISCUSSION AND ANALYSIS
OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This management's discussion and analysis is designed to provide you with a narrative explanation of our financial condition and results of operations. We recommend that you read this discussion together with our unaudited interim condensed consolidated financial statements, including the notes thereto, for the three and nine months ended September 30, 2024 and 2023, respectively, included as Exhibit 99.1 to the report on Form 6-K to which this discussion is attached as Exhibit 99.2. We also recommend that you read our "ITEM 5. Operating and financial review and prospects" and our audited consolidated financial statements for fiscal year 2023, and the notes thereto, which appear in our Annual Report on Form 20-F for the year ended December 31, 2023, or the Annual Report, filed with the U.S. Securities and Exchange Commission, or the SEC. In addition, we recommend that you read any public announcements made by InflaRx N.V.

The following discussion is based on our financial information prepared in accordance with IFRS as issued by the IASB, which may differ in material respects from generally accepted accounting principles in the United States and other jurisdictions. We maintain our books and records in euros. Unless otherwise indicated, all references to currency amounts in this discussion are in euros. We have made rounding adjustments to some of the figures included in this discussion and analysis. Accordingly, numerical figures shown as totals in some tables may not be arithmetic aggregations of the figures that precede them.

The following discussion includes forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those described under "ITEM 3. Key Information—Risk factors" in the Annual Report and risks described in our subsequent SEC filings.

Unless otherwise indicated or the context otherwise requires, all references to "InflaRx" or the "Company," "we," "our," "ours," "us" or similar terms refer to InflaRx N.V. and its subsidiaries InflaRx GmbH and InflaRx Pharmaceuticals, Inc.

Overview

We are a biopharmaceutical company pioneering anti-inflammatory therapeutics targeting the complement system by focusing on applying our proprietary anti-C5a and C5aR technologies to discover, 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. Our 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. We are also developing INF904, an oral, small molecule drug candidate that targets the C5a receptor (C5aR).

Vilobelimab for the treatment of pyoderma gangrenosum

We are developing vilobelimab for the treatment of pyoderma gangrenosum, or PG. PG is a rare, chronic inflammatory form of neutrophilic dermatosis characterized by accumulation of neutrophils in the affected skin areas. The exact pathophysiology is not fully understood, but it is postulated that inflammatory cytokine production as well as neutrophil activation and dysfunction contribute to a sterile inflammation in the skin. PG often presents as painful pustule or papule, mainly on the lower extremities, which can rapidly progress to an extremely painful enlarging ulcer. Associated symptoms include fever, malaise, weight loss and myalgia. PG usually has a devastating effect on a patient's life due to the severe pain and induction of significant movement impairment depending on lesions' location. The exact prevalence of PG is not yet known but is estimated that up to 51,000 patients in the United States and Europe are affected by this disease.

Vilobelimab has been granted orphan drug designation for the treatment of PG by both the FDA in the United States and the European Medicines Agency, or EMA, in Europe as well as fast-track designation by the FDA.

In November 2023, we announced the enrollment of the first patient in the Phase 3 trial. The Phase 3 study is designed to enroll patients in the United States, Europe and selected countries in other regions. The study design is based on detailed feedback and recommendations from the FDA Division of Dermatology and Dentistry and was developed in close collaboration with the Company's advisors from the United States, Europe and other regions. The multi-national, randomized, double-blind, placebo-controlled Phase 3 trial has two arms: vilobelimab (2,400mg every other week) plus a low dose of corticosteroids and placebo plus the same low dose of corticosteroids. In both arms, corticosteroid treatment will be initiated on day one and will be tapered off within the first eight weeks of the treatment period. The primary endpoint of the study will be complete closure of the target ulcer on two consecutive visits at any time up to 26 weeks after initiation of treatment. Treatment will be discontinued for patients whose disease progresses or fails to improve at defined time points during the study. 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 study has an adaptive trial 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 have been treated, divided equally between the two arms of the study. 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. As of November 2024, approximately 30 patients had initiated dosing in the trial. The interim analysis is expected to occur in the second quarter of 2025.

GOHIBIC (vilobelimab) for the treatment of critically ill, invasively mechanically ventilated COVID-19 patients

In April 2023, we received an Emergency Use Authorization, or the EUA, from the U.S. Food and Drug Administration, or FDA, for GOHIBIC (vilobelimab) for the treatment of critically ill, invasively mechanically ventilated COVID-19 patients. Specifically, we received the EUA for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation, or IMV, or extracorporeal membrane oxygenation, or ECMO. GOHIBIC (vilobelimab) is not FDA-approved for any indication, including for the treatment of COVID-19 in critically ill, invasively mechanically ventilated patients.

To achieve full commercial scale and successfully reach the full market potential of the product in the United States in the future, we also aspire to obtain full market approval for GOHIBIC (vilobelimab). We are therefore planning the submission of a Biologics License Applications, BLA, for full approval of GOHIBIC (vilobelimab) in our COVID-19 indication and potentially, in the future, in similar indications that may apply to other virally induced acute respiratory distress conditions. In October 2023, in furtherance of our continued efforts to obtain a BLA, we had an encouraging Type C meeting with the FDA. In that meeting, the FDA indicated their willingness to collaborate with us in identifying a development pathway towards a BLA for a broader acute respiratory distress syndrome, or ARDS, label. To achieve this, we would need to conduct an additional well-controlled and adequately powered study in a broader ARDS setting that demonstrates the safety and efficacy of vilobelimab.

