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 17, 2022

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 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 17, 2022, Milestone Pharmaceuticals Inc. (the "Company") issued a press release announcing topline results from Phase 3 RAPID clinical trial of etripamil. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In connection with the announcement, the Company will host a call and webcast on October 17, 2022 at 8:00 a.m. E.T. Call details are contained in the press release. Accompanying slides may be accessed through the "Investors" section of the Company's website at www.milestonepharma.com.

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 the Exchange Act, 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 U.S. Securities Exchange Commission, or the SEC, made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release, dated October 17, 2022
104	Cover Page Interactive Data File (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: October 17, 2022

Exhibit 99.1

Milestone Pharmaceuticals Announces Positive Results from Phase 3 RAPID Clinical Trial of Etripamil Nasal Spray in Patients with Paroxysmal Supraventricular Tachycardia

- Trial met its primary endpoint, with 64.3% of patients self-administering etripamil converting to sinus rhythm within 30 minutes compared to 31.2% on placebo (HR = 2.62, p<0.001)
- Consistent safety and tolerability data support potential self-administration of etripamil
- Analyses of pooled data show statistically significant reduction in medical interventions and visits to the emergency department
- Company plans to submit an NDA to the U.S. FDA in mid-2023
- Conference call and webcast to be held today at 8:00 a.m. Eastern Time

MONTREAL and CHARLOTTE, N.C., October 17, 2022 /PRNewswire/ -- Milestone Pharmaceuticals Inc. (Nasdaq: MIST), a biopharmaceutical company focused on the development and commercialization of innovative cardiovascular medicines, today announced positive topline efficacy and safety data from the Phase 3 RAPID clinical trial of etripamil, the Company's investigational calcium channel blocker, in patients with paroxysmal supraventricular tachycardia (PSVT).

"PSVT is an unpredictable, disruptive burden on patients, with current interventions restricted to the costly and inconvenient acute care setting," said Bruce Stambler, M.D., F.H.R.S., Director of Cardiac Arrhythmia Research and Education, Piedmont Heart Institute, Atlanta, GA. "I am highly encouraged by the findings from the RAPID trial, which demonstrate that patients who administered etripamil converted to normal sinus rhythm significantly more often than placebo patients without experiencing serious adverse events, and independent of medical supervision. These data further support the potential for etripamil to deliver a clinically meaningful benefit to patients and an important and valuable tool for their physicians."

"Today marks an important achievement for Milestone and for patients with PSVT," said Joseph Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. "We believe that etripamil, if approved, has the potential to empower patients to take control of their condition as well as provide value to the healthcare system, in part by reducing visits to the Emergency Department. We look forward to working with the U.S. Food and Drug Administration (FDA) to make available what we believe is the first of its kind, self-administered therapy. On behalf of the Milestone team, I would like to thank the patients, their caregivers, and the healthcare professionals who took part in the RAPID trial."

The multi-center, randomized, double-blind, placebo-controlled RAPID trial enrolled 706 patients across clinical sites in North America and Europe. Patients were randomized 1:1 to a nasal spray of either etripamil or placebo without medical monitoring. To maximize the potential treatment effect of etripamil, patients who did not experience symptom relief within 10 minutes were directed to self-administer a repeat dose of study drug. The RAPID trial achieved its primary endpoint, with patients taking etripamil demonstrating a highly statistically significant and clinically meaningful difference in time to PSVT conversion compared to placebo. A Kaplan Meier analysis shows a statistically significantly greater proportion of patients who took etripamil converted within thirty minutes compared to placebo (64.3% vs. 31.2%; hazard ratio [HR] = 2.62; 95% CI 1.66, 4.15; p<0.001). In addition, the median time to conversion for patients in RAPID who took etripamil was three times faster than for patients who took placebo. Statistically significant reductions in time to conversion in patients who took etripamil were evident early and persisted throughout the observation window of the study compared to placebo.

The safety and tolerability data from the RAPID trial continue to support the potential self-use of etripamil, with findings consistent with those observed in prior trials. The most common randomized treatment emergent adverse events (RTEAEs), adverse events (AEs) which occurred within 24 hours of study drug administration, were related to the nasal administration site. Overall, the majority of RTEAEs were reported as mild (68%) to moderate (31%). There were no reported serious AEs related to etripamil. To date, the Company's overall PSVT clinical program has resulted in more than 1,600 unique patient exposures of etripamil doses of ≥70 mg.

