

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended **March 31, 2024**

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: **001-38899**

Milestone Pharmaceuticals Inc.

(Exact Name of Registrant as Specified in its Charter)

Québec

(State or other jurisdiction of
incorporation or organization)

Not applicable

(I.R.S. Employer
Identification No.)

**1111 Dr. Frederik-Philips Boulevard , Suite 420
Montréal, Québec CA H4M 2X6
(514) 336-0444**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of May 13th, 2024, the registrant had 53,260,467 common shares, no par value per share, outstanding.

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"Milestone Pharmaceuticals" and the Milestone logo appearing in this Quarterly Report on Form 10-Q are unregistered trademarks of Milestone Pharmaceuticals Inc. All other trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Quarterly Report on Form 10-Q may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert their rights thereto.

This Quarterly Report on Form 10-Q contains references to United States dollars and Canadian dollars. All dollar amounts referenced, unless otherwise indicated, are expressed in United States dollars. References to "\$" are to United States dollars and references to "C\$" are to Canadian dollars.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future financial condition, future operations, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "positioned," "potential," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions, including risks described in the section titled "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q, regarding, among other things:

- the initiation, timing, progress and results of our current and future clinical trials of etripamil, including our Phase 3 clinical trials of etripamil for the treatment of paroxysmal supraventricular tachycardia, our Phase 2 clinical trial of etripamil for the treatment of atrial fibrillation and rapid ventricular rate, and of our research and development programs;
- our ability to develop and, if approved by regulatory authorities, commercialize etripamil in China, Hong Kong, Macau and Taiwan through our license agreement with Ji Xing Pharmaceuticals;
- our plans to develop and commercialize etripamil and any future product candidates;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to establish collaborations or obtain additional funding;
- our ability to obtain regulatory approval of our current and future product candidates;
- our expectations regarding the potential market size and the rate and degree of market acceptance of etripamil and any future product candidates;
- our ability to fund our working capital requirements and expectations regarding the sufficiency of our capital resources;
- the implementation of our business model and strategic plans for our business, etripamil and any future product candidates;
- our intellectual property position and the duration of our patent rights;

- developments or disputes concerning our intellectual property or other proprietary rights;
- our expectations regarding government and third-party payer coverage and reimbursement;
- our ability to compete in the markets we serve;
- the impact of government laws and regulations;
- developments relating to our competitors and our industry; and
- other factors that may impact our financial results.

The foregoing list of risks is not exhaustive. Other sections of this Quarterly Report on Form 10-Q and the section titled "Risk Factors" previously disclosed in Part I, Item 1A. in our Annual Report on Form 10-K may include additional factors that could harm our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report on Form 10-Q, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. You should refer to the section titled "Risk Factors" previously disclosed in Part I, Item 1A. in our Annual Report on Form 10-K, filed with the SEC and under Milestone's SEDAR profile at www.sedarplus.com on March 21, 2024, for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	<u>March 31, 2024</u>	<u>December 31, 2023</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 10,131	\$ 13,760
Short-term investments	79,350	52,243
Research and development tax credits receivable	711	643
Prepaid expenses	2,362	3,178
Other receivables	1,413	3,208
Total current assets	<u>93,967</u>	<u>73,032</u>
Operating lease right-of-use assets	1,785	1,917
Property and equipment	249	277
Total assets	<u>\$ 96,001</u>	<u>\$ 75,226</u>
Liabilities, and Shareholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	\$ 3,575	\$ 6,680
Operating lease liabilities	555	546
Total current liabilities	<u>4,130</u>	<u>7,226</u>
Operating lease liabilities, net of current portion	1,306	1,457
Senior secured convertible notes	50,644	49,772
Total liabilities	<u>56,080</u>	<u>58,455</u>
Shareholders' Equity		
Common shares, no par value, unlimited shares authorized 53,245,165 shares issued and outstanding as of March 31, 2024, 33,483,111 shares issued and outstanding as of December 31, 2023	287,879	260,504
Pre-funded warrants - 12,910,590 issued and outstanding as of March 31, 2024 and 9,577,257 as of December 31, 2023	53,076	48,459
Additional paid-in capital	35,346	33,834
Accumulated deficit	(336,380)	(326,026)
Total shareholders' equity	<u>39,921</u>	<u>16,771</u>
Total liabilities and shareholders' equity	<u>\$ 96,001</u>	<u>\$ 75,226</u>

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

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

	Three months ended March 31,	
	2024	2023
Revenue	\$ —	\$ 1,000
Operating expenses		
Research and development, net of tax credits	3,639	10,257
General and administrative	3,953	3,889
Commercial	<u>2,884</u>	<u>2,356</u>
Loss from operations	(10,476)	(15,502)
Interest income	994	585
Interest expense	<u>(872)</u>	<u>(33)</u>
Net loss and comprehensive loss	<u>\$ (10,354)</u>	<u>\$ (14,950)</u>
Weighted average number of shares and pre-funded warrants outstanding, basic and diluted	<u>50,155,111</u>	<u>42,853,275</u>
Net loss per share, basic and diluted	<u>\$ (0.21)</u>	<u>\$ (0.35)</u>

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

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Milestone Pharmaceuticals Inc.
Condensed Consolidated Statements of Shareholders' Equity (Unaudited)
(in thousands of US dollars, except share data)

	Common Shares		Pre-funded warrants		Additional paid-in capital	Accumulated deficit	Total
	Number of shares	Amount	Number of warrants	Amount			
Balance as of December 31, 2022	34,286,002	\$ 273,900	8,518,257	\$ 34,352	\$ 24,437	\$ (266,341)	\$ 66,348
Transactions in three-month period ended March 31, 2023							
Net loss	—	—	—	—	—	(14,950)	(14,950)
Exercise of stock options	67,224	213	—	—	(89)	—	124
Pre-funded warrants - Private Placement, net of issuance costs	—	—	1,059,000	14,107	—	—	14,107
Share-based compensation	—	—	—	—	2,293	—	2,293
Exchange of common shares	(1,059,000)	(14,115)	—	—	—	—	(14,115)
Employee stock purchase plan purchases	42,988	128	—	—	—	—	128
Balance as of March 31, 2023	33,337,214	\$ 260,126	9,577,257	\$ 48,459	\$ 26,641	\$ (281,291)	\$ 53,935
Balance as of December 31, 2023	33,483,111	\$ 260,504	9,577,257	\$ 48,459	\$ 33,834	\$ (326,026)	\$ 16,771
Transactions in three-month period ended March 31, 2024							
Net loss	—	—	—	—	—	(10,354)	(10,354)
Pre-funded warrants, net of issuance costs	—	—	3,333,333	4,617	—	—	4,617
Share-based compensation	—	—	—	—	1,512	—	1,512
Issuance of common shares, net of issuance costs	19,666,667	27,258	—	—	—	—	27,258
Employee stock purchase plan purchases	95,387	117	—	—	—	—	117
Balance as of March 31, 2024	53,245,165	\$ 287,879	12,910,590	\$ 53,076	\$ 35,346	\$ (336,380)	\$ 39,921

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

Milestone Pharmaceuticals Inc.
Condensed Consolidated Statements of Cash Flows (Unaudited)
(in thousands of US dollars)

	Three months ended March 31,	
	2024	2023
Cash flows used in operating activities		
Net loss	\$ (10,354)	\$ (14,950)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	28	18
Amortization of debt costs	87	—
Accretion of investment discount	(93)	(50)
Non-cash interest expense related to debt	785	—
Share-based compensation expense	1,512	2,293
Changes in operating assets and liabilities:		
License receivable	—	(1,000)
Other receivables	1,795	188
Research and development tax credits receivable	(68)	(83)
Prepaid expenses	816	558
Operating lease assets and liabilities	(10)	1
Accounts payable and accrued liabilities	(3,432)	(912)
Interest Payable	—	33
Net cash used in operating activities	<u>(8,934)</u>	<u>(13,904)</u>
Cash provided by (used in) investing activities		
Acquisition of property and equipment	—	(32)
Acquisition of short-term investments	(52,514)	(15,000)
Redemption of short-term investments	<u>25,500</u>	<u>45,000</u>
Net cash provided by (used in) investing activities	<u>(27,014)</u>	<u>29,968</u>
Cash provided by financing activities		
Proceeds from exercise of options	—	124
Proceeds from issuance of senior secured convertible debt	—	50,000
Proceeds from issuance of common shares, net of issuance costs	27,538	—
Proceeds from issuance of pre-funded warrants, net of issuance costs	4,664	—
Proceeds from employee stock purchase plan	<u>117</u>	<u>129</u>
Cash provided by financing activities	<u>32,319</u>	<u>50,253</u>
Net increase (decrease) in cash and cash equivalents	<u>(3,629)</u>	<u>66,317</u>
Cash and cash equivalents – Beginning of period	<u>13,760</u>	<u>7,636</u>
Cash and cash equivalents – End of period	<u>\$ 10,131</u>	<u>\$ 73,953</u>

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

Milestone Pharmaceuticals Inc.
Notes to Condensed Consolidated Financial Statements
For the Three Months Ended March 31, 2024 and 2023 (Unaudited)
(in thousands of US dollars, except where noted and for share and per share data)

1 Organization and Nature of Operations

Milestone Pharmaceuticals Inc. (Milestone or the Company) is a biopharmaceutical company incorporated under the *Business Corporations Act* (Québec). Milestone is focused on the development and commercialization of cardiovascular medicines. Milestone's lead product candidate, etripamil, is a novel, potent rapid-onset calcium channel blocker that the Company designed and is developing as a rapid-onset nasal spray to be administered by patients. The Company is developing etripamil to treat paroxysmal supraventricular tachycardia, atrial fibrillation, and other cardiovascular indications.