In June 2023, we began the commercialization of GOHIBIC (vilobelimab) in the United States for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV or ECMO. We entered into agreements with certain subsidiaries of Cencora Inc. to act as our U.S. distributor and to make GOHIBIC (vilobelimab) available for order by U.S. hospital customers under the EUA. Cencora provides cold storage, cold-chain distribution services, inventory management and secondary labeling/packaging, among other services. To support our commercial efforts, we have hired and are continuing to hire U.S. experts with relevant experience in the commercialization of medical products in the hospital market, including in the areas of sales, sales operations, marketing, market access, distribution, medical affairs and others. In addition, we are expanding the necessary infrastructure, including IT systems, supply chain, financial reporting systems and inventory management systems both internally and with the assistance of external service providers.

In July 2023, we also submitted a Marketing Authorization Application, or MAA, for SARS-CoV-2 induced septic ARDS receiving IMV or ECMO to the EMA. The application is now under regulatory review by the European Committee for Medicinal Products for Human Use, or CHMP, under the centralized procedure, which applies to all 27 member states of the European Union, or EU. In October 2024, the CHMP convened to review the submitted MAA. The regulatory review process is ongoing, which has included discussions between the Company and the CHMP. A CHMP opinion is anticipated during Q4 of 2024.

In June 2024, InflaRx announced that GOHIBIC (vilobelimab) has been selected by the Biomedical Advanced Research and Development Authority, or BARDA, as one of three investigational therapies BARDA will assess in a Phase 2 clinical platform study exploring potential new options for the treatment of ARDS. The Company signed a Clinical Trial Collaboration Agreement with BARDA as funding party and PPD as study sponsor to agree upon rights and obligations regarding this study, including but not limited to the clinical supply of vilobelimab.

C5aR inhibitor INF904

Inhibition of the C5a/C5aR axis provides strong anti-inflammatory effects in a variety of diseases. Blockade of C5a using highly specific antibodies, such as vilobelimab, may offer a fast, effective, and safe way to control C5a-induced inflammation. In addition to this approach, inhibition of C5aR by oral small molecules may provide the ease of administration required for effective long-term treatment for more chronic inflammatory diseases. To expand the breadth of our anti-C5a/C5aR technologies, we are also developing INF904, an oral, small molecule drug candidate that targets C5aR. C5aR, a G-protein-coupled-receptor expressed primarily by granulocytes, mediates the pathophysiological effects of C5a. In INF904, we discovered a small molecule C5aR inhibitor that in pre-clinical studies has shown potential for superior characteristics to the only approved C5aR inhibitor, avacopan. INF904 has provided higher plasma exposure in animals, including non-human primates, and improved inhibitory activity in a hamster neutropenia model compared to avacopan. Furthermore, in contrast to avacopan, in vitro experiments showed INF904 has substantially less inhibition of the cytochrome P450 3A4/5 (CYP3A4/5) enzymes, which play an important role in the metabolism of a variety of drugs, including glucocorticoids. No obvious toxicological findings, even in the highest dose groups tested in required GLP toxicity analyses, were identified. INF904 demonstrated potential for anti-inflammatory therapeutic effects in several preclinical disease models.

We conducted the first part of a double-blind, placebo-controlled Phase 1 trial with INF904 from November 2022 to September 2023, which enrolled 62 healthy volunteers within six different dosing groups from 3 mg to 240 mg who were randomly assigned to receive INF904 or a placebo into the single ascending dose, or SAD, part of the trial. The results showed that INF904 was well tolerated in treated patients and resulted in no safety signals of concern in any of the doses tested. The overall percentage of adverse events (AEs) was lower in the INF904 treated patients compared to the placebo group, and no serious or severe AEs were observed at any dosing level. No related AEs were reported in conjunction with INF904 dosing. Analysis of INF904 PK in subject plasma samples revealed sustained exposure to INF904 with six hours to maximum concentration, or t_{max} . INF904 plasma levels were dose proportional for systemic exposure (AUC_{last}) and nearly dose proportional for maximum concentration (C_{max}) over the dose range used in the study. With the 30 mg dose, INF904 reached a C_{max} of 289 ng/ml with an AUC_{last} of 5197 h.ng/ml, which are approximately 3-fold and 10-fold, respectively, higher than the published Phase 1 data from the only marketed comparator, avacopan. Single doses of 30 mg or higher of INF904 achieved $\geq 90\%$ blocking of C5a induced up-regulation of the activation marker CD11b on neutrophils in plasma samples from subjects ex vivo at 24 hours post dosing. This inhibition was achieved when 12.6 nM recombinant C5a was added as stimulus in this assay, a C5a concentration which can be observed in patients with severe inflammatory conditions such as the immuno-dermatological disease, hidradenitis suppurativa, or HS, or during life-threatening inflammation (e.g., in critically ill COVID-19 patients or septic patients). Thus, INF904 inhibition of C5a-induced neutrophil activation in human plasma achieved the set goal for effective C5aR control at disease relevant C5a levels.

In January 2024, we announced topline results from the multiple ascending dose, or MAD, part of the Phase 1 trial for INF904, which had been conducted between September 2023 and January 2024 with 24 participants who received multiple doses of INF904 for 14 days of either 30 mg once per day, or QD, 30 mg twice per day, or BID, or 90 mg BID. The PK and pharmacodynamic, or PD parameters confirm the favorable data we observed during the SAD part of the study, which provides support for the best-in-class potential of INF904. INF904 was well tolerated and there were no adverse safety events of concern after repeated dosing in participants over the entire tested dose range.

