

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 2023

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 shall be deemed to be incorporated by reference into (i) the registration statement on Form S-8 (File No. 333-221656) 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333-273058) of InflaRx N.V. and to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 on Form 6-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), 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, or the Exchange Act.

EXHIBIT INDEX

Exhibit No. Description

99.1	InflaRx N.V. Unaudited Condensed Consolidated Financial Statements as of and for the Three and Nine Months Ended September 30, 2023
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 1, 2023

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 1, 2023

By: /s/ Niels Riedemann

Name: Niels Riedemann

Title: Chief Executive Officer

INFLARX N.V.

UNAUDITED CONDENSED CONSOLIDATED

FINANCIAL STATEMENTS – SEPTEMBER 30, 2023

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.

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for the three and nine months ended September 30, 2023

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

	Note	For the three months ended September 30,		For the nine months ended September 30	
		2023 (unaudited)	2022 (unaudited)	2023 (unaudited)	2022 (unaudited)
		(in €, except for share data)			
Revenues	2	60,803	—	60,803	—
Cost of Sales	3	(255,116)	—	(255,116)	—
Gross profit		(194,313)	—	(194,313)	—
Sales and marketing expenses		(1,562,473)	—	(1,838,524)	—
Research and development expenses		(7,305,541)	(7,537,350)	(32,957,044)	(29,190,231)
General and administrative expenses		(2,897,732)	(3,087,285)	(10,047,091)	(11,821,694)
Other income	4	808,866	2,030,406	13,437,963	16,473,540
Other expenses		339	—	(2,851)	(844)
Operating Result		(11,150,854)	(8,594,230)	(31,601,861)	(24,539,229)
Finance income	5	1,189,826	199,758	2,732,873	310,121
Finance expenses	5	(4,897)	(6,845)	(15,476)	(39,376)
Foreign exchange result	5	2,292,938	882,370	1,923,274	3,173,883
Other financial result	5	221,577	(402,724)	223,818	(363,724)
Income Taxes		—	—	—	—
Income (Loss) for the Period		(7,451,410)	(7,921,671)	(26,737,373)	(21,458,325)
Other comprehensive income (loss) that may be reclassified to profit or loss in subsequent periods:					
Exchange differences on translation of foreign currency		73,574	4,317,134	56,459	10,035,949
Total Comprehensive Income (Loss)		(7,377,836)	(3,604,538)	(26,680,914)	(11,422,376)
Share Information (based on Income (Loss) for the Period)					
Weighted average number of shares outstanding		58,883,272	44,203,763	53,598,594	44,203,763
Income (Loss) per share (basic/diluted)		(0.13)	(0.18)	(0.50)	(0.49)

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

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

	Note	September 30, 2023 (unaudited)	December 31, 2022
(in €)			
ASSETS			
Non-current assets			
Property and equipment		298,344	328,920
Right-of-use assets		1,076,402	1,311,809
Intangible assets		66,734	138,905
Other assets	7	270,526	308,066
Financial assets	8	237,564	2,900,902
Total non-current assets		<u>1,949,570</u>	<u>4,988,602</u>
Current assets			
Inventories	6	1,639,490	—
Current other assets	7	7,779,994	14,170,510
Current tax assets		3,398,481	1,432,087
Financial assets from government grants	8	1,164,217	732,971
Other financial assets	8	91,857,945	64,810,135
Cash and cash equivalents	10	21,695,607	16,265,355
Total current assets		<u>127,535,734</u>	<u>97,411,058</u>
TOTAL ASSETS		<u><u>129,485,304</u></u>	<u><u>102,399,660</u></u>
EQUITY AND LIABILITIES			
Equity			
Issued capital	11	7,065,993	5,364,452
Share premium		334,211,338	282,552,633
Other capital reserves		39,597,055	36,635,564
Accumulated deficit		(270,197,663)	(243,460,290)
Other components of equity		7,313,540	7,257,081
Total equity		<u>117,990,262</u>	<u>88,349,440</u>
Non-current liabilities			
Lease liabilities	8	771,814	987,307
Other liabilities		36,877	36,877
Total non-current liabilities		<u>808,691</u>	<u>1,024,184</u>
Current liabilities			
Trade and other payables	8	5,999,200	4,987,538
Liabilities from government grants	8	—	6,209,266
Lease liabilities	8	354,151	369,376
Employee benefits		1,285,355	1,312,248
Other liabilities	9	3,047,646	147,608
Total current liabilities		<u>10,686,351</u>	<u>13,026,036</u>
Total Liabilities		<u>11,495,042</u>	<u>14,050,220</u>
TOTAL EQUITY AND LIABILITIES		<u><u>129,485,304</u></u>	<u><u>102,399,660</u></u>

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

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

(in €, except for share data)	Note	Shares outstanding	Issued capital	Share premium	Other capital reserves	Accumulated deficit	Other compo- nents of equity	Total equity
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	10	14,059,252	1,687,110	54,796,819	—	—	—	56,483,929
Transaction costs	10	—	—	(3,360,626)	—	—	—	(3,360,626)
Equity-settled share-based payments	11	—	—	—	2,961,491	—	—	2,961,491
Share options exercised	11	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
Balance as of January 1, 2022		44,203,763	5,304,452	280,310,744	30,591,209	(213,975,679)	3,050,271	105,280,996
Loss for the period		—	—	—	—	(21,458,325)	—	(21,458,325)
Exchange differences on translation of foreign currency		—	—	—	—	—	10,035,949	10,035,949
Total comprehensive loss		—	—	—	—	(21,458,325)	10,035,949	(11,422,376)
Equity-settled share-based payments	11	—	—	—	5,581,021	—	—	5,581,021
Balance as of September 30, 2022*		44,203,763	5,304,452	280,310,744	36,172,229	(235,434,004)	13,086,220	99,439,640

*unaudited

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

	Note	For the nine months ended September 30, 2023 (unaudited)	2022 (unaudited)
(in €)			
Operating activities			
Loss for the period		(26,737,373)	(21,458,325)
Adjustments for:			
Depreciation & amortization of property and equipment, right-of-use assets and intangible assets		432,248	448,323
Net finance income	5	(4,864,488)	(3,080,904)
Share-based payment expense	11	2,961,491	5,581,021
Net foreign exchange differences	5	(82,574)	189,088
Changes in:			
Financial assets from government grants	8	(431,246)	(5,954,754)
Other assets		4,468,239	3,087,177
Employee benefits		(26,893)	(221,982)
Other liabilities		2,893,461	5,061
Liabilities from government grants received	8	(6,209,266)	(6,849,415)
Trade and other payables		1,011,662	(1,135,817)
Inventories	6	(1,639,490)	—
Interest received	5	1,302,391	903,647
Interest paid	5	(15,773)	(38,978)
Net cash used in operating activities		<u>(26,937,611)</u>	<u>(28,525,857)</u>
Investing activities			
Purchase of intangible assets, property and equipment		(45,942)	(17,908)
Purchase of current financial assets		(91,590,134)	(47,031,216)
Proceeds from the maturity of financial assets		71,113,455	64,600,049
Net cash from/(used in) investing activities		<u>(20,522,621)</u>	<u>17,550,925</u>
Financing activities			
Proceeds from issuance of common shares	10	56,483,929	—
Transaction costs from issuance of common shares	10	(3,360,626)	—
Proceeds from exercise of share options	11	236,943	—
Repayment of lease liabilities		(279,075)	(273,092)
Net cash from/(used in) financing activities		<u>53,081,170</u>	<u>(273,092)</u>
Net increase/(decrease) in cash and cash equivalents		5,620,938	(11,248,024)
Effect of exchange rate changes on cash and cash equivalents		(190,686)	2,976,033
Cash and cash equivalents at beginning of period		16,265,355	26,249,995
Cash and cash equivalents at end of period	9	<u>21,695,607</u>	<u>17,978,003</u>

The accompanying notes are an integral part of these 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 focused 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 (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 Company and its wholly-owned subsidiaries, InflaRx GmbH, Jena, Germany, and InflaRx Pharmaceuticals Inc., Ann Arbor, Michigan, United States (together referred to as the "Group").

b) Basis of preparation

These interim condensed consolidated financial statements for the three- and nine-month reporting periods ended September 30, 2023, and 2022 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, 2022 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 October 31, 2023.

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. Effective January 1, 2023, the functional currency of InflaRx N.V. changed from the U.S. dollar to the euro due to a change in the Company's operational function and, in turn, a change in the primary currency of its underlying transactions. This change in functional currency has been accounted for prospectively.

All financial information presented in euros have been rounded. 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, 2022, except for the adoption of new standards effective as of January 1, 2023, 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.

Accounting policies for the following IFRS standards have been applied starting in Q2 2023 for the first time, as no transactions in the scope of these IFRS standards had been previously recognized.

- IAS 2 Inventories

According to IAS 2, inventories are stated at the lower amount of their cost or at their net realizable value. Cost comprises direct materials and, where applicable, direct labor costs and those overhead costs that have been incurred in bringing the inventories to their present location and condition. Cost is calculated using the weighted average cost method. Net realizable value represents the estimated selling price less all estimated costs of completion and costs to be incurred in marketing, selling and distribution. Recognizing inventories at net realizable value includes write down of inventories expected to be unsellable, not meeting quality standards or at-risk of shelf-life expiry prior to sale.

- IFRS 15 Revenue from contracts with customers

At present, the Company exclusively uses distributors to sell its product to end customers (e.g., hospitals). The end customers (e.g. hospitals) have been determined to be the customer in these sales arrangements. Revenue is therefore recognized when a performance obligation has been satisfied through the transfer of a promised good or service to a customer, that is, when the customer obtains control of that asset and is measured considering estimated return liabilities and expected rebates or cash discounts. The following amendments were adopted effective January 1, 2023, and do not have a material impact on the consolidated financial statements of the Group:

- IFRS 17 Insurance Contracts
- Amendments to IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors: Definition of Accounting Estimates
- Amendments to IAS 12 Deferred Tax related to Assets and Liabilities arising from a Single Transaction
- Amendments to IAS 1 and IFRS Practice Statement 2 - Disclosure of Accounting Policies -

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 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 21 Effects of Changes in Foreign Exchange Rates: Lack of exchangeability

2. Revenues

	For the three months ended September 30,		For the nine months ended September 30	
	2023 (unaudited)	2022 (unaudited)	2023 (unaudited)	2022 (unaudited)
	(in €)			
Revenues	60,803	—	60,803	—
Total	<u>60,803</u>	<u>—</u>	<u>60,803</u>	<u>—</u>

In June 2023, the Group began the commercialization of Gohibic (vilobelimab) in the United States. In connection with the start of the commercialization, the Group entered into agreements with certain subsidiaries of Cencora Inc. (formerly known as AmerisourceBergen Corp.) to act as the Group's U.S. distributor and make Gohibic (vilobelimab) available for order by U.S. hospital customers. Cencora provides cold storage, cold-chain distribution services, inventory management and secondary labeling/packaging, among other services.

