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 10, 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 2.02. Results of Operations and Financial Condition.

On August 10, 2023, Milestone Pharmaceuticals Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 2023, which also provided a clinical and corporate update. A copy of the press release is attached as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated August 10, 2023.
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 10, 2023

Exhibit 99.1

Milestone Pharmaceuticals Reports Second Quarter 2023 Financial Results and Provides Clinical and Corporate Update

- *NDA submission for etripamil in patients with PSVT expected in October 2023*
- *Data featured during oral session at Heart Rhythm 2023 Annual Meeting support the potential of etripamil in patients with AFib-RVR*
- *Enrollment complete in Phase 2 ReVeRA study of etripamil in patients with AFib-RVR; topline data expected in fourth quarter of 2023*

Montreal and Charlotte, N.C., August 10, 2023 -- Milestone Pharmaceuticals Inc. (Nasdaq: MIST), a biopharmaceutical company focused on the development and commercialization of innovative cardiovascular medicines, today reported financial results for the second quarter ended June 30, 2023, and provided a clinical and corporate update.

"The remainder of 2023 represents a transformative time for the Company as we approach our first New Drug Application (NDA) submission for etripamil and continue to lay the groundwork required to successfully launch what could serve as the first and only U.S. Food and Drug Administration (FDA) approved treatment for patients to self-treat their paroxysmal supraventricular tachycardia (PSVT)," said Joseph Oliveto, President, and Chief Executive Officer of Milestone Pharmaceuticals. "Expanding assessment of the potential clinical utility of etripamil, we have completed enrollment in ReVeRA, our Phase 2 study of etripamil in patients with atrial fibrillation with rapid ventricular rate (AFib-RVR), and we look forward to sharing topline data from this study in the fourth quarter of this year."

Recent Program Updates

Etripamil for PSVT

- **NDA Submission for Etripamil Nasal Spray in Patients with PSVT Expected in October.** Milestone expects to submit its first NDA for etripamil, the Company's investigational calcium channel blocker that is administered by patients outside of the healthcare setting, in patients with PSVT in October. Based on feedback from the FDA, data from the Company's previously completed global Phase 3 clinical program, including the RAPID and RAPID-extension studies, NODE-303 and NODE-301, are expected to fulfill the safety and efficacy requirements for the planned NDA submission.

- **Results from Phase 3 RAPID Clinical Trial of Etripamil Nasal Spray in Patients with PSVT Published in *The Lancet*.** Results from the Company's Phase 3 RAPID clinical study were recently published in *The Lancet*. The publication, titled "*Self-administered Intranasal Etripamil Using a Symptom-Prompted, Repeat-Dose Regimen for Atrioventricular-Nodal Dependent Supraventricular Tachycardia: The Randomised, Controlled RAPID Trial*," can be accessed via the following link: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)00776-6/fulltext.

Etripamil for AFib-RVR

- **Data Featured During Oral Session at Heart Rhythm 2023 Annual Meeting Support Potential of Etripamil in Patients with AFib-RVR.** Data from an analysis of a subset of patients with AFib-RVR in the NODE-303 study, which evaluated etripamil in patients with PSVT, were featured during an oral session at the Heart Rhythm 2023 Annual Meeting in May. Data demonstrated that self-administration of etripamil in patients experiencing AFib-RVR episodes resulted in a substantial reduction in ventricular rate which was sustained over 60 minutes. The safety and tolerability data from the analysis of these AFib-RVR episodes were consistent with those observed across prior studies in PSVT.

