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):
May 13, 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 2.02. Results of Operations and Financial Condition.

On May 13, 2026, Milestone Pharmaceuticals Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2026 and other business highlights. A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

The information provided in this Item 2.02, including Exhibit 99.1 hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated May 13, 2026
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: May 13, 2026

Exhibit 99.1

Milestone Pharmaceuticals Announces First Quarter 2026 Financial Results and Provides Corporate Update

- *CARDAMYST™ (etripamil) nasal spray launch for PSVT is gaining traction; breadth of unique prescribers supports potential future adoption*
- *Express Scripts national formulary coverage secured as company makes progress toward broad patient access*
- *Atrial Fibrillation-RVR Phase 3 registration trial initiated: patient enrollment to begin in H2 2026*
- *Strong balance sheet of $184.2M provides runway into H2 2027 to fund commercial and operational priorities*
- *Company to host investor call and webcast at 8:30am ET today*

Montreal and Charlotte, N.C., May 13, 2026 – Milestone® Pharmaceuticals Inc. (Nasdaq: MIST) a biopharmaceutical company focused on the development and commercialization of innovative cardiovascular medicines, today announced financial results for the first quarter ending March 31, 2026, and provided corporate and regulatory updates.

"We're excited to report on our first quarter of sales for CARDAMYST for paroxysmal supraventricular tachycardia, or PSVT. Healthcare professionals' initial reaction to the product is positive and we are very encouraged by the early breadth of unique prescribers writing for their patients," said Joseph Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. "Gaining Express Scripts' national formulary coverage in March reflects meaningful early payor adoption, highlighting the value CARDAMYST offers to insurers. We are also observing clinician enthusiasm for expanded development of etripamil in patients with AFib-RVR, as we have now kicked off our Phase 3 pivotal trial and are actively engaging potential clinical trial sites."

Launch Progress for CARDAMYST

- **Promotional launch for CARDAMYST™ (etripamil) nasal spray was initiated in mid-February 2026.** The product was commercialized within approximately eight weeks of U.S. Food and Drug Administration (FDA) approval, including a 60-person national sales force engaging primarily with cardiologists, electrophysiologists and advanced practice providers in an office-based setting.
  - A total of approximately 600 scripts for CARDAMYST have been filled for 560 patients with PSVT through April.
  - Approximately 400 unique prescribers have started patients on CARDAMYST.
  - Over 25% of commercially insured lives in the U.S. now have coverage for CARDAMYST.

- **Express Scripts added CARDAMYST nasal spray to its commercial national formularies, effective March 27, 2026.** This inclusion made CARDAMYST broadly accessible and more affordable for their commercially insured lives across the United States.

- **Etripamil global expansion advancing in Europe and China.**
  - The marketing authorization application (MAA) for etripamil nasal spray in PSVT was accepted for review by the European Medicines Agency (EMA). The MAA incorporates the global clinical data package that supported the FDA approval of etripamil for the treatment of PSVT. TACHYMIST™ is the conditionally approved brand name for etripamil nasal spray in Europe. A European decision on approval is expected by the first half of 2027.

  - Separately, in March 2026, Everest Medicines announced it had acquired the rights from the Company's China licensing partner, Corxel Pharmaceuticals to develop, manufacture, and commercialize CARDAMYST in Greater China, including Chinese Mainland, Hong Kong, Macao and Taiwan regions. In China, the New Drug Application (NDA) for etripamil nasal spray was accepted by the National Medical Products Administration (NMPA) on January 17, 2025.

Clinical Updates and Presentations

- Details on **RESET-PSVT, a planned Phase 4, multicenter, prospective, observational registry intended to generate real-world evidence on the use of CARDAMYST in adults with PSVT** were presented at the Preventive Cardiovascular Nurses Association (PCNA) 2026 Cardiovascular Nursing Symposium in Scottsdale, Ariz. The study will be led by the Duke Clinical Research Institute (DCRI).

- **"Minimal Blood Pressure Effects of Intranasal Etripamil for PSVT" was presented at the American College of Cardiology (ACC) Annual Scientific Session in New Orleans.** The presentation summarizes analysis of mean heart rate and blood pressure changes measured during clinical trials of CARDAMYST. The results demonstrate minimal blood pressure reductions during test dose and rare symptoms consistent with hypotension, supporting the potential safe self-administration of CARDAMYST for PSVT treatment.

- **"Reduction in Health Care Utilization & Emergency Department Visits with Acutely Self-Administered Etripamil for SVT: Study Data"** was presented at the Stanford BioDesign Arrhythmia Technologies Meeting held prior to HRS.2026 in Chicago, Ill. Data were described on the level and growth in U.S. healthcare burden from PSVT along with relevant data from the CARDAMYST development program.

Etripamil for Patients with Atrial Fibrillation with Rapid Ventricular Rate (AFib-RVR)

- **Phase 3 program in AFib-RVR now initiated.** The Company has initiated a Phase 3 registrational program to evaluate self-administered etripamil as a potential treatment for patients with AFib-RVR, and is currently onboarding clinical sites. The Company expects to enroll the first patient in the trial in the second half of 2026. The Company intends to follow the supplemental New Drug Application (sNDA) regulatory approval pathway and expects to leverage the initial PSVT indication and its safety database along with the results from the planned single Phase 3 study in AFib-RVR.