In Q3 2023, the Company realized revenues from the product sales for the first time since its inception. Revenues reported are sales to end customers (hospitals). Sales to distributors do not constitute revenue for the Company under IFRS 15.

3. Cost of Sales

	For the three months ended June 30,		For the nine months ended June 30	
	2023 (unaudited)	2022 (unaudited)	2023 (unaudited)	2022 (unaudited)
	(in €)			
Cost of Sales	(255,116)	—	(255,116)	—
Total	<u>(255,116)</u>	<u>—</u>	<u>(255,116)</u>	<u>—</u>

Cost of sales recognized during the three and nine months ended September 30, 2023, are related to Gohibic (vilobelimab) revenues in the United States. Costs of sales for products sold in these periods do not include costs of materials, as the associated costs of these materials were incurred in prior periods, before granting of an EUA for Gohibic (vilobelimab). These materials were recorded as research and development expenses in the period they were incurred.

The cost of sales during the three and nine month ended September 30, 2023 mainly consists of write-downs of inventories that will expire prior to their expected sale. Early product batches capitalized in inventory were produced with material which had been manufactured in previous years.

4. Other income

	For the three months ended September 30,		For the nine months ended September 30	
	2023 (unaudited)	2022 (unaudited)	2023 (unaudited)	2022 (unaudited)
	(in €)			
Other income				
Income from government grants	772,604	2,019,684	13,382,393	16,435,051
Other	36,262	10,722	55,570	38,489
Total	<u>808,866</u>	<u>2,030,406</u>	<u>13,437,963</u>	<u>16,473,540</u>

Other income for the three months ended September 30, 2023 amounted to €0.8 million (PY: €2.0 million) and for the nine months ended September 30, 2023 amounted to €13.4 million (PY: €16.5 million), which is primarily attributable to income recognized from grant payments received from the German federal government for the development of vilobelimab as treatment for critically ill COVID patients, including expenses related to clinical development and manufacturing process development. The decrease in income from government grants is primarily due to the end of the grant period on June 30, 2023.

5. Net financial result

	For the three months ended September 30,		For the nine months ended September 30	
	2023 (unaudited)	2022 (unaudited)	2023 (unaudited)	2022 (unaudited)
	(in €)			
Interest income	1,189,826	199,758	2,732,873	310,121
Interest expenses	(327)	(878)	(1,108)	(22,980)
Interest on lease liabilities	(4,570)	(5,967)	(14,368)	(16,396)
Finance Result	<u>1,184,929</u>	<u>192,913</u>	<u>2,717,397</u>	<u>270,745</u>
Foreign exchange income	4,007,995	1,634,121	6,389,514	5,691,750
Foreign exchange expense	(1,715,057)	(751,751)	(4,466,240)	(2,517,867)
Foreign exchange result	<u>2,292,938</u>	<u>882,370</u>	<u>1,923,274</u>	<u>3,173,883</u>
Other financial result	221,577	(402,724)	223,818	(363,724)
Net financial result	<u>3,699,444</u>	<u>672,559</u>	<u>4,864,488</u>	<u>3,080,904</u>

Net financial result increased by €3.0 million to a gain of €3.7 million for the three months ended September 30, 2023 from €0.7 million for the three months ended September 30, 2022. This increase is mainly attributable to an increase of interest income on marketable securities by €1.0 and an increase of foreign exchange gains of €2.4 million. Other financial result consists of an adjustment for expected credit losses on marketable securities.

Net financial result increased by €1.8 million to €4.9 million for the nine months ended September 30, 2023, from €3.1 million for the nine months ended September 30, 2022. This increase was mainly attributable to higher interest income which increased by €2.4 million, partly compensated by the decrease in foreign exchange result of €1.2 million.

6. Inventory

	As of September 30, 2023 (unaudited)	As of December 31, 2022
	(in €)	
Raw material and supplies	1,115,243	—
Unfinished goods	261,124	—
Finished goods	263,123	—
Total	<u>1,639,490</u>	<u>—</u>

The Company initially valued inventories at manufacturing cost in its consolidated statement of financial position. The manufacturing cost for the initial commercial product batches do not include costs relating to production of active ingredient or formulated product before the granting of an EUA for Gohibic (vilobelimab), since those were expensed in previous reporting periods as research and development expenses in the period incurred.

Subsequent measurement of inventories reflect their realizable value. In the three and nine months ended September 30, 2023, inventory write-downs of €0.3 million were recognized due to the expected expiry of their shelf-life and are included in cost of sales.

7. Other assets

	As of September 30, 2023 (unaudited)	As of December 31, 2022
	(in €)	
Non-current other assets		
Prepaid expenses	270,526	308,066
Total	270,526	308,066
Current other assets		
Prepayments on research & development projects	3,414,177	9,776,505
Prepayments on commercial production	3,636,868	—
Prepaid expenses	703,898	1,841,935
Others	25,052	2,552,071
Total	7,779,995	14,170,511
Total other assets	8,050,521	14,478,577

As of September 30, 2023, prepayments on research & development projects amounted to €3.4 million compared to €9.8 million as of December 31, 2022, and consist of prepayments on clinical and R&D material production contracts. The decrease in prepayments results from manufacturing development activities, which were partly completed in the nine months ended September 30, 2023.

As of September 30, 2023, prepayments on commercial production amounted to €3.6 million and consist of prepayments to our Contract Manufacturing Organization for the manufacturing of additional commercial material. These prepayments are not refundable.

Prepaid expenses mainly consist of prepaid clinical trial and transportation insurance expense.

The reduction of the amounts in the category “others” primarily relate to credit notes issued by contract research organizations to the Company, which were outstanding as of December 31, 2022 and received in 2023.

8. 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, 2023 and December 31, 2022:

	As of September 30, 2023 (unaudited)	As of December 31, 2022
	(in €)	
Financial assets at amortized cost		
Non-current financial assets		
Financial assets from government grants	1,164,217	732,971
Other current financial assets	91,857,945	64,791,088
Financial liabilities at amortized cost		
Liabilities from government grants	—	6,209,266
Trade and other payables	5,999,200	4,987,538

As of September 30, 2023, the fair value of current and non-current financial assets (primarily quoted debt securities) amounted to €91.5 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, 2023, financial assets from government grants amounted to €1.2 million. The grant period expired on June 30, 2023. The amount of €1.2 million represents the Company’s current judgement before reconciliation of remaining activities and outstanding payments. The amount is expected to be received before the end of the year 2023 as a final payment to the Company once all residual activities under the grant have been completed, all our reporting obligations including reports to government agencies have been submitted and all formal aspects for the completion of the grant are fulfilled.

As of September 30, 2023, due to the expiration of the grant period, there were no liabilities from government grants.

9. Other liabilities

	As of September 30, 2023 (unaudited)	As of December 31, 2022
	(in €)	
Liabilities from commercial partner	2,875,722	—
Miscellaneous other liabilities	171,924	147,608
Total	3,047,646	147,608

In September 2023, the Company received €2.9 million for Gohibic (vilobelimab) product shipments from a subsidiary of Cencora which acts as a U.S. distributor for the company. The majority of this product will remain in stock at the distributor awaiting sale to customers. In accordance with IFRS 15, InflaRx recognizes revenue when control of the products is transferred to the end customer (hospital). Therefore, InflaRx recognized a liability in liabilities from commercial partners in the amount of €2.9 million. For each unit sold to the end customer, this liability is reduced with a corresponding amount recognized in revenue.

10. Cash and cash equivalents

	As of September 30, 2023 (unaudited)	As of December 31, 2022
	(in €)	
Short-term deposits		
Deposits held in U.S. dollars	3,637,579	3,422
Deposits held in euros	4,450,000	—
Total	8,087,579	3,422
Cash at banks		
Cash held in U.S. dollars	10,030,927	8,645,014
Cash held in euros	3,577,101	7,616,918
Total	13,608,027	16,261,932
Total cash and cash equivalents	21,695,606	6,265,354

11. Equity

In April 2023, the Company issued 3,235,723 ordinary shares under its at-the-market (ATM) program resulting in \$15.7 million (or €14.4 million) in net proceeds. The ATM program expired in July 2023 and no more shares are issuable under this program.

Through an underwritten public offering in April 2023, the Company sold and issued an aggregate of 10,823,529 ordinary shares, of which 1,411,764 were sold pursuant to the exercise of an overallotment option by the underwriters. The ordinary shares were sold at a price of \$4.25 per share and have a nominal value of €0.12 per share. Proceeds of this offering after deducting €2.5 million (\$2.8 million) in underwriting discounts amounted to €39.1 million (\$43.2 million). Other offering expenses amounted to €0.4 million, resulting in a total of €38.7 million in net proceeds from this offering.

12. 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:

	2023	2022
Number of share options		
Outstanding as of January 1,	148,433	148,433
Exercised during the nine months ended September 30	—	—
Outstanding as of September 30, thereof vested	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	2023	2022
Outstanding as of January 1,	888,632	888,632
Exercised during the nine months ended September 30	—	—
Outstanding as of September 30, thereof vested	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, 2023 under the 2017 LTIP was as follows:

Number of share options	2023	2022
Total number of options outstanding as of January 1,	4,985,523	3,170,046
Granted during the nine months ended September 30,	1,735,750	1,561,666
Exercised during the nine months ended September 30,	(105,327)	—
Forfeited during the nine months ended September 30,	(26,000)	(136,259)
Outstanding as of September 30, thereof vested	6,589,946	4,595,453
	5,170,321	3,762,203

The number of share options granted during the nine months ended September 30, 2023 under the 2017 LTIP was as follows:

Share options granted 2023	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 24	1,454,250	\$ 2.11	0.9008	€ 1.90	\$ 2.37	1.35	5.30	3.571%
January 24	52,500	\$ 2.13	0.9008	€ 1.92	\$ 2.37	1.35	5.50	3.565%
May 31	60,500	\$ 3.61	0.9361	€ 3.38	\$ 4.19	1.35	4.50	3.820%
July 7	57,000	\$ 3.59	0.9184	€ 3.30	\$ 3.89	1.46	5.50	4.320%
July 7	100,000	\$ 3.64	0.9184	€ 3.34	\$ 3.89	1.46	6.10	4.286%
July 19	4,000	\$ 3.55	0.8911	€ 3.16	\$ 3.99	1.46	5.50	4.320%
September 18	7,500	\$ 3.15	0.9378	€ 2.95	\$ 3.54	1.46	5.50	4.320%
	<u>1,735,750</u>							

Of the 1,735,750 options granted during the nine months ended September 30, 2023 (ended September 30, 2022: 1,561,666), 1,396,000 options (September 30, 2022: 1,362,500) 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, 2023, the Company has recognized €3.0 million (ended September 30, 2022: €5.6 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, 2023, 105,327 shares (ended September 30, 2022: 0) were issued upon the exercise of share options, resulting in proceeds to the Company in the amount of €98 thousand (ended September 30, 2022: 0). All share options exercised during the nine months ended September 30, 2023 were granted under the 2017 LTIP.

