



Milestone Pharmaceuticals Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Regulatory and Corporate Update

March 13, 2025

FDA PDUFA review goal date of March 27, 2025 for CARDAMYST™ (etripamil) nasal spray for Paroxysmal Supraventricular Tachycardia (PSVT)

Assuming FDA approval, proposed launch in PSVT targeted for mid-2025

Milestone well-capitalized to commercialize upon approval with royalty financing

MONTREAL and CHARLOTTE, N.C., March 13, 2025 (GLOBE NEWSWIRE) -- Milestone® Pharmaceuticals Inc. (Nasdaq: MIST) today reported financial results for the fourth quarter and full year ended December 31, 2024 and provided a regulatory and corporate update.

"We are focused on the potential FDA approval for CARDAMYST and the opportunity to help the millions of patients suffering from PSVT," said Joseph Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. "Our launch preparations are well underway. We have resources secured to make CARDAMYST available to patients and healthcare providers mid-year, assuming FDA approval."

Fourth Quarter 2024 and Recent Program Updates

CARDAMYST for patients with PSVT

- **New Drug Application (NDA) for CARDAMYST for PSVT under review at U.S. FDA** Milestone is currently working to obtain U.S. Food and Drug Administration (FDA) marketing approval of CARDAMYST for the treatment of PSVT. The FDA accepted the NDA for CARDAMYST in May 2024 and has set a Prescription Drug User Fee Act (PDUFA) review goal date for March 27, 2025.
- **Milestone hosted a Commercial Launch Plan investor event** The event, which took place in New York City on February 25, 2025, provided an in-depth overview of the company's commercial strategy for CARDAMYST, if approved. A replay of the event, as well as a copy of the slides, can be found on the corporate website [here](#).
- **Notice of Allowance received from the U.S. Patent and Trademark Office (USPTO) on a new Method of Use patent for etripamil nasal spray** The new patent covers the repeat dose regimen used in the [RAPID Phase 3 study](#) that evaluated CARDAMYST in PSVT and proposed for the package insert as part of the CARDAMYST NDA. The issuance of the Notice of Allowance potentially extends the intellectual property protection for CARDAMYST in the United States until July 2042, which is an additional 6 years of potential protection for the company's intellectual property portfolio.
- **Poster on Etripamil to be presented at American College of Cardiology Annual Meeting (ACC.25)** The poster "Consistency and Predictiveness of Conversion Among Multiple Episodes of Paroxysmal Supraventricular Tachycardia (PSVT) treated with Etripamil: Outcomes from the NODE-303 trial" is scheduled to be presented on March 30, 2025 by James Ip, M.D., Division of Cardiology, Weill Cornell Medicine, New York Presbyterian Hospital.
- **Milestone hosted a key opinion leader webinar entitled "Learnings from the Field: Managing PSVT and Studying AFib-RVR in the Community Setting"** The webinar, which took place October 8, 2024, was the second of a series of planned webinars learning from community-based health care providers, featured Aamer H. Jamali, MD, FACC and Farhad Rafii, MD, FACC, both from Interventional Cardiology Medical Group in West Hills, CA. A replay of the webinar is available on the Milestone corporate website [here](#).

Etripamil for patients with AFib-RVR

- **Milestone is on track to initiate a Phase 3 trial evaluating etripamil in AFib-RVR in 2025.** The protocol of a Phase 3, potentially registrational study has been finalized and study start-up has commenced. The study will use the patient self-administration 70-mg repeat-dose regimen, of etripamil nasal spray, outside of the medically supervised setting, similar to that used in the PSVT development program.

Fourth Quarter and Full Year 2024 Financial Results

- As of December 31, 2024, Milestone had cash, cash equivalents, and short-term investments of \$69.7 million, compared to \$66.0 million on December 31, 2023.
- There was no revenue recorded for the fourth quarter or full year ended December 31, 2024, compared to \$1.0 million in the year ended December 31, 2023. Revenue in 2023 was related to a milestone payment received from Corxel Pharmaceuticals, formerly known as Ji Xing Pharmaceuticals, under the Company's License and Collaboration Agreement.
- Research and development expense for the fourth quarter of 2024 was \$3.9 million, compared with \$5.5 million for the prior year period. For the full year ended December 31, 2024, research and development expense was \$14.4 million, compared with \$31.1 million for the prior year. The decrease year over year was primarily due to lower clinical expenses

as a result of the completion of phase 3 studies.