The safety analysis of INF904 in the MAD part of the Phase 1 study demonstrated that it was well tolerated in participants over the entire dose range and resulted in no safety signals of concern. The overall percentage of AEs in INF904 treated participants was 77.8%, which was lower than the 83.3% observed in the placebo group. There were no serious or severe AEs observed at any dosing level.

Analysis of the PK profile showed that potential target AUC_{0-12h} , C_{max} , and trough values were achieved rapidly within 14 days of 30 mg BID dosing. INF904 exposure further increased proportionally with dosing up to 90 mg BID. These results were demonstrated even when participants ingested the drug in a fasted state, suggesting that food is not required to achieve potentially therapeutic drug levels.

Analysis of the PD profile showed that the blocking activity of C5a-induced neutrophil activation by INF904 reached equal to or above 90% over the 14-day dosing period for all tested doses in an ex vivo challenge assay where physiological and disease-relevant levels of C5a were added to blood samples provided by the trial participants.

In parallel, we have progressed with the development of a commercially viable formulation of INF904 which we plan to introduce into Phase 2 development in Q4 2024.

We are currently also conducting additional required pre-clinical studies, including long-term chronic toxicology studies, to enable longer-term dosing of INF904 for chronic inflammatory diseases. We initially plan to develop INF904 for the treatment of two initial immuno-dermatology indications: HS and chronic spontaneous urticaria, or CSU. We plan to initiate an open-label Phase 2a “basket study” in Q4 2024 to explore at least three different doses of INF904 for a duration of four weeks and to assess PK and PD parameters in HS and CSU patients, as well as provide safety data and certain early efficacy readouts. Data from this Phase IIa study is expected to be available in 2025. Depending on the results of this study, we expect to initiate a larger and longer-term Phase 2b study in one or both indications in 2025 as well.

CSU and HS are chronic inflammatory skin conditions in which C5a has been suggested to play a significant role and where a high unmet need exists. Being an oral drug with a mechanism of action currently not addressed by other drugs in development for these indications, we see a unique opportunity to improve standard of care for patients with these conditions.

CSU is a debilitating and unpredictable skin disease characterized by intensely itchy hives / wheals and angioedema. The burden of this chronic disease is high and impacts sleep, mental health, quality of life and productivity due to absences from school and work. CSU is estimated to affect around 40 million people worldwide. CSU patients have been reported to show elevated C5a levels, a major activator of mast cells and basophils, which are thought to be significant contributors to CSU pathogenesis. In addition, studies suggest that complement activation (including C5a) in CSU can lead to histamine release. Current treatments are limited, and a significant unmet need exists in a sizable proportion of patients. As an orally available agent with a favorable PK / PD profile that could drive a broad dose range for systemic exposure, INF904 could find a differentiated position in the CSU market.

HS is a chronic, recurrent, debilitating neutrophil-driven inflammatory disease that can persist for years and tremendously impacts quality of life; it is characterized by abscesses, nodules and draining tunnels, or dTs, which can flare and cause scarring. INF904 inhibits the known C5a-induced effects on neutrophil activation and tissue accumulation of immune cells, including generation of tissue damaging mechanisms (enzyme release and oxidative radical formation) as well as induction of NETosis, which are mechanisms thought to be involved in HS progression and dT formation. Clinical evidence with existing C5a/C5aR inhibitors also supports that blocking this pathway reduces lesion counts. Patients’ responses to treatment with currently approved drugs are known to wane over time in a significant number of cases, and treatments with new mechanisms of action are needed for these patients.

Anti-C5a antibody IFX002

We are also developing IFX002 for the treatment of chronic inflammatory diseases. IFX002 is a highly potent anti- C5a antibody, which binds to the same domain of the C5a protein as vilobelimab, but which has a higher humanization grade and altered PK properties compared to vilobelimab. IFX002 is currently in preclinical development. We consider IFX002 to be a life-cycle management product to vilobelimab, given the long remaining patent life of IFX002.

Financial highlights

As of September 30, 2024, we had available funds amounting 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 equivalent, 4.2 million are held in euros and 24.6 million are held in U.S. dollars, this is equivalent to €22.0 million at an exchange rate of 1.1196 on 30 September 2024. All marketable securities are held in U.S. dollars and have a nominal value of \$40.5 million. We believe that our current funds on hand will be sufficient to fund our planned operations into 2026.

We anticipate that our expenses might increase if and as we:

- continue to develop and conduct clinical trials with respect to our lead product candidate, vilobelimab;
- continue research, preclinical and clinical development efforts for any future product candidates, including INF904 and IFX002;

- actively seek to identify additional research programs and additional product candidates;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials, if any;
- establish sales, marketing, distribution and other commercial infrastructure now and in the future to commercialize various products for which we may obtain marketing authorization or approval, if any;
- require the scale-up and validation of the manufacturing process and the manufacturing of larger quantities of product candidates for clinical development and, potentially, commercialization;
- collaborate with strategic partners to optimize the manufacturing process for vilobelimab, IFX002, INF904 and other pipeline products;
- maintain, expand and protect our intellectual property portfolio;
- hire and retain additional personnel, such as commercial, marketing, clinical, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development as well as commercialization and help us comply with our obligations as a public company.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue unless and until we are, or any future collaborator is, able to obtain full marketing authorization or approval for, and successfully commercialize, one or more of our product candidates. Successful commercialization will require achievement of key milestones, including completing clinical trials of vilobelimab, INF904 and any other product candidates, obtaining marketing authorization or approval for these product candidates, manufacturing, marketing and selling those products for which we, or any of our future collaborators, may obtain marketing authorization or approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately predict the timing and amount of revenues, and if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we do, or any future collaborators do, we may never generate revenue that is large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. In order to succeed, we will need to transition from a company with a research and development focus to a company capable of undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays, and may not be successful in such a transition.

