UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported):
March 21, 2024

MILESTONE PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Québec	**001-38899**	**Not applicable**
(state or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

1111 Dr. Frederik-Philips Boulevard, **Suite 420** **Montréal, Québec CA**	**H4M 2X6**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(514) 336-0444**

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Shares	MIST	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b–2 of the Securities Exchange Act of 1934 (§ 240.12b–2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 2.02. Results of Operations and Financial Condition.

On March 21, 2024, Milestone Pharmaceuticals Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 31, 2023, which also provided a regulatory and corporate update. A copy of the press release is attached as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated March 21, 2024.
104	Cover Page Interactive Data File--the cover page XBRL tags are embedded within the Inline XBRL document

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 hereunto duly authorized.

MILESTONE PHARMACEUTICALS INC.

By: /s/Amit Hasija
Amit Hasija
Chief Financial Officer

Dated: March 21, 2024

Exhibit 99.1

Milestone Pharmaceuticals Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Regulatory and Corporate Update

- On track to resubmit NDA for etripamil in PSVT early 2Q 2024

- Recent financing extends cash runway into 2026

- FDA reiterated prior guidance on regulatory pathway for AFib-RVR, End of Phase 2 Meeting expected mid-2024

MONTREAL and CHARLOTTE, N.C., March 21, 2024 -- Milestone Pharmaceuticals Inc. (Nasdaq: MIST) today reported financial results for the fourth quarter and year ended December 31, 2023 and provided a regulatory and corporate update.

"We look forward to resubmitting our NDA imminently. With the completion of our recent financing and potential future synthetic royalty payment, we believe we are well positioned to advance etripamil through potential approval and launch in PSVT," said Joseph Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. "We're excited to continue this positive momentum as we execute on our programs and advance etripamil."

Corporate Updates

- **In March 2024, completed a public offering of common shares and pre-funded warrants, raising net proceeds of approximately $32.4 million.** Milestone intends to use the proceeds from the Offering to continue the development of etripamil in its lead indication of paroxysmal supraventricular tachycardia (PSVT) and its subsequent indication of atrial fibrillation with a rapid ventricular rate (AFib-RVR), as well as for working capital and other general corporate purposes.

Recent Program Updates

Etripamil for Patients with PSVT

- **Announced Plans to Resubmit New Drug Application (NDA) for Etripamil for PSVT in early 2Q 2024.** Milestone held a Type A meeting with the FDA in February 2024 regarding steps required to resolve the items raised in the Refusal to File (RTF) letter received in December 2023. The Company is working to restructure the data sets that capture timing of reported adverse events (AEs) in the clinical etripamil studies and is reformatting certain data files to facilitate FDA's analyses. The Company expects a standard NDA review period following resubmission of the NDA.

Etripamil for Patients with AFib-RVR

- **Phase 3 guidance received from FDA in 1Q2024 meeting.** FDA reiterated prior guidance regarding the availability of a single-study supplemental New Drug Application (sNDA) pathway contingent on obtaining approval for the NDA in PSVT. FDA further concurred with respect to key study elements including powering, inclusion criteria, patient population, and statistical analyses, and offered clarification with respect to the endpoints to guide the design of the Phase 3 study. We anticipate progressing to an End of Phase 2 meeting to finalize the registrational study protocol in mid-2024.

- **Positive Results from ReVeRA Phase 2 Study of Etripamil in AFib-RVR Presented as Featured Science at the American Heart Association (AHA) Scientific Sessions 2023 and Simultaneously Published in *Circulation: Arrhythmia and Electrophysiology*.** In November 2023, Milestone announced positive data from the ReVeRA Phase 2 study that show that patients with AFib-RVR receiving etripamil demonstrated rapid and statistically superior ventricular rate reduction and improved symptom-relief when compared to placebo. Safety and tolerability reported in the 56-patient safety population who received etripamil was generally consistent with that observed in the Company's extensive safety database from the PSVT program. The results were presented as a Featured Science presentation at the American Heart Association (AHA) Scientific Sessions 2023 and simultaneously published in *Circulation: Arrhythmia and Electrophysiology*, which can be found here.

Fourth Quarter and Full Year 2023 Financial Results

- As of December 31, 2023, Milestone had cash, cash equivalents, and short-term investments of $66.0 million, compared to $64.6 million as of December 31, 2022.

- There was no revenue recorded for the fourth quarter of 2023, compared with $3.5 million the fourth quarter of 2022. Revenue for the full year ended December 31, 2023 was $1.0 million compared to $5.0 million in the year ended December 31, 2022. Revenue in 2023 was related to a milestone payment received from Ji Xing Pharmaceuticals, under the Company's License and Collaboration Agreement. Revenue in 2022 was related to two milestone payments received under the agreement with Ji Xing Pharmaceuticals.

