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 12, 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 November 12, 2024, Milestone Pharmaceuticals Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 2024, 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 12, 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: November 12, 2024

Exhibit 99.1

Milestone Pharmaceuticals Reports Third Quarter 2024 Financial Results and Provides Regulatory and Corporate Update

NDA for CARDAMYST™ in PSVT under review by FDA; PDUFA March 27, 2025

MONTREAL and CHARLOTTE, N.C., Nov. 12, 2024 (GLOBE NEWSWIRE) -- Milestone® Pharmaceuticals Inc. (Nasdaq: MIST) today reported financial results for the third quarter ended September 30, 2024 and provided a corporate update.

"Our primary focus at Milestone is preparing for potential FDA approval of CARDAMYST (etripamil) nasal spray for the management of PSVT," said Joseph Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. "We believe that CARDAMYST has the potential to improve how PSVT is managed and positions Milestone to deliver meaningful value to patients, providers, and payors. Complementing our efforts in PSVT, we are very encouraged by clinician interest in the etripamil Phase 3 study in AFib-RVR which we are working toward commencing in the first half of 2025."

Third Quarter and Recent Program Updates

CARDAMYST for patients with paroxysmal supraventricular tachycardia (PSVT)

- **New Drug Application (NDA) for CARDAMYST for PSVT under review by U.S. FDA.** The FDA accepted the NDA for CARDAMYST in May 2024 and has set a Prescription Drug User Fee Act (PDUFA) target date for March 27, 2025. Preparations for a commercial launch in 2025 are underway.

- **Milestone's partner, Corxel (formerly Ji Xing Pharmaceuticals Ltd), announced positive top line results from a Phase 3 trial of etripamil conducted in China.** In September, Corxel announced positive results from the multi-center, randomized, double-blind, placebo-controlled trial which expands the etripamil global development program to more than 2,000 unique patients treated with etripamil. The trial (JX02002) successfully met its primary endpoint, with a Kaplan Meier analysis showing a statistically significantly greater proportion of patients who self-administered etripamil converted from PSVT to sinus rhythm within 30 minutes compared to placebo (40.5% vs. 15.9%, respectively; hazard ratio [HR] = 3.00; $p<0.001$). Statistically significant ($p<0.05$) results were also achieved for the secondary efficacy endpoints for percent of patients' PSVT converting to sinus rhythm by 10, 15, 45, and 60 minutes after self-administration of study drug. The safety and tolerability data from the trial were consistent with previous clinical studies. Milestone entered into an agreement with Ji Xing in 2021, granting it an exclusive license to develop and, if approved, commercialize etripamil in PSVT in Greater China.

- **Milestone hosted a KOL webinar entitled "Learnings from the Field: Managing PSVT and Studying AFib-RVR in the Community Setting."** The event, which is the second of a series of planned webinars learning from community-based health care providers, featured Aamer H. Jamali, MD, FACC and Farhad Rafii, MD, FACC, both from Interventional Cardiology Medical Group in West Hills, CA. The physicians discussed how they manage patients with PSVT and atrial fibrillation with rapid ventricular rate (AFib-RVR) and highlighted clinical trial experience in PSVT as well as upcoming trials in AFib-RVR with the potential to impact the current standard of care. A replay of the webinar is available on the Milestone corporate website here.

- **Patient Reported Outcomes (PRO) data from PSVT patients receiving etripamil were presented at the annual meeting of the European Society of Cardiology (ESC Congress) in London.** On August 30, 2024 Professor John Camm of St. George's University of London, UK, presented PRO data from the NODE-303 Phase 3 trial of etripamil in PSVT in a moderated poster presentation. The poster presentation is available here.

Etripamil for patients with AFib-RVR

- **Milestone is on track to initiate a Phase 3 trial evaluating etripamil in AFib-RVR in H1 2025.** The Company has been in communication with the FDA regarding Phase 3 study design and is planning a trial that will be conducted in the at-home setting, comprising approximately 150 events from patients with a history of symptomatic episodes and using a repeat-dose regimen of 70 mg per dose (the same as the self-administration dosing regimen approach that was studied in the RAPID trial in PSVT).

Corporate Updates

- **In September, Joseph Papa was appointed to the board of directors.** Mr. Papa brings more than 35 years of experience, having previously served as Chairman and CEO of Bausch + Lomb, Bausch Health and Perrigo and as a director of SparingVision and Candel Therapeutics. He has broad commercial experience and proven capabilities of advancing innovative products aimed at significantly enhancing patients' lives.

