
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported):
March 24, 2022

MILESTONE PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

Québec
(state or other jurisdiction of incorporation)

001-38899
(Commission File Number)

Not applicable
(I.R.S. Employer Identification No.)

**1111 Dr. Frederik-Philips Boulevard,
Suite 420
Montréal, Québec CA**
(Address of principal executive offices)

H4M 2X6
(Zip Code)

Registrant's telephone number, including area code: **(514) 336-0444**

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---------------------|-------------------|---|
| Common Shares | MIST | The Nasdaq Stock Market LLC |

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On March 24, 2022, Milestone Pharmaceuticals Inc. (the “Company”) filed with the Securities and Exchange Commission (the “Commission”) its Annual Report on Form 10-K (the “Form 10-K”), which includes, at Item 8 thereof, its audited consolidated financial statements for the year ended December 31, 2021, and the report thereon of its Independent Registered Public Accounting Firm, PricewaterhouseCoopers LLP. (“PwC”), dated March 24, 2022.

Exhibit 99.1 to this Current Report on Form 8-K also includes the Company’s audited consolidated financial statements for the year ended December 31, 2021, and the report of PwC thereon. The sole difference between Exhibit 99.1 to this Current Report on Form 8-K and Item 8 to the Form 10-K is the inclusion in the audit report set forth in Exhibit 99.1 hereto of the Quebec professional permit number of the lead audit partner of PwC, which was intentionally omitted from the Report of Independent Registered Public Accounting Firm as included in the Form 10-K. The Company is furnishing this Current Report on Form 8-K in order to comply with the Quebec professional license requirements regulating chartered professional accountants of the Province of Quebec, Canada, as applicable to PwC.

The information contained in Item 2.02 and Exhibit 99.1 of this Current Report on Form 8-K is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 7.01. Other Events.

On March 24, 2022, the Company issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 31, 2021 and providing a clinical and corporate update. A copy of the press release is attached as Exhibit 99.2 hereto and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

| Exhibit No. | Description |
|----------------------|---|
| 99.1 | Milestone Pharmaceuticals Inc.’s consolidated audited annual financial statements for the financial year ended December 31, 2021 and the Report of Independent Registered Public Accounting Firm thereon. |
| 99.2 | Press Release dated March 24, 2022. |
| 104 | Cover Page Interactive Data File--the cover page XBRL tags are embedded within the Inline XBRL document |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MILESTONE PHARMACEUTICALS INC.

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

Dated: March 24, 2022

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Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of Milestone Pharmaceuticals Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Milestone Pharmaceuticals Inc. and its subsidiary (together, the “Company”) as of December 31, 2021 and 2020, and the related consolidated Statements of Loss, and shareholders’ equity for each of the years then ended, including the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP¹
Montreal, Canada
March 24, 2022

We have served as the Company’s auditor since 2016

¹ CPA auditor, CA, public accountancy permit No.125677

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

| | <u>December 31, 2021</u> | <u>December 31, 2020</u> |
|---|--------------------------|--------------------------|
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | \$ 114,141 | \$ 72,310 |
| Short-term investments | — | 70,000 |
| Research and development tax credits receivable | 356 | 725 |
| Prepaid expenses | 4,299 | 5,428 |
| Other receivables | 127 | 223 |
| Total current assets | <u>118,923</u> | <u>148,686</u> |
| Operating lease assets | 711 | 980 |
| Property and equipment | 215 | 308 |
| Total assets | <u>\$ 119,849</u> | <u>\$ 149,974</u> |
| Liabilities, and Shareholders' Equity | | |
| Current liabilities | | |
| Accounts payable and accrued liabilities | \$ 6,551 | \$ 5,914 |
| Operating lease liabilities | 224 | 245 |
| Total current liabilities | <u>6,775</u> | <u>6,159</u> |
| Operating lease liabilities (net of current portion) | 474 | 696 |
| Total liabilities | <u>7,249</u> | <u>6,855</u> |
| Commitments and contingencies (Note 13) | | |
| Shareholders' Equity | | |
| Common shares, no par value, unlimited shares authorized 29,897,559 shares issued and outstanding as of December 31, 2021, 29,827,997 shares issued and outstanding as of December 31, 2020 | 251,901 | 251,682 |
| Pre-funded warrants - 12,327,780 issued and outstanding as of December 31, 2021 and 11,417,034 as of December 31, 2020 | 52,941 | 48,007 |
| Additional paid-in capital | 15,711 | 8,530 |
| Cumulative translation adjustment | (1,634) | (1,634) |
| Accumulated deficit | <u>(206,319)</u> | <u>(163,466)</u> |
| Total shareholders' equity | <u>112,600</u> | <u>143,119</u> |
| Total liabilities and shareholders' equity | <u>\$ 119,849</u> | <u>\$ 149,974</u> |

