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

August 12, 2025

FDA Accepted the Company's Response to the CRL for CARDAMYST™ (etripamil) Nasal Spray; New PDUFA Target Date of December 13, 2025

Milestone Strengthens Balance Sheet to Fully Commercialize CARDAMYST if Approved

Public Offering Raised Total Gross Proceeds of up to $170 Million if all Warrants are Exercised

$75 Million Royalty Purchase Agreement Payment from RTW Extended Through End of 2025

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

"With the FDA's recent acceptance of our response to the CRL, our team is energized as we work toward the potential approval of CARDAMYST in its first indication, PSVT," said Joe Oliveto, President and Chief Executive Officer of Milestone. "In parallel to our regulatory progress, we completed an equity financing in July with high-quality investors which strengthened our balance sheet and extended our operating runway. Our goal is to make CARDAMYST quickly available to PSVT patients, should the FDA grant approval this year."

Second Quarter and Recent Program Updates

Etripamil for patients with PSVT

- **FDA accepted the Company's response to the Complete Response Letter (CRL) for CARDAMYST™ (etripamil) Nasal Spray and set a new Prescription Drug User Fee Act (PDFUA) target date of December 13, 2025.** In June, Milestone submitted to the FDA its response to a CRL for CARDAMYST, its lead investigational product for the management of paroxysmal supraventricular tachycardia (PSVT). On July 11, 2025, the Company announced the FDA accepted the response to issues raised in the CRL and assigned a new PDUFA target date of December 13, 2025. Milestone has maintained its launch infrastructure that was in place prior to the CRL and has restarted targeted pre-launch activities given the new potential approval date of CARDAMYST.

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

- **Phase 3 protocol of etripamil in AFib-RVR finalized.** Milestone has finalized the Phase 3 study protocol following FDA's review and obtained concurrence with the Agency to proceed. The Company has paused initiation of enrollment in the study to prioritize resources for the preparation of the expected launch of etripamil in PSVT.

Second Quarter and Recent Corporate Updates

- **In July 2025, Milestone completed a public equity offering, raising total gross proceeds of up to $170 million, if all Series A and B warrants are exercised for cash, including immediate net proceeds of approximately $48.7 million.** Milestone intends to use the proceeds from the underwritten public offering (the "Offering"), together with existing cash and cash equivalents, to fund the continued development and commercial launch of CARDAMYST in its lead indication of PSVT, as well as for working capital and other general corporate purposes. The Offering consisted of the sale and issuance of (i) 31,500,000 of its common shares (the "Shares"), accompanying Series A common warrants (the "Series A Common Warrants") to purchase an aggregate of 31,500,000 common shares and accompanying Series B common warrants (the "Series B Common Warrants") to purchase an aggregate of 31,500,000 common shares , at a combined public offering price of $1.50 per share and accompanying Series A Common Warrant and Series B Common Warrant and (ii) in lieu of common shares to certain investors that so choose, pre-funded warrants to purchase 3,502,335 common shares, accompanying Series A Common Warrants to purchase an aggregate of 3,502,335 common shares and accompanying Series B Common Warrants to purchase an aggregate of 3,502,335 common shares, at a combined public offering price of $1.499 per pre-funded warrant and accompanying Series A Common Warrant and Series B Common Warrant, which represented the combined public offering price for the Shares and accompanying common warrants less the $0.001 per share exercise price for each such pre-funded warrant. The net proceeds to the Company received from the Offering were approximately $48.7 million after deducting underwriting commissions and estimated offering expenses payable by the Company.

- **Amended Royalty Agreement with RTW.** Milestone extended the marketing approval deadline in its $75 million purchase and sale agreement (the "Royalty Purchase Agreement") with existing shareholder, RTW Investments, LP, and certain of its affiliates (RTW) from September 30, 2025 to December 31, 2025. The proceeds from the Royalty Purchase Agreement are

expected to fund the continued development and commercial launch of CARDAMYST in its lead indication of PSVT, following potential FDA approval and satisfaction of other customary closing conditions.