Third Quarter 2024 Financial Results

- As of September 30, 2024, Milestone had cash, cash equivalents, and short-term investments of $76.4 million, compared to $66.0 million as of December 31, 2023.

- Research and development expense, net of tax credits for the third quarter of 2024 was $4.0 million, compared with $6.7 million for the same period in 2023. For the nine months ended September 30, 2024, research and development expense, net of tax credits was $10.4 million compared with $25.6 million for the same period in 2023. This decrease in research and development expenses was driven by lower clinical development costs and clinical personnel-related costs driven by completion of phase 3 studies, as well as a decrease in drug manufacturing and regulatory costs.

- General and administrative expense for the third quarter of 2024 was $3.7 million, compared with the $4.2 million reported for the same period in 2023. For the nine months ended September 30, 2024, general and administrative expense was $12.7 million, compared with the with $12.6 million for the prior year period. The decrease between the third quarter periods is primarily due to a decrease in personnel costs, partially offset by an increase in outside service costs.

- Commercial expense for the third quarter of 2024 was $1.9 million, compared with $4.4 million for the same period in 2023. For the nine months ended September 30, 2024, commercial expense was $6.6 million compared with $10.1 million for the prior year period. The decreases are a result of decreases in personnel costs, professional costs and other operational expenses related to commercialization.

- For the third quarter of 2024, net loss was $9.4 million, compared to $15.1 million for the prior year period. For the nine months ended September 30, 2024, Milestone's net loss was $29.2 million, compared to $46.1 million in the prior year period.

For further details on the Company’s financials, refer to the quarterly report on Form 10-Q for the quarter ended September 30, 2024, filed with the SEC on November 12, 2024.

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™ (etripamil) nasal spray, 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 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 review of the NDA; the ability of CARDAMYST to improve how PSVT is managed and position Milestone to deliver meaningful value to patients and providers; the timing of the commercial launch of etripamil for PSVT; and the timing, design and outcomes of our clinical trials, including our Phase 3 study in AFib-RVR. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, but are not limited to, 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 (SEC), including in its annual report on Form 10-K for the year ended December 31, 2023 and its quarterly report on Form 10-Q for the quarter ended September 30, 2024, under the caption "Risk Factors," as such discussion may be updated from time to time by subsequent filings Milestone may make with the SEC. 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.

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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,	
	2024	**2023**	**2024**	**2023**
Revenue	$ —	$ —	$ —	$ 1,000
Operating expenses				
Research and development, net of tax credits	3,963	6,721	10,417	25,600
General and administrative	3,742	4,227	12,741	12,561
Commercial	1,911	4,412	6,596	10,137
Loss from operations	(9,616)	(15,360)	(29,754)	(47,298)
Interest income	1,080	1,120	3,260	2,921
Interest expense	(903)	(841)	(2,662)	(1,697)
Net loss and comprehensive loss	$ (9,439)	$ (15,081)	$ (29,156)	$ (46,074)
Weighted average number of shares and pre-funded warrants outstanding, basic and diluted	66,190,302	42,973,160	60,856,495	42,920,620
Net loss per share, basic and diluted	$ (0.14)	$ (0.35)	$ (0.48)	$ (1.07)

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

	September 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 12,799	$ 13,760
Short-term investments	63,620	52,243
Research and development tax credits receivable	837	643
Prepaid expenses	2,523	3,178
Other receivables	1,211	3,208
Total current assets	80,990	73,032
Operating lease right-of-use assets	1,515	1,917
Property and equipment	201	277
Total assets	$ 82,706	$ 75,226
Liabilities, and Shareholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 4,676	$ 6,680
Operating lease liabilities	582	546
Total current liabilities	5,258	7,226
Operating lease liabilities, net of current portion	1,002	1,457
Senior secured convertible notes	52,434	49,772
Total liabilities	58,694	58,455
Shareholders' Equity		
Common shares, no par value, unlimited shares authorized 53,327,908 shares issued and outstanding as of September 30, 2024, 33,483,111 shares issued and outstanding as of December 31, 2023	288,006	260,504
Pre-funded warrants - 12,910,590 issued and outstanding as of September 30, 2024 and 9,577,257 as of December 31, 2023	53,076	48,459
Additional paid-in capital	38,112	33,834
Accumulated deficit	(355,182)	(326,026)
Total shareholders' equity	24,012	16,771
Total liabilities and shareholders' equity	$ 82,706	$ 75,226