Accordingly, we may seek to further fund our operations through public or private equity or debt financings or other sources, including strategic collaborations. We may, however, be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop vilobelimab or any additional product candidates.

Our failure to become and remain profitable could depress the market price of our ordinary shares and could impair our ability to raise capital, pay dividends, expand our business, diversify our product offerings or continue our operations. If we continue to suffer losses as we have in the past, investors may not receive any return on their investment and may lose their entire investment.

Research and development expenses

Research and development expenses have consisted principally of:

- expenses incurred under agreements with CROs, contract manufacturing organizations, or CDMOs, consultants and independent contractors that conduct research and development, preclinical and clinical activities on our behalf;
- employee-related expenses, including salaries, benefits and stock-based compensation expense based upon employees' role within the organization; and
- professional fees for lawyers related to the protection and maintenance of our intellectual property.

Our research and development expenses primarily relate to the following key programs:

- **Vilobelimab.** We expect our expenses associated with vilobelimab will continue to increase in 2024 compared to 2023, as we progress in the Phase 3 clinical study in PG. In addition, we are incurring and expect to further incur expenses in conjunction with the preparation and filing of full market authorizations for vilobelimab in the United States, Europe and elsewhere. We may also consider development of vilobelimab in additional indications. In addition, we are also incurring expenses related to the manufacturing of clinical trial material and the completion of activities towards the final establishment of commercial scale production.
- **INF904.** We are developing INF904, a product candidate that targets C5aR. We expect to incur additional costs by advancing the clinical and non-clinical development of INF904. Specifically, we expect to incur expenses by developing a new formulation, conducting long-term toxicological studies in several animal species and initiating Phase 2 clinical trials. We plan to study INF904 in complement-mediated, chronic autoimmune and inflammatory conditions where an oral low molecular weight compound might have advantages or is needed for patients and where oral delivery is the medically preferred route of administration.
- **IFX002.** We are developing IFX002 for the treatment of chronic inflammatory indications. IFX002 is a highly potent anti-complement C5a antibody with a higher humanization grade and altered PK properties compared to vilobelimab and is currently in pre-clinical development. Expenses for this program mainly consist of salaries, costs for preclinical testing conducted by CROs and costs to produce preclinical material.
- **Other development programs.** Our other research and development expenses relate to our preclinical studies of other product candidates and discovery activities, expenses for which mainly consist of salaries, costs for production of preclinical compounds and costs paid to CROs.

In 2023, we incurred €41.0 million in research and development expenses. For the nine months ended September 30, 2024 and 2023, we incurred research and development expenses of €28.5 million and €33.0 million, respectively. The decrease in our research and development expenses was attributable to higher R&D expenses in the first nine months of 2023 for the completion of the development activities for vilobelimab for the treatment of critically ill COVID-19 patients, for which the FDA granted the EUA in April 2023. The 2023 expenses are comprised of costs attributable to the establishment of a commercial scale manufacturing process for vilobelimab and regulatory expenses in conjunction with the EUA filing and other regulatory activities, as well as for the manufacturing of clinical trial-related material.

We use our employee and infrastructure resources across multiple research and development programs directed toward developing our therapeutics in different indications and in our pre-clinical and clinical programs. We manage certain activities such as contract research and manufacturing of therapeutics and our discovery programs through our third-party vendors.

Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, including due to timing of clinical trial initiation and conduct.

We expense research and development costs as incurred. We recognize costs for certain development activities, such as preclinical studies and clinical trials, based on an evaluation of the progress towards completion of specific tasks. We use information provided to us by our vendors such as patient enrollment or clinical site activations for services received and efforts expended. Research and development activities are central to our business model.

The successful development and commercialization of our product candidates is highly uncertain. We cannot reasonably and accurately predict the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from, any of our product candidates. For a discussion of our other key financial statement line items, please see "ITEM 5. Operating and Financial Review and Prospects—Operating results" in the Annual Report.

General and administrative expenses

We expect that our general and administrative expenses will increase in the future as our business expands. Such expenses relate primarily to personnel within administrative functions, legal and consulting fees, audit fees, directors' and officers' liability insurance premiums and costs associated with investor relations activities.

In 2023, we incurred €12.6 million in general and administrative expenses. For each of the nine months ended September 30, 2024 and 2023, we incurred general and administrative expenses of €9.6 million and €10.0 million, respectively.

Sales and marketing expenses

Sales and marketing expenses include costs for commercial operations, distribution and logistics, sales, marketing and comparable activities. We incur these costs either directly through the employment of our own personnel and in-house activities, or through commissioning third parties to assist in different aspects of commercializing our products. For each of the nine months ended September 30, 2024 and 2023, we incurred sales and marketing expenses of €5.0 million and €1.8 million, respectively. We started with its commercialization activities in June 2023, after the EUA was granted in April 2023. Prior to that, no sales and marketing expenses had been incurred.

