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):
February 26, 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 8.01. Other Events.

On February 26, 2024, Milestone Pharmaceuticals Inc. (the "Company") issued a press release announcing the feedback it received during a Type A meeting with the U.S. Food and Drug Administration (the "FDA") and plans to resubmit the Company's New Drug Application for self-administered etripamil nasal spray for the treatment of paroxysmal supraventricular tachycardia to the FDA. A copy of the press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press release, dated February 26, 2024.
104	Cover Page Interactive Data File (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.

Date: February 26, 2024

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

Exhibit 99.1

Milestone Pharmaceuticals Announces Plan to Resubmit NDA for Etripamil for the Treatment of PSVT

Resubmission of NDA expected 2Q2024

Operating Runway Extended Into Mid-2025 with Cash Conservation Measures

Montreal, QC and Charlotte, N.C., February 26, 2024 -- Milestone® Pharmaceuticals Inc. (Nasdaq: MIST) today announced plans to resubmit the New Drug Application (NDA) for etripamil to the U.S. Food and Drug Administration (FDA) for paroxysmal supraventricular tachycardia (PSVT).

Following the previously announced receipt of a Refusal to File letter, Milestone held a Type A Meeting with FDA. FDA indicated that the timing of adverse events (AEs) in question had minimal impact on the overall characterization of the etripamil safety profile. To align with FDA's guidance, the Company will restructure the data sets that capture timing of reported AEs, reformat certain data files to facilitate FDA's analyses, and resubmit the NDA. Based on the guidance received during the Type A Meeting, the Company expects that this approach will address the Refusal to File letter from FDA. FDA has not requested that the Company complete additional clinical efficacy or safety trials prior to resubmitting the NDA. The Company expects a standard NDA review period following resubmission of the NDA for etripamil for PSVT, which is planned for 2Q2024.

"We thank FDA for its thoughtful consideration of our materials and direction on the NDA resubmission," said Joseph Oliveto, President, and Chief Executive Officer of Milestone Pharmaceuticals. "The feedback we continue to receive from key stakeholders, including patients and health care providers, reinforces our belief that etripamil nasal spray has the potential to be a valuable new option for patients with PSVT that may establish a new standard of care, if approved. We are committed to working with FDA to bring this potentially important new treatment to patients and our recent meeting underscores this commitment."

Considering the revised timeline for NDA submission, the Company has undertaken certain cash conservation measures to reduce spend through program deferrals and team restructuring and expects that the Company's existing cash resources will fund operations into mid-2025, including the expected Prescription Drug User Fee Act (PDUFA) date for the NDA resubmission. If FDA approval is granted, the Company expects to receive a $75 million payment under an existing royalty agreement, which is intended to fund the potential commercial launch of etripamil for PSVT.

About Paroxysmal Supraventricular Tachycardia (PSVT)

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 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 atrial fibrillation with rapid ventricular rate (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 of the Company’s NDA resubmission; the ability of the Company’s approach to the NDA resubmission to address the December 2023 requests from the FDA; the timing and outcomes the FDA's potential review of the NDA following resubmission; the potential for etripamil nasal spray to be a valuable new option for patients with PSVT; the Company’s current cash runway; the timing of any royalty payments. 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, 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.

Contact:

Kim Fox, Vice President, Communications
kfox@milestonepharma.com
704-803-9295

Investor Relations

Chris Calabrese
ccalabrese@lifesciadvisors.com
Kevin Gardner
kgardner@lifesciadvisors.com