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):
March 29, 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 March 29, 2023, Milestone Pharmaceuticals Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 31, 2022, 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 March 29, 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: March 29, 2023

Exhibit 99.1

Milestone Pharmaceuticals Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Clinical and Corporate Update

- *Year-end cash resources, together with $125 million proceeds from March 2023 strategic financing, expected to fund operations into mid-2025*

- *NDA submission for etripamil in patients with PSVT expected for 3Q23*

Montreal and Charlotte, N.C., Mar. 29, 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 fourth quarter and year ended December 31, 2022 and provided a clinical and corporate update.

"Following our strategic financing, we believe we are securely positioned to advance etripamil for paroxysmal supraventricular tachycardia (PSVT) through the approval process and into launch," said Joseph Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. "With U.S. Food and Drug Administration (FDA) guidance in hand and our Phase 3 studies complete, we are one step closer to achieving our goal of establishing etripamil as the first fast-acting, patient-administered treatment for PSVT. We remain on track for a New Drug Application (NDA) submission in the third quarter of this year."

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 has 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.** Milestone appointed Seth H.Z. Fischer to the Company's Board of Directors, effective March 21, 2023. 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.

Mr. Oliveto added, "It Is a pleasure to welcome Seth Fischer to our Board of Directors. Equipped with his commercialization experience, Seth will be an important expert for Milestone as we work to gain market approval of etripamil for patients with PSVT."

Recent Program Updates

- **NDA Submission for Etripamil Nasal Spray in Patients with PSVT 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 from a Subset of Patients with Atrial Fibrillation with Rapid Ventricular Rate (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.

- **Announced Positive Topline Efficacy and Safety Results from Phase 3 RAPID Clinical Trial of Etripamil Nasal Spray in Patients with PSVT.** In October 2022, the Company announced that the Phase 3 RAPID clinical trial of etripamil in patients with PSVT met its primary endpoint, with 64.3% of patients self-administering etripamil converting to sinus rhythm within 30 minutes compared to 31.2% on placebo (HR = 2.62, $p<0.001$). Safety and tolerability data from the RAPID trial continue to support the potential for at-home use of etripamil, with findings consistent with those observed in prior trials and now including data with an optional repeat dose. The most common randomized treatment emergent adverse events, meaning adverse events which occurred within 24 hours of study drug administration, were related to the nasal administration site.

- **Additional Data from the RAPID Trial Featured During Late-Breaking Session at the American Heart Association (AHA) Scientific Sessions 2022.** In November 2022, additional data from the Phase 3 RAPID trial were presented at the AHA Scientific Sessions. Data showed statistically significant and clinically meaningful conversion rates in favor of etripamil over placebo at timepoints even beyond the 30-minute mark, including etripamil conversion rates reaching approximately 74% and 80% by 60 and 90 minutes, respectively. Data demonstrating the faster median time to conversion, 17.2 minutes after administration of etripamil compared to more than 3 times longer with placebo, were also included. In addition, the presentation featured detailed pooled analyses of the Phase 3 RAPID and NODE-301 studies that showed significant reductions in emergency department visits and lower use of additional medical interventions in favor of etripamil. A complete evaluation of adjudicated ambulatory electrocardiogram measures was also presented, revealing no occurrences of second-degree or greater atrioventricular block in either arm.

Fourth Quarter and Full Year 2022 Financial Results

- As of December 31, 2022, Milestone had cash, cash equivalents, and short-term investments of $64.6 million, compared to $114.1 million as of December 31, 2021, and 34.3 million common shares issued and outstanding, with an additional 8.5 million common shares issuable upon exercise of pre-funded warrants. Milestone expects its cash, cash equivalents, and short-term investments as of December 31, 2022, plus gross proceeds of $50.0 million from March 2023 private placement financing to fund operations into the middle of 2025.

- Research and development expense for the fourth quarter of 2022 was $10.6 million, compared with $10.9 million for the prior year period. For the full year ended December 31, 2022, research and development expense was $39.8 million, compared with $38.7 million for the prior year. The increase of research and development expense is due primarily to an increase in clinical consulting fees and CRO costs associated with the conduct of the RAPID Phase 3 trial.