Second Quarter 2025 Financial Results

- As of June 30, 2025, Milestone had cash, cash equivalents, and short-term investments of $43.4 million, compared to $69.7 million as of December 31, 2024. Subsequent to the end of the quarter, the company raised net proceeds of approximately $48.7 million from the Offering, as described above.
- There was no revenue for the second quarter ended June 30, 2025 or for the second quarter of 2024.
- Research and development expense for the second quarter of 2025 was $3.7 million, compared with $2.8 million for the prior year period. For the six months ended June 30, 2025, research and development expense was $8.6 million compared with $6.5 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 second quarter of 2025 was $3.8 million, compared with $5.0 million for the prior year period. For the six months ended June 30, 2025, general and administrative expense was $8.9 million, compared with the $9.0 million for the prior year period. The decrease between the quarters is primarily due to a decrease in legal fees, professional fees, and personnel costs.
- Commercial expense for the second quarter of 2025 was $5.1 million, compared with $1.8 million for the prior year period. For the six months ended June 30, 2025, commercial expense was $15.5 million compared with $4.7 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. As a result of the CRL, Milestone temporarily paused the ramping of operational expenditures related to launch, but has maintained the capability to launch quickly, pending approval of CARDAMYST by the FDA.
- For the second quarter of 2025, net loss was $13.0 million, compared to $9.4 million for the prior year period. For the six months ended June 30, 2025, Milestone's net loss was $33.7 million, compared to $19.7 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 ended June 30, 2025, filed with the SEC.

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 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.

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

	June 30, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 42,499	$ 25,314
Short-term investments	918	44,381
Research and development tax credits receivable	1,079	901
Prepaid expenses	748	1,840
Other receivables	924	1,490
Total current assets	46,168	73,926
Operating lease right-of-use assets	1,090	1,376
Property and equipment	159	197
Total assets	$ 47,417	$ 75,499
Liabilities, and Shareholders' (Deficit) Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 8,768	$ 7,555
Operating lease liabilities	515	571
Total current liabilities	9,283	8,126
Operating lease liabilities, net of current portion	641	874
Senior secured convertible notes	55,238	53,352
Total liabilities	65,162	62,352
Shareholders’ (Deficit) Equity		
Common shares, no par value, unlimited shares authorized, 53,494,261 shares issued and outstanding as of June 30, 2025, 53,353,984 shares issued and outstanding as of December 31, 2024	288,263	288,048
Pre-funded warrants - 12,910,590 issued and outstanding as of June 30, 2025 and 12,910,590 as of December 31, 2024	53,076	53,076
Additional paid-in capital	42,188	39,568
Accumulated deficit	(401,272)	(367,545)
Total shareholders’ (deficit) equity	(17,745)	13,147
Total liabilities and shareholders’ equity	$ 47,417	$ 75,499

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

	Three months ended June 30,		Six months ended June 30,	
	2025	2024	2025	2024
Revenue	$ —	$ —	$ —	$ —
Operating expenses				

Research and development, net of tax credits	3,669	2,815	8,647	6,454
General and administrative	3,759	5,046	8,926	8,999
Commercial	5,103	1,801	15,481	4,685
Loss from operations	(12,531)	(9,662)	(33,054)	(20,138)
Interest income	516	1,186	1,213	2,180
Interest expense	(951)	(887)	(1,886)	(1,759)
Net loss and comprehensive loss	$ (12,966)	$ (9,363)	$ (33,727)	$ (19,717)
Weighted average number of shares and pre-funded warrants outstanding, basic and diluted	66,380,118	66,165,461	66,333,024	58,160,286
Net loss per share, basic and diluted	$ (0.20)	$ (0.14)	$ (0.51)	$ (0.34)

Source: Milestone Pharmaceuticals Inc.