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

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

| | Year ended December 31, | |
|---|--------------------------------|--------------------|
| | 2021 | 2020 |
| Revenue | \$ 15,000 | \$ — |
| Operating expenses | | |
| Research and development, net of tax credits | 38,671 | 34,488 |
| General and administrative | 12,399 | 10,285 |
| Commercial | 7,003 | 5,937 |
| Loss from operations | (43,073) | (50,710) |
| Interest income, net | 220 | 726 |
| Loss before income taxes | (42,853) | (49,984) |
| Income tax benefit | — | 17 |
| Net loss | <u>\$ (42,853)</u> | <u>\$ (49,967)</u> |
| Weighted average number of shares and pre-funded warrants outstanding, basic and diluted | <u>41,833,861</u> | <u>29,344,993</u> |
| Net loss per share, basic and diluted | <u>\$ (1.02)</u> | <u>\$ (1.70)</u> |

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

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

| | Common Shares | | Pre-funded warrants | | Additional paid-in capital | Cumulative translation adjustment | Accumulated deficit | Total |
|---|-------------------|-------------------|---------------------|------------------|----------------------------|-----------------------------------|---------------------|-------------------|
| | Number of shares | Amount | Number of warrants | Amount | | | | |
| Balance as of December 31, 2019 | <u>24,505,748</u> | <u>\$ 226,245</u> | <u>—</u> | <u>\$ —</u> | <u>\$ 3,805</u> | <u>\$ (1,634)</u> | <u>\$ (113,499)</u> | <u>\$ 114,917</u> |
| Transactions during 2020 | | | | | | | | |
| Net loss | — | — | — | — | — | — | (49,967) | (49,967) |
| Exercise of stock options | 226,352 | 520 | — | — | (220) | — | — | 300 |
| Share-based compensation | — | — | — | — | 4,945 | — | — | 4,945 |
| Pre-funded warrants - Private Placement | — | — | 6,655,131 | 24,771 | — | — | — | 24,771 |
| Public Offering | 5,095,897 | 24,917 | 4,761,903 | 23,236 | — | — | — | 48,153 |
| Balance as of December 31, 2020 | <u>29,827,997</u> | <u>\$ 251,682</u> | <u>11,417,034</u> | <u>\$ 48,007</u> | <u>\$ 8,530</u> | <u>\$ (1,634)</u> | <u>\$ (163,466)</u> | <u>\$ 143,119</u> |
| Balance as of December 31, 2020 | <u>29,827,997</u> | <u>\$ 251,682</u> | <u>11,417,034</u> | <u>\$ 48,007</u> | <u>\$ 8,530</u> | <u>\$ (1,634)</u> | <u>\$ (163,466)</u> | <u>\$ 143,119</u> |
| Transactions during 2021 | | | | | | | | |
| Net loss | — | — | — | — | — | — | (42,853) | (42,853) |
| Exercise of stock options | 69,562 | 219 | — | — | (98) | — | — | 121 |
| Private Placement | — | — | 910,746 | 4,934 | — | — | — | 4,934 |
| Share-based compensation | — | — | — | — | 7,279 | — | — | 7,279 |
| Balance as of December 31, 2021 | <u>29,897,559</u> | <u>\$ 251,901</u> | <u>12,327,780</u> | <u>\$ 52,941</u> | <u>\$ 15,711</u> | <u>\$ (1,634)</u> | <u>\$ (206,319)</u> | <u>\$ 112,600</u> |