13. Protective foundation

According to the Articles of Association of the Company, up to 110,000,000 ordinary shares and up to 110,000,000 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 shareholders approved the right of an independent foundation under Dutch law, or protective foundation, to exercise a call option on preferred shares. Pursuant to the call option agreement, the Company shall issue an amount of preferred shares to the protective foundation, amounting to up to 100% of the Company's issued capital held by others than the protective foundation, minus one share. In order to exercise its right to such share issue, 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.

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. We believe that the call option does not represent a significant fair value based on a Level 3 valuation, since the preference shares are restricted in use and can be canceled by the Company.

During the nine months ended September 30, 2023, the Company expensed €60 thousand (2022: €45 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, 2023 and 2022, 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 2022, and the notes thereto, which appear in our Annual Report on Form 20-F for the year ended December 31, 2022 (the "Annual Report") filed with the U.S. Securities and Exchange Commission (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 focused 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.

Gohibic (vilobelimab) for the treatment of critically ill COVID-19 patients

In April 2023, we received an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (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 (IMV) or extracorporeal membrane oxygenation (ECMO). Gohibic (vilobelimab) is not FDA-approved for any indication, including for the treatment of COVID-19.

The EUA is supported by the previously announced results of the multicenter Phase III PANAMO trial. PANAMO is one of the largest 1:1 randomized, double-blind placebo-controlled trials in IMV COVID-19 patients in intensive care units. A total of 369 patients were randomly assigned to the vilobelimab treatment group (six 800 mg infusions) or the placebo group. Both groups also received standard of care, which included treatment with anticoagulants, corticosteroids like dexamethasone and other immunomodulators. The data showed that the vilobelimab treatment improved survival with a relative reduction in 28-day all-cause mortality by 23.9% compared to the placebo in the global data set. The data were published in *The Lancet Respiratory Medicine* in September 2022.

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. (Cencora, formerly known as AmerisourceBergen Corp.) 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.

As we expand our commercial efforts, we continue to enhance our commercial strategic plan, further expanding our sales force and medical affairs teams, preparing relevant promotional and medical education materials to target healthcare providers and other stakeholders, refining our medical affairs strategy to increase awareness of the EUA among the medical community, and initiating our sales efforts.

In July 2023 and subsequently in October 2023, the National Institute of Health (NIH) published and subsequently updated their guidelines for the treatment of COVID-19 patients. The NIH guidelines stipulate that there is insufficient evidence to recommend either for or against the use of vilobelimab for the treatment of critically ill COVID-19 patients. This neutral NIH guideline has negatively affected the commercial adoption of Gohibic (vilobelimab) as many healthcare providers, particularly hospitals, rely on NIH treatment guidelines when drafting their formularies and placing new orders. We believe that the NIH analysis does not take into account positive factors that the FDA considered in granting the EUA, and we are working to provide as much scientific evidence as possible to the NIH and others in the medical community with the goal of reaching concurrence of the NIH guideline committee position with the detailed published FDA review and thus reconsidering their recommendation for the treatment of critically ill COVID-19 patients with Gohibic (vilobelimab).

In July 2023, we submitted a Marketing Authorization Application (MAA) for SARS-CoV-2 induced septic acute respiratory distress syndrome (ARDS) receiving IMV or ECMO to the European Medicines Agency (EMA). In August 2023, the EMA validated the MAA. This means that the application is now under regulatory review by the European Committee for Medicinal Products for Human Use (CHMP) under the centralized procedure, which applies to all 27 member states of the European Union (EU).

To achieve full commercial scale and successfully reach the full market potential of the product 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 (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. During the meeting, we discussed different options for such a trial, including potential trial designs, patient population and trial power aspects.

We are actively evaluating and working towards next steps to enable such a trial in a broader ARDS setting and are currently exploring different funding options, including government grants as well as collaborations with third parties.

In October 2021, we announced that we received a grant of up to €43.7 million from the German Ministry of Education and Research and the German Ministry of Health to support our development of vilobelimab for the treatment of severe COVID-19 patients. Due to subsequent changes in our research and development plan and fewer costs projected within the timeframe of the grant, we were notified that the amount available to us is €41.4 million. The grant is structured as a reimbursement of 80% of certain pre-specified expenses related to the clinical development and manufacturing of vilobelimab. The grant period ended on June 30, 2023. In total, during the duration of the grant period up to the date hereof, we have received €32.7 million to support our activities regarding the development of vilobelimab as a new therapeutic agent for the treatment of critically ill COVID-19 patients and for the establishment of a commercial scale manufacturing process to ensure the ability of being able to provide such treatment to the broader population. As of the date hereof, financial assets from government grants amounted to €1.2 million. This amount represents our current judgement before reconciliation of remaining activities and outstanding payments. The amount is expected to be received before the end of the year 2023 as a final payment once all residual activities under the grant have been completed, all our reporting obligations including reports to government agencies have been submitted and all formal aspects for the completion of the grant are fulfilled.

Vilobelimab for the treatment of Pyoderma Gangrenosum

We are developing vilobelimab for the treatment of pyoderma gangraenosum (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 pustules or papules, mainly on the lower extremities, which can rapidly progress to an extremely painful enlarging ulcers. Associated symptoms include fever, malaise, weight loss and myalgia. PG has a devastating impact on a patient's life due to the severe pain and induction of significant movement impairment depending on lesions' locations. The exact prevalence of PG is not yet known, but it is estimated that up to 51,000 patients in the United States and Europe are affected by this disease.

In April 2021, we completed an open-label, multicenter Phase IIa exploratory study enrolling 19 patients with moderate to severe PG in Canada, the United States and Poland with the goal to evaluate the safety and efficacy of vilobelimab in three different doses. The reported final results of this study show a dose-dependent treatment effect, whereby in the highest dose cohort of 2,400 mg, six out of seven patients showed a clinical remission (PGA score ≤ 1) and closure of the target ulcer. The seventh patient showed a slight improvement (PGA score 4), with a decrease of the target ulcer area of over 50%. During the follow-up period, ulcers remained closed two months after treatment completion in all but one patient, and a sustained suppression of C5a was observed for up to 20 days after the last dosing. Final results from all patients were presented at the American Academy of Dermatology Association (AAD) Annual Meeting in March 2022.

With these results, vilobelimab was granted orphan drug designation for the treatment of PG by both the FDA in the United States and the EMA in Europe, as well as fast-track designation by the FDA. In January 2023, we announced details related to the design of our pivotal Phase III study with vilobelimab in ulcerative PG. The 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 medical advisors from the United States, Europe and other regions. The randomized, double-blinded controlled study will comprise an active arm of 2,400 mg of vilobelimab versus its passive arm that will receive a placebo every other week for a treatment period of 26 weeks. Both arms will be initiated with a low-dose corticosteroid treatment, which will be tapered off during the first 8 weeks of the treatment period. The study will be conducted with an adaptive trial design, providing for a planned interim analysis after enrollment of 30 patients (15 per arm). At least 48 patients and up to 90 patients will be enrolled in the trial and be treated for a period of 26 weeks. Patients dropping out of the treatment will be considered as non-responders to the treatment. The interim analysis by an independent data safety monitoring committee (blinded for the sponsor and investigators) will consider the then-observed difference in complete target ulcer closure between the two arms based on a set of predefined rules, and accordingly, the trial sample size will be continued with a 2:1 randomization in favor of vilobelimab, adapted in size, or the trial will be stopped due to futility.

We have submitted a Phase III clinical trial protocol to the FDA and initiated the preparatory activities for the study, including selection of clinical trial sites, obtaining regulatory and ethics approvals to conduct the study and expect to start the trial by enrolling patients in the United States, Europe and selected other regions in H2 2023. As of the date hereof, we have initiated several clinical sites in the United States and have already screened the first patients, as we foresee being able to start treating the first patient very soon. The total enrollment period is projected to be at least two years, depending on the trial size after potential sample size adaptation.

C5aR inhibitor INF904

We are developing INF904, an oral small-molecule drug candidate that targets the C5aR receptor. We plan on targeting complement-mediated, chronic autoimmune and inflammatory conditions for which an oral small molecule is the preferred route of administration for patients. In our investigational new drug (IND)-enabling preclinical studies we demonstrated the absence of any obvious toxicological findings even in the highest dose groups in required GLP toxicity analyses. In these preclinical studies, oral INF904 showed higher plasma exposure in animals, including non-human primates, and improved inhibitory activity in a hamster neutropenia model compared to the marketed C5aR inhibitor avacopan. Anti-inflammatory therapeutic effects in several preclinical disease models were also demonstrated by INF904. Further, in contrast to the marketed C5aR inhibitor avacopan, in vitro experiments showed that 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. We are currently conducting a Phase I single ascending dose (SAD) and multiple ascending dose (MAD) study in healthy volunteers with the goal of confirming the safety of INF904 and to establish the pharmacokinetic and pharmacodynamic profile of this development candidate.

In September 2023, we announced topline results from the SAD part of the randomized, double-blind, placebo-controlled Phase I trial of the orally administered INF904. In the SAD part of the study, INF904 demonstrated a favorable safety and tolerability profile as well as a favorable pharmacokinetic (PK) and pharmacodynamic (PD) profile. The SAD part of the Phase I first-in-human trial 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. Different drug concentrations were tested for the 60 mg dosing group. The main objectives were to assess safety and tolerability of single ascending doses under fasting conditions. Secondary endpoints included several PK parameters, and the effect of INF904 on C5a-induced neutrophil activation in blood samples from treated volunteers *ex vivo* also was explored.

Analysis of INF904 PK in subject plasma samples revealed sustained exposure to INF904 with six hours to maximum concentration (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 I 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 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.

The MAD part of the Phase 1 trial is ongoing, and we expect to present results from 24 healthy volunteers at the beginning of 2024. We are currently preparing to initiate additional required pre-clinical studies, including chronic toxicology studies, in order to enable the future Phase II clinical development of INF904 in chronic inflammatory diseases. In parallel, we are evaluating select potential indications for future development.