- General and administrative expense for the fourth quarter of 2024 was \$4.0 million, compared with \$3.4 million for the prior year period. For the full year ended December 31, 2024, general and administrative expense was \$16.7 million, compared with \$15.9 million for the prior year. The increase was driven primarily by an increase in outside service costs, partially offset by a decrease in personnel costs.
- Commercial expense for the fourth quarter of 2024 was \$4.4 million, compared with \$5.0 million for the prior year period. For the full year ended December 31, 2024, commercial expense was \$11.0 million, compared with \$15.1 million for the prior year. While successfully resolving the Refusal to File letter issued by the FDA in December 2023, we implemented a reduction in personnel costs, professional costs and other operational expenses related to commercialization.
- For the fourth quarter of 2024, net loss was \$12.4 million or \$0.19 per share, compared to a net loss of \$13.6 million or \$0.32 per share for the prior year period. For the full year ended December 31, 2024, Milestone's net loss was \$41.5 million or \$0.67 per share, compared to a net loss of \$59.7 million or \$1.39 per share for the prior year.

For further details on the Company's financials, refer to the Annual Report on Form 10-K for the year ended December 31, 2024, filed with the SEC on March 13, 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 timing and outcomes of future interactions with U.S. and foreign regulatory bodies, including the FDA; the PDUFA review goal date and the potential approval by the FDA of CARDAMYST for PSVT; commercialization plans for CARDAMYST, if approved; Milestone's plans to commence and timing of a Phase 3 study in AFib-RVR; the potential extension of protection under Milestone's intellectual property portfolio; the potential of etripamil to provide health care providers with a new treatment option to enable on-demand care and patient self-management and provide patients with active management and a greater sense of control over their condition; and other statements not related to historical fact. 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; whether the clinical trials will validate the safety and efficacy of etripamil for PSVT or other indications; 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, including in its annual report on Form 10-K for the year ended December 31, 2024, under the caption "Risk Factors," as such discussion may be updated from time to time by subsequent filings Milestone may make with the U.S. Securities & Exchange Commission. 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:

Kim Fox, Vice President, Communications, kfox@milestonepharma.com

Investor Relations

Kevin Gardner, kgardner@lifesciadvisors.com

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

	<u>December 31, 2024</u>	<u>December 31, 2023</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 25,314	\$ 13,760
Short-term investments	44,381	52,243
Research and development tax credits receivable	901	643
Prepaid expenses	1,840	3,178
Other receivables	1,490	3,208
Total current assets	<u>73,926</u>	<u>73,032</u>
Operating lease right-of-use assets	1,376	1,917
Property and equipment	197	277
Total assets	<u>\$ 75,499</u>	<u>\$ 75,226</u>
Liabilities, and Shareholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	\$ 7,555	\$ 6,680
Operating lease liabilities	571	546
Total current liabilities	<u>8,126</u>	<u>7,226</u>
Operating lease liabilities, net of current portion	874	1,457
Senior secured convertible notes	53,352	49,772
Total liabilities	<u>62,352</u>	<u>58,455</u>
Shareholders' Equity		
Common shares, no par value, unlimited shares authorized 53,353,984 shares issued and outstanding as of December 31, 2024, 33,483,111 shares issued and outstanding as of December 31, 2023	288,048	260,504
Pre-funded warrants - 12,910,590 issued and outstanding as of December 31, 2024 and 9,577,257 as of December 31, 2023	53,076	48,459
Additional paid-in capital	39,568	33,834
Accumulated deficit	(367,545)	(326,026)
Total shareholders' equity	<u>13,147</u>	<u>16,771</u>
Total liabilities and shareholders' equity	<u>\$ 75,499</u>	<u>\$ 75,226</u>

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

	Years Ended	
	December 31,	
	<u>2024</u>	<u>2023</u>
Revenue	\$ —	\$ 1,000
Operating expenses		
Research and development, net of tax credits	\$ 14,357	\$ 31,052
General and administrative	16,742	15,932
Commercial	11,003	15,114
Loss from operations	<u>(42,102)</u>	<u>(61,098)</u>
Interest income	4,164	3,967
Interest expense	(3,581)	(2,554)
Net loss and comprehensive loss	<u>\$ (41,519)</u>	<u>\$ (59,685)</u>

Weighted average number of shares and pre-funded warrants outstanding, basic and diluted

62,210,702 42,955,779

Net loss per share, basic and diluted

\$ (0.67) \$ (1.39)



Source: Milestone Pharmaceuticals Inc.