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

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

| | Year ended December 31, | |
|--|--------------------------------|------------------|
| | 2021 | 2020 |
| Cash flows used in operating activities | | |
| Net loss | \$ (42,853) | \$ (49,967) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation of property and equipment | 93 | 97 |
| Share-based compensation expense | 7,279 | 4,945 |
| Changes in operating assets and liabilities: | | |
| Other receivables | 96 | 35 |
| Research and development tax credits receivable | 369 | (147) |
| Prepaid expenses | 1,129 | (3,583) |
| Operating lease assets and liabilities | 26 | (29) |
| Accounts payable and accrued liabilities | 637 | (2,083) |
| Net cash used in operating activities | (33,224) | (50,732) |
| Cash provided by (used in) investing activities | | |
| Acquisition of short-term investments | (15,000) | (90,000) |
| Redemption of short-term investments | 85,000 | 20,000 |
| Net cash provided by (used in) investing activities | 70,000 | (70,000) |
| Cash provided by financing activities | | |
| Proceeds from exercise of options | 121 | 300 |
| Net proceeds from issuance of common shares in a public offering, net of issuance cost | — | 24,917 |
| Net proceeds from issuance of pre-funded warrants in a public offering, net of issuance cost | — | 23,236 |
| Proceeds from issuance of pre-funded warrants, net of issuance cost | 4,934 | 24,771 |
| Cash provided by financing activities | 5,055 | 73,224 |
| Net increase (decrease) in cash and cash equivalents | 41,831 | (47,508) |
| Cash and cash equivalents – Beginning of year | 72,310 | 119,818 |
| Cash and cash equivalents – End of year | \$ 114,141 | \$ 72,310 |

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

1 Organization and Nature of Operations

Milestone Pharmaceuticals Inc. (Milestone or the Company) is a biopharmaceutical company incorporated under the Business Corporations Act of Québec. Milestone is focused on the development and commercialization of innovative cardiovascular medicines. Milestone's lead product candidate, etripamil, is a novel, potent short-acting 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 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

These consolidated financial statements of the Company have been presented in United States dollars (USD) and have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP), including the applicable rules and regulations of the Securities and Exchange Commission (SEC) regarding financial reporting.

The preparation of consolidated financial statements in conformity with US 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 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 direct, and the resulting share-based compensation expense, using the Black-Scholes option-pricing model.

The ongoing COVID-19 pandemic has had an impact on the Company's business, operations and clinical development timelines. The pandemic has resulted in many state, local and foreign governments implementing, and making adjustments to, various orders and restrictions in order to control the spread of the disease, which have impacted patient recruitment, enrollment and follow-up visits at clinical sites. The Company will continue to evaluate the COVID-19 pandemic impact on the development timelines of its clinical programs. Estimates and assumptions about future events and their effects cannot be determined with certainty and therefore require the exercise of judgment. As of the date of issuance of these consolidated financial statements, the Company is not aware of any specific event or circumstance that would require the Company to update its estimates, assumptions and judgments. These estimates may change as new events occur and additional information is obtained and are recognized in the consolidated financial statements as soon as they become known. Actual results could differ from those estimates and any such differences may be material to the Company's consolidated financial statements.

c) Segment Information

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions while focusing on the development and commercialization of innovative cardiovascular medicines.

d) Revenue Recognition

Collaborative Arrangements

The Company considers the nature and contractual terms of arrangements and assesses whether an arrangement involves a joint operating activity pursuant to which the Company is an active participant and is exposed to significant risks and rewards dependent on the commercial success of the activity. If the Company is an active participant and is exposed to significant risks and rewards dependent on the commercial success of the activity, the Company accounts for such an arrangement as a collaborative arrangement under Accounting Standards Codification (ASC) 808, Collaborative Arrangements (ASC 808), which requires that certain transactions between the Company and collaborators be recorded in its consolidated statements of comprehensive loss on either a gross basis or net basis, depending on the characteristics of the collaborative relationship, and requires enhanced disclosure of collaborative relationships. The Company evaluates its collaboration agreements for proper classification in its consolidated statements of comprehensive loss based on the nature of the underlying activity. If payments to and from collaborative partners are not within the scope of other authoritative accounting literature, the consolidated statements of loss classification for the payments is based on a reasonable, rational analogy to authoritative accounting literature that is applied in a consistent manner. If the Company concludes that it has a customer relationship with one of its collaborators, the Company follows the guidance in Accounting Standards Codification (ASC) Topic 606, Revenue From Contracts With Customers (ASC 606).