Vilobelimab for the treatment of cutaneous squamous cell carcinoma (cSCC)

We are also developing vilobelimab for the treatment of PD-1 / PD-L1 inhibitor resistant / refractory, locally advanced or metastatic cutaneous squamous cell carcinoma (cSCC). cSCC is the second most common skin cancer. The incidence of cSCC increases with cumulative sun exposure and age, and individuals with fair skin and hair are more often affected. The potential for local recurrence or metastasis of cSCC varies with the pathologic variant and localization of the primary lesion, and the risk for metastasis in cSCC is approximately 2%-5%. Advanced cSCC 10-year survival rates are less than 20% with regional lymph node involvement and less than 10% with distant metastases.

In the study, which was initiated in April 2021, we recruited patients in two independent arms, vilobelimab alone (Arm A) and vilobelimab in combination with pembrolizumab (Arm B). The main objectives of the trial are to assess the safety and antitumor activity of vilobelimab monotherapy, to determine the maximum tolerated or recommended dose in combination with pembrolizumab, as well as to evaluate the safety and antitumor activity in the combination treatment arm in cSCC patients.

As of the date hereof, 10 patients were enrolled in Arm A, in which they received a run-in dose of 800 mg of vilobelimab on days 1, 4, 8 and 15, followed by a dose of 1,600 mg vilobelimab every two weeks starting on day 22. An interim analysis in Arm A of the 10 patients was conducted in July 2023 and the treatment responses in Arm A were evaluated. The interim efficacy analysis showed that one patient had a complete response (CR) and one patient continued with stable disease according to the protocol and as per “Response Evaluation Criteria In Solid Tumors” (RECIST). The patient with the CR is still on treatment.

In Arm B, as of the date hereof, three patients have been treated in the first dosing cohort of the study (400 mg intravenous infusions of vilobelimab on days 1, 4, 8 and 15 and 800 mg from day 22 and every two weeks thereafter, in addition to 400 mg of pembrolizumab on day 8 and every six weeks thereafter). Six patients were treated in the next higher (second) dose cohort (600 mg intravenous infusions of vilobelimab on days 1, 4, 8 and 15 and 1,200 mg from day 22 and every two weeks thereafter, in addition to 400 mg of pembrolizumab on day 8 and every six weeks thereafter). In the third dosing cohort, six patients were treated at the highest planned dose per protocol (800 mg intravenous infusions of vilobelimab on days 1, 4, 8 and 15 and 1,600 mg from day 22 and every two weeks thereafter, in addition to 400 mg of pembrolizumab on day 8 and every six weeks thereafter). Each dose escalation was done per recommendation and after review of the safety data by an independent Steering Committee comprised of external clinical advisors. In total, as of the date hereof, 15 patients were enrolled in Arm B (3+6+6 in the three dosing cohorts). Before proceeding with the second stage of the study in Arm B, the interim efficacy data as assessed in recent discussions with our panel of experts showed one patient with partial response from the second cohort, and one patient with partial response from the third cohort, who are still in treatment.

The treatment responses in the single dose Arm A and the initially observed results in the combination Arm B of the study are encouraging. However, in view of the recent emergence of new alternative treatments for cSCC and the recommendation by our U.S. and international experts to change course and to study additional patients with a higher dose of vilobelimab as monotherapy in a larger cohort, we have decided to cease the development in cSCC for the time being. While we remain interested in further understanding the potential monotherapeutic effect of vilobelimab in this oncology indication, further research would require substantial resources and significantly extend the timeline of the ongoing clinical program. Therefore, we decided to prioritize our efforts and to reallocate our resources towards the development of our orally available C5aR inhibitor INF904.

Patients who are currently in treatment will be treated for up to 24 months according to the protocol. However, we will not enroll any new patients in the study and we will close clinical sites in which no patients are being treated. Our decision to wind down this clinical study does not preclude us from considering the development of vilobelimab or INF904 in this or similar oncological indications in the future.

Anti-C5a antibody IFX002

To expand the breadth of our anti-C5a technology, we are also developing IFX002 for the treatment of chronic inflammatory indications. IFX002 shares the same mechanism of action as vilobelimab, blocking C5a with high specificity, but is designed to have a dosing regimen that may be more suitable for chronic therapy through a potentially less frequent necessity to administer the product. IFX002 is currently in pre-clinical development.

Financial highlights

As of September 30, 2023, we had cash and cash equivalents of €21.7 million and marketable securities of €91.3 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 expand the commercialization of Gohibic (vilobelimab) in the United States by investing in our commercial infrastructure and seek partners to support commercialization of our other products;
- 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;
- invest in our working capital;
- actively seek to identify additional research programs and additional product candidates;
- pursue full BLA and centralized MAA approvals for Gohibic (vilobelimab), especially after the EMA's validation of our MAA in August 2023;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials, if any;
- establish sales, marketing, distribution and other commercial infrastructure in the future to commercialize various products for which we may obtain marketing approval, if any;
- require further scale-up, transfer, validation or other activities for our manufacturing process for vilobelimab, including the manufacturing of larger quantities for further commercial needs and for clinical development;
- 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, administrative, clinical, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development 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. Historically, we had no products or services from which we could generate revenues. In April 2023, the FDA issued the EUA for the use of Gohibic (vilobelimab) for the treatment of COVID-19 in hospitalized adults. Gohibic (vilobelimab) is not yet FDA-approved for any indication, including for the treatment of COVID-19. Subsequently to obtaining the EUA in this indication, in June 2023 we launched Gohibic (vilobelimab) into the U.S. market by making it available through the ordering channels for hospitals. In Q3 2023, revenues from Gohibic (vilobelimab) were €61 thousand. As long as the product is authorized under the EUA, we may continue to generate revenues through sales of Gohibic (vilobelimab) to U.S. hospitals.

Successful commercialization of our products and product candidates will require achievement of key milestones, including successfully completing clinical trials; obtaining marketing approval for these product candidates; manufacturing, marketing and selling those products for which we, or any of our future collaborators, may obtain marketing approval; satisfying any post-marketing requirements of the FDA and other regulatory agencies, the inclusion of our products in hospital formularies, 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.

Our expenses in any quarter may not be indicative of our expenses in future periods, and in particular we expect that our expenses, and therefore our net losses, could vary depending on the going-forward strategy relating to the full regulatory approval of vilobelimab for the treatment of critically ill COVID-19 patients, our development plans in PG and additional indications, as well as for other product candidates like INF904 or any potential addition of a technology platform or assets.

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.

Research and Development Expenses

Research and development expenses have consisted principally of:

- expenses incurred under agreements with contract research organizations, or CROs, and contract manufacturing organizations, or CMOs, 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 expenses based upon employees' roles within the organization; and
- professional fees for lawyers related to the protection and maintenance of our intellectual property and consulting fees for the support of our regulatory, medical affairs and related activities.

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

- Vilobelimab. We expect our expenses associated with vilobelimab to increase in 2023 compared to 2022, as we are initiating the Phase III clinical study in PG. In addition, although we are winding down our Phase II clinical program in cSCC, we expect to continue incurring expenses in connection with such program until we complete the winding down process. We also incurred expenses with the submission of an EUA with the FDA and a MAA with the EMA for the treatment of adult patients with SARS-CoV-2 induced septic acute respiratory distress syndrome (ARDS) receiving IMV or ECMO and expect to further incur expenses in conjunction with filing market authorizations for vilobelimab in the United States and elsewhere, including expenses to obtain full BLA and MAA approval for Gohibic (vilobelimab). We might also potentially 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 establishing a commercial scale production process for vilobelimab.

- INF904. We are also developing INF904, a product candidate that targets the C5aR receptor. We have been conducting a Phase I single and multiple ascending dose clinical study since November 2022 and expect to incur additional costs by advancing the development of INF904. We plan to study INF904 in complement-mediated, chronic autoimmune and inflammatory conditions for which an orally administered low molecular weight compound might have advantages or is needed for patients and for which oral delivery is the medically preferred route of administration.
- IFX002. We are also 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 pharmacokinetic properties compared to vilobelimab and is currently in preclinical 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 2022, we incurred €37.5 million in research and development expenses. For the nine months ended September 30, 2023 and 2022, we incurred research and development expenses of €33.0 million and €29.2 million, respectively. The increase in our research and development expenses was attributable to 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. These expenses 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.

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 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 and we are increasing commercial operations in conjunction with the recently granted EUA for Gohibic (vilobelimab); this will not only result in higher sales and marketing costs as already reported, but we believe it will also result in a future increase in general and administrative costs. There will also be additional costs associated with operating as a public company. It is expected that the costs of commercialization will also result in additional personnel, additional consulting costs in connection with the expansion of our ERP system and internal and external reporting. Public company-related costs relate primarily to additional personnel, additional professional and legal fees, audit fees, directors’ and officers’ liability insurance premiums and costs associated with investor relations.

In 2022, we incurred €14.9 million in general and administrative expenses. For the nine months ended September 30, 2023 and 2022, we incurred general and administrative expenses of €10.0 million and €11.8million, 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 own personnel and in-house activities or through commissioning third parties to assist in different aspects of commercializing our products.

We expect that our sales and marketing expenses will further increase in the future as our business expands and we are increasing commercial operations in conjunction with the recently granted EUA for Gohibic (vilobelimab). In the nine-months ended September 30, 2023, we reported marketing and sales expenses for the first time. These expenses amounted to €1.8 million in the nine-months ended September 30, 2023.

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, 2023 and 2022

	three months ended September 30,		
	2023	2022	Change
	(in €)		
Revenues	60,803	—	60,803
Cost of Sales	(255,116)	—	(255,116)
Gross profit	(194,313)	—	(194,313)
Operating expenses			
Sales and marketing expenses	(1,562,473)	—	(1,562,473)
Research and development expenses	(7,305,541)	(7,537,350)	231,809
General and administrative expenses	(2,897,732)	(3,087,285)	189,553
Total operating expenses	(11,765,746)	(10,624,636)	(1,141,110)
Other income	808,866	2,030,406	(1,221,540)
Other expenses	339	—	339
Operating result	(11,150,854)	8,594,230	(19,745,084)
Finance income	1,189,826	199,758	990,068
Finance expenses	(4,897)	(6,845)	1,948
Foreign exchange result	2,292,938	882,370	1,410,568
Other financial result	221,577	(402,724)	624,301
Income (loss) for the period	(7,451,410)	(7,921,671)	470,261
Exchange differences on translation of foreign currency	73,574	4,317,134	(4,243,560)
Total comprehensive income (loss)	(7,377,836)	(3,604,538)	(3,773,298)

Revenues

	three months ended September 30,		
	2023	2022	Change
	(in €)		
Revenues	60,803	—	60,803
Total	60,803	—	60,803

In June 2023, we began the commercialization of Gohibic (vilobelimab) in the United States. In connection with the start of the commercialization, we entered into agreements with certain subsidiaries of Cencora to act as our U.S. distributor and make Gohibic (vilobelimab) available for order by U.S. hospital customers. Cencora provides cold storage, cold-chain distribution services, inventory management and secondary labeling/packaging, among other services.