2 Summary of Significant Accounting Policies

a) Basis of Consolidation

The condensed consolidated financial statements include the accounts of the Company and Milestone Pharmaceuticals USA, Inc. All intercompany transactions and balances have been eliminated.

b) Basis of Presentation and Use of Accounting Estimates and Significant Accounting Policies

These unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or "U.S. GAAP", and on a basis consistent with those accounting principles followed by the Company and disclosed in Note 2 of its most recent annual consolidated financial statements. Certain information, in particular the accompanying notes normally included in the annual financial statements prepared in accordance with U.S. GAAP have been omitted or condensed. Accordingly, these unaudited interim condensed consolidated financial statements do not include all the information required for full annual financial statements, and therefore, should be read in conjunction with the annual consolidated financial statements and the notes thereto for the year ended December 31, 2023.

In the opinion of the Company's management, the accompanying unaudited interim condensed consolidated financial statements contain all adjustments, consisting of only normal recurring adjustments, necessary for a fair statement of its balance sheet as of March 31, 2024, and its statements of loss, shareholders' equity and cash flows for the three months ended March 31, 2024 and 2023.

The condensed consolidated balance sheet as of December 31, 2023, was derived from audited annual consolidated financial statements, but does not contain all the footnote disclosures required by accounting principles generally accepted in the United States of America.

These unaudited interim condensed consolidated financial statements are presented in US dollars, which is the Company's functional currency.

The preparation of unaudited interim condensed consolidated financial statements in conformity with U.S. GAAP requires the Company to make estimates and judgments that affect certain reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the period. The Company bases its estimates and assumptions on current facts, historical experience and various other factors that it believes are reasonable under the circumstances, to determine the carrying values of assets and liabilities that are not readily apparent from other sources. Significant estimates and judgments include, but are not limited to,

- Estimates of the percentage of work completed of the total work over the life of the individual trial in accordance with agreements established with clinical research organizations, or CROs, contract manufacturing organizations, or CMOs, and clinical trial sites which in turn impact the research & development expenses.

Milestone Pharmaceuticals Inc.
Notes to Condensed Consolidated Financial Statements
For the Three Months Ended March 31, 2024 and 2023 (Unaudited)
(in thousands of US dollars, except where noted and for share and per share data)

- Estimate of the grant date fair value share options granted to employees, consultants and directors, and the resulting share-based compensation expense, using the Black-Scholes option-pricing model.

c) Significant Risks and Uncertainties

The Company is subject to challenges and risks specific to its business and its ability to execute on its strategy, as well as risks and uncertainties common to companies in the pharmaceutical industry, including, without limitation, risks and uncertainties associated with: obtaining regulatory approval of its product candidate; delays or problems in the supply of its study drug or failure to comply with manufacturing regulations; identifying, acquiring or in-licensing product candidates; pharmaceutical product development and the inherent uncertainty of clinical success; and the challenges of protecting and enhancing its intellectual property rights; and complying with applicable regulatory requirements.

Further, the Company may be impacted by general economic, political, and market conditions, including deteriorating market conditions due to investor concerns regarding inflation, armed conflicts, and overall fluctuations in the financial markets in the U.S. and abroad.

d) Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASU 2023-07"), which requires public entities to disclose information about their reportable segments' significant expenses on an interim and annual basis. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is evaluating the effect of adopting this new accounting guidance on its financial statements, but does not intend to early adopt.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09"). The amendments in this update require that public business entities on an annual basis (1) disclose specific categories in the rate reconciliation and (2) provide additional information for reconciling items that meet a quantitative threshold (if the effect of those reconciling items is equal to or greater than 5 percent of the amount computed by multiplying pretax income [or loss] by the applicable statutory income tax rate). The amendments also require entities on an annual basis to disclose disaggregated amounts of income taxes paid. ASU 2023-09 is effective for annual periods beginning after December 15, 2024. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. The Company is evaluating the effect of adopting this new accounting guidance on its financial statements, but does not intend to early adopt.

e) Sources of Liquidity and Funding Requirements

The Company incurred operating losses and has experienced negative operating cash flows since its inception and anticipates continuing to incur losses for at least the next several years. Further, in connection with the revised timeline for our NDA submission, we have undertaken certain cash conservation measures to reduce spending through program deferrals and team restructuring. These cash conservation measures were substantially completed during the first quarter of 2024. These cash conservation measures were partially offset by \$1.1 million in termination benefits paid as a result of the team restructuring. As of March 31, 2024, the Company had cash, cash equivalents and short-term investments of \$89.5 million and an accumulated deficit of \$ 336.4 million. Management has evaluated the Company's operating plan, including the previously mentioned cash conservation measures, against its existing cash and cash equivalents and short-term investments and determined that the Company expects to be able to support its operations for at least the next 12 months from the date of issuance of these unaudited interim consolidated financial statements.

Milestone Pharmaceuticals Inc.
Notes to Condensed Consolidated Financial Statements
For the Three Months Ended March 31, 2024 and 2023 (Unaudited)
(in thousands of US dollars, except where noted and for share and per share data)

3 Revenues

The Company recorded no revenue for the three months ended March 31, 2024. The Company recorded \$ 1.0 million in revenue for the three months ended March 31, 2023. This revenue was the result of having reached a milestone pursuant to our License and Collaboration Agreement, dated May 15, 2021, with Ji Xing Pharmaceuticals Limited (such party "Ji Xing" and , such agreement, the "Ji Xing License Agreement") due upon the successful initiation of a Phase 1 Clinical Trial of a pharmaceutical product that uses a device to deliver etripamil by nasal spray by or on behalf of Ji Xing for the treatment of PSVT in the People's Republic of China, or the Territory, including mainland China, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan. For details on the arrangement with Ji Xing, see Note 3 to our audited consolidated financial statements for the year ended December 31, 2023, filed on Form 10-K.

4 Short-term Investments

Short-term investments are classified as held-to-maturity, are initially recognized at fair value and are subsequently accounted for at amortized cost. They are comprised of guaranteed investment certificates with a maturity greater than 90 days but less than one year and, as such, are classified as current assets.

As of March 31, 2024, \$0.5 million in short-term investments were pledged as collateral for a letter of credit.

5 Debt

On March 29, 2023, we closed the transactions contemplated by a note purchase agreement, or the "Note Purchase Agreement", with RTW Investments LP and certain of its affiliates, or collectively, RTW , and issued and sold \$ 50.0 million principal amount of 6.0% Convertible Senior Notes due 2029, or the "2029 Convertible Notes", to the holders.

The 2029 Convertible Notes are senior secured obligations and are guaranteed on a senior secured basis by our wholly owned subsidiary, Milestone Pharmaceuticals USA, Inc. Interest at the annual rate of 6.0% is payable quarterly in cash or, at our option, payable in kind for the first three years. The maturity date for the 2029 Convertible Notes is March 31, 2029, the "Maturity Date". The obligations under the 2029 Convertible Notes are secured by substantially all of our and our subsidiary guarantor's assets.

Each \$1,000 of principal of the 2029 Convertible Notes (including any interest added thereto as payment in kind) is convertible into 191.0548 shares of our common shares, equivalent to an initial conversion price of approximately \$ 5.23 per share, subject to customary anti-dilution and other adjustments. In addition, following a notice of redemption or certain corporate events that occur prior to the Maturity Date, we will, in certain circumstances, increase the conversion rate for a holder who elects to convert its 2029 Convertible Notes in connection with such notice of redemption or corporate event.

On or after March 27, 2027, the 2029 Convertible Notes are redeemable by us, subject to certain conditions, if the closing sale price of the common shares exceeds 150% of the conversion price then in effect for at least 20 trading days (whether or not consecutive), including the trading day immediately preceding the date on which we provide notice of redemption, during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption, at a redemption price equal to 100% of the principal amount of the 2029 Convertible Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

In accounting for the issuance of the Convertible Notes, the Company determined there were no embedded features, which require bifurcation between debt and equity components. As a result, the Convertible Notes are accounted for as a liability. As of March 31, 2024, the estimated fair value of the Convertible Notes was approximately \$47.5 million based on level 2 inputs.

