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):
November 7, 2023

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 7.01. Regulation FD Disclosure.

On November 7, 2023, Milestone Pharmaceuticals Inc. ("Milestone" or the "Company") issued a press release announcing the Company will host a virtual investor and analyst webcast on Monday, November 13, 2023 at 8:00 a.m. ET, which will focus on results from the ReVeRA Phase 2 study of investigational new drug etripamil in patients with atrial fibrillation with rapid ventricular rate. A copy of the press release is attached hereto as Exhibit 99.1. To access a live or recorded webcast of the event and accompanying slides, please visit the News & Events section of Milestone's investor relations website at investors.milestonepharma.com.

The Company intends to use its website as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD. Such disclosures will be included on its website in the "Investors & Media" section. Accordingly, investors should monitor such portions of its website, in addition to following press releases, filings with the U.S. Securities and Exchange Commission (the "SEC") and public conference calls and webcasts.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, or the Securities Act. The information in this Item 7.01, including Exhibit 99.1, shall not be deemed incorporated by reference into any other filing with the SEC, made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press release, dated November 7, 2023
104	Cover Page Interactive Data File (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.

Date: November 7, 2023

By: /s/ Amit Hasija
Amit Hasija
Chief Financial Officer Principal Financial Officer

Exhibit 99.1

Milestone Pharmaceuticals to Host Investor and Analyst Webcast to Review Data from ReVeRA Phase 2 Study of Etripamil in AFib-RVR

- *Cardiac Electrophysiology Key Opinion Leaders joining the webcast include A. John Camm, MD, and Sean Pokorney, MD*

- *Conference call and webcast on Monday, November 13, 2023 at 8:00 a.m. ET*

MONTREAL and CHARLOTTE, N.C., Nov. 7, 2023 /PRNewswire/ -- Milestone Pharmaceuticals Inc. (Nasdaq: MIST) today announced that the Company will host a virtual investor and analyst webcast on Monday, November 13, 2023 at 8:00 a.m. ET. The webcast will focus on results from the ReVeRA Phase 2 study of investigational new drug etripamil in patients with atrial fibrillation with rapid ventricular rate (AFib-RVR), which is being presented as a Featured Science presentation at the American Heart Association (AHA) Scientific Sessions 2023.

Joining Milestone's management team will be:

- A. John Camm, M.D., Author on the ReVeRA AHA Featured Science presentation and British Heart Foundation Emeritus Professor of Clinical Cardiology, The Cardiology Clinical Academic Group, Molecular and Clinical Sciences Research Institute, St. George's University of London, London, UK
- Sean Pokorney, MD, MBA, Director of the Arrhythmia Core Laboratory, Duke Clinical Research Institute, Assistant Professor of Medicine, Duke University School of Medicine, Durham, NC

To access the live call by phone, dial (877) 870-4263 (domestic) or (412) 317-0790 (international) and ask to be connected to the Milestone Pharmaceuticals call. To access a live or recorded webcast of the event and accompanying slides, please visit the News & Events section of Milestone's investor relations website at investors.milestonepharma.com.

About Atrial Fibrillation with Rapid Ventricular Rate

An estimated five million Americans suffer from atrial fibrillation (AFib), a common arrhythmia marked by an irregular, disruptive and often rapid heartbeat. Incidence of atrial fibrillation (AFib) in the United States is expected to grow to approximately 10 million by 2025 and up to about 12 million by 2030. A subset of AFib patients experience episodes of abnormally high heart rate most often accompanied by palpitations, shortness of breath, dizziness, and weakness. While these episodes, known as AFib-RVR, may be treated by oral calcium channel blockers and/or beta blockers, patients frequently seek acute care in the emergency department to address symptoms. In 2016, nearly 800,000 patients were admitted to the emergency department due to AFib symptoms where treatment includes medically supervised intravenous administration of calcium channel blockers or beta blockers, or electrical cardioversion. With little available data for AFib-RVR, Milestone's initial market research indicates that 30-40% of patients with AFib experience one or more symptomatic episodes of RVR per year that require treatment, suggesting a target addressable market of approximately three to four million patients in 2030 for etripamil in patients with AFib.

About Etripamil

Etripamil is Milestone's lead investigational product. It is a novel calcium channel blocker nasal spray under clinical development for elevated and often highly symptomatic heart-rate attacks associated with paroxysmal supraventricular tachycardia (PSVT) and atrial fibrillation with a rapid ventricular rate (AFib-RVR). It is designed to be a rapid-response therapy that is self-administered by the patient, without the need for direct 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. If approved, the portable treatment, studied as self-administered, may provide patients with active management and a greater sense of control over their condition. Etripamil, proposed brand name CARDAMYST™, 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 proof-of-concept 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 medicines to benefit people living with certain heart conditions. Milestone recently submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for etripamil for treatment of an abnormal heart rhythm, paroxysmal supraventricular tachycardia or PSVT. Find out more at www.milestonepharma.com.

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" 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 anticipated growth of incidence of AFib and AFib-RVR by 2030; and the ability of etripamil to act as a rapid-response therapy that is self-administered by the patient, without the need for direct medical oversight and to provide health care providers with a new treatment option to enable on demand care and patient self-management. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, but are not limited to, the risks inherent in biopharmaceutical product development and clinical trials, including the lengthy and uncertain regulatory approval process; 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 and Russian hostilities in Ukraine 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, including in its annual report on Form 10-K for the year ended December 31, 2022, under the caption "Risk Factors," as such discussion may be updated from time to time by subsequent filings, we may make with the U.S. Securities and 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

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