In Q3 2023, we realized revenues from the product sales for the first time since its inception. Revenues reported are actual sales to end customers (hospitals). Sales to distributors do not constitute revenue for the Company under IFRS 15.

Cost of sales

	three months ended September 30,		
	2023	2022	Change
	(in €)		
Cost of Sales	(255,116)	—	(255,116)
Total	<u>(255,116)</u>	<u>—</u>	<u>(255,116)</u>

Cost of sales recognized during the three months ended September 30, 2023, are related to Gohibic (vilobelimab) revenues in the United States. Costs of sales for products sold in this period does not include costs of materials, as the associated costs of these materials were incurred in prior periods, before granting of an EUA for Gohibic (vilobelimab). These materials were recorded as research and development expenses in the period they were incurred.

The cost of sales during the three months ended September 30, 2023 mainly consists of write-downs of inventories that will expire prior to their expected sale. Early product batches, capitalized in inventory, were produced with material which had been manufactured in previous years. The inventory write-down for the three months ended September 30, 2023 amounted to €0.3 million, mainly attributable to shelf-life expiration within the next nine months in the amount of €0.3 million.

Sales and marketing expenses

	three months ended September 30,		
	2023	2022	Change
	(in €)		
Third-party expenses	974,500	—	974,500
Personnel expenses	500,010	—	500,010
Legal and consulting fees	81,355	—	81,355
Other expenses	6,608	—	6,608
Total sales and marketing expenses	<u>1,562,473</u>	<u>—</u>	<u>1,562,473</u>

In the three-months ended September 30, 2023, we incurred €1.6 million of sales and marketing expenses. These expenses are primarily comprised of €0.5 million in personnel costs and €1.0 million in external services for distribution.

Research and development expenses

	three months ended September 30,		
	2023	2022	Change
	(in €)		
Third-party expenses	4,224,875	5,164,843	(939,968)
Personnel expenses	1,780,148	1,599,452	180,696
Legal and consulting fees	372,788	668,408	(295,620)
Other expenses	927,730	104,646	823,084
Total research and development expenses	<u>7,305,541</u>	<u>7,537,350</u>	<u>(231,809)</u>

We use our employee and infrastructure resources across multiple research and development programs directed toward developing vilobelimab in different indications and in our pre-clinical programs. We manage certain activities such as contract research and manufacturing of vilobelimab and our discovery programs through our third-party vendors. Research and development expenses incurred for the three months ended September 30, 2023 decreased by €0.2 million compared to the three months ended September 30, 2022.

General and administrative expenses

	three months ended September 30,		
	2023	2022	Change
	(in €)		
Personnel expenses	1,206,958	1,413,560	(206,602)
Legal, consulting and audit fees	751,086	533,648	217,438
Other expenses	939,688	1,140,078	(200,390)
Total general and administrative expense	<u>2,897,732</u>	<u>3,087,286</u>	<u>(189,554)</u>

General and administrative expenses decreased by €(0.2) million to €2.9 million for the three months ended September 30, 2023, from €3.1 million for the three months ended September 30, 2022. This decrease is attributable to lower expenses associated with equity-settled share-based compensation recognized in personnel expenses of €0.2 million.

Legal, consulting and audit fees increased by €0.2 million, which was offset by a decrease in other general and administrative expenses of €0.2 million.

Other income

	three months ended September 30,		
	2023	2022	Change
	(in €)		
Income from government grants	772,604	2,019,684	(1,247,080)
Other	36,262	10,722	25,540
Total other income	<u>808,866</u>	<u>2,030,406</u>	<u>(1,221,540)</u>

Other income decreased by €1.2 million to €0.8 million for the three months ended September 30, 2023, from €2.0 million for the three months ended September 30, 2022 and is primarily attributable to income recognized from the grant payments received from the German federal government for the development of Gohibic (vilobelimab) as treatment for critically ill COVID-19 patients. The decrease in income from government grants is primarily due to the end of the grant period on June 30, 2023.

Net financial result

	three months ended September 30,		
	2023	2022	Change
	(in €)		
Interest income	1,189,826	199,758	990,068
Interest expenses	(327)	(878)	551
Interest on lease liabilities	(4,570)	(5,967)	1,397
Finance result	<u>1,184,929</u>	<u>192,913</u>	<u>992,016</u>
Foreign exchange income	4,007,995	1,634,121	2,373,874
Foreign exchange expense	(1,715,057)	(751,751)	(963,306)
Foreign exchange result	<u>2,292,938</u>	<u>882,370</u>	<u>1,410,568</u>
Other financial result	<u>221,577</u>	<u>(402,724)</u>	<u>624,301</u>
Net financial result	<u>3,699,444</u>	<u>672,559</u>	<u>3,026,885</u>

Net financial result increased by €3.0 million to a gain of €3.7 million for the three months ended September 30, 2023 from €0.7 million for the three months ended September 30, 2022. This increase is mainly attributable to an increase of interest income on marketable securities by €1.0 million and an increase of foreign exchange gains of €2.4 million. Other financial result consists of an adjustment for expected credit losses on marketable securities.

2. Comparison of the nine months ended September 30, 2023 and 2022

	nine months ended September 30,		
	2023	2022	Change
	(in €)		
Revenue	60,803	—	60,803
Cost of Sales	(255,116)	—	(255,116)
Gross profit	(194,313)	—	(194,313)
Operating expenses			
Sales and marketing expenses	(1,838,524)	—	(1,838,524)
Research and development expenses	(32,957,044)	(29,190,231)	(3,766,813)
General and administrative expenses	(10,047,091)	(11,821,694)	1,774,603
Total operating expenses	(44,842,659)	(41,011,925)	(3,830,734)
Other income	13,437,963	16,473,540	(3,035,577)
Other expenses	(2,851)	(844)	(2,007)
Operating result	(31,601,861)	(24,539,229)	(7,062,632)
Finance income	2,732,873	310,121	2,422,752
Finance expenses	(15,476)	(39,376)	23,900
Foreign exchange result	1,923,274	3,173,883	(1,250,609)
Other financial result	223,818	(363,724)	587,542
Income (loss) for the period	(26,737,373)	(21,458,325)	(5,279,048)
Exchange differences on translation of foreign currency	56,459	10,035,949	(9,979,490)
Total comprehensive income (Loss)	(26,680,914)	(11,422,376)	(15,258,538)

Revenue

	nine months ended September 30,		
	2023	2022	Change
	(in €)		
Revenues	60,803	—	60,803
Total	60,803	—	60,803

In June 2023, we began the commercialization of Gohibic (vilobelimab) in the United States. In connection with the start of the commercialization, we entered into agreements with certain subsidiaries of Cencora to act as our U.S. distributor and make Gohibic (vilobelimab) available for order by U.S. hospital customers. Cencora provides cold storage, cold-chain distribution services, inventory management and secondary labeling/packaging, among other services.

In Q3 2023, we realized revenues from the product sales for the first time since its inception. Revenues reported are actual sales to end customers (hospitals). Sales to distributors do not constitute revenue for the Company under IFRS 15.

Cost of sales

	nine months ended September 30,		
	2023	2022	Change
	(in €)		
Cost of Sales	255,116	—	(255,116)
Total	(255,116)	—	255,116

Cost of sales recognized during the nine months ended September 30, 2023, are related to Gohibic (vilobelimab) revenues in the United States. Costs of sales for products sold in this period does not include costs of materials, as the associated costs of these materials were incurred in prior periods, before granting of an EUA for Gohibic (vilobelimab). These materials were recorded as research and development expenses in the period they were incurred.

The cost of sales during the nine months ended September 30, 2023 mainly consists of write-downs of inventories that will expire prior to their expected sale. Early product batches, capitalized in inventory, were produced with material which had been manufactured in previous years. The inventory write-down for the nine months ended September 30, 2023 amounted to €0.3 million, mainly attributable to shelf-life expiration within the next nine months in the amount of €0.3 million.

Sales and marketing expenses

	nine months ended September 30,		
	2023	2022	Change
	(in €)		
Third-party expenses	1,099,430	—	1,099,430
Personnel expenses	604,894	—	604,894
Legal and consulting fees	124,247	—	124,247
Other expenses	9,954	—	9,954
Total sales and marketing expenses	1,838,524	—	1,838,524

In the nine months ended September 30, 2023 we incurred €1.8 million of sales and marketing expenses. These expenses are mainly composed of €0.6 million personnel costs and €1.1 external services for distribution.

Research and development expenses

	nine months ended September 30,		
	2023	2022	Change
	(in €)		
Third-party expenses	24,724,877	21,947,799	2,777,078
Personnel expenses	5,190,156	5,825,051	(634,895)
Legal and consulting fees	1,459,954	1,139,769	320,185
Other expenses	1,582,057	277,613	1,304,444
Total research and development expenses	32,957,044	29,190,231	3,766,813

We use our employee and infrastructure resources across multiple research and development programs directed toward developing vilobelimab in different indications and in our pre-clinical programs. We manage certain activities such as contract research and manufacturing of vilobelimab and our discovery programs through our third-party vendors. Research and development expenses incurred for the nine months ended September 30, 2023 increased by €3.7 million compared to the nine months ended September 30, 2022.

General and administrative expenses

	nine months ended September 30,		
	2023	2022	Change
	(in €)		
Personnel expenses	4,199,908	5,943,286	(1,743,378)
Legal, consulting and audit fees	2,822,519	2,445,355	377,164
Other expenses	3,024,665	3,433,052	(408,387)
Total general and administrative expense	10,047,091	11,821,694	(1,774,603)

General and administrative expenses decreased by €1.8 million to €10.0 million for the nine months ended September 30, 2023, from €11.8 million for the nine months ended September 30, 2022. This decrease is primarily attributable to a decrease in expenses associated with equity-settled share-based compensation recognized in personnel expenses.

Other income

	nine months ended September 30,		
	2023	2022	Change
	(in €)		
Income from government grants	13,382,393	16,435,051	(3,052,658)
Other	55,570	38,489	17,081
Total other income	13,437,963	16,473,540	(3,035,577)

Other income decreased by €3.0 million to €13.4 million for the nine months ended September 30, 2023, from €16.5 million for the nine months ended September 30, 2022 and is primarily attributable to income recognized from the grant payments received from the German federal government for the development of Gohibic (vilobelimab) in severe COVID-19 cases, including our expenses related to clinical development and manufacturing process development. The decrease in income from government grants is primarily due to the end of the grant period on June 30, 2023.