- **Enrollment Complete in the ReVeRA Phase 2 Proof-of-Concept Trial in Patients with AFib-RVR, With Topline Data Expected in the Fourth Quarter of 2023.** Enrollment is complete in ReVeRA, Milestone's Phase 2 double-blind, placebo-controlled, proof-of-concept trial of etripamil nasal spray in emergency department patients experiencing AFib-RVR. The trial, in which patients were randomized 1:1 to receive either 70 mg of etripamil or placebo, is designed to assess the safety and efficacy of etripamil nasal spray to reduce elevated ventricular rates in patients with symptomatic AFib-RVR. The primary endpoint will assess reduction in ventricular rate, with key secondary endpoints including the time to achieve the maximum reduction in rate and duration of the effect. Milestone expects to report topline data from this trial in the fourth quarter of 2023.

Second Quarter 2023 Financial Results

- As of June 30, 2023, Milestone had cash, cash equivalents, and short-term investments of $87.6 million and 33.4 million common shares issued and outstanding, with an additional 9.6 million common shares issuable upon exercise of pre-funded warrants. Cash resources as of June 30, 2023 are expected to fund operations into mid-2025.

- Research and development expense for the second quarter of 2023 was $8.6 million, compared with $10.7 million for the prior year period. For the six months ended June 30, 2023, research and development expense was $18.9 million compared with $19.4 million for the prior year period. The decreases in research and development expenses were related to decreases in clinical developmental costs and clinical personnel-related costs as a result of the Company’s Phase 3 studies reaching completion.

- General and administrative expense for the second quarter of 2023 was $4.4 million, compared with $3.9 million for the prior year period. For the six months ended June 30, 2023, general and administrative expense was $8.3 million compared with $7.6 million for the prior year period. The increases were related to an increase in personnel-related costs and consulting fees for general and administrative expenses.

- Commercial expense for the second quarter of 2023 was $3.4 million, compared with $2.2 million for the prior year period. For the six months ended June 30, 2023, commercial expense was $5.7 million compared with $3.9 million for the prior year period. The increases were related to additional personnel and professional costs required to expand capabilities and operations in anticipation of potential commercialization.

- For the second quarter of 2023, operating loss was $16.4 million, compared to $16.8 million for the prior year period. For the six months ended June 30, 2023, Milestone's operating loss was $31.9 million, compared to $30.9 million in the prior year period.

About Paroxysmal Supraventricular Tachycardia

Paroxysmal Supraventricular Tachycardia (PSVT) is a highly symptomatic and impactful heart arrhythmia characterized by unpredictable attacks of a racing heart that afflicts approximately two million Americans. Symptoms of PSVT, including palpitations, chest pressure, and shortness of breath are often debilitating, causing the patient to stop their current activities or avoid pursuits altogether. The impact and morbidity from an attack can be especially detrimental in patients with underlying cardiovascular or medical conditions, such as heart failure, obstructive coronary disease, or dehydration. The uncertainty of when an episode of SVT will strike or how long it will persist can provoke anxiety in patients, which can have a negative impact on their day-to-day life. Many doctors are unsatisfied by the lack of effective treatment options besides a prolonged, unpleasant, and costly trip to the emergency department or, for some patients, an invasive ablation procedure.

About Atrial Fibrillation with Rapid Ventricular Rate

Atrial fibrillation (AFib) is a common arrhythmia marked by an irregular and often rapid heartbeat. AFib is estimated to affect five million patients in the United States, a prevalence projected by the Centers for Disease Control to increase to twelve million patients by 2030. Atrial fibrillation with rapid ventricular rate (AFib-RVR) is a condition that many patients with AFib experience and includes episodes of abnormally high heart rate, often with symptoms of palpitations, shortness of breath, dizziness, and weakness. Oral calcium channel blockers and/or beta blockers are used to reduce the heart rate in this condition. When AFib-RVR occurs, symptoms are often burdensome enough to cause patients to seek acute care in the emergency department, where standard-of-care procedures include intravenous administration of calcium channel blockers or beta blockers, or electrical cardioversion, under medical supervision. 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, Milestone's lead investigational product, is a novel calcium channel blocker nasal spray. It is designed to be a rapid-response therapy that is self-administered by the patient, without the need for direct medical oversight, and is being developed for elevated and often highly symptomatic heart rate attacks associated with PSVT and AFib-RVR. If approved, etripamil is intended to provide health care providers with a new tool to enable virtual care and patient self-management, and to impart upon the patient a greater sense of control over their condition. Milestone is conducting a comprehensive development program for etripamil, with Phase 3 trials completed and an NDA submission expected in October 2023 in paroxysmal supraventricular tachycardia (PSVT). Milestone also has a Phase 2 proof-of-concept trial that has completed enrollment and will report topline data in patients experiencing atrial fibrillation with rapid ventricular rate (AFib-RVR) in the fourth quarter of 2023.

