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 (PD-L1) 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.

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	**1,949,570**	**4,988,602**
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	127,535,734	97,411,058
TOTAL ASSETS	**129,485,304**	**102,399,660**
EQUITY AND LIABILITIES		
Equity		
Issued capital	7,065,993	5,364,452
Share premium	334,211,338	282,552,633
Other capital reserves	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	**117,990,262**	**88,349,440**
Non-current liabilities		
Lease liabilities	771,814	987,307
Other liabilities	36,877	36,877
Total non-current liabilities	**808,691**	**1,024,184**
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	**10,686,351**	**13,026,036**
Total Liabilities	11,495,042	14,050,220
TOTAL EQUITY AND LIABILITIES	**129,485,304**	**102,399,660**

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 (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	(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	**(26,937,611)**	**(28,525,857)**
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	**(20,522,621)**	**17,550,925**
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	**53,081,170**	**(273,092)**
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	**21,695,607**	**17,978,003**

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.

The COVID-19 related work described herein is partly funded by the German Federal Government through grant number 16LW0113 (VILO-COVID). All responsibility for the content of this work lies with InflaRx.

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FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "estimate," "believe," "predict," "potential" or "continue," among others. Forward-looking statements appear in a number of places throughout this release and may include statements regarding our intentions, beliefs, projections, outlook, analyses and current expectations concerning, among other things, 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 overview; our ability to comply with enacted and future legislation in seeking marketing approval and commercialization; our future growth and ability to compete, which depends on our retaining key personnel and recruiting additional 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.