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):
May 11, 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 May 11, 2023, Milestone Pharmaceuticals Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 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 May 11, 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: May 11, 2023

Exhibit 99.1

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

- *NDA submission for etripamil in patients with PSVT currently on track for 3Q23*
- *Company to host virtual KOL event focused on etripamil for the potential treatment of AFib-RVR on Monday, May 22, 2023*
- *Topline data from Phase 2 ReVeRA study evaluating etripamil in patients with AFib-RVR expected in 2H, 2023*
- *Cash resources as of March 31, 2023, together with strategic March 2023 financing, expected to fund operations into mid-2025*

Montreal and Charlotte, N.C., May 11, 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 first quarter ended March 31, 2023, and provided a clinical and corporate update.

"With a New Drug Application (NDA) submission currently on track for the third quarter of this year and the expansion of our market preparation activities, we believe we are well positioned to execute on our mission of establishing etripamil as the first fast-acting, patient-administered treatment for paroxysmal supraventricular tachycardia (PSVT)," said Joseph Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. "In parallel, we increased our efforts toward assessing the potential application of etripamil in patients experiencing atrial fibrillation with rapid ventricular rate (AFib-RVR) and we are making significant progress in our Phase 2 ReVeRA program which we expect to deliver topline data from later this year. We look forward to hosting a virtual KOL event later this month highlighting this important therapeutic area with data from a subset of patients with AFib-RVR in the NODE-303 study."

Recent Program Updates

Etripamil for PSVT

- **NDA Submission for Etripamil Nasal Spray in Patients with PSVT Currently on Track for the Third Quarter of 2023.** In March 2023, Milestone announced completion and database closures of the NODE-303 open-label safety and RAPID extension studies of etripamil, the Company's investigational calcium channel blocker that is administered by patients outside of the healthcare setting, in patients with PSVT. Data from these studies are being included in the PSVT NDA for etripamil which is currently expected to be submitted to the FDA in the third quarter of 2023. The Company believes feedback received from the FDA supports the proposed approach for the NDA.

- **Data Highlighting Decreased Emergency Department (ED) Utilization in Patients with PSVT Treated with Etripamil Featured at the Professional Society for Health Economics and Outcomes Research (ISPOR) Annual Meeting**. In May 2023, data highlighting decreased ED utilization in patients treated with etripamil in the Phase 3 NODE-301 Part 1 and RAPID studies were featured during a poster session at the ISPOR Annual Meeting. The previously presented data showed that relative to placebo, etripamil was associated with a significant reduction in use of the ED for medical intervention (14% of etripamil patients vs. 22% of placebo patients in the prespecified RAPID and NODE-301 Part 1 pooled analysis), reflecting a 39% relative risk reduction.

Etripamil for AFib-RVR

- **Data from a Subset of Patients with AFib-RVR to be Presented at Heart Rhythm 2023 Annual Meeting.** Data from a subset of patients with AFib-RVR in the NODE-303 study, which evaluated etripamil in patients with PSVT, will be featured during an oral session at the Heart Rhythm 2023 Annual Meeting: "*Effect of Etripamil Nasal Spray on Ventricular Rate in Patients Experiencing Symptomatic Atrial Fibrillation*," on Friday, May 19, 2023 at 3:00 p.m. CT.

- **Company to Host Virtual Key Opinion Leader Event on Etripamil for the Treatment of AFib-RVR.** Milestone will host a virtual KOL event on Monday, May 22, 2023 at 8:00 a.m. ET to discuss etripamil for the potential treatment of patients with AFib-RVR. The event will feature a review of data being featured at the upcoming Heart Rhythm 2023 Annual Meeting, an overview of AFib-RVR, including the current treatment landscape and etripamil characteristics, and commentary on next steps for the etripamil development program in this potential indication. For details on how to access the live event or replay, please visit https://investors.milestonepharma.com/events-and-presentations.

- **Topline data from ReVeRA Phase 2 Proof-of-Concept Trial in Patients with AFib-RVR Expected in the Second Half of 2023.** Enrollment continues 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 are 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 second half of 2023.

Recent Corporate Updates

- **Announced $125 Million Strategic Financing with RTW Investments to Support the Advancement of Etripamil for PSVT.** In March 2023, Milestone announced that it entered into a $125 million strategic financing with existing shareholder, RTW Investments, LP and certain of its affiliates ("RTW"). RTW has extended its investment relationship with Milestone by purchasing $50 million of senior secured convertible promissory notes in a private placement transaction. In addition, under the terms of a purchase and sale agreement, following FDA approval of etripamil and subject to certain conditions, RTW provided a $75 million non-dilutive synthetic royalty financing commitment to Milestone in return for tiered rate, cash royalty payments based on aggregate net sales of etripamil within the United States.