- Research and development expense for the fourth quarter of 2023 was $5.5 million, compared with $10.6 million for the prior year period. For the full year ended December 31, 2023, research and development expense was $31.1 million, compared with $39.8 million for the prior year. The decrease year over year was primarily due to lower clinical expenses as a result of the completion of Phase 3 studies, partially offset by an increase in drug manufacturing consulting costs, drug manufacturing personnel costs and regulatory consulting costs.

- General and administrative expense for the fourth quarter of 2023 was $3.4 million, compared with $4.1 million for the prior year period. For the full year ended December 31, 2023, general and administrative expense was $15.9 million, compared with $15.7 million for the prior year.

- Commercial expense for the fourth quarter of 2023 was $5.0 million, compared with $2.6 million for the prior year period. For the full year ended December 31, 2023, commercial expense was $15.1 million, compared with $9.1 million for the prior year. The increase in commercial expense year over year was a result of additional personnel and professional costs required to expand capabilities and operations in anticipation of potential commercialization.

- For the fourth quarter of 2023, net loss was $13.6 million, compared to $13.2 million for the prior year period. For the full year ended December 31, 2023, Milestone's net loss was $59.7 million, compared to $58.4 million for the prior year.

For further details on the Company's financials, refer to Form 10-K for the year ended December 31, 2023, filed with the SEC.

About Paroxysmal Supraventricular Tachycardia

An estimated two million people in the United States are currently diagnosed with PSVT which is a type of arrhythmia or abnormal heart rhythm. PSVT is characterized by episodes of sudden onset rapid heartbeats often exceeding 150 to 200 beats per minute. The heart rate spike is unpredictable and may last several hours. The rapid heart rate often causes disabling severe palpitations, shortness of breath, chest discomfort, dizziness or lightheadedness, and distress, forcing patients to limit their daily activities. The uncertainty of when an episode of PSVT will strike or how long it will persist can provoke anxiety in patients and negatively impact their day-to-day life between episodes. The impact and morbidity from an attack can be especially detrimental in patients with underlying cardiovascular or medical conditions, such as heart failure, obstructive coronary disease, or dehydration. Many health care providers are dissatisfied with the lack of effective treatment options with patients often requiring prolonged, burdensome, and costly trips to the emergency department or even invasive cardiac ablation procedures.

About Atrial Fibrillation with Rapid Ventricular Rate

An estimated five million Americans suffer from AFib, a common arrhythmia marked by an irregular, disruptive and often rapid heartbeat. The incidence of AFib is expected to grow to approximately 10 million by 2025 and up to about 12 million by 2030. A subset of patients with AFib experience episodes of abnormally high heart rate most often accompanied by palpitations, shortness of breath, dizziness, and weakness. While these episodes, known as AFib-RVR, may be treated by oral calcium channel blockers and/or beta blockers, patients frequently seek acute care in the emergency department to address symptoms. In 2016, nearly 800,000 patients were admitted to the emergency department due to AFib symptoms where treatment includes medically supervised intravenous administration of calcium channel blockers or beta blockers, or electrical cardioversion. With little available data for AFib-RVR, Milestone's initial market research indicates that 30 to 40% of patients with AFib experience one or more symptomatic episodes of RVR per year that require treatment, suggesting a target addressable market of approximately three to four million patients in 2030 for etripamil in patients with AFib-RVR.

About Etripamil

Etripamil is Milestone's lead investigational product. It is a novel calcium channel blocker nasal spray under clinical development for frequent and often highly symptomatic episodes of PSVT and AFib-RVR. It is designed as a self-administered rapid response therapy for patients thereby bypassing the need for immediate medical oversight. If approved, etripamil is intended to provide health care providers with a new treatment option to enable on-demand care and patient self-management. This portable, self-administered treatment may provide patients with active management and a greater sense of control over their condition. CARDAMYST™, the conditionally approved brand name for etripamil nasal spray, is well studied with a robust clinical trial program that includes a completed Phase 3 clinical-stage program for the treatment of PSVT and Phase 2 trial for the treatment of patients with AFib-RVR.