- General and administrative expense for the fourth quarter of 2022 was $4.1 million, compared with $3.8 million for the prior year period. For the full year ended December 31, 2022, general and administrative expense was $15.7 million, compared with $12.4 million for the prior year. The increase of general and administrative expense is due to an increase in personnel-related costs and professional and consulting costs associated with supporting a growing number of full-time employees.

- Commercial expense for the fourth quarter of 2022 was $2.6 million, compared with $2.2 million for the prior year period. For the full year ended December 31, 2022, commercial expense was $9.1 million, compared with $7.0 million for the prior year. The increase of commercial expense is due to an increase in marketing and personnel-related costs related to preparation for potential market approval and commercialization.

- For the fourth quarter of 2022, operating loss was $13.2 million, compared to $16.9 million for the prior year period. For the full year ended December 31, 2022, Milestone's operating loss was $58.4 million, compared to $42.9 million for the prior year.

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 within the next 10 years. Atrial fibrillation with rapid ventricular rate (AFib-RVR) is a condition that some patients with AFib experience and includes episodes of abnormally high heart rate, often with symptoms such as palpitations, shortness of breath, dizziness and weakness. Oral calcium channel blockers and/or beta blockers are commonly used to reduce the heart rate in this condition. When AFib-RVR occurs, symptoms often 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 under medical supervision. Milestone's 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 has completed the Phase 3 clinical program to support an NDA 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 potential for clinical trial data from the phase 3 RAPID clinical trial of etripamil nasal spray in patients with PSVT to support an NDA in the third quarter of 2023; Milestone's ability to execute on the remainder of the PSVT program; Milestone's ongoing plans to study etripamil in atrial fibrillation patients; the sufficiency of Milestone's current cash resources to support its operations; and estimates about the addressable market and commercial potential for treatments of atrial fibrillation with rapid ventricular rate. 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 December 31,		Years ended December 31,	
	2022	**2021**	**2022**	**2021**
Revenue	$ 3,500	$ —	$ 5,000	$ 15,000
Operating expenses				
Research and development, net of tax credits	10,578	10,916	$ 39,829	$ 38,671
General and administrative	4,123	3,787	15,718	12,399
Commercial	2,558	2,215	9,095	7,003
Loss from operations	(13,759)	(16,918)	(59,642)	(43,073)
Interest income, net	582	34	1,254	220
Net loss	$ (13,177)	$ (16,884)	$ (58,388)	$ (42,853)
Weighted average number of shares and pre-funded warrants outstanding, basic and diluted	42,780,252	42,208,636	42,450,316	41,833,861
Net loss per share, basic and diluted	$ (0.31)	$ (0.40)	$ (1.38)	$ (1.02)

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

	December 31, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 7,636	$ 114,141
Short-term investments	56,949	—
Research and development tax credits receivable	331	356
Prepaid expenses	6,005	4,299
Other receivables	882	127
Total current assets	71,803	118,923
Operating lease assets	2,423	711
Property and equipment	257	215
Total assets	$ 74,483	$ 119,849
Liabilities, and Shareholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 5,644	$ 6,551
Operating lease liabilities	495	224
Total current liabilities	6,139	6,775
Operating lease liabilities (net of current portion)	1,996	474
Total liabilities	8,135	7,249
Shareholders' Equity		
Common shares, no par value, unlimited shares authorized 34,286,002 shares issued and outstanding as of December 31, 2022, 29,897,559 shares issued and outstanding as of December 31, 2021	273,900	251,901
Pre-funded warrants - 8,518,257 issued and outstanding as of December 31, 2022 and 12,327,780 as of December 31, 2021	34,352	52,941
Additional paid-in capital	24,437	15,711
Accumulated deficit	(266,341)	(207,953)
Total shareholders' equity	66,348	112,600
Total liabilities and shareholders' equity	$ 74,483	$ 119,849

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