- **Seth H.Z. Fischer Appointed to Board of Directors.** In March 2023, Milestone appointed Seth H.Z. Fischer to the Company's Board of Directors. Mr. Fischer brings deep operational and commercial expertise, gained through over 40 years in the pharmaceutical and medical device industry. He previously served as the chief executive officer and as a director of Vivus, Inc. Prior to Vivus, Mr. Fischer served in senior positions of increasing responsibility at Johnson & Johnson, most recently as company group chairman, Johnson & Johnson and worldwide franchise chairman of Cordis Corporation. Mr. Fischer also currently serves on the boards of Agile Therapeutics, Inc., Marinus Pharmaceuticals, Inc., Spectrum Pharmaceuticals, Inc., and Esperion Therapeutics.

First Quarter 2023 Financial Results

- As of March 31, 2023, Milestone had cash, cash equivalents, and short-term investments of $101.0 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 March 31, 2023, together with strategic March 2023 financing, expected to fund operations into mid-2025.

- Research and development expense for the first quarter of 2023 was $10.3 million, compared with $8.8 million for the prior year period. The increase was related to an increase in clinical expenses.

- General and administrative expense for the first quarter of 2023 was $3.9 million, compared with $3.6 million for the prior year period. The increase was related to increases in personnel-related costs and consulting fees for general and administrative expenses.

- Commercial expense for the first quarter of 2023 was $2.4 million, compared with $1.6 million for the prior year period. The increase was related to an increase in personnel as well as professional costs required to expand operations in anticipation of the potential market approval and commercialization.

- For the first quarter of 2023, operating loss was $15.0 million, compared to $14.0 million for 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, 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 soon to be submitted in the third quarter of 2023 in paroxysmal supraventricular tachycardia (PSVT). Milestone also has a Phase 2 proof-of-concept trial that is ongoing in patients with atrial fibrillation with rapid ventricular rate (AFib-RVR).

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 clinical trial data from the Phase 2 ReVeRA program later this year; 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.
Consolidated Statements of Loss
(in thousands of US dollars, except share and per share data)

	Three months ended March 31,	
	2023	**2022**
Revenue	$ 1,000	$ —
Operating expenses		
Research and development, net of tax credits	10,257	8,768
General and administrative	3,889	3,643
Commercial	2,356	1,636
Loss from operations	(15,502)	(14,047)
Interest income, net	552	40
Net loss and comprehensive loss	$ (14,950)	$ (14,007)
Weighted average number of shares and pre-funded warrants outstanding, basic and diluted	42,853,275	42,243,021
Net loss per share, basic and diluted	$ (0.35)	$ (0.33)

The accompanying notes are an integral part of these interim condensed consolidated financial statements.

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

	March 31, 2023	December 31,2022
Assets		
Current assets		
Cash and cash equivalents	$ 73,953	$ 7,636
Short-term investments	27,000	56,949
License receivable	1,000	—
Research and development tax credits receivable	414	331
Prepaid expenses	5,447	6,005
Other receivables	694	882
Total current assets	108,508	71,803
Operating lease assets	2,300	2,423
Property and equipment	272	257
Total assets	$ 111,080	$ 74,483
Liabilities, and Shareholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 7,423	$ 5,644
Operating lease liabilities	507	495
Interest Payable	33	—
Total current liabilities	7,963	6,139
Operating lease liabilities, net of current portion	1,862	1,996
Senior secured convertible notes	47,320	—
Total liabilities	57,145	8,135
Shareholders' Equity		
Common shares, no par value, unlimited shares authorized 33,337,214 shares issued and outstanding as of March 31, 2023, 34,286,002 shares issued and outstanding as of December 31, 2022	260,126	273,900
Pre-funded warrants - 9,577,257 issued and outstanding as of March 31, 2023 and 8,518,257 as of December 31, 2022	48,459	34,352
Additional paid-in capital	26,641	24,437
Accumulated deficit	(281,291)	(266,341)
Total shareholders' equity	53,935	66,348
Total liabilities and shareholders' equity	$ 111,080	$ 74,483

The accompanying notes are an integral part of these interim condensed consolidated financial statements.

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