Results of operations

The information below was derived from our unaudited interim condensed consolidated financial statements included elsewhere herein. The discussion below should be read along with these unaudited interim condensed consolidated financial statements and our Annual Report.

1. Comparison of the three months ended September 30, 2024 and 2023

	three months ended September 30,		
	2024	2023	Change
	(in €)		
Revenues	123,819	60,803	63,016
Cost of sales	72,555	(255,116)	327,671
Gross profit	196,374	(194,313)	390,687
Operating expenses			
Sales and marketing expenses	(1,707,748)	(1,562,473)	(145,275)
Research and development expenses	(11,140,152)	(7,305,541)	(3,834,611)
General and administrative expenses	(2,808,820)	(2,897,732)	88,912
Total operating expenses	(15,656,720)	(11,765,746)	(3,890,974)
Other income	101,108	808,866	(707,758)
Other expenses	(589)	339	(928)
Operating result	(15,359,827)	(11,150,854)	(4,208,973)
Finance income	768,326	1,189,826	(421,500)
Finance expenses	(5,032)	(4,897)	(135)
Foreign exchange result	(2,847,692)	2,292,938	(5,140,630)
Other financial result	—	221,577	(221,577)
Income taxes	(5,217)	—	(5,217)
Income (loss) for the period	(17,449,441)	(7,451,410)	(9,998,031)
Exchange differences on translation of foreign currency	(75,420)	73,574	(148,994)
Total comprehensive income (loss)	(17,524,861)	(7,377,836)	(10,147,025)

Revenues

	three months ended September 30,		
	2024	2023	Change
	(in €)		
Revenues	123,819	60,803	63,016
Total	<u>123,819</u>	<u>60,803</u>	<u>63,016</u>

For the three months ended September 30, 2024, we realized revenues from the product sales of GOHIBIC (vilobelimab) in the amount of €124 thousand.

Revenues reported are sales to end customers (hospitals). Sales to distributors do not constitute revenue for the Company under IFRS 15. All revenues are attributed to sales made in the United States.

Cost of sales

	three months ended September 30,		
	2024	2023	Change
	(in €)		
Cost of sales	(72,555)	255,116	(327,671)
Total	<u>(72,555)</u>	<u>255,116</u>	<u>(327,671)</u>

Cost of sales during the three months ended September 30, 2024 was related to a reversal of write-downs in the amount of €75 thousand as a consequence to an updated sales forecast.

Sales and marketing expenses

	three months ended September 30,		
	2024	2023	Change
	(in €)		
Third-party expenses	371,433	974,500	(603,067)
Personnel expenses	523,442	500,010	23,432
Legal and consulting fees	84,701	81,355	3,346
Other expenses	728,172	6,608	721,564
Total sales and marketing expenses	<u>1,707,748</u>	<u>1,562,473</u>	<u>145,275</u>

Sales and marketing expenses incurred for the three months ended September 30, 2024 increased by €0.1 million compared to the three months ended September 30, 2023. To support our commercial efforts, we have hired sales professionals with relevant experience in the hospital market. The reduction of third-party expenses in the period is mainly attributable to the in-sourcing of our sales staff which has previously been provided through a third party. Other expenses increased mainly due to the initiation of extensive marketing activities in the U.S. market for GOHIBIC (vilobelimab).

Research and development expenses

	three months ended September 30,		
	2024	2023	Change
	(in €)		
Third-party expenses	8,718,231	4,224,874	4,493,357
Personnel expenses	1,868,749	1,780,148	88,601
Legal and consulting fees	361,957	372,788	(10,831)
Other expenses	191,215	927,730	(736,515)
Total research and development expenses	<u>11,140,152</u>	<u>7,305,541</u>	<u>3,834,611</u>

Research and development expenses incurred for the three months ended September 30, 2024 increased by €3.8 million compared to the three months ended September 30, 2023. This increase is primarily due to higher third-party expenses incurred in connection with the Company's efforts to develop INF904.

General and administrative expenses

	three months ended September 30,		
	2024	2023	Change
	(in €)		
Personnel expenses	1,365,179	1,206,958	158,221
Legal, consulting and audit fees	438,931	751,086	(312,155)
Other expenses	1,004,710	939,688	65,022
Total general and administrative expense	<u>2,808,820</u>	<u>2,897,732</u>	<u>(88,912)</u>

General and administrative expenses amounted to €2.8 million for the three months ended September 30, 2024 and are nearly unchanged in comparison to the period in the previous year. Other expenses mainly relate to D&O insurance, Board of Directors' remuneration, IT expenses and travel.

Other income

	three months ended September 30,		
	2024	2023	Change
	(in €)		
Income from government grants	—	772,604	(772,604)
Other	101,108	36,262	64,846
Total other income	<u>101,108</u>	<u>808,866</u>	<u>(707,758)</u>

Other income for the three months ended September 30, 2024 amounted to €0.1 million (2023: €0.8 million). There was no income from government grants in 2024 due to the end of the grant period (i.e. German government grant for the development of vilobelimab for the treatment of critically ill COVID-19 patients) on June 30, 2023.