Net financial result

	nine months ended September 30,		
	2023	2022	Change
	(in €)		
Interest income	2,732,873	310,121	2,422,752
Interest expenses	(1,108)	(22,980)	21,872
Interest on lease liabilities	(14,368)	(16,396)	2,028
Finance Result	2,717,397	270,745	2,446,652
Foreign exchange income	6,389,514	5,691,750	697,764
Foreign exchange expense	(4,466,240)	(2,517,867)	(1,948,373)
Foreign exchange result	1,923,274	3,173,883	(1,250,609)
Other financial result	223,818	(363,724)	587,542
Net financial result	4,864,488	3,080,904	1,783,584

Net financial result increased by €1.8 million to €4.9 million for the nine months ended September 30, 2023, from €3.1 million for the nine months ended September 30, 2022. This increase was mainly attributable to higher interest income which increased by €2.4 million, partly offset by the decrease in foreign exchange result of €1.2 million.

Liquidity and capital resources

Since inception, we have incurred significant operating losses. For the nine months ended September 30, 2023, we incurred a net loss of €26.7 million. To date, we have financed our operations primarily through the sale of our securities. As of September 30, 2023, we had cash, cash equivalents in the amount of €21.7 million and financial assets in the amount of €93.3 million, comprised of marketable securities in the amount of €91.3 million and other financial assets amounting to €1.9 million, including receivables from our governmental grant. 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, 2023 and 2022:

	nine months ended September 30, 2023	2022
	(in €)	
Net cash used in operating activities	(26,937,611)	(28,525,857)
Net cash from/ (used in) investing activities	(20,522,621)	17,550,925
Net cash from/ (used in) financing activities	53,081,170	(273,092)
Cash and cash equivalents at the beginning of the period	16,265,355	26,249,995
Exchange gains/ (losses) on cash and cash equivalents	(190,686)	2,976,033
Cash and cash equivalents at the end of the period	<u>21,695,607</u>	<u>17,978,003</u>

3. Net cash 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 decreased to €26.9 million in the nine months ended September 30, 2023, from €28.5 million in the nine months ended September 30, 2022.

4. Net cash from/used in investing activities

Net cash from investing activities decreased by €38.1 million in the nine months ended September 30, 2023, mainly due to higher investments in marketable securities in the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022.

5. Net cash from/used in financing activities

Net cash from financing activities increased by €53.4 million in the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022.

In the nine months ended September 30, 2023, we issued 3,235,723 ordinary shares under our at-the-market (ATM) program, resulting in €14.4 million in net proceeds. The ATM program expired in July 2023.

Through an underwritten public offering in April 2023, the Company sold and issued an aggregate of 10,823,529 ordinary shares, of which 1,411,764 were sold pursuant to the exercise of an overallotment option by the underwriters. The ordinary shares were sold at a price of \$4.25 per share and have a nominal value of €0.12 per share. Proceeds of this offering after deducting €2.5 million (\$2.8 million) in underwriting discounts amounted to €39.1 million (\$43.2 million). Other offering expenses amounted to €0.4 million, resulting in a total of €38.7 million in net proceeds from this offering.

Funding requirements

We expect our expenses associated with vilobelimab to increase in 2023 compared to 2022, 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 commercialization of Gohibic (vilobelimab) under the EUA for emergency use as granted by the FDA, complete developing vilobelimab in other indications, including PG in our Phase III trial, and wind down the Phase II clinical program in cSCC. In addition, we also incur expenses related to the manufacturing of clinical trial material 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 an EUA.

We also plan to advance the development of INF904 by completing the ongoing Phase I clinical program consisting of a SAD and a MAD arm. We expect to present results from the MAD part of the Phase I trial from the approximately 24 healthy volunteers at the beginning of 2024. In parallel, we are also continuing with non-clinical development activities in relation to CMC and additional non-clinical animal studies in order to prepare for the future initiation of a Phase II clinical 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 a common 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.

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, 2023, 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

As of the date of this discussion and analysis, we had entered a contractual manufacturing obligation with our contract manufacturing organization in China for the production of additional commercial products which currently amounts to €7.6 million. Apart from that, 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.

Quantitative and qualitative disclosures about market risk

During the nine months ended September 30, 2023, 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 and our quarterly report for the three months ended March 31, 2023 and June 30, 2023, included as Exhibit 99.1 and 99.2 to the Report on Form 6-K, filed on May 11, 2023 and August 10, 2023, respectively.

The manufacturing and distribution of Gohibic (vilobelimab) is subject to a number of risks that could harm our reputation, business, financial condition and operating results.

- **Manufacturing:** The manufacturing processes of Gohibic (vilobelimab) is complex. We may encounter manufacturing difficulties, including difficulties related to product storage and shelf-life. Such difficulties could result from the complexities of manufacturing product batches at a larger scale, equipment failure, availability of excipients and other product components/ingredients (including related to choice and quality of raw materials), analytical testing technology and product instability. Specifically, insufficient product stability or shelf-life of Gohibic (vilobelimab) or its components could materially limit or delay our or our collaborators’ ability to distribute and commercialize Gohibic (vilobelimab) at the current price or at all. Further, if Gohibic (vilobelimab) becomes subject to a product recall, including as the result of manufacturing errors, design/labeling defects or other deficiencies, our reputation would be adversely affected.

- Distribution: Gohibic (vilobelimab) is a “cold-chain product” that must be shipped and stored at cold temperatures. We could lose supply of Gohibic (vilobelimab) due to distribution difficulties, including generally related supply chain management (e.g., shelf-life expiration) and specifically related to shipping and storing Gohibic (vilobelimab) at cold temperatures. If so, we could incur additional manufacturing costs in order to supply required quantities to U.S. hospitals under the EUA.

Any such manufacturing and distribution difficulties may harm our reputation, business, financial condition and operating results.

Our ability to successfully commercialize and generate revenue from sales of Gohibic (vilobelimab) is subject to a number of risks that could harm our business, financial condition and operating results.

Our ability to successfully commercialize Gohibic (vilobelimab) is subject to a number of risks that could impact our business, financial condition and operating results. Specifically, our ability to generate revenue from sales of Gohibic (vilobelimab) is uncertain, including due to the market opportunity for, and interest and perception in, Gohibic (vilobelimab). In particular, given fluctuations in the number of patients developing severe symptoms from COVID-19 infections, the size of the addressable patient population and, thus, the market opportunity for Gohibic (vilobelimab) is uncertain and may shrink over time. In addition, since Gohibic (vilobelimab) has the EUA, but not FDA approval, sales of Gohibic (vilobelimab) depend on whether healthcare providers at U.S. hospitals are interested in and receptive to providing Gohibic (vilobelimab) as a treatment for COVID-19. Specifically, if Gohibic (vilobelimab) is not included in the treatment guidelines issued by medical institutions and other third-party medical/healthcare organizations, such as the National Institute of Health, or if such institutions and organizations do not recommend Gohibic (vilobelimab), hospitals may not be willing to make Gohibic (vilobelimab) available for treatment of patients. For example, the NIH guidelines stipulate that there is insufficient evidence to recommend either for or against the use of Gohibic (vilobelimab) for the treatment of critically ill COVID-19 patients. This neutral NIH guideline has negatively affected the commercial adoption of Gohibic (vilobelimab) as many healthcare providers, particularly hospitals, rely on NIH treatment guidelines when deciding to include prescription drugs to their formularies allowing for the placement of product orders by hospital staff. Ultimately, if we are unable to successfully commercialize and generate revenue from sales of Gohibic (vilobelimab), our business, financial condition and operating results could be adversely affected.

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 other than a change in the functional currency of the InflaRx N.V. entity from the U.S. dollar to the euro and other than a change in accounting policies for the IFRS standard IAS 2 and IFRS 15. Refer to our unaudited interim condensed consolidated financial statements and notes as of September 30, 2023 for additional information.

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:

- the receptiveness of Gohibic (vilobelimab) as a treatment for COVID-19 by COVID-19 patients and U.S. hospitals and related treatment recommendations by medical/healthcare institutes and other third-party organizations;

- our ability to successfully commercialize Gohibic (vilobelimab) and our other product candidates;
- our expectations regarding the size of the patient populations for, market opportunity for, estimated returns and return accruals for, coverage and reimbursement 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;
- the success of our future clinical trials for vilobelimab and any other product candidates and whether such clinical results will reflect results seen in previously conducted pre-clinical studies and clinical trials;
- the timing, progress and results of pre-clinical studies and clinical trials of our product candidates, including the MAD part of the Phase I trial with C5aR inhibitor INF904, and statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, the costs of such trials and our research and development programs generally;
- our interactions with regulators regarding the results of clinical trials and potential regulatory approval pathways, including related to our MAA submission for vilobelimab and our BLA submission for Gohibic (vilobelimab), and our ability to obtain and maintain full regulatory approval of vilobelimab or Gohibic (vilobelimab) for any indication;
- whether the FDA, the EMA, or any comparable foreign regulatory authority will accept or agree with the number, design, size, conduct or implementation of our clinical trials, including any proposed primary or secondary endpoints for such trials;
- our expectations regarding the scope of any approved indication for vilobelimab;
- our ability to leverage our proprietary anti-C5a and C5aR technologies to discover and develop therapies to treat complement-mediated autoimmune and inflammatory diseases;
- our ability to protect, maintain and enforce our intellectual property protection for vilobelimab and any other product candidates, and the scope of such protection;
- our manufacturing capabilities and strategy, including the scalability and cost of our manufacturing methods and processes and the optimization of our manufacturing methods and processes, and our ability to continue to rely on our existing third-party manufacturers and our ability to engage additional third-party manufacturers for our planned future clinical trials and for commercial supply of vilobelimab and for the finished product Gohibic (vilobelimab);
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;
- our ability to defend against liability claims resulting from the testing of our product candidates in the clinic or, if approved, any commercial sales;
- if any of our product candidates obtain regulatory approval, our ability to comply with and satisfy ongoing obligations and continued regulatory oversight;
- our ability to comply with enacted and future legislation in seeking marketing approval and commercialization;
- our future growth and ability to compete, which depends on our retaining key personnel and recruiting additional qualified personnel; and
- our competitive position and the development of and projections relating to our competitors in the development of C5a and C5aR inhibitors or our industry.