Analyses of pooled data from the NODE-301 and RAPID trials show that etripamil treatment provided a statistically significant reduction in the use of additional medical interventions, and a statistically significant reduction in visits to the emergency department.

Full results from the Phase 3 RAPID clinical trial are expected to be presented at an upcoming medical meeting and submitted to a peer-reviewed journal for publication.

As previously communicated, the Company believes results from the RAPID trial together with the data from the already completed NODE-301 trial could fulfill the efficacy requirement for a New Drug Application (NDA) submission for etripamil in patients with PSVT. The Company continues to enroll patients in the open label NODE-303 safety trial and plans to submit an NDA application in mid-2023 pending agency feedback.

Conference Call and Webcast

Milestone will host a conference call and webcast to discuss the results of the RAPID trial today, October 17, 2022 at 8:00 a.m. ET. To access the live call by phone, dial (877) 870-4263 (domestic) or (412) 317-0790 (international); the conference ID is 10171280. A live audio webcast of the event and accompanying slides may also be accessed through the "Investors" section of Milestone's website at www.milestonepharma.com. A replay of the webcast will be available for one year following the event.

About Paroxysmal Supraventricular Tachycardia

Paroxysmal supraventricular tachycardia (PSVT) is a condition affecting approximately two million Americans that is characterized by intermittent episodes of a rapid heartbeat that starts and stops suddenly. Episodes of supraventricular tachycardia (SVT) are often associated with symptoms such as palpitations, sweating, chest pressure or pain, shortness of breath, sudden onset of fatigue, lightheadedness or dizziness, fainting, and anxiety. Certain intravenous medications, including adenosine, beta-blockers and calcium channel blockers, have long been used for the acute treatment of PSVT. However, these medications must be administered under medical supervision, usually in an emergency department or other acute care setting.

About Etripamil

Etripamil, a new chemical entity, is Milestone's lead investigational product. It is a novel calcium channel blocker designed to be a rapid-response therapy for episodic cardiovascular conditions. As a nasal spray that is self-administered by the patient, etripamil has the potential to shift the current treatment experience for many patients from the emergency department to a medically unsupervised setting. Milestone is conducting a comprehensive development program for etripamil, with Phase 3 trials ongoing in paroxysmal supraventricular tachycardia (PSVT) and a Phase 2 proof-of-concept trial that is underway in patients with atrial fibrillation with rapid ventricular rate (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 is currently in a Phase 3 clinical-stage program for the treatment of paroxysmal supraventricular tachycardia (PSVT) and in a Phase 2 proof-of-concept trial for the treatment of patients with atrial fibrillation with rapid ventricular rate (AFib-RVR). Milestone Pharmaceuticals operates in Canada and the United States. For more information, visit www.milestonepharma.com and follow Milestone on Twitter at @MilestonePharma.

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," "design," "develop," "estimate," "expect," "further," "look forward," "ongoing," "plan," "potential," "progress," "will," "would," 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 efficacy, safety and tolerability of etripamil; the potential of etripamil to deliver a clinically meaningful benefit to patients with PSVT in the home-setting environment and to empower patients to take control of their condition as well as provide value to the healthcare system; the design, progress, timing, scope and results of the RAPID trial; Milestone's ability to execute on the remainder of the PSVT program; the presentation and publication of unblind RAPID results and topline data with respect to the Company's RAPID trial and the timing of such presentation and publication; the timing of Milestone's NDA application, the ability of the results from the RAPID study to fulfil the efficacy requirements of such NDA application and the timing of agency feedback on the application; and Milestone's ongoing plans to study etripamil in atrial fibrillation patients and estimates about the addressable market and commercial potential for treatments of atrial fibrillation with rapid ventricular rate. 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 and evaluation of 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, AFib-RVR or other indications, among others, as well as risks related to pandemics and public health emergencies, including those related to the ongoing COVID-19 pandemic, and risks related the sufficiency of Milestone's capital resources and its ability to raise additional capital. 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, 2021, 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.

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