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):
November 13, 2023

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 November 13, 2023, Milestone Pharmaceuticals Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 2023, which also provided a clinical 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 November 13, 2023.
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: November 13, 2023

Exhibit 99.1

Milestone Pharmaceuticals Reports Third Quarter 2023 Financial Results and Provides Clinical and Corporate Updates

- *New Drug Application submitted to the U.S. Food and Drug Administration for CARDAMYST™, the conditionally approved brand name for etripamil nasal spray, for patients with PSVT*

- *Positive Phase 2 data evaluating etripamil in AFib-RVR were a Featured Science Presentation at 2023 AHA Scientific Sessions; Phase 3 program expected to begin enrollment in mid-2024*

- *Company to host Investor and Analyst Webcast to review data from ReVeRA Phase 2 study of etripamil in atrial fibrillation with rapid ventricular rate today at 8:00 a.m. ET*

Montreal and Charlotte, N.C., November 13, 2023 -- Milestone Pharmaceuticals Inc. (Nasdaq: MIST) today reported financial results for the third quarter ended September 30, 2023, and provided a clinical and corporate update.

"This quarter was transformational for our company. We believe the combination of the submission of our first New Drug Application for CARDAMYST in treating PSVT and the release of positive results from our Phase 2 study evaluating etripamil to treat patients with AFib-RVR, demonstrates that we are on track to advance our clinical development program," said Joseph Oliveto, President, and Chief Executive Officer of Milestone Pharmaceuticals. "We are approaching 2024 with a well-defined strategy and even greater confidence around the potential of our lead asset, etripamil, to help people living with these serious heart arrythmias."

Recent Program Updates

Etripamil for Patients with PSVT

· **New Drug Application (NDA) Submitted to U.S. Food and Drug Administration (FDA) for Etripamil in Patients with Paroxysmal Supraventricular Tachycardia (PSVT).** In October, Milestone announced the submission of an NDA to the FDA for etripamil (CARDAMYST™ conditionally approved tradename, subject to FDA final review) in patients with PSVT. Representing the largest data package ever studied in PSVT, the Company believes the clinical trial program demonstrates that etripamil provided superior time to conversion to normal heart rhythm compared to placebo. The primary analysis and supportive assessments from the pivotal RAPID Phase 3 clinical trial were recently published in *The Lancet*. The FDA determination of whether the NDA is complete and accepted for review is expected by the end of 2023. If accepted, Milestone Pharmaceuticals expects a standard review of 10 months from the the filing of the company's NDA. Milestone continues to advance commercial preparations to support the anticipated launch of etripamil.

Etripamil for Patients with AFib-RVR

· **Positive Results from ReVeRA Phase 2 Study of Etripamil in Atrial Fibrillation with Rapid Ventricular Rate (AFib-RVR) Presented at the American Heart Association (AHA) Scientific Sessions 2023 and Simultaneously Published in *Circulation: Arrhythmia and Electrophysiology*.** In November, Milestone announced 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 program for PSVT. 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*.

- **AFib-RVR Phase 3 Registrational Program Planned to Begin in 2024.** Based on preliminary guidance from FDA, Milestone is developing a Phase 3 registrational program to evaluate self-administered etripamil as a potential treatment for patients with AFib-RVR. The Company expects to initiate this program in mid-2024.

Third Quarter 2023 Financial Results

- As of September 30, 2023, Milestone had cash, cash equivalents, and short-term investments of $75.7 million and 33.5 million common shares issued and outstanding, with an additional 9.6 million common shares issuable upon exercise of pre-funded warrants. Cash resources as of September 30, 2023 are expected to fund operations into mid-2025.

- Research and development expense for the third quarter of 2023 was $6.7 million, compared with $9.8 million for the prior year period. For the nine months ended September 30, 2023, research and development expense was $25.6 million compared with $29.3 million for the prior year period. The decreases in research and development expenses were related to lower clinical expenses and clinical personnel-related costs as a result of the completion of phase 3 studies.

- General and administrative expense for the third quarter of 2023 was $4.2 million, compared with $4.0 million for the prior year period. For the nine months ended September 30, 2023, general and administrative expense was $12.6 million compared with $11.6 million for the prior year period. The increases were related to personnel-related costs and consulting fees.

- Commercial expense for the third quarter of 2023 was $4.4 million, compared with $2.7 million for the prior year period. For the nine months ended September 30, 2023, commercial expense was $10.1 million compared with $6.5 million for the prior year period. The increases were related to additional personnel and professional costs required to expand capabilities and operations in anticipation of potential commercialization.

- For the third quarter of 2023, operating loss was $15.4 million, compared to $15.0 million for the prior year period. For the nine months ended September 30, 2023, Milestone's operating loss was $47.3 million, compared to $45.9 million in the prior year period.