Milestone Pharmaceuticals Inc.
Notes to Condensed Consolidated Financial Statements
For the Three Months Ended March 31, 2024 and 2023 (Unaudited)
(in thousands of US dollars, except where noted and for share and per share data)

The net carrying amount of the Convertible Note were as follows:

	March 31, 2024	December 31, 2023
Original principal	\$ 50,000	\$ 50,000
Paid in kind (PIK) interest	3,094	2,310
Unamortized debt discount	(528)	(547)
Unamortized debt issuance costs	(1,922)	(1,991)
Total	\$ 50,644	\$ 49,772

The following table presents the total amount of interest cost recognized relating to the 2029 Convertible Notes:

	Three months ended March 31,	
	2024	2023
Contractual interest expense	\$ 785	\$ 30
Amortization of debt discount	18	1
Amortization of debt issuance costs	69	2
Total interest expense	\$ 872	\$ 33

6 Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities are comprised of the following:

	March 31, 2024	December 31, 2023
Trade accounts payable	\$ 1,727	\$ 3,981
Accrued compensation and benefits payable	824	712
Accrued research and development liabilities	518	894
Accrued commercial liabilities	40	710
Other accrued liabilities	466	383
Total	\$ 3,575	\$ 6,680

7 Shareholders' Equity

Authorized Share Capital

The Company has authorized and issued common shares, voting and participating, without par value, of which unlimited shares were authorized and 53,245,165 shares were issued and outstanding as of March 31, 2024.

As of March 31, 2024, there were 1,798,766 common shares available for issuance under the Employee Stock Purchase Plan, or the ESPP, of which 1,561,373 are available for future purchases.

On February 28, 2024, we entered into an underwriting agreement, or the Underwriting Agreement, related to an underwritten public offering, or the Offering, of 16,666,667 of our common shares, without par value, at a public offering price of \$1.50 per share and, in lieu of common shares to certain investors, pre-funded warrants to purchase 3,333,333 Shares at a public offering price of \$1.499 per pre-funded warrant. Each pre-funded warrant has an exercise price of \$0.001

Milestone Pharmaceuticals Inc.
Notes to Condensed Consolidated Financial Statements
For the Three Months Ended March 31, 2024 and 2023 (Unaudited)
(in thousands of US dollars, except where noted and for share and per share data)

per share. The pre-funded warrants were exercisable immediately upon issuance, subject to certain beneficial ownership limitations. Under the terms of the Underwriting Agreement, we granted the underwriters party thereto, or the Underwriters, an option to purchase up to an additional 3,000,000 common shares at the same price per share as the other common shares sold in the Offering, which was exercised by the Underwriters in full on February 29, 2024.

On March 22, 2023, the Company entered into an exchange agreement, or the Exchange Agreement, with entities affiliated with RTW, or the Exchanging Stockholders, pursuant to which the Company exchanged an aggregate of 1,059,000 shares of the Company's common shares owned by the Exchanging Stockholders for pre-funded warrants, or the Exchange Warrants, to purchase an aggregate of 1,059,000 common shares, with an exercise price of \$0.001 per share and no expiration date. The Exchange Warrants are exercisable immediately and no additional cash consideration was rendered in exchange for the warrants. A holder of the Exchange Warrants (together with its affiliates and other attribution parties) may not exercise any portion of an Exchange Warrant to the extent that immediately prior to or after giving effect to such exercise the holder, together with its affiliates, would beneficially own more than 9.99% of the Company's outstanding common shares immediately after exercise, which percentage may be increased or decreased to any other percentage specified not in excess of 9.99% at the holder's election upon 61 days' notice to the Company subject to the terms of the Exchange Warrants.

8 Share Based Compensation

Stock Options

Under the Company's 2019 Equity Incentive Plan, or the 2019 Plan, and the Company's Stock Option Plan, or the 2011 Plan, unless otherwise decided by the Board of Directors, options vest and are exercisable as follows: 25% vest and are exercisable on the one year anniversary of the grant date and one thirty-sixth (1/36th) of the remaining options vest and are exercisable each month thereafter, such that options are vested in full on four-year anniversary of the grant date.

On January 1, 2024, the number of the Company's common shares reserved for issuance under the 2019 Plan automatically increased by 1,339,324 common shares. In addition, 125,323 options have been forfeited under the 2011 Plan since the adoption of the 2019 Plan and have become available for issuance under the 2019 Plan. Further, since the adoption of the plan, 561,000 of previously issued options were cancelled and were made available for future grants. As of March 31, 2024, there were 9,522,270 common shares available for issuance under the 2019 Plan, of which 3,399,059 common shares were available for future grants.

On November 10, 2021, the Company established a 2021 Inducement Plan, or the Inducement Plan, through the granting of awards. This 2021 Inducement Plan is intended to help the Company provide an inducement material for certain individuals to enter into employment with the Company, incentives for such persons to exert maximum efforts for the success of the Company and provide a means by which employees may benefit from increases in value of the common shares. As of March 31, 2024, there were 1,000,000 shares available for issuance under the 2021 Inducement Plan, of which 473,250 shares were available for future grants.

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The total outstanding and exercisable options from the 2011 Plan, 2019 Plan and Inducement Plan as of March 31 were as follows:

2024					
	Number of shares		Weighted average exercise price		
	2019 Plan	Inducement Plan	2011 Plan	Total	
Outstanding at beginning of year - 2011 Plan	—	—	1,694,233	1,694,233	\$ 2.09
Outstanding at beginning of year - 2019 Plan	6,406,897	—	—	6,406,897	5.82
Outstanding at beginning of year - Inducement Plan	—	625,000	—	625,000	5.74
Granted - 2019 Plan	45,000	—	—	45,000	1.45
Forfeited - Inducement Plan	—	(98,250)	—	(98,250)	4.33
Forfeited - 2019 Plan	(386,053)	—	—	(386,053)	4.42
Expired - 2019 Plan	(13,722)	—	—	(13,722)	6.36
Outstanding at end of period	6,052,122	526,750	1,694,233	8,273,105	\$ 5.11
Outstanding at end of period - Weighted average exercise price	\$ 5.88	\$ 6.00	\$ 2.09	\$ 5.763,917	\$ 5.24
Exercisable at end of period	3,819,413	250,271	1,694,233	5,763,917	\$ 5.24
Exercisable at end of period - Weighted average exercise price	\$ 6.56	\$ 6.42	\$ 2.09	\$ 6.22	\$ 6.22
2023					
	Number of shares		Weighted average exercise price		
	2019 Plan	Inducement Plan	2011 Plan	Total	
Outstanding at beginning of year - 2011 Plan	—	—	1,802,672	1,802,672	\$ 2.05
Outstanding at beginning of year - 2019 Plan	5,314,312	—	—	5,314,312	8.35
Outstanding at beginning of year - Inducement Plan	—	503,000	—	503,000	6.41
Granted - 2019 Plan	1,487,400	—	—	1,487,400	3.59
Granted - Inducement Plan	—	—	—	—	—
Exercised - 2019 Plan	(7,000)	—	—	(7,000)	3.74
Exercised - 2011 Plan	—	—	(60,224)	(60,224)	1.63
Forfeited - Inducement Plan	—	—	—	—	—
Forfeited - 2019 Plan	(5,323)	—	—	(5,323)	7.45
Forfeited - 2011 Plan	—	—	—	—	—
Expired - 2019 Plan	(24,617)	—	—	(24,617)	17.80
Expired - 2011 Plan	—	—	—	—	—
Outstanding at end of period	6,764,772	503,000	1,742,448	9,010,220	\$ 6.22
Outstanding at end of period - Weighted average exercise price	\$ 7.28	\$ 6.41	\$ 2.07	\$ 6.22	\$ 6.22
Exercisable at end of period	2,896,996	89,375	1,742,448	4,728,819	\$ 6.62
Exercisable at end of period - Weighted average exercise price	\$ 9.36	\$ 6.47	\$ 2.07	\$ 6.62	\$ 6.62

The weighted average remaining contractual life was 6.7 and 7.7 years for outstanding options as of March 31, 2024 and 2023, respectively. The weighted average remaining contractual life was 5.9 and 6.6 years for vested options, as of March 31, 2024 and 2023, respectively.

There was \$8.6 million and \$17.7 million of total unrecognized compensation cost related to non-vested share options as of March 31, 2024 and 2023, respectively. The share options are expected to be recognized over a remaining weighted average vesting period of 2.3 years and 2.6 years as of March 31, 2024 and 2023, respectively.

Options granted are valued using the Black-Scholes option pricing model. This model also requires assumptions, including expected option life, volatility, risk-free interest rate and dividend yield, which greatly affect the calculated values.

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Amortization of the fair value of the options over vesting years has been expensed and credited to additional paid-in capital in shareholders' equity.

