



Milestone Pharmaceuticals Reports Third Quarter 2025 Financial Results and Provides Regulatory and Corporate Update

November 12, 2025

PDUFA Target Date of December 13, 2025 for CARDAMYST™ (etripamil) Nasal Spray in Paroxysmal Supraventricular Tachycardia (PSVT)

Promotional Launch Plans Set with Quick-Start Capability Upon Potential FDA Approval

\$82.6 million in Cash at September 30; Successful Equity Offering and Amended Royalty Purchase Agreement Provide Resources for Successful Launch

MONTREAL and CHARLOTTE, N.C., Nov. 12, 2025 (GLOBE NEWSWIRE) -- Milestone Pharmaceuticals Inc. (Nasdaq: MIST) today reported financial results for the third quarter ending September 30, 2025, and provided corporate and regulatory updates.

"We are approaching our December 13 Prescription Drug User Fee Act (PDUFA) date with optimism and excitement for the opportunity to bring CARDAMYST (etripamil) nasal spray to patients suffering from symptomatic PSVT," said Joseph Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. "Our team has recently increased our pre-launch activities to better enable market readiness. We strengthened our balance sheet with a successful equity financing last quarter, and together with the \$75 million royalty payment upon FDA approval, we believe we have resources in place to drive a successful commercial launch."

Third Quarter and Program Updates

Etripamil for patients with PSVT

- **A New Drug Application (NDA) for CARDAMYST is currently being reviewed by the U.S. Food and Drug Administration (FDA), with a PDUFA action date of December 13, 2025.** Milestone has strengthened our commercialization capabilities and plans to launch CARDAMYST quickly following FDA approval.
- **[New analysis](#) of etripamil clinical data presented at the American Heart Association (AHA) Scientific Sessions 2025 on November 10.** Results from more than 600 unique enrolled patients showed aligned efficacy and safety of etripamil across multiple study phases, types of trial design, and geographic regions, with etripamil treatment achieving consistently greater conversion rates for symptomatic PSVT episodes compared with placebo arms.
- **Recent presentations and peer-reviewed publications** highlight the growing body of data supporting etripamil nasal spray as a potential rapid, self-administered treatment for PSVT and AFib-RVR. Importantly, etripamil was referenced in recent [AHA ACLS Guidelines](#) noting the potential of intranasal calcium channel blockers for future treatment algorithms. Separately, NODE-303 long-term safety data were published in the [Journal of Cardiovascular Electrophysiology](#).

Etripamil for patients with atrial fibrillation with rapid ventricular rate (AFib-RVR)

- **Phase 3 protocol of etripamil in AFib-RVR (ReVeRA-301) finalized.** Milestone is poised to enter a pivotal Phase 3 program in AFib-RVR, on the strength of the successful ReVeRA Phase 2 trial. The Company intends to follow the supplemental NDA regulatory approval pathway, discussed with the FDA, and expects to leverage data from the PSVT NDA along with the results from the planned single AFib-RVR Phase 3 study for what would potentially be a second indication for etripamil. The [ReVeRA-301 study](#) design for etripamil in AFib-RVR was presented at HRX 2025.

Third Quarter and Recent Corporate Updates

- **Milestone well-financed for potential CARDAMYST launch from recent public equity offering and amended Royalty Purchase Agreement (RPA).** The Company [completed](#) an underwritten public offering providing immediate net proceeds of approximately \$48.7 million and amended RPA in July 2025. The proceeds from the offering and RPA are expected to fund the continued development and commercial launch of CARDAMYST in its lead indication of PSVT, following potential FDA approval around the PDUFA date of December 13th.

Third Quarter 2025 Financial Results

- As of September 30, 2025, Milestone had cash, cash equivalents, and short-term investments of \$82.6 million, compared to \$69.7 million as of December 31, 2024.

- No revenue was reported in the third quarter ended September 30, 2025 or for the third quarter of 2024.
- Research and development expense for the third quarter of 2025 was \$3.9 million, compared with \$4.0 million for the prior year period. For the nine months ended September 30, 2025, research and development expense was \$12.6 million compared with \$10.4 million for the same period in 2024. The increase was primarily due to higher consulting and outside service costs that were partially offset by lower personnel-related costs.
- General and administrative expense for the third quarter of 2025 was \$3.3 million, compared with \$3.7 million for the prior year period. For the nine months ended September 30, 2025, general and administrative expense was \$12.2 million, compared with the \$12.7 million for the prior year period. The decrease between the quarters is primarily due to a decrease in professional fees and personnel costs.
- Commercial expense for the third quarter of 2025 was \$4.6 million, compared with \$1.9 million for the prior year period. For the nine months ending September 30, 2025, commercial expense was \$20.1 million compared with \$6.6 million for the prior year period. These increases are a result of additional personnel costs, professional costs and other operational expenses related to preparation for the launch of CARDAMYST. With the resolution of the Complete Response Letter (CRL) we are now ramping operational expenditures in order to launch quickly following the potential approval of CARDAMYST by the FDA.
- For the third quarter of 2025, net loss was \$11.9 million, compared to \$9.4 million for the prior year period. For the nine months ended September 30, 2025, Milestone's net loss was \$45.6 million, compared to \$29.2 million in the prior year period.

