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):
August 12, 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 August 12, 2026, Milestone Pharmaceuticals Inc. issued a press release announcing its financial results for the second quarter ended June 30, 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 August 12, 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: August 12, 2026

Exhibit 99.1

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

Over 50% of commercially insured lives in the U.S., representing a recent and significant increase, now have coverage for CARDAMYST® (etripamil) nasal spray

Phase 3 registrational trial of etripamil for atrial fibrillation with rapid ventricular rate (AFib-RVR) first clinical sites activated, advancing Milestone's potential, second cardiovascular indication

$170.6 million in cash, cash equivalents and short-term investments as of June 30, 2026, provides runway into H2 2027

Company to host investor call and webcast at 8:30am ET today

MONTREAL and CHARLOTTE, N.C., August 12, 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 second quarter ended June 30, 2026, and provided corporate and regulatory updates.

"We continue to make steady progress on the launch of CARDAMYST for PSVT supported by prescription growth from a widening base of new prescribers and a meaningful recent increase in insurance coverage. We are confident that this increased coverage paired with optimized sales and marketing strategies positions us to drive acceleration of CARDAMYST prescriptions moving forward," said Joseph Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. "Separately, we have activated several sites in our Phase 3 ReVeRA-301 trial in AFib-RVR and look forward to enrolling the first patient. AFib-RVR is one of the most common heart arrhythmias, affecting millions of Americans. The trial is evaluating the same self-administered regimen already approved in PSVT, giving us a clear path toward extending etripamil to a larger, adjacent patient population."

Launch Progress for CARDAMYST

CARDAMYST® (etripamil) nasal spray was launched for paroxysmal supraventricular tachycardia (PSVT) in mid-February 2026.

- More than 800 unique prescribers have started patients on CARDAMYST through June 30, compared to approximately 200 at the end of Q1.
- More than 1,500 scripts for CARDAMYST have been filled for more than 1,300 patients with PSVT through June 30, 2026, compared to approximately 300 scripts for 300 patients at the end of Q1.
- Commercial lives covered remained relatively unchanged through Q2 at approximately 25%; however, covered lives have significantly grown to approximately 50% to date as a result of recently reported formulary coverage for CARDAMYST from UnitedHealthcare and several other prominent commercial insurers.

- CARDAMYST has been nominated for the 2026 Prix Galien USA Awards for “Best Pharmaceutical Product.”

Regulatory and Clinical Updates

Regulatory review of the marketing authorization application for etripamil for PSVT in Europe remains on track for a decision from the European Medicines Agency (EMA) in the first half of 2027. The New Drug Application for etripamil for PSVT in China is currently under review by China’s National Medical Products Administration (NMPA). Our partner, Everest Medicines, is responsible for engagement with the NMPA for the program.

Two new articles have been published in the peer-reviewed *Journal of the American College of Cardiology: Advances,* supporting the efficacy, safety and emerging role of CARDAMYST for the management of PSVT.

- Paroxysmal Supraventricular Tachycardia Treatment: Evaluating the Evidence for Established and Newly Approved Options, a summarization of the current acute PSVT treatment landscape, that includes the limitations of existing management approaches and the emerging role of etripamil nasal spray as an acute, self-administered option for outside of the healthcare setting.

- Minimal Blood Pressure Effects of Intranasal Etripamil for Paroxysmal Supraventricular Tachycardia, an analysis showing that intranasal etripamil has minimal blood pressure effects, with hypotension and syncope occurring rarely across more than 1,600 clinical trial participants.

Additionally, “The Impact of Paroxysmal Supraventricular Tachycardia on Patients’ Daily Life and Quality of Life Between Episodes,” an analysis which demonstrates the substantial burden between PSVT episodes, PSVT patients’ quality of life and full participation in daily activities, will be presented at the upcoming European Society of Cardiology (ESC) Congress, August 28-31, 2026.

Phase 3 registrational trial in atrial fibrillation with rapid ventricular rate (AFib-RVR) is now open and enrolling patients. The ReVeRA-301 Phase 3 registrational trial evaluating self-administered etripamil as a potential treatment for patients with AFib-RVR is now open, with several sites activated and evaluating patients for enrollment. Previously announced plans to enroll the first patient in the second half of 2026 remain on track. 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 Phase 3 study in AFib-RVR.

Second Quarter 2026 Financial Results

As of June 30, 2026, Milestone had cash, cash equivalents, and short-term investments of $170.6 million, compared to $106.0 million as of 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.