The non-vested options as of March 31 were as follows:

	2024				
	Number of options			Total	Weighted average fair value
	2019 Plan	Inducement Plan	2011 Plan		
Non-vested share options at beginning of year - 2019 Plan	3,178,475	—	—	3,178,475	3.64
Non-vested share options at beginning of year - Inducement Plan	—	403,167	—	403,167	4.07
Granted - 2019 Plan	45,000	—	—	45,000	1.12
Vested, outstanding 2019 Plan	(604,713)	—	—	(604,713)	3.54
Vested, outstanding Inducement Plan	—	(28,438)	—	(28,438)	4.85
Forfeited - Inducement Plan	—	(98,250)	—	(98,250)	3.31
Forfeited - 2019 Plan	(386,053)	—	—	(386,053)	3.47
Non-vested share options at end of period	<u>2,232,709</u>	<u>276,479</u>	—	<u>2,509,188</u>	<u>\$ 3.71</u>
Non-vested share options at end of period - Weighted average fair value	<u>\$ 3.64</u>	<u>\$ 4.26</u>	<u>\$ —</u>		
2023					
	Number of options			Weighted average fair value	
	2019 Plan	Inducement Plan	2011 Plan	Total	Weighted average fair value
Non-vested share options at beginning of year - 2011 Plan	—	—	2,126	2,126	\$ 6.64
Non-vested share options at beginning of year - 2019 Plan	2,923,763	—	—	2,923,763	5.30
Non-vested share options at beginning of year - Inducement Plan	—	503,000	—	503,000	4.84
Granted - 2019 Plan	1,487,400	—	—	1,487,400	2.86
Vested, outstanding 2011 Plan	—	—	(2,126)	(2,126)	6.64
Vested, outstanding 2019 Plan	(538,064)	—	—	(538,064)	5.37
Vested, outstanding Inducement Plan	—	(89,375)	—	(89,375)	4.88
Forfeited - 2019 Plan	(5,323)	—	—	(5,323)	5.69
Non-vested share options at end of period	<u>3,867,776</u>	<u>413,625</u>	—	<u>4,281,401</u>	<u>\$ 4.40</u>
Non-vested share options at end of period - Weighted average fair value	<u>\$ 4.35</u>	<u>\$ 4.83</u>	<u>\$ —</u>		

The fair value of options granted for the 2011 Plan, 2019 Plan and Inducement Plan were estimated using the Black-Scholes option pricing model, resulting in the following weighted average assumptions for the options granted:

	Three months ended March 31,	
	2024	2023
Exercise price	\$ 1.45	\$ 3.59
Share price	\$ 1.45	\$ 3.59
Volatility	91 %	97 %
Risk-free interest rate	4.26 %	3.95 %
Expected life	6.08 years	6.08 years
Dividend	0 %	0 %

Expected volatility is determined using comparable companies for which the information is publicly available. The risk-free interest rate is determined based on the U.S. sovereign rates benchmark in effect at the time of grant with a remaining term equal to the expected life of the option. Expected option life is determined based on the simplified method as the Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term. The simplified method is an average of the contractual term of the options and its ordinary vesting period. Dividend yield is based on the share option's exercise price and expected annual dividend rate at the time of grant.

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Employee Stock Purchase Plan

On July 15, 2022, the Company offered an ESPP, in which participation is available to our employees in the United States and Canada who meet certain service eligibility requirements. Eligible employees may authorize an amount up to 15% of their salary to purchase common stock at the lower of a 15% discount to the beginning price of the participation period or a 15% discount to the ending price of each six-month purchase interval. The ESPP also provides for an automatic reset feature to start participants on a new twelve-month participation period in the event that the common stock market value on a purchase date is less than the common stock value on the first day of the twelve-month offering period.

On January 1, 2024, the number of common shares reserved for issuance under the ESPP automatically increased by 334,831 shares. As of March 31, 2024, the Company has 1,797,766 common shares available for issuance under the ESPP, of which 237,393 shares of common stock have been issued. Compensation expense for purchase rights under the ESPP related to the purchase discount and the "look-back" option were determined using a Black-Scholes option pricing model.

The Company recognized total share-based compensation expense for all plans as follows:

	Three months ended March 31,	
	2024	2023
Administration	\$ 910	\$ 1,201
Research and development	471	786
Commercial activities	131	306
Total	\$ 1,512	\$ 2,293

9 Net Loss Per Share

Basic and diluted net loss per common share is determined by dividing net loss applicable to common shareholders by the weighted average number of common shares and pre-funded warrants outstanding during the period. In addition to the conversion feature on the 2029 Convertible Notes described above, which the Company reviewed and concluded that if-converted would be anti-dilutive due to the facts surrounding the feature, the following potentially dilutive securities have also been excluded from the computation of diluted weighted average shares outstanding as of March 31, as they would be anti-dilutive:

	2024	2023
Share options	8,273,105	9,010,220

Amounts above reflect the common share equivalents of the noted instruments.

10 Royalty Purchase Agreement

On March 27, 2023, we entered into a purchase and sale agreement, or the "Royalty Purchase Agreement", with RTW.

Pursuant to the Royalty Purchase Agreement, RTW agreed to purchase, following the U.S. Food and Drug Administration approval of etripamil (subject to certain conditions), in exchange for a purchase price of \$75.0 million, the right to receive a tiered quarterly royalty payments, or the "Royalty Interest", on the annual net product sales of etripamil in the United States in an amount equal to: (i) 7%, or the "Initial Tier Royalty", of annual net sales up to \$ 500 million, (ii) 4% of annual net sales greater than \$500 million and less than or equal to \$ 800 million, and (iii) 1% of annual net sales greater than \$800 million. If certain revenue thresholds for aggregate annual net sales are not met, the Initial Tier Royalty will increase to 9.5% beginning on January 1 of the following calendar year until a subsequent sales threshold is attained, at which time the Initial Tier Royalty would revert back to 7%.

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Based on the Company's assessment of the terms and conditions under the Royalty Purchase Agreement, there is no accounting recognition required in these interim financial statements.

11 Other receivables

Other receivables comprised of the following:

	March 31, 2024	December 31, 2023
Interest receivable	\$ 813	\$ 528
Sales tax receivable	218	264
Clinical receivable	381	2,400
Other current receivable	1	16
	<hr/> \$ 1,413	<hr/> \$ 3,208

As of March 31, 2024, the Company recognized \$ 0.4 million in clinical receivables for clinical upfront payments made to CROs. For the year ended December 31, 2023, the Company recognized a clinical receivable of \$2.4 million for clinical upfront payments made to CROs.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following information should be read in conjunction with the unaudited interim condensed consolidated statements and the notes thereto included in this Quarterly Report on Form 10-Q and the audited annual consolidated financial statements and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the Securities and Exchange Commission, or SEC, on March 21, 2024. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed in "Risk Factors" and in other parts of this Quarterly Report on Form 10-Q.

Company Overview

We are a biopharmaceutical company focused on the development and commercialization of innovative cardiovascular medicines. Our lead product candidate, etripamil, is a novel and potent calcium channel blocker that we designed as a rapid-onset nasal spray to be self-administered by patients. We are developing etripamil for the treatment of specific arrhythmias with a lead indication to treat paroxysmal supraventricular tachycardia, or PSVT, and an indication to treat atrial fibrillation with rapid ventricular rate, or AFib-RVR.

PSVT is a condition characterized by an abnormality in the electrical system of the heart causing patients to have unexpected, often severely symptomatic episodes of rapid heart rate. Patients experiencing episodes of supraventricular tachycardia, or SVT, often experience symptoms including palpitations, sweating, chest pressure or pain, shortness of breath, sudden onset of fatigue, lightheadedness or dizziness, fainting and anxiety. Calcium channel blockers have long been approved for the treatment of PSVT as well as other cardiac conditions. Calcium channel blockers available in oral form are sometimes used prophylactically to attempt to control the frequency and duration of future episodes of SVT. For treatment of episodes of SVT, approved calcium channel blockers are administered intravenously under medical supervision, usually in the emergency department. We believe the combination of convenient nasal-spray delivery and rapid-onset of etripamil has the potential to shift the current treatment paradigm for episodes of SVT away from the burdensome and costly emergency department setting.

Atrial Fibrillation, or AFib, is a common form of arrhythmia with an irregular and often rapid heart rate that is often markedly symptomatic and, without proper treatment, can increase the risk of stroke, heart failure, and other cardiovascular complications. A common complication of AFib is a rapid ventricular rate, or AFib-RVR, which is frequently defined as a heart rate ≥ 110 beats per minute. The occurrence of a rapid ventricular rate in patients with atrial fibrillation increases the likelihood of marked symptoms including heart palpitations, shortness of breath and weakness. There are two commonly used pharmacological approaches to chronically manage AFib, rhythm control and rate control. Regardless of the chronic approach, when faced with a sudden episode of AFib-RVR, acute rate control is needed, and most treatments are oral AV-nodal targeted drugs such as a beta blocker or calcium channel blockers. However, these oral rate control drugs, when used acutely, do not adequately provide immediate or adequate ventricular rate control due to a 30- to 90-minute delayed onset of action, and, as a result, many patients need faster and more certain rate-reduction and symptom-resolution and so seek acute-medical care by going to the emergency department for treatment utilizing intravenous rate control and/or electrical cardioversion of their atrial fibrillation. Similar to PSVT, patients feel a loss of control by needing to visit the emergency department for overcoming their atrial fibrillation attack and the unpredictable nature of RVR episodes; doctors are frustrated by the lack of options for patients to self-manage these acute rate attacks; and payor organizations would prefer to treat the AFib-RVR attacks in a more cost effective and time-efficient manner.

PSVT Clinical Development Program

In the first quarter of 2024, we resubmitted the New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, seeking approval to sell and market etripamil for the treatment of paroxysmal supraventricular tachycardia, or PSVT. The NDA for etripamil was resubmitted based on guidance from the FDA after receipt of a Refusal to File (RTF) letter from the FDA on December 26, 2023 in connection with the original NDA submission on October 23, 2023. In the letter and upon preliminary review, the FDA determined that the NDA was not sufficiently complete to permit substantive review. The FDA requested clarification about the data recorded for the time of adverse events in Phase 3 clinical trials; FDA did not express concerns about the nature or severity of adverse events. In February 2024, Milestone held a Type A Meeting with the FDA to determine the next steps for the resubmission of the NDA. The Agency indicated that the adverse

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events, or AEs, hourly timing data in question had minimal impact on the overall characterization of the etripamil safety profile. As a result, data sets that capture timing of AEs reported in the Phase 3 pivotal studies were revised to align with FDA requests and resubmitted as supplementary information to the original NDA. The resubmission package included restructured data sets that captured timing of reported AEs and certain data files reformatted to facilitate FDA's analyses. No additional efficacy or safety data were requested as part of the RTF. The Company expects a standard NDA review if the NDA is accepted for filing by the FDA. If approved, we believe that etripamil will be the first self-administered therapy for the rapid termination of episodes of SVT wherever and whenever they occur.