For further details on the Company's financials, refer to the Quarterly Report on Form 10-Q for the quarter ending September 30, 2025, filed with the SEC on November 12, 2025.

About Etripamil

Etripamil is Milestone's lead investigational product. It is a novel calcium channel blocker nasal spray under clinical development for frequent and often highly symptomatic episodes of PSVT and AFib-RVR. It is designed as a self-administered rapid response therapy for patients thereby bypassing the need for immediate medical oversight. If approved, etripamil is intended to provide health care providers with a new treatment option to enable on-demand care and patient self-management. This portable, self-administered treatment may provide patients with active management and a greater sense of control over their condition. CARDAMYST™, the conditionally approved brand name for etripamil nasal spray, is well studied with a robust clinical trial program that includes a completed Phase 3 clinical-stage program for the treatment of PSVT and Phase 2 trial for the treatment of patients with AFib-RVR.

About Milestone Pharmaceuticals

Milestone Pharmaceuticals Inc. (Nasdaq: MIST) is a biopharmaceutical company developing and commercializing innovative cardiovascular solutions to improve the lives of people living with complex and life-altering heart conditions. The Company's focus on understanding unmet patient needs and improving the patient experience has led us to develop new treatment approaches that provide patients with an active role in self-managing their care. Milestone's lead investigational product is etripamil, a novel calcium channel blocker nasal spray that is being studied for patients to self-administer without medical supervision to treat symptomatic episodic attacks associated with PSVT and AFib-RVR.

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 outcomes of future interactions with the FDA, including the potential approval of the NDA for CARDAMYST for PSVT; Milestone's ability to receive additional cash proceeds from the warrants issued in the Offering; Milestone's ability to receive the \$75.0 million royalty payment under the Royalty Purchase Agreement on the timeline provided, or at all; Milestone's expected operating runway; CARDAMYST's potential as a novel treatment option to help patients with PSVT; Milestone's ability to make CARDAMYST quickly available to PSVT patients following FDA approval, if received; the success of Milestone's launch infrastructure; the timing of patient enrollment in the Phase 3 study of etripamil for 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, whether our future interactions with the FDA will have satisfactory outcomes; whether and when, if at all, our NDA for etripamil will be approved by the FDA; 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, international tariffs, Russian hostilities in Ukraine and ongoing disputes in Israel and Gaza 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 and its quarterly report on Form 10-Q for the quarter ended June 30, 2025, in each case 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

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

	<u>September 30, 2025</u>	<u>December 31, 2024</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 46,685	\$ 25,314
Short-term investments	35,900	44,381
Research and development tax credits receivable	808	901
Prepaid expenses	2,577	1,840
Other receivables	700	1,490
Total current assets	86,670	73,926
Operating lease right-of-use assets	944	1,376
Property and equipment	136	197
Total assets	\$ 87,750	\$ 75,499
Liabilities, and Shareholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	\$ 10,041	\$ 7,555
Operating lease liabilities	483	571
Total current liabilities	10,524	8,126
Operating lease liabilities, net of current portion	519	874
Senior secured convertible notes	56,206	53,352
Total liabilities	67,249	62,352
Shareholders' Equity		
Common shares, no par value, unlimited shares authorized, 85,169,344 shares issued and outstanding as of September 30, 2025, 53,353,984 shares issued and outstanding as of December 31, 2024	311,776	288,048
Pre-funded warrants - 16,412,925 issued and outstanding as of September 30, 2025 and 12,910,590 as of December 31, 2024	55,649	53,076
Additional paid-in capital	66,270	39,568
Accumulated deficit	(413,194)	(367,545)
Total shareholders' equity	20,501	13,147
Total liabilities and shareholders' equity	\$ 87,750	\$ 75,499

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

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses				
Research and development, net of tax credits	3,940	3,963	12,587	10,417
General and administrative	3,263	3,742	12,189	12,741
Commercial	4,626	1,911	20,107	6,596
Loss from operations	(11,829)	(9,616)	(44,883)	(29,754)

Interest income	874	1,080	2,087	3,260
Interest expense	(967)	(903)	(2,853)	(2,662)
Net loss and comprehensive loss	<u>\$ (11,922)</u>	<u>\$ (9,439)</u>	<u>\$ (45,649)</u>	<u>\$ (29,156)</u>
Weighted average number of shares and pre-funded warrants outstanding, basic and diluted	<u>96,494,588</u>	<u>66,190,302</u>	<u>76,497,361</u>	<u>60,856,495</u>
Net loss per share, basic and diluted	<u>\$ (0.12)</u>	<u>\$ (0.14)</u>	<u>\$ (0.60)</u>	<u>\$ (0.48)</u>



Source: Milestone Pharmaceuticals Inc.