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):
October 24, 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 7.01. Regulation FD Disclosure.

On October 24, 2023, Milestone Pharmaceuticals Inc. ("Milestone" or the "Company") issued a press release announcing the submission of a New Drug Application ("NDA") to the U.S. Food and Drug Administration (the "FDA") for etripamil for the treatment of paroxysmal supraventricular tachycardia ("PSVT"). A copy of the press release is attached hereto as Exhibit 99.1.

The Company intends to use its website as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD. Such disclosures will be included on its website in the "Investors & Media" section. Accordingly, investors should monitor such portions of its website, in addition to following press releases, filings with the U.S. Securities Exchange Commission (the "SEC") and public conference calls and webcasts.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, or the Securities Act. The information in this Item 7.01, including Exhibit 99.1, shall not be deemed incorporated by reference into any other filing with the SEC, made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01. Other Events.

On October 24, 2023, the Company announced the submission of an NDA to the FDA for etripamil for the treatment of PSVT, which follows the primary analysis and supportive assessments from the pivotal RAPID Phase 3 clinical trial that were recently published in *The Lancet*. PSVT is a condition characterized by an abnormality in the electrical system of the heart causing patients to have unexpected, often severely symptomatic episodes of rapid heart rate.

The FDA has a 60-day filing review period to determine whether the NDA is complete and acceptable for filing, after which the FDA will notify the Company. The Company continues to advance commercial preparations to support the anticipated launch of etripamil with the proposed trade name, CARDAMYST™. The brand name has been conditionally approved by the FDA.

Forward-Looking Statements

This report 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 report. 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 anticipated launch of etripamil; the success of the NDA submission for etripamil nasal spray and the timing of the FDA's approval of the NDA; and the FDA's final approval of etripamil's proposed trade name. 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 and Russian hostilities in Ukraine 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 SEC, 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, we 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.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press release, dated October 24, 2023
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: October 24, 2023

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

Exhibit 99.1

Milestone Pharmaceuticals Announces Submission of New Drug Application to the U.S. FDA for Etripamil

- *Submission seeks approval for treatment of an abnormal heart rhythm, Paroxysmal Supraventricular Tachycardia or PSVT*
- *Comprehensive data package includes positive results from pivotal Phase 3 RAPID trial which Company believes demonstrates new calcium channel blocker, etripamil, is twice as effective and three times as fast as a placebo in restoring normal heart rhythm for patients suffering from PSVT*
- *CARDAMYST™, the conditionally approved brand name for etripamil nasal spray, if approved, will be the first rapid, reliable and at-the-ready option in the treatment of serious heart arrhythmias*

Montreal and Charlotte, N.C., October 24, 2023 -- Milestone® Pharmaceuticals Inc. (Nasdaq: MIST) today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for etripamil for the treatment of paroxysmal supraventricular tachycardia (PSVT). PVST is a condition characterized by an abnormality in the electrical system of the heart causing patients to have unexpected, often severely symptomatic episodes of rapid heart rate.

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*.

“With the achievement of our first NDA submission, we want to thank the investigators, clinical trial teams, our colleagues and, most importantly, patients whose contributions were critical to completing our registration trials,” said Joseph Oliveto, President, and Chief Executive Officer of Milestone Pharmaceuticals. “With this submission, we are one step closer to getting etripamil into the hands of patients who are seeking a new treatment option that will allow them to take an active role in managing their PSVT.”

The FDA has a 60-day filing review period to determine whether the NDA is complete and accepted for review. If accepted, Milestone Pharmaceuticals expects a standard review of 10 months of the company’s NDA. Milestone continues to advance commercial preparations to support the anticipated launch of etripamil with the proposed trade name, CARDAMYST™. The brand name is conditionally approved by the FDA.

About Pivotal RAPID Phase 3 Trial

Recently published in *The Lancet*, RAPID is a global, randomized, double-blind phase 3 clinical trial of etripamil versus placebo in patients with PSVT. The trial was designed to evaluate the safety and efficacy of self-administered etripamil for treating PSVT. The RAPID trial achieved its primary endpoint with 64% of patients who self-administered etripamil converting from supraventricular tachycardia (SVT) to sinus rhythm within 30 minutes compared to 31% on placebo (HR = 2.62, $p<0.001$). At one hour, the benefit was demonstrated in 73% of patients. In addition, significant reductions in time to conversion in patients who took etripamil were evident early and durable, with a median time to conversion of 17 minutes (95% CI: 13.4, 26.5) for patients treated with etripamil versus 54 minutes (95% CI: 38.7, 87.3) for patients treated with placebo. Data demonstrated statistically significant improvement in multiple defined symptoms of PSVT in patients receiving etripamil compared to placebo, using a patient-reported outcome (PRO) questionnaire. The safety and tolerability profile of etripamil is supportive of the NDA submission.

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 doctors 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 Etripamil

Etripamil is Milestone's lead investigational product. It is a novel calcium channel blocker nasal spray being developed for elevated and often highly symptomatic heart-rate attacks associated with PSVT and atrial fibrillation with a rapid ventricular rate (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 virtual care and patient self-management. If approved, the portable treatment, studied as self-administered, may provide patients with active management and a greater sense of control over their condition. Etripamil, proposed brand name CARDAMYST™, is well studied with a robust clinical trial program that includes a completed Phase 3 clinical-stage program for the treatment of PSVT and soon-to-be-reported 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 is in a Phase 2 proof-of-concept trial for the treatment of patients with AFib-RVR. The AFib-RVR study**,** ReVeRA, was selected for a Featured Science presentation at the American Heart Association (AHA) Scientific Sessions 2023. 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 the potential of etripamil nasal spray to be the first rapid, reliable, safe, and at-the-ready option in the treatment of serious heart arrhythmias; the continued ability of etripamil provided superior time to conversion to normal heart rhythm compared to placebo; the timing of the anticipated launch of etripamil; the success of the NDA submission for etripamil nasal spray and the timing of the FDA's approval of the NDA; the FDA's final approval of etripamil's proposed trade name; and the status and timing of the Phase 2 proof-of-concept trial of etripamil for the treatment of patients with 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, 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 and Russian hostilities in Ukraine 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, we 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