On October 17, 2022, we announced positive and statistically significant topline efficacy and safety data from our Phase 3 RAPID clinical trial evaluating etripamil in patients with PSVT. These results from the RAPID trial were presented on November 7, 2022, as a Late-Breaking Clinical Trial at the American Heart Association Scientific Sessions (Chicago, IL). These results were also published in *The Lancet* on July 8, 2023. RAPID, our multi-center, randomized, double-blind, placebo-controlled, event-driven Phase 3 trial, enrolled 706 patients across clinical sites in North America and Europe. Patients were randomized 1:1 using a self-administered regimen consisting of a first dose of study drug, and a repeat dose 10 minutes later if symptoms persisted. Self-administration was prompted by a patient's symptoms and performed in the at-home setting without medical supervision. The RAPID trial achieved its primary endpoint with etripamil demonstrating a highly statistically significant and clinically meaningful difference in time to SVT conversion as compared to placebo. A Kaplan Meier analysis demonstrated a significantly greater proportion of patients who took etripamil converted to sinus rhythm within thirty minutes compared to patients that took placebo (64.3% vs. 31.2%; hazard ratio, or HR, 2.62; 95% CI 1.66, 4.15; p<0.001). By 90 minutes post-study drug administration, 80.6% of patients taking etripamil converted to sinus rhythm compared to 60.7% of patients taking placebo (HR = 1.93; 95% CI 1.349, 2.752; p=0.001). Statistically significant reductions in time to conversion in patients who took etripamil were evident early and persisted throughout the observation window of the trial compared to patients that took placebo. The median time-to-conversion for patients in the RAPID trial who self-administered etripamil was 17.2 minutes compared to 53.3 minutes for patients taking placebo. The safety and tolerability data from the RAPID trial supports the potential self-administration of etripamil, with findings consistent with those observed in prior trials. The most common randomized-treatment emergent adverse events, or RTEAEs, and adverse events, or AEs, occurred within 24 hours of etripamil administration and were related to the nasal local administration site. Overall, the majority of RTEAEs were reported as mild (68%) or moderate (31%). No serious adverse effects related to etripamil were reported.

The use of additional medical interventions and emergency department utilization were key secondary endpoints for both the RAPID and NODE-301 trials. In a pre-planned pooled analysis across both trials, patients who self-administered etripamil sought additional medical interventions 43% less frequently (15% vs. 25%; p=0.013) and had 39% fewer visits to the emergency department (14% vs. 22%; p=0.035) than patients in the placebo arm.

We believe that PSVT is a large and under-recognized market that we estimate affects approximately two million Americans and results in over 150,000 emergency department visits and hospital admissions and up to 80,000 ablations per year. From this diagnosed population, we define the target addressable market for etripamil as 40 to 60% of patients who experience frequent and longer, moderate to severe episodes each year. After being exposed to the data from the RAPID clinical study in market research, Cardiologists reported a willingness to prescribe etripamil to approximately 50% of the patients with PSVT in their care, which suggests 500,000 to 800,000 patients can potentially be treated with etripamil in the peak year. Additionally, we believe that these target patients will use etripamil to treat a median of five episodes per year based on the projected number of longer or more intense episodes (self-reported) experienced by the patient. This implies demand in the US for etripamil of 2.5 million to 4 million episodes treated in the peak year.

AFib RVR Clinical Development Program

In the first quarter of 2024, we met with the FDA in a Type C meeting. In this meeting, the FDA reiterated its prior guidance from our Pre-IND meeting regarding the availability of an sNDA pathway for the marketing approval for etripamil for the indication of AFib-RVR. The sNDA pathway potentially permits a single pivotal efficacy study to be sufficient for filing for marketing approval if etripamil is already approved for PSVT. FDA further concurred with respect to key proposed study elements including powering, inclusion criteria, patient population, and statistical analyses, and offered clarification with respect to the endpoints to guide the design of the Phase 3 study. In our mid-2023 Pre-IND

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meeting, the FDA provided guidance that our primary endpoint can be the reduction of ventricular rate, and the primary analysis would be on the intent to treat, or ITT, population. In addition, the study would have to show statistical significance ($p<0.05$) on the key secondary endpoint of symptom relief as a patient benefit, also in the ITT population. The secondary endpoint could use a patient-reported outcomes measure, or PRO, and the application of a seven-point anchored scale was discussed with the FDA. We anticipate progressing to an End of Phase 2 meeting in mid-2024 as an important step to finalize the Phase 3 study protocol.

We plan to propose to the FDA a Phase 3 clinical study for AFib-RVR conducted in the at-home setting consisting of patients with a history of symptomatic episodes and using a repeat-dose regimen of 70mg per dose similar to what was studied in the RAPID trial in patients with PSVT. Our target population would be patients with verified AFib-RVR, and the ITT population would be all patients self-administering the study drug for perceived AFib-RVR. The primary endpoint being considered is the mean change from baseline ventricular rate to nadir ventricular rate for patients treated with etripamil vs placebo, as was studied in the ReVeRA trial. Our key secondary endpoint would be based on a PRO acceptable to the FDA and the same or similar to ones we have used in our PSVT and AFib-RVR programs. We estimate that the study size would be approximately 150 to 200 unique patients treating an episode.

On November 11, 2023, we presented positive Phase 2 data from the ReVeRA study, as a Featured Science Presentation at the American Heart Association Scientific Meetings (Philadelphia, PA) and as simultaneously published in *Circulation: Arrhythmia and Electrophysiology*. The randomized, placebo-controlled Phase 2 ReVeRA trial enrolled 87 patients and dosed 56 patients aged 18 years and older with AFib who experienced a ventricular rate of 110 or more beats per minute (bpm) prior to receiving etripamil nasal spray. The trial was designed to assess the reduction in ventricular rate (primary endpoint), the time to achieve maximum reduction in ventricular rate, duration of effect, and patient satisfaction with treatment using the Treatment Satisfaction Questionnaire 9 (TSQM-9) patient reported outcome (PRO) tool (key secondary endpoints).

Data from ReVeRA trial showed that delivery of etripamil nasal spray significantly and rapidly reduced ventricular rate, consistent with the drug's pharmacologic profile. Etripamil achieved the primary endpoint with high statistical significance with patients experiencing a ventricular rate reduction of 29.91 bpm (95% confidence interval: -40.31, -19.52; $p<0.0001$) in the etripamil arm compared to placebo. The maximum reduction in rate reported by a patient taking etripamil was 34.97 bpm. The median time to maximum reduction in ventricular rate was 13 minutes in patients taking etripamil. A greater number of patients taking etripamil achieved a ventricular rate of less than 100 bpm (58.3%) than those taking placebo (4%). Furthermore, 67% of patients taking etripamil achieved ventricular rate reductions of more than 20% and 96% of patients receiving etripamil achieved more than 10% in ventricular rate reductions in the first 60 minutes compared to 0% and 20% in patients taking placebo, respectively. Using the TSQM-9, compared to placebo, patients treated with etripamil demonstrated significant improvements in two satisfaction ratings: effectiveness ($p<0.0001$) and relief of symptoms ($p=0.0002$).

Treatment-emergent serious adverse events, or TESAEs, were rare, with two occurring in one patient in the etripamil arm (3.7%) and four occurring in two patients in the placebo arm (6.9%). The TESAEs in the etripamil arm (transient severe bradycardia and syncope, assessed as due to hyper-vagotonia) occurred in a patient with a history of vagal events, and fully resolved by placing the patient supine and was without sequelae. The most common ($\geq 5\%$) adverse events were mild or moderate in intensity and included nasal discomfort, rhinorrhea, increased lacrimation, throat irritation and dizziness.

An estimated five million Americans suffer from AFib. The Centers for Disease Control projects the prevalence of AFib will grow to an estimated 12 million patients 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 resolve symptoms. In 2016, nearly 800,000 patients were admitted to the emergency department due to AFib symptoms. Treatment for such symptoms typically includes medically supervised intravenous administration of calcium channel blockers or beta blockers, or electrical cardioversion.

Operations Overview

Since the commencement of our operations in 2003, we have devoted substantially all of our resources to performing research and development activities in support of our product development efforts, hiring personnel, raising capital to support and expand such activities, providing general and administrative support for these operations and, more recently preparing for commercialization. We operate our business using a significant outsourcing model. As such, our team is composed of a relatively smaller core of employees who direct a significantly larger number of team members who are outsourced in the form of vendors and consultants to enable execution of our operational plans. We do not currently have any products approved for sale, and we continue to incur significant research and development and general administrative expenses related to our operations.