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 2023

Financial Results and Provides Business Update

- Single ascending dose (SAD) Phase I data confirm best-in-class potential of orally available C5aR inhibitor INF904; multiple ascending dose (MAD) part ongoing
- Six clinical sites initiated; first patients screened in Phase III trial of vilobelimab in pyoderma gangrenosum (PG)
- FDA regulatory pathway towards BLA in broader acute respiratory distress syndrome (ARDS) indication discussed in encouraging FDA Type C meeting
- MAA for vilobelimab for treatment of SARS-CoV-2 induced septic ARDS in critically ill COVID-19 patients submitted and validated by EMA
- Update on development of vilobelimab in cutaneous squamous cell carcinoma (cSCC)
- First commercial sales for Gohibic (vilobelimab) recorded in the third quarter 2023
- Cash, cash equivalents and marketable securities of €113 million, expected to fund operations at least into 2026

Jena, Germany, November 1, 2023 – InflaRx N.V. (Nasdaq: IFRX), a biotechnology company pioneering anti-inflammatory therapeutics targeting the complement system, announced today financial results for the three and nine months ended September 30, 2023, and provided an operating update.

“In recent months, we have made exciting progress with both vilobelimab and our small molecule C5aR inhibitor INF904. With the commercial launch of Gohibic (vilobelimab) in the United States now underway, we are also advancing vilobelimab in pyoderma gangrenosum, recently initiating a Phase III trial in this debilitating skin disease,” said Prof. Niels C. Riedemann, Chief Executive Officer and Co-Founder of InflaRx.

He continued: “With INF904, we set out to develop an orally bioavailable inhibitor of C5a signaling with best-in-class potential, and the initial data from our Phase I trial strongly support this. We look forward to seeing additional data from this ongoing study with this promising treatment candidate. Ultimately, we are planning to develop INF904 in a chronic inflammatory condition and dedicate more resources towards this exciting new development going forward.”



Recent Highlights and Business Update

INF904 – Positive Topline Results from Single Ascending Dose (SAD) Part of Phase I Trial Support Best-in-Class Potential as Orally Administered C5aR Inhibitor

InflaRx recently announced positive topline results from the SAD part of a randomized, double-blind, placebo-controlled Phase I trial in healthy volunteers to assess the safety, tolerability and pharmacokinetic / pharmacodynamic (PK/PD) properties of InflaRx's low molecular weight C5aR inhibitor INF904.

The results showed that INF904 was well tolerated and resulted in no safety signals of concern in single doses ranging from 3 mg to 240 mg. Analysis of INF904 in subject plasma samples revealed a favorable PK profile that, at the 30 mg dose and above, surpassed the values for systemic exposure (AUC_{last}) and maximum concentration (C_{max}) of published Phase I data from the only marketed comparator. Further, ex vivo assays showed that INF904 achieved the set goal for effective C5aR control at disease relevant C5a levels.

The multiple ascending dose (MAD) part of the Phase 1 trial is ongoing, and the Company expects to present results from the approximately 24 healthy volunteers enrolled in this part of the study at the beginning of 2024. InflaRx is currently preparing to initiate additional required pre-clinical studies, including chronic toxicology studies, for the future clinical development of INF904 in chronic inflammatory diseases. In parallel, the Company is evaluating selected potential indications for future development.

Development of Vilobelimab in Pyoderma Gangrenosum (PG):

InflaRx is well underway in a pivotal Phase III study with vilobelimab for the treatment of ulcerative PG. As of today, InflaRx has initiated the first six clinical sites in the United States and is actively screening patients. The Company foresees being able to start treating the first patient very soon. The multi-national, randomized, double-blind, placebo-controlled trial has two arms: vilobelimab (2400mg every other week) plus a low dose of corticosteroids and placebo plus the same low 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.

The study has an adaptive trial design with an interim analysis blinded for the sponsor and investigators planned upon enrollment of approximately 30 patients (15 per arm). Depending on the results of the interim analysis, the trial sample size will be adapted, or the trial will be stopped due to futility. The enrollment period is projected to be at least two years, depending on the total trial size after sample size adaptation.



Marketing Authorization Application (MAA) for Vilobelimab for Treatment of Critically Ill COVID-19 Patients under Review by European Medicines Agency (EMA)

This summer, the Company submitted an MAA for the treatment of adult patients with SARS-CoV-2 induced septic acute respiratory distress syndrome (ARDS) receiving invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO) to the EMA. The EMA has validated the MAA, which means that the application is now under regulatory review by the European Committee for Medicinal Products for Human Use (CHMP) under the centralized procedure, which applies to all 27 member states of the European Union.

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

In April 2023, the U.S. Food and Drug Administration (FDA) issued an EUA for Gohibic (vilobelimab) for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV or ECMO. Gohibic (vilobelimab) has been commercially available to hospitals across the United States since late Q2 and initial sales were made in Q3.

InflaRx is currently developing its commercial strategic plan and seeking to increase awareness of Gohibic (vilobelimab). In parallel, the Company is also exploring paths to gain full market approval via a biologics license application (BLA) in the United States. In October 2023, InflaRx held an encouraging Type C meeting with the FDA related to additional steps towards a BLA. The FDA indicated that FDA is committed to working with InflaRx to address challenges and expedite development of vilobelimab as a treatment for ARDS. In order to obtain a BLA for ARDS, the Company would need to conduct an additional well-controlled and adequately powered study in a broader ARDS setting. InflaRx is exploring different funding options, including government grants as well as collaborations with third parties.

InflaRx Stops Development of Vilobelimab in Cutaneous Squamous Cell Carcinoma (cSCC) to Prioritize Other Programs

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

An interim analysis of ten evaluable patients in the monotherapy Arm A showed first evaluable signals of efficacy. In Arm B, 15 patients were enrolled (3+6+6 in three dosing cohorts). Before proceeding with the second stage of the study in Arm B, the interim efficacy data were assessed and showed two partial responses - one patient in the second cohort and one patient in the third cohort. Both patients are still on treatment.



While these results are encouraging, the recent emergence of new alternative treatments for cSCC and the recommendation by the Company's U.S. and international experts to study additional patients with a higher dose of vilobelimab as monotherapy would require substantial resources and significantly extend the timelines of the ongoing clinical program. InflaRx has therefore decided to stop development in cSCC for the time being and reallocate resources towards the development of the promising orally available C5aR inhibitor, INF904.

Patients who are currently still in treatment will be treated for up to 24 months according to the protocol; however, no new patients will be enrolled in the study and clinical sites in which no patients are currently being treated will be closed down. The decision to wind down this clinical study does not preclude InflaRx from developing vilobelimab or INF904 in cSCC or similar oncology indications in the future.

Financing Activities

In October 2021, InflaRx announced the receipt of a grant of up to €43.7 million from the German Ministry of Education and Research and the German Ministry of Health to support the development of vilobelimab for the treatment of severe COVID-19 patients. Due to subsequent changes in InflaRx's research and development plan and fewer costs projected within the timeframe of the grant, the Company was notified that the amount available would be €41.4 million. The grant was structured as a reimbursement of 80% of certain pre-specified expenses related to the clinical development and manufacturing of vilobelimab. The grant period ended on June 30, 2023. During the duration of the grant period and up to this date, InflaRx has received a total amount of €32.7 million. An amount of €1.2 million remains outstanding. Such amount is, and will continue to be, held back by the federal German government until all conditions of the grant have been fulfilled, including the government review of the final written report.

Dr. Thomas Taapken, Chief Financial Officer of InflaRx, said: "This quarter was the first time that InflaRx has recorded sales revenues, an achievement that very few biotech companies reach. We are further expanding our commercial activities over the coming months as cases of severe COVID-19 are anticipated to increase over the winter months. Our company is funded to support operations well into 2026, which is important in the continued challenging financial market environment."



Financial Highlights – Q3 2023

Revenue

In Q3 2023, the Company realized revenues from product sales for the first time since its inception. Revenues reported are actual sales to end customers (hospitals). Sales to distributors, of which €2.9 million were incurred in Q3, do not constitute revenue for the Company under IFRS 15 but rather were recorded as other financial liability as of September 30, 2023. Revenues for the nine months ended September 30, 2023, amounted to 60 thousand EUR.

Cost of Sales

Cost of sales recognized during the nine months ended September 30, 2023, are related to Gohibic (vilobelimab) revenues in the United States. Costs of sales for products sold in this period do not include costs of materials, as the associated costs of these materials were incurred in prior periods, before granting of an EUA for Gohibic (vilobelimab). These materials were recorded as research and development expenses in the period they were incurred.

The Cost of sales during the first nine months of 2023 mainly consisted of write-downs of inventories that will expire prior to their expected sale. Early product batches, capitalized in inventory, were produced with material which had been manufactured in previous years. The inventory write-down for the nine months ended September 30, 2023, amounted to €0.3 million, mainly attributable to shelf-life expiration within the next nine months.

Sales and Marketing Expenses

In the nine months ended September 30, 2023, InflaRx incurred €1.8 million of sales and marketing expenses. These expenses were mainly composed of €0.6 million personnel costs and €1.1 million external services for distribution.

Research and Development Expenses

Research and development expenses incurred for the nine months ended September 30, 2023, increased by €3.7 million to € 33.0 million compared to the nine months ended September 30, 2022, and were predominantly 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.

General and Administrative Expenses

General and administrative expenses decreased by €1.8 million to €10.0 million for the nine months ended September 30, 2023, from €11.8 million for the nine months ended September 30, 2022. This decrease was primarily attributable to a decrease in expenses associated with equity-settled share-based compensation recognized in personnel expenses.



Other Income

Other income decreased by €3.0 million to €13.4 million for the nine months ended September 30, 2023, from €16.5 million for the nine months ended September 30, 2022 and was primarily attributable to income recognized from the grant payments received from the German federal government for the development of Gohibic (vilobelimab) in severe COVID-19, including InflaRx's expenses related to clinical development and manufacturing process development. The decrease in income from government grants was primarily due to the completion of activities under the grant. The grant period ended on June 30, 2023.

Net Financial Result

Net financial result increased by €1.8 million to €4.9 million for the nine months ended September 30, 2023, from €3.1 million for the nine months ended September 30, 2022. This increase was mainly attributable to higher interest income which increased by €2.4 million, partly offset by the decrease in foreign exchange result of €1.2 million.

Net Loss

Net loss for the first nine months of 2023 amounted to €26.7 million, compared to €21.5 million in the first nine months of 2022.

Net Cash Used in Operating Activities

Net cash used in operating activities for the first nine months of 2023 decreased to €26.9 million from €28.5 million for the comparable period in 2022.