About Milestone Pharmaceuticals

Milestone Pharmaceuticals Inc. (Nasdaq: MIST) is a biopharmaceutical company focused on the development and commercialization of innovative cardiovascular medicines. Milestone's lead product candidate etripamil recently completed its Phase 3 clinical-stage program for the treatment of paroxysmal supraventricular tachycardia (PSVT) and is in a Phase 2 proof-of-concept trial for the treatment of patients with atrial fibrillation with rapid ventricular rate (AFib-RVR). Milestone Pharmaceuticals operates in Canada and the United States. For more information, visit www.milestonepharma.com and follow Milestone on Twitter at @MilestonePharma.

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 potential of etripamil to serve as a promising therapy for PSVT patients; the timing of the NDA submission for etripamil nasal spray; the potential for etripamil to serve as the first and only FDA-approved treatment for patients to self-treat their PSVT; the potential for clinical trial data from the Phase 2 ReVeRA program later this year; the ability for the data from the Company’s previously completed global Phase 3 clinical program, including the RAPID and RAPID-extension studies, NODE-303, and NODE-301, to fulfill the safety and efficacy requirements for the planned NDA submission; and our ability to fund operations into the middle of 2025. 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 & 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.

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,	
	2023	**2022**	**2023**	**2022**
Revenue	$ —	$ —	$ 1,000	$ —
Operating expenses				
Research and development, net of tax credits	8,622	10,657	18,879	19,425
General and administrative	4,445	3,918	8,334	7,561
Commercial	3,369	2,231	5,725	3,867
Loss from operations	(16,436)	(16,806)	(31,938)	(30,853)
Interest income	1,213	158	1,801	198
Interest expense	(820)	—	(856)	—
Net loss and comprehensive loss	$ (16,043)	$ (16,648)	$ (30,993)	$ (30,655)
Weighted average number of shares and pre-funded warrants outstanding, basic and diluted	42,937,036	42,278,563	42,895,387	42,260,682
Net loss per share, basic and diluted	$ (0.37)	$ (0.39)	$ (0.72)	$ (0.73)

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

	June 30, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 32,591	$ 7,636
Short-term investments	55,000	56,949
Research and development tax credits receivable	483	331
Prepaid expenses	5,400	6,005
Other receivables	1,092	882
Total current assets	94,566	71,803
Operating lease assets	2,175	2,423
Property and equipment	278	257
Total assets	$ 97,019	$ 74,483
Liabilities, and Shareholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 6,287	$ 5,644
Operating lease liabilities	522	495
Total current liabilities	6,809	6,139
Operating lease liabilities, net of current portion	1,729	1,996
Senior secured convertible notes	48,073	—
Total liabilities	56,611	8,135
Shareholders' Equity		
Common shares, no par value, unlimited shares authorized 33,363,971 shares issued and outstanding as of June 30, 2023, 34,286,002 shares issued and outstanding as of December 31, 2022	260,169	273,900
Pre-funded warrants - 9,577,257 issued and outstanding as of June 30, 2023 and 8,518,257 as of December 31, 2022	48,459	34,352
Additional paid-in capital	29,114	24,437
Accumulated deficit	(297,334)	(266,341)
Total shareholders' equity	40,408	66,348
Total liabilities and shareholders' equity	$ 97,019	$ 74,483

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