Since inception, we have incurred significant operating losses. For the three months ended March 31, 2024 and 2023, we recorded net losses of \$10.4 million and \$14.9 million, respectively. As of March 31, 2024, we had an accumulated deficit of \$336.4 million. We expect to continue to incur significant losses for the foreseeable future. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on completing the necessary development activities required for obtaining regulatory approval and preparing for potential commercialization of our product candidates. We had \$10.1 million of cash and cash equivalents and \$79.4 million of short-term investments at March 31, 2024.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. Our net losses may fluctuate significantly from period to period, depending on the timing of our planned clinical trials and expenditures on other research and development activities. We expect our expenses will increase over time as we:

- continue our ongoing and planned development of etripamil, including and potentially future Phase 4 clinical trials for the treatment of PSVT and future Phase 3 clinical trials for the treatment of AFib-RVR;
- seek marketing approvals for etripamil for the treatment of PSVT, AFib-RVR and other cardiovascular indications;
- establish a sales, marketing, manufacturing and distribution capability, either directly or indirectly through third parties, to commercialize etripamil or any future product candidate for which we may obtain marketing approval;
- build a portfolio of product candidates through development, or the acquisition or in-license of drugs, product candidates or technologies;
- initiate preclinical studies and clinical trials for etripamil for any additional indications we may pursue, including the clinical trials for the treatment of atrial fibrillation and rapid ventricular rate as well as other areas of unmet medical need, and for any additional product candidates that we may pursue in the future;
- maintain, protect and expand our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting, insurance and other expenses associated with operating as a public company.

Recent Developments

New Real-World Application of Etripamil

In April 2024, the Company announced new clinical data demonstrating real-world application of etripamil, an investigational new drug, for conversion of recurrent PSVT. Conducted in North and South America, an open label, Phase 3 study of etripamil in PSVT was presented at The American College of Cardiology Scientific Sessions. NODE-303 evaluated self-administered etripamil (70 mg, nasal spray) in an outpatient setting for up to four episodes of PSVT, without prior test dosing. It did not exclude patients with a history of co-morbid atrial fibrillation (AFib) or atrial flutter. The results demonstrated that symptom-prompted treatment with etripamil restored sinus rhythm as compared to placebo with a median time-to-conversion of 17.0 minutes and was generally well tolerated. The conversion of PSVT to sinus rhythm was similar among multiple PSVT episodes and the frequency of treatment-emergent adverse events at 24 hours decreased with successive episodes. Adverse events were predominantly localized to the drug's nasal administration site, consistent with prior trial findings. The protocol was amended during the trial to allow for a repeat dose of drug if symptoms persisted 10 minutes following the first dose. Efficacy of etripamil for PSVT conversion (restoration of sinus rhythm) in NODE-303 was 60% by 30 minutes after drug self-administration, and 69.9% by 60 minutes after drug self-administration; these rates of conversion are similar to those demonstrated in double-blinded and other open-label studies. This data supports a potentially significant shift in the management approach for recurrent PSVT.

The Macroeconomic Climate

The recent trends towards rising inflation may also materially adversely affect our business and corresponding financial position and cash flows. Inflationary factors, interest rates and overhead costs may adversely affect our operating results. Rising interest and inflation rates also present a recent challenge impacting the U.S. economy and could make it more difficult for us to obtain traditional financing on acceptable terms, if at all, in the future, the Russia-Ukraine war, unrest and/or further escalation in Israel and Gaza, recent banking instabilities and other U.S. geopolitical issues affecting other territories and employee availability and wage increases, and economic markets all of which may result in additional stress on our working capital resources.

Components of Results of Operations

Revenues

We have not generated any revenues from product sales to date and we do not expect to generate revenues from product sales in the near future. We recorded no revenue for the three months ended March 31, 2024, and \$1.0 million in revenue during the three months ended March 31, 2023. This revenue is due to a milestone reached as a result of the successful initiation of a Phase 1 Clinical Trial of the product by or on behalf of Ji Xing for the treatment of PSVT in the Territory.

Research and Development Expenses

Research and development expenses consist primarily of salaries and fees paid to external service providers and also include personnel costs, including share-based compensation expense and other related compensation expenses. We expense research and development costs in the periods in which they are incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors, collaborators and third-party service providers.

To date, substantially all of our research and development expenses have been related to the preclinical and clinical development of etripamil. As we advance etripamil or other product candidates for other indications, we expect to allocate our direct external research and development costs across each of the indications or product candidates. Further, we expect our research and development costs to increase for the development of etripamil in atrial fibrillation with rapid ventricular rate, and we expect our research and development expenses related to the development of etripamil for PSVT decrease as a percentage of our total research and development expenses.

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The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming and is subject to uncertainties and delays. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates, if at all.

We recognize the benefit of Canadian research and development tax credits as a reduction of research and development costs for fully refundable investment tax credits.

General and Administrative Expenses

General and administrative expenses include personnel and related compensation costs, expenses for outside professional services, lease expense, insurance expense and other general administrative expenses. Personnel costs consist of salaries, bonuses, benefits, related payroll taxes and share-based compensation. Outside professional services consist of legal, accounting and audit services and other consulting fees.

We expect to continue to incur expenses as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission, or SEC, and those of any national securities exchange on which our securities are traded, additional insurance expenses, investor relations activities, and other administrative and professional services.

Commercial Expenses

Commercial expenses consist primarily of personnel and related compensation costs, market and health economic research, and market development activities for PSVT and, to a lesser extent, AFib-RVR. The focus of these expenses is three-fold: first, we want to leverage rigorous primary and secondary research to fully understand our target disease states from the perspective of the patient, healthcare provider, and payer; second, we want to understand and document the burden of disease posed by PSVT and AFib-RVR from an epidemiology, healthcare resource use, and cost perspective; and third, we want to engage our target patient, physician, and payer stakeholders with evidence-based and compliant educational materials that serve to increase the awareness and understanding of the impact of PSVT and AFib-RVR on patients and the overall healthcare system.

If the FDA approves the NDA, we anticipate our commercial expenses will increase as we invest in the infrastructure, personnel, and operational expenses required to launch our first product in the United States.

Interest Income

Interest income primarily consists of interest income from our cash equivalents and short-term investments.

Interest Expense

Interest expense primarily consists of contractual debt interest expense and the amortization of debt costs.

Results of Operations

Comparison of the Three Months Ended March 31, 2024 and 2023

The following table summarizes our results of operations and changes:

(in thousands)	Three months ended March 31,			
	2024	2023	\$ Change	% Change
Revenue	\$ —	\$ 1,000	\$ (1,000)	100.0%
Operating expenses				
Research and development, net of tax credits	3,639	10,257	(6,618)	(64.5)%
General and administrative	3,953	3,889	64	1.7%
Commercial	2,884	2,356	528	22.4%
Total operating expenses	<u>10,476</u>	<u>16,502</u>	<u>(6,026)</u>	<u>(36.5)%</u>
Loss from operations	(10,476)	(15,502)	5,026	(32.4)%
Interest income	994	585	409	69.9%
Interest expense	(872)	(33)	(839)	100.0%
Net loss	<u>(10,354)</u>	<u>(14,950)</u>	<u>4,596</u>	<u>(30.7)%</u>

Revenue

We recorded no revenue for the three months ended March 31, 2024 and \$1.0 million in revenue during the three months ended March 31, 2023. This revenue was the result of having reached a milestone pursuant to our License and Collaboration Agreement, dated May 15, 2021, with Ji Xing Pharmaceuticals Limited (such party "Ji Xing" and, such agreement, the "Ji Xing License Agreement") due upon the successful initiation of a Phase 1 Clinical Trial of a pharmaceutical product that uses a device to deliver etripamil by nasal spray by or on behalf of Ji Xing for the treatment of PSVT in the People's Republic of China, or the Territory, including mainland China, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan.

Research and Development Expenses

The following table shows our research and development expenses by type of activity for the three months ended March 31, 2024 and 2023, respectively.

(in thousands)	Three months ended March 31,			
	2024	2023	\$ Change	% Change
Clinical	\$ 1,894	\$ 8,101	\$ (6,207)	(76.6)%
Drug manufacturing and formulation	820	1,266	(446)	(35.2)%
Regulatory and other costs	993	973	20	2.1%
Less: R&D tax credits	(68)	(83)	15	(18.1)%
Total R&D expenses	<u>\$ 3,639</u>	<u>\$ 10,257</u>	<u>\$ (6,618)</u>	<u>(64.5)%</u>

Research and development expenses decreased by \$6.6 million, or 64.5%, for the three months ended March 31, 2024 compared to the three months ended March 31, 2023. The decrease was primarily due to lower clinical expenses. This decrease in clinical expenses was driven by lower clinical development costs and clinical personnel-related costs as a result of the completion of phase 3 studies. This decrease was also driven by a delay in drug manufacturing costs due to the impacts of the RTF.

We recognize the benefit of Canadian research and development tax credits as a reduction of research and development costs for fully refundable investment tax credits.

General and Administrative

General and administrative expenses remained consistent for the three months ended March 31, 2024 and the three months ended March 31, 2023.

Commercial

Commercial expenses increased by \$0.5 million, or 22.4%, for the three months ended March 31, 2024, compared to the same period in 2023. This increase is a result of additional personnel costs, professional costs and other operational expenses related to commercialization.