Net financial result

	three months ended September 30,		
	2024	2023	Change
	(in €)		
Interest income	768,326	1,189,826	(421,500)
Interest expenses	(321)	(327)	6
Interest on lease liabilities	(4,711)	(4,570)	(141)
Finance result	<u>763,294</u>	<u>1,184,929</u>	<u>(421,635)</u>
Foreign exchange income	319,442	4,007,995	(3,688,553)
Foreign exchange expense	(3,167,134)	(1,715,057)	(1,452,077)
Foreign exchange result	<u>(2,847,692)</u>	<u>2,292,938</u>	<u>(5,140,630)</u>
Other financial result	—	221,577	(221,577)
Net financial result	<u>(2,084,398)</u>	<u>3,699,444</u>	<u>(5,783,842)</u>

Net financial result decreased by €5.8 million to a loss of €2.1 million for the three months ended September 30, 2024 from an gain of €3.7 million for the three months ended September 30, 2023. This decrease is mainly attributable to a decrease of the foreign exchange result by €5.1 million due to the weakening of the U.S. dollar during the three months ended September 30, 2024 and a decrease of interest income on marketable securities by €0.4 million, in each case, compared to the three months ended September 30, 2023. This decline is mainly due to a lower level of investment in marketable securities in 2024.

2. Comparison of the nine months ended September 30, 2024 and 2023

	nine months ended September 30,		
	2024	2023	Change
	(in €)		
Revenues	166,212	60,803	105,409
Cost of sales	(496,119)	(255,116)	(241,003)
Gross profit	<u>(329,907)</u>	<u>(194,313)</u>	<u>(135,594)</u>
Operating expenses			
Sales and marketing expenses	(4,995,915)	(1,838,524)	(3,157,391)
Research and development expenses	(28,458,832)	(32,957,044)	4,498,212
General and administrative expenses	(9,614,068)	(10,047,091)	433,023
Total operating expenses	<u>(43,068,815)</u>	<u>(44,842,659)</u>	<u>1,773,844</u>
Other income	153,839	13,437,963	(13,284,124)
Other expenses	(297)	(2,851)	2,554
Operating result	<u>(43,245,179)</u>	<u>(31,601,861)</u>	<u>(11,643,318)</u>
Finance income	2,522,475	2,732,873	(210,398)
Finance expenses	(15,876)	(15,476)	(400)
Foreign exchange result	(311,905)	1,923,274	(2,235,179)
Other financial result	103,285	223,818	(120,533)
Income taxes	(5,217)	—	(5,217)
Income (loss) for the period	<u>(40,952,418)</u>	<u>(26,737,373)</u>	<u>(14,215,045)</u>
Exchange differences on translation of foreign currency	(72,584)	56,459	(129,043)
Total comprehensive income (Loss)	<u>(41,025,002)</u>	<u>(26,680,914)</u>	<u>(14,344,088)</u>

Revenues

	nine months ended September 30,		
	2024	2023	Change
	(in €)		
Revenues	166,212	60,803	105,409
Total	<u>166,212</u>	<u>60,803</u>	<u>105,409</u>

For the nine months ended September 30, 2024, we realized revenues from product sales of GOHIBIC (vilobelimab) in the amount of €166 thousand. Revenues reported are sales to end customers (hospitals). Sales to distributors do not constitute revenue for the Company under IFRS 15. All revenues are attributed to sales made in the United States.

Cost of sales

	nine months ended September 30,		
	2024	2023	Change
	(in €)		
Cost of sales	496,119	255,116	241,003
Total	<u>496,119</u>	<u>255,116</u>	<u>241,003</u>

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

Sales and marketing expenses

	nine months ended September 30,		
	2024	2023	Change
	(in €)		
Third-party expenses	1,942,332	1,099,430	842,902
Personnel expenses	1,178,687	604,894	573,793
Legal and consulting fees	571,225	124,247	446,978
Other expenses	1,303,671	9,954	1,293,717
Total sales and marketing expenses	4,995,915	1,838,524	3,157,391

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 the initialization of our commercialization of GOHIBIC (vilobelimab) in June 2023. Sales and marketing expenses were incurred for all of the nine months ended September 30, 2024. To support our commercial efforts, we have hired sales professionals with relevant experience in the hospital market. Other expenses increased mainly due to the initiation of extensive marketing activities in the U.S. market for GOHIBIC (vilobelimab).

Research and development expenses

	nine months ended September 30,		
	2024	2023	Change
	(in €)		
Third-party expenses	19,517,620	24,724,877	(5,207,257)
Personnel expenses	6,521,819	5,190,156	1,331,663
Legal and consulting fees	1,053,147	1,459,954	(406,807)
Other expenses	1,366,246	1,582,057	(215,811)
Total research and development expenses	28,458,832	32,957,044	(4,498,212)

Research and development 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 first nine months of 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 equity-settled share-based compensation.

General and administrative expenses

	nine months ended September 30,		
	2024	2023	Change
	(in €)		
Personnel expenses	5,082,285	4,199,908	882,377
Legal, consulting and audit fees	1,709,887	2,822,519	(1,112,632)
Other expenses	2,821,896	3,024,665	(202,769)
Total general and administrative expense	9,614,068	10,047,091	(433,023)

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. The decrease is attributable to a decrease in legal, consulting and audit fees due to lower recruiting cost and cost savings resulting from insourcing external services and a decrease in other expenses associated with insurance expenses. This decrease is offset by an increase in personnel expenses by €0.9 million due to higher equity-settled share-based compensation recognized in personnel expenses.