Product revenues were $0.6 during the three months ended June 30, 2026. There was no product revenue during the three months ended June 30, 2025. For the six months ended June 30, 2026, product revenues were $0.8 million. There was no product revenue during the six months ended June 30, 2025.

Research and development expense for the three months ended June 30, 2026, was $3.5 million, compared with $3.7 million for the prior year period. For the six months ended June 30, 2026, research and development expense was $6.8 million, compared with $8.6 million for the same period in 2025. The decrease was a result of a decrease in outside service costs related to drug development and research.

Selling, general and administrative expense for the three months ended June 30, 2026, was $22.6 million, compared with $8.9 million for the prior year period. For the six months ended June 30, 2026, selling, general and administrative expense was $43.3 million, compared with $24.4 million for the same period in 2025. The increase was a result of additional personnel costs, professional costs, and other operational expenses related to the launch of CARDAMYST.

For the three months ended June 30, 2026, net loss was $28.6 million or $0.21 per share, compared to a net loss of $13.0 million or $0.20 per share for the prior year period. For the six months ended June 30, 2026, net loss was $54.7 million, or $0.41 per share, compared with $33.7 million, or $0.51 per share, for the same period in 2025.

For further details on the Company’s financials, refer to the Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, filed with the U.S. Securities and Exchange Commission (SEC) today.

Conference Call and Webcast Details

Conference Dial-in:	1-877-407-0792
International Dial-in:	1-201-689-8263
Conference ID:	13761073
Webcast link:	click here

CallMe™ link:

https://callme.viavid.com/viavid/?callme=true&passcode=13756738&h=true&info=company-email&r=true&B=6

CallMe™: Participants can use guest dial-in numbers above and be answered by an operator OR click the CallMe™ link for instant telephone access to the event. The CallMe™ 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 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.

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 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 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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Contact:

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

	June 30, 2026	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	$ 169,728	$ 73,046
Short-term investments	881	32,914
Accounts receivable, net	2,720	—
License receivable	—	1,546
Research and development tax credits receivable	515	316
Prepaid expenses	1,035	1,805
Inventory, net	4,722	648
Other receivables	726	1,646
Total current assets	180,327	111,921
Operating lease right-of-use assets	829	1,129
Property and equipment, net	469	511
Total assets	$ 181,625	$ 113,561
Liabilities, and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 8,454	$ 5,645
Accrued liabilities	11,983	7,644
Operating lease liabilities	670	647
Deferred revenue	1,034	—
Other current liabilities	43	43
Total current liabilities	22,184	13,979
Operating lease liabilities, net of current portion	192	539
Senior secured convertible notes	59,207	57,191
Royalty financing obligation, long-term	81,763	—
Other long-term liabilities	61	83
Total liabilities	163,407	71,792
Shareholders' Equity		
Common shares, no par value, unlimited shares authorized, 124,497,980 shares issued and outstanding as of June 30, 2026, 106,236,344 shares issued and outstanding as of December 31, 2025	384,985	352,619
Pre-funded warrants - 16,412,925 issued and outstanding as of June 30, 2026, and 16,412,925 as of December 31, 2025	55,649	55,649
Additional paid-in capital	62,867	64,104
Accumulated deficit	(485,283)	(430,603)
Total shareholders' equity	18,218	41,769
Total liabilities and shareholders' equity	$ 181,625	$ 113,561

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

	Three months ended June 30,		Six months ended June 30,	
	2026	**2025**	**2026**	**2025**
Revenues				
Product revenue, net	$ 559	$ —	$ 797	$ —
License and other revenue	—	—	—	—
Total revenues	559	—	797	—
Operating Expenses				
Cost of product sales	32	—	46	—
Research and development, net of tax credits	3,509	3,669	6,760	8,647
Selling, general and administrative	22,648	8,862	43,284	24,407
Total operating expenses	26,189	12,531	50,090	33,054
Loss from operations	(25,630)	(12,531)	(49,293)	(33,054)
Interest income	1,741	516	3,473	1,213
Interest expense	(4,725)	(951)	(8,860)	(1,886)
Net loss and comprehensive loss	$ (28,614)	$ (12,966)	$ (54,680)	$ (33,727)
Weighted average number of shares and pre-funded warrants outstanding, basic and diluted	138,691,580	66,380,118	134,512,026	66,333,024
Net loss per share, basic and diluted	$ (0.21)	$ (0.20)	$ (0.41)	$ (0.51)