We anticipate our commercial expenses will increase as we invest in the infrastructure, personnel and operational expenses required to launch our first product in the United States, if the FDA approves the NDA.

Interest Income

Interest income was \$1.0 million and \$0.6 million for the three months ended March 31, 2024 and 2023, respectively. The increase in interest income was due to higher interest rates earned on investments in 2024 when compared to 2023.

Interest Expense

Interest expense was \$0.9 million for the three months ended March 31, 2024, compared to a de minimis amount interest expense for the three months ended March 31, 2023. The increase in interest expense was due to the issuance of the 2029 Convertible Notes on March 29, 2023.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred operating losses and experienced negative operating cash flows since our inception, and we anticipate continuing to incur losses for at least the next several years. As of March 31, 2024, we had cash, cash equivalents and short-term investments of \$89.5 million and an accumulated deficit of \$336.4 million.

On February 28, 2024, we entered into an underwriting agreement, or the Underwriting Agreement, related to an underwritten public offering, or the Offering, of 16,666,667 of our common shares, without par value, at a public offering price of \$1.50 per share and, in lieu of common shares to certain investors, pre-funded warrants to purchase 3,333,333 Shares at a public offering price of \$1.499 per pre-funded warrant. Under the terms of the Underwriting Agreement, we granted the Underwriters an option to purchase up to an additional 3,000,000 common shares at the same price per share as the other common shares sold in the Offering, which was exercised by the Underwriters in full on February 29, 2024.

Each pre-funded warrant has an exercise price of \$0.001 per share. The pre-funded warrants were exercisable immediately upon issuance, subject to certain beneficial ownership limitations.

The net proceeds to the Company from the Offering, including the proceeds from the exercise by the Underwriters of their option to purchase the additional 3,000,000 common shares in full, was \$31.9 million after deducting underwriting commissions and offering expenses payable by the Company.

On March 27, 2023, we entered into a purchase and sale agreement, or the Royalty Purchase Agreement, and a note purchase agreement, or the Note Purchase Agreement, with RTW Investments, LP and certain of its affiliates, or collectively, RTW.

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On March 29, 2023, the Company closed the transaction contemplated by the Note Purchase Agreement and issued and sold the \$50 million principal amount of 6.0% Convertible Senior Notes due 2029, or the 2029 Convertible Notes, to the holders in a private placement transaction.

The 2029 Convertible Notes are senior secured obligations and are guaranteed on a senior secured basis by our wholly owned subsidiary, Milestone Pharmaceuticals USA, Inc. Interest, at the annual rate of 6.0%, is payable quarterly in cash or, at our option, payable in kind for the first three years. The maturity date for the 2029 Convertible Notes will be March 31, 2029. The obligations under the 2029 Convertible Notes are secured by substantially all of our and our subsidiary guarantor's assets.

Each \$1,000 of principal of the 2029 Convertible Notes (including any interest added thereto as payment in kind) is convertible into 191.0548 shares of our common shares, equivalent to an initial conversion price of approximately \$5.23 per share, subject to customary anti-dilution and other adjustments. Subject to specified conditions, on or after March 27, 2027, the 2029 Convertible Notes are redeemable by us subject to certain conditions, at a redemption price equal to 100% of the principal amount of the 2029 Convertible Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

On July 29, 2020, we entered into an Open Market Sale Agreement SM, or the Sales Agreement, with Jefferies LLC with respect to an at-the-market offering program, or the ATM Program, under which the Company may issue and sell its common shares having an aggregate offering price of up to \$50 million through Jefferies as its sales agent or principal. The common shares to be sold under the Sales Agreement, are offered and sold pursuant to our shelf registration statement on Form S-3 (File No. 333-239318), which was declared effective by the SEC on July 6, 2020. During 2022, we issued 361,236 shares under the Sales Agreement, resulting in net proceeds of \$2.6 million (net of issuance costs of \$0.1 million). No shares were sold under the Sales Agreement during the three months ended March 31, 2024.

We expect that our operating plan, existing cash and cash equivalents and short-term investments to be sufficient to fund our operations for at least the next 12 months from the date of issuance of this 10-Q for the quarter ending March 31, 2024 and that there are no events or conditions that may cast substantial doubt on our ability to continue as a going concern for at least the next 12 months from the date of this filing.

Contingent future source of funding

Pursuant to the Royalty Purchase Agreement, RTW agreed to purchase, following U.S. Food and Drug Administration (FDA) approval of etripamil (subject to certain conditions), in exchange for a purchase price of \$75.0 million, the right to receive a tiered quarterly royalty payments, or "royalty interest", on the annual net product sales of etripamil in the United States. This represents a contingent future source of funding, in order for the Company to receive the \$75 million dollars, the closing conditions specified in the Royalty Purchase Agreement, which includes the Company receiving marketing approval from the FDA on or prior to September 30, 2025, must be met.

Funding Requirements

We use our cash primarily to fund research and development expenditures. We expect our research and development expenses to increase as we continue the development of etripamil and prepare to pursue regulatory approval. We expect to incur increasing operating losses for the foreseeable future as we continue the clinical development of our product candidate. At this time, due to the inherently unpredictable nature of clinical development, we cannot reasonably estimate the costs we will incur and the timelines that will be required to complete development, obtain marketing approval, and commercialize etripamil or any future product candidates, if at all. For the same reasons, we are also unable to predict when, if ever, we will generate revenue from product sales or whether, or when, if ever, we may achieve profitability. Clinical and preclinical development timelines, the probability of success, and development costs can differ materially from expectations.

In addition, we have exclusive development and commercialization rights for etripamil for all indications that we may pursue and as such have the potential to license development and or commercialization rights for etripamil to a potential partner in regions outside of Greater China. We plan to establish commercialization and marketing capabilities using a

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direct sales force to commercialize etripamil in the United States. Outside of the United States, we are considering commercialization strategies that may include collaborations with other companies.

For other new product candidates, our efforts are focused on licensing development and/or commercialization rights from potential partners. In the case of either in-licensing or out-licensing, we cannot forecast when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development and commercialization plans and capital requirements.

The timing and amount of our operating expenditures will depend largely on:

- the timing, progress and results of our ongoing and planned clinical trials and other development activities of etripamil in PSVT, AFib-RVR and in other cardiovascular indications;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials of etripamil for additional indications or any future product candidates that we may pursue;
- our ability to establish additional collaborations on favorable terms, if at all;
- the ability of vendors and third-party service providers to accurately forecast expenses and deliver on expectations;
- the costs, timing and outcome of regulatory review of etripamil and any future product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for etripamil and any future product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of etripamil and any future product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the extent to which we acquire or in-license other product candidates and technologies.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to fund our operations and capital funding needs through equity and/or debt financing. We may also consider entering into collaboration arrangements or selectively partnering for clinical development and commercialization. The sale of additional equity would result in additional dilution to our shareholders. The incurrence of debt financing would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that restrict our operations or our ability to incur additional indebtedness or pay dividends, among other items. If we are not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially and adversely affect our business, financial condition and results of operations.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

(in thousands)	Three months ended March 31,			
	2024	2023	\$ Change	% Change
Net cash (used in) provided by:				
Operating activities	\$ (8,934)	\$ (13,904)	4,970	(35.8)%
Investing activities	(27,014)	29,968	(56,982)	(190.1)%
Financing activities	32,319	50,253	(17,934)	(35.7)%
Net increase (decrease) in cash and cash equivalents during the period	<u>\$ (3,629)</u>	<u>\$ 66,317</u>	<u>(69,946)</u>	

Operating Activities

Net cash used in operating activities during the three months ended March 31, 2024 was \$8.9 million, which consisted primarily of a net loss of \$10.4 million and a net cash decrease of \$0.9 million related to the change in assets and liabilities. These decreases were offset by non-cash charges of \$1.5 million related to share-based compensation and non-cash interest charges of \$0.8 million related to the convertible note.

Net cash used in operating activities during the three months ended March 31, 2023 was \$13.9 million, which consisted primarily of a net loss of \$14.9 million and a net cash decrease of \$1.2 million related to the change in assets and liabilities. These decreases were offset by non-cash charges of \$2.3 million related to share-based compensation and depreciation expenses.

Investing Activities

In the three months ended March 31, 2024 we acquired \$52.5 million of short-term investments, and we redeemed \$25.5 million in short-term investments. In the three months ended March 31, 2023, we acquired \$15.0 million of short-term investments, and we redeemed \$45.0 million of short-term investments.

Financing Activities

In the three months ended March 31, 2024, our financing activities provided cash proceeds of \$32.3 million. These proceeds were primarily a result of the \$32.2 million received from the issuance of common shares and pre-funded warrants, net of \$2.3 million in issuance costs paid, under the Underwriting Agreement.

In the three months ended March 31, 2023, our financing activities provided cash proceeds of \$50.3 million. These proceeds were primarily a result of the \$50 million received from the issuance of convertible notes under the Note Purchase Agreement, along with proceeds of \$0.3 million from the exercise of stock options and the issuance of shares under the employee stock purchase plan.

We have not entered into off-balance sheet arrangements.