Other income

	nine months ended September 30,		
	2024	2023	Change
	(in €)		
Income from government grants	—	13,382,393	(13,382,393)
Other	153,839	55,570	98,269
Total other income	153,839	13,437,963	(13,284,124)

Other income for the nine months ended September 30, 2024 amounted to €0.2 million (2023: €13.4 million). For the nine month ended September 30, 2024 an amount of €0.1 million is mainly related to a claim resulting from damages associated to a service contract with one of our vendors. There was no income from government grants (i.e. German government grant for the development of vilobelimab for the treatment of critically ill COVID-19 patients) in 2024 due to the end of the grant period on June 30, 2023.

Net financial result

	nine months ended September 30,		
	2024	2023	Change
	(in €)		
Interest income	2,522,475	2,732,873	(210,398)
Interest expenses	(297)	(1,108)	811
Interest on lease liabilities	(15,580)	(14,368)	(1,212)
Finance Result	2,506,599	2,717,397	(210,798)
Foreign exchange income	4,123,268	6,389,514	(2,266,246)
Foreign exchange expense	(4,435,173)	(4,466,240)	31,067
Foreign exchange result	(311,905)	1,923,274	(2,235,179)
Other financial result	103,285	223,818	(120,533)
Net financial result	2,297,978	4,864,488	(2,566,510)

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 decrease of the foreign exchange result by €2.2 million compared to the nine month ended September 30, 2023.

Liquidity and capital resources

Since inception, we have incurred significant operating losses. For the nine months ended September 30, 2024, we incurred a net loss of €41.0 million. To date, we have financed our operations primarily through the sale of our securities. As of September 30, 2024, we had cash, cash equivalents in the amount of €26.2 million and financial assets in the amount of €36.4 million, comprised of marketable securities in the amount of €35.8 million and other financial assets amounting to €0.6 million. Our cash and cash equivalents primarily consist of bank deposit accounts and fixed U.S. dollar term deposits.

Cash flows

The table below summarizes our consolidated statement of cash flows for the nine months ended September 30, 2024 and 2023:

	nine months ended September 30,	
	2024	2023
	(in €)	
Net cash used in operating activities	(36,661,890)	(26,937,611)
Net cash from/ (used in) investing activities	50,407,963	(20,522,621)
Net cash from/ (used in) financing activities	(290,145)	53,081,170
Cash and cash equivalents at the beginning of the period	12,767,943	16,265,355
Exchange gains/ (losses) on cash and cash equivalents	(17,934)	(190,686)
Cash and cash equivalents at the end of the period	<u>26,205,938</u>	<u>21,695,607</u>

1. Net cash from/used in operating activities

The use of cash in all periods resulted primarily from our net losses, adjusted for non-cash charges and changes in components of working capital.

Net cash used in operating activities increased to €36.7 million in the nine months ended September 30, 2024, from €26.9 million in the nine months ended September 30, 2023.

2. Net cash from/used in investing activities

Net cash from investing activities increased by €70.9 million in the nine months ended September 30, 2024, mainly due to higher proceeds from the maturity of marketable securities in the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. These proceeds were reinvested into interest bearing bank deposits, which are accounted for as part of cash and cash equivalents.

3. Net cash from/used in financing activities

Net cash from financing activities decreased by €53.4 million in the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023, due to a capital increase in 2023 and no capital increase in 2024.

Funding requirements

We expect our expenses associated with vilobelimab to increase in 2024 compared to 2023, as we continue discussions with the FDA related to the planned submission of a BLA for full approval of GOHIBIC (vilobelimab) to treat severe COVID-19 and potentially additional related indications, continue to pursue commercializing of GOHIBIC (vilobelimab) under the EUA for emergency use as granted by the FDA, and complete development of vilobelimab in other indications, including PG in our Phase 3 trial. In addition, we also incur expenses related to the manufacturing of clinical trial materials and in connection with further optimizing our manufacturing process for vilobelimab in compliance with regulatory standards. Furthermore, we also have established commercial scale production options and have initiated manufacturing campaigns to be able to serve the market needs in the United States under the granted EUA.

We also plan to advance the development of INF904 by the initiation of Phase 2 clinical development by year-end 2024. In parallel, we are also continuing with non-clinical development activities in relation to the manufacturing and additional non-clinical animal studies in order to prepare for this future development.

If clinical data is supportive, we may seek marketing approval for any product candidates that we successfully develop. Additionally, we will validate and further develop the manufacturing process of our products to be able to apply for marketing authorization and to be able to provide a commercial-grade product. If we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to establishing sales, marketing, distribution, and other commercial infrastructure to commercialize such products. We will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce, or eliminate our research and development programs or future commercialization efforts. We believe that our existing cash and cash equivalents and financial assets will enable us to fund our operating expenses and capital expenditure requirements under our current business plan into 2026.

Until such time, if ever, that we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, royalty-based financings, future collaborations, strategic alliances, licensing arrangements and revenues from product sales. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the interest of our current shareholders will be diluted, and the terms of these securities may include voting or other rights that adversely affect your rights as an ordinary shareholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us.

At-the-market program

On June 28, 2024, the Company entered into a Sales Agreement with Leerink Partners LLC, or Leerink, to sell ordinary shares of the Company from time to time through an at-the-market, or ATM, equity offering program of up to \$75.0 million under which Leerink will act as sales agent.

On June 30, 2023, the Company filed a form F-3 with the SEC with respect to the offer and sale of up to \$250.0 million of securities of the Company.

As of the date of this report, the Company had not issued any ordinary shares under the ATM program.

For more information as to the risks associated with our future funding needs, see “ITEM 3. Key Information—Risk factors” in our Annual Report.