About Milestone Pharmaceuticals

Milestone Pharmaceuticals Inc. (Nasdaq: MIST) is a biopharmaceutical company developing and commercializing innovative cardiovascular solutions to improve the lives of people living with complex and life-altering heart conditions. The Company’s focus on understanding unmet patient needs and improving the patient experience has led us to develop new treatment approaches that provide patients with an active role in self-managing their care. Milestone's lead investigational product is etripamil, a novel calcium channel blocker nasal spray that is being studied for patients to self-administer without medical supervision to treat highly symptomatic episodic attacks associated with PSVT and AFib-RVR.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believe," "continue," "could," "demonstrate," "designed," "develop," "estimate," "expect," "may," "pending," "plan," "potential," "progress," "will", “intend” and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Milestone's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include statements regarding: the timing and outcomes of future interactions with U.S. and foreign regulatory bodies, including the FDA, including the timing of the FDA’s potential review of the NDA, once resubmitted, and the timing of the End of Phase 2 meeting; our cash runway; our ability to receive the synthetic royalty payment; our ability to advance etripamil through approval and launch in PSVT; our ability to launch etripamil for PSVT; our intended use of proceeds from the March 2024 public offering of common shares and pre-funded warrants; our future target addressable market; and the ability of etripamil to provide health care providers with a new treatment option to enable on-demand care and patient self-management and to provide patients with active management and a greater sense of control over their condition. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, but are not limited to, whether a Type A meeting will be granted and whether our future interactions with the FDA will have satisfactory outcomes; whether and when, if at all, our NDA for etripamil will be approved by the FDA; whether the FDA will require additional trials or data which may significantly delay and put at risk our efforts to obtain approval and may not be successful, the risks inherent in biopharmaceutical product development and clinical trials, including the lengthy and uncertain regulatory approval process; uncertainties related to the timing of initiation, enrollment, completion, evaluation and results of our clinical trials; risks and uncertainty related to the complexity inherent in cleaning, verifying and analyzing trial data; and whether the clinical trials will validate the safety and efficacy of etripamil for PSVT or other indications, among others, general economic, political, and market conditions, including deteriorating market conditions due to investor concerns regarding inflation, Russian hostilities in Ukraine and ongoing disputes in Israel and Gaza and overall fluctuations in the financial markets in the United States and abroad, risks related to pandemics and public health emergencies, and risks related the sufficiency of Milestone's capital resources and its ability to raise additional capital in the current economic climate. These and other risks are set forth in Milestone's filings with the U.S. Securities and Exchange Commission, including in its annual report on Form 10-K for the year ended December 31, 2023, under the caption "Risk Factors," as such discussion may be updated from time to time by subsequent filings Milestone may make with the U.S. Securities & Exchange Commission. Except as required by law, Milestone assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Milestone Pharmaceuticals Inc.
Consolidated Statements of Loss
(in thousands of US dollars, except share and per share data)

	Years Ended December 31,	
	2023	**2022**
Revenue	$ 1,000	$ 5,000
Operating expenses		
Research and development, net of tax credits	$ 31,052	$ 39,829
General and administrative	15,932	15,718
Commercial	15,114	9,095
Loss from operations	(61,098)	(59,642)
Interest income	3,967	1,254
Interest expense	(2,554)	—
Net loss and comprehensive loss	$ (59,685)	$ (58,388)
Weighted average number of shares and pre-funded warrants outstanding, basic and diluted	42,955,779	42,450,316
Net loss per share, basic and diluted	$ (1.39)	$ (1.38)

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

Milestone Pharmaceuticals Inc.
Consolidated Balance Sheets
(in thousands of US dollars, except share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 13,760	$ 7,636
Short-term investments	52,243	56,949
Research and development tax credits receivable	643	331
Prepaid expenses	3,178	6,005
Other receivables	3,208	882
Total current assets	73,032	71,803
Operating lease right-of-use assets	1,917	2,423
Property and equipment	277	257
Total assets	$ 75,226	$ 74,483
Liabilities, and Shareholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 6,680	$ 5,644
Operating lease liabilities	546	495
Total current liabilities	7,226	6,139
Operating lease liabilities, net of current portion	1,457	1,996
Senior secured convertible notes	49,772	—
Total liabilities	58,455	8,135
Shareholders' Equity		
Common shares, no par value, unlimited shares authorized 33,483,111 shares issued and outstanding as of December 31, 2023, 34,286,002 shares issued and outstanding as of December 31, 2022	260,504	273,900
Pre-funded warrants - 9,577,257 issued and outstanding as of December 31, 2023 and 8,518,257 as of December 31, 2022	48,459	34,352
Additional paid-in capital	33,834	24,437
Accumulated deficit	(326,026)	(266,341)
Total shareholders' equity	16,771	66,348
Total liabilities and shareholders' equity	$ 75,226	$ 74,483

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