Contractual Obligations

During the three months ended March 31, 2024, there were no material changes to our contractual obligations and commitments described under Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K, filed with the SEC on March 21, 2024.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our unaudited interim consolidated financial statements as of March 31, 2024, which have been prepared in accordance with United

States generally accepted accounting principles, or U.S. GAAP and on a basis consistent with those accounting principles followed by us. The preparation of these consolidated financial statements requires our management to make judgments and estimates that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated, and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Significant estimates and judgments include, but are not limited to:

- Estimates of the percentage of work completed of the total work over the life of the individual trial in accordance with agreements established with CROs, CMOs and clinical trial sites which in turn impact the research & development expenses.
- Estimate of the grant date fair value share options granted to employees, consultants and directors, and the resulting share-based compensation expense, using the Black-Scholes option-pricing model.

Accordingly, actual results may differ from these judgments and estimates under different assumptions or conditions and any such differences may be material. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

a) Research & Development Expenses — Accruals

Research and development costs are charged against income in the period of expenditure. Our research and development costs consist primarily of salaries and fees paid to CROs and to CMOs.

Clinical trial expenses include direct costs associated with CROs, direct CMO costs for the formulation and packaging of clinical trial material, as well as investigator and patient-related costs at sites at which our trials are being conducted. Direct costs associated with our CROs and CMOs are generally payable on a time-and-materials basis, or when milestones are achieved. The invoicing from clinical trial sites can lag several months. We record expenses for our clinical trial activities performed by third parties based upon estimates of the percentage of work completed of the total work over the life of the individual trial in accordance with agreements established with CROs and clinical trial sites. We determine the estimates through discussions with internal clinical personnel, CROs and CMOs as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services based on facts and circumstances known to us as of each consolidated balance sheet date. The actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending upon a number of factors, including our clinical development plan. If the actual timing of the performance of services of the level of effort varies from the estimate, we will adjust the accrual accordingly. Adjustments to prior period estimates have not been material. We recognize the benefit of Canadian research and development tax credits as a reduction of research and development costs for fully refundable investment tax credits and as a reduction of income taxes for investment tax credits that can only be claimed against income taxes payable when there is reasonable assurance that the claim will be recovered.

b) Share-Based Compensation

We recognize compensation costs related to share options granted to employees, consultants and directors based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting share-based compensation expense, using the Black-Scholes option-pricing model. This Black-Scholes option pricing model uses various inputs to measure fair value, including estimated fair value of our underlying common shares at the grant date, expected term, estimated volatility, risk-free interest rate and expected dividend yields of our common shares. The estimated volatility creates a critical estimate because we have not been a public company long enough to demonstrate our own historical volatility. The grant date fair value of the share-based awards is recognized on a straight-line basis over the requisite service periods, which are generally the vesting period of the respective awards. Forfeitures are accounted for as they occur.

Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASU 2023-07"), which requires public entities to disclose information about their reportable segments' significant expenses on an interim and annual basis. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is evaluating the effect of adopting this new accounting guidance on its financial statements, but does not intend to early adopt.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09"). The amendments in this update require that public business entities on an annual basis (1) disclose specific categories in the rate reconciliation and (2) provide additional information for reconciling items that meet a quantitative threshold (if the effect of those reconciling items is equal to or greater than 5 percent of the amount computed by multiplying pretax income [or loss] by the applicable statutory income tax rate). The amendments also require entities on an annual basis to disclose disaggregated amounts of income taxes paid. ASU 2023-09 is effective for annual periods beginning after December 15, 2024. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. The Company is evaluating the effect of adopting this new accounting guidance on its financial statements, but does not intend to early adopt.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012 permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to "opt out" of this provision and, as a result, we comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rate risks. We had cash, cash equivalents and short-term investments of \$89.5 million as of March 31, 2024, which consist primarily of bank deposits and guaranteed investment certificates. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our investment portfolio, we do not believe an immediate 10% increase or decrease in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

We undertake certain transactions in Canadian dollars and as such are subject to risk due to fluctuations in exchange rates. Canadian dollar denominated payables are paid at the converted rate as due. We do not use derivative instruments or have a formal hedging program to hedge exposure to foreign exchange rate risk due to the low volume of transactions denominated in foreign currencies. On March 31, 2024, our net monetary exposure denominated in Canadian dollars was \$1.7 million.

Our operating results and financial position are reported in U.S. dollars in our consolidated financial statements. The fluctuation of the Canadian dollar in relation to the U.S. dollar might, consequently, have an impact upon our loss and may also affect the value of our assets and the amount of shareholders' equity.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be

disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2024. Based upon the evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have an adverse effect on our business, operating results or financial condition.

Item 1A. Risk Factors

There have been no material changes from the risk factors previously disclosed in Part I, Item 1A. in our Annual Report on Form 10-K, filed with the SEC and under Milestone's SEDAR+ profile at www.sedarplus.com on March 21, 2024.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Not applicable

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Item 3. Defaults Upon Senior Securities.

Not applicable

Item 4. Mine Safety Disclosures.

Not applicable

Item 5. Other Information.

Not applicable

Item 6. Exhibits.

Exhibit Number	Description
3.1	Amended Articles of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38899), filed with the SEC on May 15, 2019).
3.2	Amended and Restated Bylaws of the Company (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-38899), filed with the SEC on May 15, 2019).
4.1	Form of Pre-Funded Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-38899), filed with the SEC on March 4, 2024).
10.1	Non-Employee Director Compensation Policy, as amended.
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, formatted in Inline XBRL.

* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Exchange Act, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the "Exchange Act (whether made before or after the date of the Form 10-Q)", irrespective of any general incorporation language contained in such filing.

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 thereunto duly authorized.

MILESTONE PHARMACEUTICALS INC.

Date: May 13, 2024

By: /s/ Joseph Oliveto

Joseph Oliveto
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 13, 2024

By: /s/ Amit Hasija

Amit Hasija
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

MILESTONE PHARMACEUTICALS INC.

AMENDED AND RESTATED NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Each member of the Board of Directors (the “**Board**”) of Milestone Pharmaceuticals Inc. (the “**Company**”) who is not also serving as an employee of the Company or any of its subsidiaries (each such member, an “**Eligible Director**”) will receive the compensation described in this Non-Employee Director Compensation Policy (this “**Policy**”). An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash is to be paid or equity awards are to be granted, as the case may be. This Policy may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board.

Annual Cash Compensation

The annual cash compensation amount set forth below is payable to Eligible Directors in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service, and regular full quarterly payments to be paid thereafter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:

- a. All Eligible Directors: \$42,500
- b. Non-executive chairperson of the Board: \$72,500 (inclusive of Annual Board Service Retainer)

2. Annual Committee Member ServiceRetainer:

- a. Member of the Audit Committee:
\$10,000
- b. Member of the Compensation Committee:
\$7,500
- c. Member of the Nominating and Corporate Governance Committee:
\$5,000
- d. Member of the Clinical Affairs Committee:
\$6,000

3. Annual Committee Chair Service Retainer (inclusive of Committee Member Service Retainer):

- a. Chairperson of the Audit Committee:
\$20,000
- b. Chairperson of the Compensation Committee:
\$15,000
- c. Chairperson of the Nominating and Corporate Governance Committee:
\$10,000
- d. Chairperson of the Clinical Affairs Committee:
\$12,000

The Company will also reimburse each of the Eligible Directors for his or her travel expenses incurred in connection with his or her attendance at Board and committee meetings. Such reimbursements shall be paid on the same date as the annual cash fees are paid.

Equity Compensation

The equity compensation set forth below will be granted under the Company’s 2019 Equity Incentive Plan (the “**Plan**”), subject to the approval of the Plan by the Company’s shareholders. All stock options granted under this Policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying common stock on the date of grant, and a term of 10 years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan).

1. **Initial Grant:** For each Eligible Director who is first elected or appointed to the Board following the effective date of this Policy, on the date of such Eligible Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option to purchase a number of shares of the Company's common stock equal to 42,000 shares of the Company's common stock. The shares subject to each such stock option will vest monthly over a three-year period, subject to the Eligible Director's Continuous Service (as defined in the Plan) on each vesting date.
2. **Annual Grant:** On the date of each annual shareholder meeting of the Company held after the Effective Date, each Eligible Director who continues to serve as a non-employee member of the Board following such shareholder meeting will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option to purchase 40,000 shares of the Company's common stock (the "Annual Grant"). The shares subject to the Annual Grant will vest in equal monthly installments over the 12 months following the date of grant, provided that the Annual Grant will in any case be fully vested on the date of Company's next annual shareholder meeting, subject to the Eligible Director's Continuous Service (as defined in the Plan) through such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

Approved: April 26, 2019

Effective: May 8, 2019

Amended: May 4, 2020

Amended: September 21, 2020

Amended and Restated: March 24, 2021

Amended and Restated: February 14, 2023

Amended and Restated: July 1, 2023

Amended and Restated: March 19, 2024

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Joseph Oliveto, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Milestone Pharmaceuticals Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2024

/s/ Joseph Oliveto

Joseph Oliveto
President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Amit Hasija, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Milestone Pharmaceuticals Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2024

/s/ Amit Hasija

Amit Hasija
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Joseph Oliveto, Chief Executive Officer of Milestone Pharmaceuticals Inc. (the "Company"), and Amit Hasija, Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2024, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 13, 2024

/s/ Joseph Oliveto

Joseph Oliveto
Chief Executive Officer
(Principal Executive Officer)

/s/ Amit Hasija

Amit Hasija
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)