Investor and Analyst Conference Call and Webcast

The Company will host an investor and analyst conference call and webcast on Monday, November 13, 2023, at 8:00 a.m. Eastern Time. The event will feature a review of the ReVeRA data, an overview of AFib-RVR and current treatment landscape, characteristics of etripamil, and commentary on next steps for Milestone's clinical development program for etripamil. To join the live call by phone, dial (877) 870-4263 (domestic) or (412) 317-0790 (international) and ask to be connected to the Milestone Pharmaceuticals call. To access the live or recorded webcast and accompanying slides, please visit the News & Events section of Milestone's investor relations website at investors.milestonepharma.com.

About Paroxysmal Supraventricular Tachycardia (PSVT)

An estimated 2 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 rapid heartbeats often exceeding 150 to 200 beats per minute. Key features of PSVT include the sudden occurrence of episodes and very rapid heart rate. The heart rate can spike unpredictably and rapidly during an episode. The rapid heart rate often causes 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 in addition to a prolonged, burdensome, and costly trip to the emergency department or, for some patients, an invasive ablation procedure.

About Atrial Fibrillation with Rapid Ventricular Rate (AFib-RVR)

An estimated five million Americans suffer from atrial fibrillation (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.[1,2,3] 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 elevated and often highly symptomatic heart-rate attacks associated with PSVT and AFib-RVR. It is designed to be a rapid-response therapy that is self-administered by the patient, without the need for direct 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. If approved, the 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 proof-of-concept trial for the treatment of patients with AFib-RVR.

About Milestone Pharmaceuticals

Milestone Pharmaceuticals Inc. (Nasdaq: MIST) is a biopharmaceutical company focused on the development and commercialization of innovative cardiovascular medicines. Milestone's lead product candidate etripamil recently completed its Phase 3 clinical-stage program for the treatment of PSVT and a Phase 2 proof-of-concept trial for the treatment of patients with AFib-RVR. The AFib-RVR study**,** ReVeRA, was recently presented as a Featured Science presentation at the American Heart Association (AHA) Scientific Sessions 2023 and simultaneously published in *Circulation: Arrhythmia and Electrophysiology*. Milestone Pharmaceuticals operates in Canada and the United States. Find out more at www.milestonepharma.com.

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" 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 etripamil's potential to help patients living with these serious heart arrythmias; etripamil's continued ability to achieve statistically superior ventricular rate reduction and improved symptom-relief when compared to placebo; the timing and outcome of the FDA determination of whether the NDA is complete and accepted for review; the timing of the FDA's potential review of the NDA; the timing of the launch of etripamil; the clinical benefit of etripamil for self-treating recurrent episodes of PSVT without medical supervision; the timing of a Phase 3 registrational program for etripamil; and the anticipated growth in incidences of AFib by 2025 and 2030 and the target addressable market of patients with AFib-RVR by 2030. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, but are not limited to, 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, 2022, 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.
Condensed Consolidated Statements of Loss (Unaudited)
(in thousands of US dollars, except share and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenue	$ —	$ 1,500	$ 1,000	$ 1,500
Operating expenses				
Research and development, net of tax credits	6,721	9,826	25,600	29,251
General and administrative	4,227	4,034	12,561	11,595
Commercial	4,412	2,670	10,137	6,537
Loss from operations	(15,360)	(15,030)	(47,298)	(45,883)
Interest income	1,120	474	2,921	672
Interest expense	(841)	—	(1,697)	—
Net loss and comprehensive loss	$ (15,081)	$ (14,556)	$ (46,074)	$ (45,211)
Weighted average number of shares and pre-funded warrants outstanding, basic and diluted	42,973,160	42,491,787	42,920,620	42,339,123
Net loss per share, basic and diluted	$ (0.35)	$ (0.34)	$ (1.07)	$ (1.07)

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

	September 30, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 9,879	$ 7,636
Short-term investments	65,867	56,949
Research and development tax credits receivable	569	331
Prepaid expenses	6,961	6,005
Other receivables	1,521	882
Total current assets	84,797	71,803
Operating lease assets	2,047	2,423
Property and equipment	272	257
Total assets	$ 87,116	$ 74,483
Liabilities, and Shareholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 7,584	$ 5,644
Operating lease liabilities	530	495
Total current liabilities	8,114	6,139
Operating lease liabilities, net of current portion	1,583	1,996
Senior secured convertible notes	48,915	—
Total liabilities	58,612	8,135
Shareholders' Equity		
Common shares, no par value, unlimited shares authorized 33,481,787 shares issued and outstanding as of September 30, 2023, 34,286,002 shares issued and outstanding as of December 31, 2022	260,502	273,900
Pre-funded warrants - 9,577,257 issued and outstanding as of September 30, 2023 and 8,518,257 as of December 31, 2022	48,459	34,352
Additional paid-in capital	31,958	24,437
Accumulated deficit	(312,415)	(266,341)
Total shareholders' equity	28,504	66,348
Total liabilities and shareholders' equity	$ 87,116	$ 74,483

Contact:

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