Off-balance sheet arrangements

As of September 30, 2024, and during the periods presented, we did not have any off-balance sheet arrangements other as described under “ITEM 5. Operating and financial review and prospects—off-balance sheet arrangements” in our Annual Report.

Contractual obligations and commitments

We do not have any, and during the periods presented we did not have any, contractual obligations and commitments other than as described under “ITEM 5. Operating and Financial Review and Prospects—Liquidity and capital resources—Contractual obligations and commitments” in the Annual Report. Vilobelimab, will be supplied by InflaRx to BARDA/PPD from its available stock under the Clinical Trial and Collaboration Agreement executed in June 2024 for the BARDA-Sponsored Clinical Trial to Evaluate Novel Host-Directed Therapeutics for Acute Respiratory Distress Syndrome (ARDS).

Quantitative and qualitative disclosures about market risk

During the nine months ended September 30, 2024, there were no significant changes to our quantitative and qualitative disclosures about market risk from those reported in “ITEM 11. Quantitative and Qualitative Disclosures About Market Risk” in the Annual Report.

Critical judgments and accounting estimates

There have been no material changes to the significant accounting policies and estimates described in “ITEM 5. Operating and Financial Review and Prospects—Critical judgments and accounting estimates” in the Annual Report.

Critical accounting estimates

There have been no material changes to the significant accounting policies and estimates described in Note B.2. to our consolidated financial statements in the Annual Report.

Cautionary statement regarding forward looking statements

This discussion contains forward-looking statements that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “estimate,” “believe,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions intended to identify statements about the future. These statements speak only as of the date of this discussion 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. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements include, without limitation, statements about the following:

- our ability to successfully commercialize and the receptiveness of GOHIBIC (vilobelimab) as a treatment for COVID-19 patients by U.S. hospitals, our ability to positively influence treatment recommendations by medical/healthcare institutes, guideline bodies and other third-party organizations;
- 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 the EUA, and in the future if approved for commercial use in the United States or elsewhere;
- our ability to successfully implement The InflaRx Commitment Program and estimate future write-downs due to expiry and costs in the event of the price refunds, the success of our future clinical trials for vilobelimab's treatment of other debilitating or life-threatening inflammatory indications, including ARDS, 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 preclinical studies and clinical trials of vilobelimab, INF904 and any other product candidates, including for the development of vilobelimab in several indications, including to treat PG, HS and CSU 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 and the receptiveness and approval by regulators regarding the results of clinical trials and potential regulatory approval or authorization pathways including related to our MAA submission for vilobelimab and our BLA for GOHIBIC (vilobelimab); the timing and outcome of any discussions or submission of filings for regulatory approval or authorization of vilobelimab, INF904 or any other product candidate, and the timing of and our ability to obtain and maintain full regulatory approval or the EUA, of vilobelimab or GOHIBIC (vilobelimab) for any indication;
- our ability to leverage our proprietary anti-C5a and anti-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, INF904 and any other product candidates, and the scope of such protection;
- whether the FDA, or 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;
- the success of our future clinical trials for vilobelimab, INF904 and any other product candidates and whether such clinical results will reflect results seen in previously conducted preclinical studies and clinical trials;
- our expectations regarding the size of the patient populations for, the market opportunity for, the medical need for and clinical utility of vilobelimab, INF904 or any other product candidates, if approved or authorized for commercial use;

- 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 expectations regarding the scope of any approved indication for vilobelimab;
- our ability to defend against liability claims resulting from the testing of our product candidates in the clinic or, if approved or authorized, any commercial sales;
- if any of our product candidates obtain regulatory approval or authorization, our ability to comply with and satisfy ongoing drug regulatory obligations and continued regulatory oversight;
- our ability to comply with enacted and future legislation in seeking marketing approval or authorization 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 and other therapeutic products being developed in similar medical conditions in which vilobelimab, INF904 or any other of our product candidates is being developed or our industry.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. You should refer to the “ITEM 3. Key information—Risk factors” section of our Annual Report and risks described in our subsequent SEC filings for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this discussion or in our Annual Report will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. You should, however, review the factors and risks and other information we describe in the reports we will file from time to time with the SEC after the date of this discussion.



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	<u>6,065,762</u>	<u>10,740,069</u>
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	<u>73,622,003</u>	<u>109,468,483</u>
TOTAL ASSETS	<u><u>79,687,764</u></u>	<u><u>120,208,552</u></u>
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	<u>65,282,425</u>	<u>102,581,730</u>
Non-current liabilities		
Lease liabilities	498,928	745,716
Other liabilities	36,877	36,877
Total non-current liabilities	<u>535,805</u>	<u>782,593</u>
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	<u>13,869,535</u>	<u>16,844,229</u>
Total Liabilities	<u>14,405,340</u>	<u>17,626,822</u>
TOTAL EQUITY AND LIABILITIES	<u><u>79,687,764</u></u>	<u><u>120,208,552</u></u>



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 €)	<u>Issued capital</u>	<u>Share premium</u>	<u>Other capital reserves</u>	<u>Accumulated deficit</u>	<u>Other components of equity</u>	<u>Total equity</u>
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	2023
	(unaudited)	(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	<u>(36,661,890)</u>	<u>(26,937,611)</u>
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	<u>50,407,963</u>	<u>(20,522,621)</u>
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	<u>(290,145)</u>	<u>53,081,170</u>
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	<u>26,205,938</u>	<u>21,695,607</u>



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 $\geq 90\%$ 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.
