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):
September 3, 2026

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 September 3, 2026, Milestone Pharmaceuticals Inc. issued a press release announcing that China's National Medical Products Administration has approved etripamil nasal spray for the treatment of paroxysmal supraventricular tachycardia (PSVT) in adults. A copy of the press release is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description of Exhibit
99.1	Press Release dated September 3, 2026
104	Cover Page Interactive Data (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: September 3, 2026

Exhibit 99.1

Milestone Pharmaceuticals Announces NMPA Approval of Etripamil Nasal Spray for PSVT in China, Marking First Regulatory Approval of Etripamil Outside of the United States

Everest Medicines to Lead Commercialization in Greater China, Bringing Novel Innovation to Estimated 3-6 Million Chinese Patients with PSVT

Approval Triggers $2.0 Million Payment to Milestone Pharmaceuticals

MONTREAL and CHARLOTTE, N.C., – September 3, 2026 – Milestone® Pharmaceuticals Inc. (Nasdaq: MIST), a biopharmaceutical company focused on the development and commercialization of innovative cardiovascular medicines, today announced that China's National Medical Products Administration (NMPA) has approved etripamil nasal spray for the treatment of paroxysmal supraventricular tachycardia (PSVT) in adults. Etripamil, marketed in the United States as CARDAMYST® nasal spray, is a self-administered treatment for adults with PSVT.

The NMPA decision marks the first regulatory approval of etripamil outside the United States and triggers a $2.0 million milestone payment to Milestone Pharmaceuticals. Everest Medicines has an exclusive license with Milestone to develop etripamil nasal spray in Greater China (including Mainland China, Hong Kong, Macau and Taiwan). Under the License Agreement with Everest, Milestone is also eligible to receive up to $98.0 million in commercial and development milestones and tiered royalties of up to 18% on future sales of etripamil in Greater China.

The NMPA approval was based on data from the global pivotal Phase 3 RAPID study and the Phase 3 JX02002 study conducted in China. JX02002 met its primary endpoint, demonstrating that etripamil was significantly superior to placebo in converting PSVT to sinus rhythm within 30 minutes of treatment (hazard ratio = 3.002 [95% CI: 1.578, 5.711]; p = 0.0005). Overall, treatment-emergent adverse events were comparable between the etripamil and placebo groups, and no serious adverse events were reported within 24 hours after dosing across Phase 3 studies.

"We believe the approval of etripamil nasal spray in China represents exciting progress toward our vision to help patients around the world living with PSVT," said Joseph Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. "We congratulate Everest on this achievement and look forward to continued collaboration as they launch the product in this important market."

About Paroxysmal Supraventricular Tachycardia (PSVT)

An estimated three to six million people in China and 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 electing to pursue prolonged, burdensome, and costly trips to the emergency department or even undergo invasive cardiac ablation procedures.

About CARDAMYST in the United States

CARDAMYST® (etripamil) nasal spray is approved by the U.S. Food and Drug Administration (FDA) for the conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia (PSVT) to sinus rhythm in adults. It is a novel calcium channel blocker nasal spray designed as a self-administered rapid response therapy for patients, thereby bypassing the need for immediate medical oversight. The product is intended to provide health care providers with a new treatment option to enable on-demand care and patient self-management. This portable treatment may provide patients with active management and a greater sense of control over their condition. CARDAMYST is well studied with a robust clinical trial program that includes a completed Phase 3 clinical-stage program for the treatment of PSVT. Currently, etripamil is in Phase 2 development for treatment of PSVT in pediatric patients and Phase 3 development for control of acute atrial fibrillation with rapid ventricular rate (AFib-RVR) in adults. For more information, please visit CARDAMYST.com.

U.S. FDA Indication

CARDAMYST is indicated for the conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia (PSVT) to sinus rhythm in adults.

IMPORTANT SAFETY INFORMATION FOR CARDAMYST (etripamil)

What is CARDAMYST?

CARDAMYST is a prescription medicine used to help restore normal sinus heart rhythm in adults who have symptoms of sudden episodes of fast heartbeat called paroxysmal supraventricular tachycardia (PSVT).

It is not known if CARDAMYST is safe and effective in children.

Do not use CARDAMYST if you:

- are allergic to CARDAMYST or any of its ingredients. See the Patient Information for a complete list of ingredients in CARDAMYST.
- have limitations in activities due to heart failure (moderate to severe heart failure).
- have Wolff-Parkinson-White (WPW) syndrome, Lown-Ganong-Levine syndrome, or an abnormal heart rhythm pattern called pre-excitation (delta wave) on an electrocardiogram (ECG).

- have sick sinus syndrome without a permanent pacemaker.
- have second degree or higher atrioventricular (AV) block.

Before using CARDAMYST, tell your healthcare provider about all of your medical conditions, including if you:

- have a history of fainting.
- have low blood pressure.
- are pregnant or plan to become pregnant. It is not known if CARDAMYST will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if CARDAMYST passes into your breast milk. You should stop breastfeeding for 12 hours after treatment with CARDAMYST. During this time, pump and throw away your breast milk. Talk to your healthcare provider about the best way to feed your baby after using CARDAMYST.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of CARDAMYST?

CARDAMYST may cause serious side effects, including:

- **Fainting due to CARDAMYST effects on blood pressure, heart rate, and electrical activity of the heart.** CARDAMYST may cause dizziness and fainting, especially in people with a history of fainting and certain heart problems, or people with a history of fainting during an episode of PSVT. Use CARDAMYST while sitting in a safe area where you will not fall if you become dizzy or lightheaded. Lie down if you feel dizzy or lightheaded after using CARDAMYST. If fainting occurs after using CARDAMYST, caregivers should place you on your back and seek medical help.

The most common side effects of CARDAMYST include:

• nasal discomfort • nasal congestion • runny nose	• throat irritation • nosebleed

These are not all of the possible side effects for CARDAMYST. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see the full Prescribing Information

https://milestonepharma.com/etripamilprescribinginformation.pdf for CARDAMYST.

About Milestone Pharmaceuticals

Milestone Pharmaceuticals Inc. (Nasdaq: MIST) is an emerging commercial-stage biopharmaceutical company advancing innovative cardiovascular medicines to benefit people living with certain heart conditions. Milestone's lead product is CARDAMYST® (etripamil) nasal spray, a novel calcium channel blocker, which is FDA-approved for the conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia (PSVT) to sinus rhythm in adults. Etripamil is also in Phase 3 development for the control of symptomatic episodic attacks associated with AFib-RVR. https://milestonepharma.com/

Cautionary Note on 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 commercialization and adoption of CARDAMYST; the ability of Milestone to receive up to $98 million in milestone payments and royalties on future sales of etripamil in Greater China; the expected timing of initiation, completion, and results and data of Milestone's ongoing and planned clinical studies, including the Phase 3 study in AFib-RVR; and other statements not related to historical facts. 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 Milestone's 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, international tariffs and conflicts, and overall fluctuations in the financial markets in the United States and abroad, risks related to pandemics and public health emergencies, and risks related to 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, 2025, under the caption "Risk Factors," as such discussions 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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