First Quarter 2026 Financial Results

- As of March 31, 2026, Milestone had cash, cash equivalents, and short-term investments of $184.2 million, compared to $106.0 million on December 31, 2025. The Company currently expects its cash, cash equivalents and short-term investments to be sufficient to cover operating expenses and capital expenditure into the second half of 2027, including expenses expected in connection with the initiation of the Phase 3 trial in AFib-RVR, as described above.
- Product revenues were $0.2 million during the three months ended March 31, 2026. There was no product revenue during the three months ended March 31, 2025.
- Research and development expense for the first quarter of 2026 was $3.3 million, compared with $5.0 million for the prior year period. The decrease compared with the prior year was primarily due to a decrease in outside service costs related to drug development and research.
- General and administrative expense for the first quarter of 2026 was $4.8 million, compared with $5.2 million for the prior year period. The decrease was primarily due to a decrease in professional costs partially offset by an increase in personnel costs.
- Commercial expense for the first quarter of 2026 was $15.8 million, compared with $10.4 million for the prior year period. This increase was primarily a result of additional personnel costs, professional costs, and other operational expenses related to the launch of CARDAMYST.
- For the first quarter of 2026, net loss was $26.1 million or $0.20 per share, compared to a net loss of $20.8 million or $0.31 per share for 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 March 31, 2026, filed with the SEC on May 13, 2026.

Conference Call and Webcast Details

Conference Dial-in:	1-877-407-0792
International Dial-in:	1-201-689-8263
Conference ID:	13760062
Webcast link:	click here

Call me™: Participants can use Guest dial-in numbers above and be answered by an operator OR click the Call me™ link for instant telephone access to the event. The Call me™ link will be made active 15 minutes prior to scheduled start time.

A replay of the audio webcast of the call will be available under the "Investors and Media" section of Milestone's corporate website, www.milestonepharma.com.

About CARDAMYST

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 healthcare 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.

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 development for the control of symptomatic episodic attacks associated with AFib-RVR.

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: regarding the commercialization and adoption of CARDAMYST; expectations in regards to etripamil's efficacy; the timing and outcomes of future interactions with U.S. and foreign regulatory bodies, including the FDA, EMA and NMPA; 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; Milestone's anticipated cash runway; 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, whether Milestone's future interactions with the EMA will have satisfactory outcomes; whether and when, if at all, Milestone's MMA for etripamil will be approved by the EMA; 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 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.

Contact:
Investor Relations
Kevin Gardner, kgardner@lifesciadvisors.com

Media Relations
Rebecca Novak, rnovak@milestonepharma.com

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

	March 31, 2026	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	$ 71,317	$ 73,046
Short-term investments	112,899	32,914
Accounts receivable, net	1,605	—
License receivable	1,546	1,546
Research and development tax credits receivable	425	316
Prepaid expenses	1,210	1,805
Inventory, net	1,826	648
Other receivables	1,425	1,646
Total current assets	192,253	111,921
Operating lease right-of-use assets	981	1,129
Property and equipment, net	500	511
Total assets	$ 193,734	$ 113,561
Liabilities, and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 10,023	$ 5,645
Accrued liabilities	9,803	7,644
Operating lease liabilities	659	647
Deferred revenue	416	—
Other current liabilities	43	43
Total current liabilities	20,944	13,979
Operating lease liabilities, net of current portion	366	539
Senior secured convertible notes	58,192	57,191
Royalty financing obligation, long-term	78,111	—
Other long-term liabilities	72	83
Total liabilities	157,685	71,792
Shareholders' Equity		
Common shares, no par value, unlimited shares authorized, 117,794,417 shares issued and outstanding as of March 31, 2026, 106,236,344 shares issued and outstanding as of December 31, 2025	373,702	352,619
Pre-funded warrants - 16,412,925 issued and outstanding as of March 31, 2026 and 16,412,925 as of December 31, 2025	55,649	55,649
Additional paid-in capital	63,367	64,104
Accumulated deficit	(456,669)	(430,603)
Total shareholders' equity	36,049	41,769
Total liabilities and shareholders' equity	$ 193,734	$ 113,561

Milestone Pharmaceuticals Inc.
Condensed Consolidated Statements of Loss (Unaudited)
(in thousands of US dollars, except share and per share data)

	Three months ended March 31,	
	2026	**2025**
Revenues		
Product revenue, net	$ 238	$ —
License and other revenue	—	—
Total revenues	238	—
Operating Expenses		
Cost of product sales	14	—
Research and development, net of tax credits	3,251	4,978
General and administrative	4,824	5,167
Commercial	15,812	10,378
Total operating expenses	23,901	20,523
Loss from operations	(23,663)	(20,523)
Interest income	1,732	697
Interest expense	(4,135)	(935)
Net loss and comprehensive loss	$ (26,066)	$ (20,761)
Weighted average number of shares and pre-funded warrants outstanding, basic and diluted	130,286,033	66,285,406
Net loss per share, basic and diluted	$ (0.20)	$ (0.31)