Liquidity and Capital Resources

As of September 30, 2023, the Company's total available funds were approximately €113 million, composed of €21.7 million in cash and cash equivalents and €91.4 million in marketable securities. These funds are expected to finance operations at least into 2026.

Additional Financial Information

Additional information regarding these results and other relevant information is included in the notes to the unaudited interim condensed consolidated financial statements as of September 30, 2023, and the three and nine months ended September 30, 2023, and 2022, as well as the consolidated financial statements as of and for the year ended December 31, 2022, in "ITEM 18. Financial Statements," in InflaRx's Annual Report on Form 20-F for the year ended December 31, 2022, as filed with the U.S. Securities and Exchange Commission (SEC).



InflaRx N.V. and subsidiaries

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

	For the three months ended September 30,		For the nine months ended September 30	
	2023 (unaudited)	2022 (unaudited)	2023 (unaudited)	2022 (unaudited)
	(in €, except for share data)			
Revenues	60,803	—	60,803	—
Cost of Sales	(255,116)	—	(255,116)	—
Gross profit	(194,313)	—	(194,313)	—
Sales and marketing expenses	(1,562,473)	—	(1,838,524)	—
Research and development expenses	(7,305,541)	(7,537,350)	(32,957,044)	(29,190,231)
General and administrative expenses	(2,897,732)	(3,087,285)	(10,047,091)	(11,821,694)
Other income	808,866	2,030,406	13,437,963	16,473,540
Other expenses	339	—	(2,851)	(844)
Operating Result	(11,150,854)	(8,594,230)	(31,601,861)	(24,539,229)
Finance income	1,189,826	199,758	2,732,873	310,121
Finance expenses	(4,897)	(6,845)	(15,476)	(39,376)
Foreign exchange result	2,292,938	882,370	1,923,274	3,173,883
Other financial result	221,577	(402,724)	223,818	(363,724)
Income Taxes	—	—	—	—
Income (Loss) for the Period	(7,451,410)	(7,921,671)	(26,737,373)	(21,458,325)
Other comprehensive income (loss) that may be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of foreign currency	73,574	4,317,134	56,459	10,035,949
Total Comprehensive Income (Loss)	(7,377,836)	(3,604,538)	(26,680,914)	(11,422,376)
Share Information (based on Income (Loss) for the Period)				
Weighted average number of shares outstanding	58,883,272	44,203,763	53,598,594	44,203,763
Income (Loss) per share (basic/diluted)	(0.13)	(0.18)	(0.50)	(0.49)



InflaRx N.V. and subsidiaries

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

	September 30, 2023 (unaudited)	December 31, 2022 (in €)
ASSETS		
Non-current assets		
Property and equipment	298,344	328,920
Right-of-use assets	1,076,402	1,311,809
Intangible assets	66,734	138,905
Other assets	270,526	308,066
Financial assets	237,564	2,900,902
Total non-current assets	<u>1,949,570</u>	<u>4,988,602</u>
Current assets		
Inventories	1,639,490	—
Current other assets	7,779,994	14,170,510
Current tax assets	3,398,481	1,432,087
Financial assets from government grants	1,164,217	732,971
Other financial assets	91,857,945	64,810,135
Cash and cash equivalents	21,695,607	16,265,355
Total current assets	<u>127,535,734</u>	<u>97,411,058</u>
TOTAL ASSETS	<u><u>129,485,304</u></u>	<u><u>102,399,660</u></u>
EQUITY AND LIABILITIES		
Equity		
Issued capital	7,065,993	5,364,452
Share premium	334,211,338	282,552,633
Other capital reserves	39,597,055	36,635,564
Accumulated deficit	(270,197,663)	(243,460,290)
Other components of equity	7,313,540	7,257,081
Total equity	<u>117,990,262</u>	<u>88,349,440</u>
Non-current liabilities		
Lease liabilities	771,814	987,307
Other liabilities	36,877	36,877
Total non-current liabilities	<u>808,691</u>	<u>1,024,184</u>
Current liabilities		
Trade and other payables	5,999,200	4,987,538
Liabilities from government grants	—	6,209,266
Lease liabilities	354,151	369,376
Employee benefits	1,285,355	1,312,248
Other liabilities	3,047,646	147,608
Total current liabilities	<u>10,686,351</u>	<u>13,026,036</u>
Total Liabilities	<u>11,495,042</u>	<u>14,050,220</u>
TOTAL EQUITY AND LIABILITIES	<u><u>129,485,304</u></u>	<u><u>102,399,660</u></u>



InflaRx N.V. and subsidiaries

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

(in €)	Issued capital	Share premium	Other capital reserves	Accumulated deficit	Other compo- nents of equity	Total equity
Balance as of January 1, 2023	5,364,452	282,552,633	36,635,564	(243,460,290)	7,257,081	88,349,440
Loss for the period	—	—	—	(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
Balance as of January 1, 2022	5,304,452	280,310,744	30,591,209	(213,975,679)	3,050,271	105,280,996
Loss for the period	—	—	—	(21,458,325)	—	(21,458,325)
Exchange differences on translation of foreign currency	—	—	—	—	10,035,949	10,035,949
Total comprehensive loss	—	—	—	(21,458,325)	10,035,949	(11,422,376)
Equity-settled share-based payments	—	—	5,581,021	—	—	5,581,021
Balance as of September 30, 2022	5,304,452	280,310,744	36,172,229	(235,434,004)	13,086,220	99,439,640



InflaRx N.V. and subsidiaries

Unaudited Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2023 and 2022

	For the nine months ended September 30,	
	2023	2022
	(unaudited)	(unaudited)
	(in €)	
Operating activities		
Loss for the period	(26,737,373)	(21,458,325)
Adjustments for:		
Depreciation & amortization of property and equipment, right-of-use assets and intangible assets	432,248	448,323
Net finance income	(4,864,488)	(3,080,904)
Share-based payment expense	2,961,491	5,581,021
Net foreign exchange differences	(82,574)	189,088
Changes in:		
Financial assets from government grants	(431,246)	(5,954,754)
Other assets	4,468,239	3,087,177
Employee benefits	(26,893)	(221,982)
Other liabilities	2,893,461	5,061
Liabilities from government grants received	(6,209,266)	(6,849,415)
Trade and other payables	1,011,662	(1,135,817)
Inventories	(1,639,490)	—
Interest received	1,302,391	903,647
Interest paid	(15,773)	(38,978)
Net cash used in operating activities	<u>(26,937,611)</u>	<u>(28,525,857)</u>
Investing activities		
Purchase of intangible assets, property and equipment	(45,942)	(17,908)
Purchase of current financial assets	(91,590,134)	(47,031,216)
Proceeds from the maturity of financial assets	71,113,455	64,600,049
Net cash from/(used in) investing activities	<u>(20,522,621)</u>	<u>17,550,925</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	(279,075)	(273,092)
Net cash from/(used in) financing activities	<u>53,081,170</u>	<u>(273,092)</u>
Net increase/(decrease) in cash and cash equivalents	5,620,938	(11,248,024)
Effect of exchange rate changes on cash and cash equivalents	(190,686)	2,976,033
Cash and cash equivalents at beginning of period	16,265,355	26,249,995
Cash and cash equivalents at end of period	<u>21,695,607</u>	<u>17,978,003</u>



About InflaRx

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

InflaRx (Nasdaq: IFRX) is a biotechnology company pioneering anti-inflammatory therapeutics by applying its proprietary anti-C5a and anti-C5aR technologies to discover, develop and commercialize first-in-class, 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 was founded in 2007, and the group has offices and subsidiaries in Jena and Munich, Germany, as well as Ann Arbor, MI, USA. For further information, please visit www.inflarx.com.

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FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “estimate,” “believe,” “predict,” “potential” or “continue,” among others. Forward-looking statements appear in a number of places throughout this release and may include statements regarding our intentions, beliefs, projections, outlook, analyses and current expectations concerning, among other things, the receptiveness of Gohibic (vilobelimab) as a treatment for COVID-19 by COVID-19 patients and U.S. hospitals and related treatment recommendations by medical/healthcare institutes and other third-party organizations, our ability to successfully commercialize and the receptiveness of Gohibic (vilobelimab) as a treatment for COVID-19 by COVID-19 patients and U.S. hospitals or our other product candidates; our expectations regarding the size of the patient populations for, market opportunity for, coverage and reimbursement for, estimated returns and return accruals for, and clinical utility of Gohibic (vilobelimab) in its approved or authorized indication or for vilobelimab and any other product candidates, under an EUA and in the future if approved for commercial use in the United States or elsewhere; the success of our future clinical trials for vilobelimab and any other product candidates and whether such clinical results will reflect results seen in previously conducted pre-clinical studies and clinical trials; the timing, progress and results of pre-clinical studies and clinical trials of our product candidates, including the MAD part of the Phase 1 trial with C5aR inhibitor INF904, and statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, the costs of such trials and our research and development programs generally; our interactions with regulators regarding the results of clinical trials and potential regulatory approval pathways, including related to our MAA submission for vilobelimab and our BLA submission for Gohibic (vilobelimab), and our ability to obtain and maintain full regulatory approval of vilobelimab or Gohibic (vilobelimab) for any indication; whether the FDA, the EMA or any comparable foreign regulatory authority will accept or agree with the number, design, size, conduct or implementation of our clinical trials, including any proposed primary or secondary endpoints for such trials; our expectations regarding the scope of any approved indication for vilobelimab; our ability to leverage our proprietary anti-C5a and C5aR technologies to discover and develop therapies to treat complement-mediated autoimmune and inflammatory diseases; our ability to protect, maintain and enforce our intellectual property protection for vilobelimab and any other product candidates, and the scope of such protection; our manufacturing capabilities and strategy, including the scalability and cost of our manufacturing methods and processes and the optimization of our manufacturing methods and processes, and our ability to continue to rely on our existing third-party manufacturers and our ability to engage additional third-party manufacturers for our planned future clinical trials and for commercial supply of vilobelimab and for the finished product Gohibic (vilobelimab); our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing; our ability to defend against liability claims resulting from the testing of our product candidates in the clinic or, if approved, any commercial sales; if any of our product candidates obtain regulatory approval, our ability to comply with and satisfy ongoing obligations and continued regulatory oversight; our ability to comply with enacted and future legislation in seeking marketing approval and commercialization; our future growth and ability to compete, which depends on our retaining key personnel and recruiting additional qualified personnel; and our competitive position and the development of and projections relating to our competitors in the development of C5a and C5aR inhibitors or our industry; and the risks, uncertainties and other factors described under the heading “Risk Factors” in our periodic filings with the SEC. These statements speak only as of the date of this press release and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, and we assume no obligation to update these forward-looking statements, even if new information becomes available in the future, except as required by law.