Revenue from Contracts with Customers

In accordance with ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled in exchange for these goods and services. To achieve this core principle, the Company applies the following five steps: 1) identify the customer contract; 2) identify the contract's performance obligations; 3) determine the transaction price; 4) allocate the transaction price to the performance obligations; and 5) recognize revenue when or as a performance obligation is satisfied. The Company evaluates all promised goods and services within a customer contract and determines which of such goods and services are separate performance obligations. This evaluation includes an assessment of whether the good or service is capable of being distinct and whether the good or service is separable from other promises in the contract. In assessing whether promised goods or services in licensing arrangements are distinct, the Company considers factors such as the stage of development of the underlying intellectual property and the capabilities of the customer to develop the intellectual property on their own or whether the required expertise is readily available. Licensing arrangements are analyzed to determine whether the promised goods or services, which often include licenses, research and development services and governance committee services, are distinct or whether they must be accounted for as part of a combined performance obligation. If the license is considered not to be distinct, the license would then be combined with other promised goods or services as a combined performance obligation. If the Company is involved in a governance committee, it assesses whether its involvement constitutes a separate performance obligation. When governance committee services are determined to be separate performance obligations, the Company determines the fair value to be allocated to this promised service. Certain contracts contain optional and additional items, which are considered marketing offers and are accounted for as separate contracts with the customer if such option is elected by the customer, unless the option provides a material right which would not be provided without entering into the contract. An option that is considered a material right is accounted for as a separate performance obligation. The transaction price is determined based on the consideration to which the Company will be entitled in exchange for transferring goods and services to the customer. A contract may contain variable consideration, including potential payments for both milestone and research and development services. For certain potential milestone payments, the Company estimates the amount of variable consideration by using the most likely amount method. In making this assessment, the Company evaluates factors such as the clinical, regulatory, commercial and other risks that must be overcome to achieve the milestone. Each reporting period the Company re-evaluates the probability of achievement of such variable consideration and any related constraints. Milestone will include variable consideration, without constraint, in the transaction price to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price among the performance obligations on a relative standalone selling price basis unless a portion of the transaction price is variable and meets the criteria to be allocated entirely to a performance obligation or to a distinct good or service that forms part of a single performance obligation.

The Company allocates the transaction price based on the estimated standalone selling price of the underlying performance obligations or in the case of certain variable consideration to one or more performance obligations. The Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the stand-alone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs to complete the respective performance obligation. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amount the Company would expect to receive for each performance obligation.

When a performance obligation is satisfied, revenue is recognized for the amount of the transaction price, excluding estimates of variable consideration that are constrained, that is allocated to that performance obligation on a relative standalone selling price basis. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations under an arrangement.

For performance obligations consisting of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company will recognize revenue from non-refundable, up-front fees allocated to the license at the point in time when the license is transferred to the customer and the customer is able to use and benefit from the license.

e) Cash and Cash Equivalents

Cash and cash equivalents consist of cash and highly liquid investments that are readily convertible into cash with original maturities of three months or less at acquisition date.

f) 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.

g) Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentration of credit risk consist primarily of cash and cash equivalents and investment securities classified as held to maturity. The Company maintains deposits in financial institutions. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. Additionally, the Company has adopted an investment policy that includes guidelines relative to credit quality, diversification of maturities and liquidity.

h) Currency Risk

The Company is exposed to currency risk due to financial instruments denominated in foreign currencies. The Company is exposed to the Canadian dollar currency risk and does not enter into arrangements to hedge its currency risk exposure.

i) Property and Equipment

Property and equipment is stated at historical cost less accumulated amortization. Expenditures for maintenance and repairs are recorded to expense as incurred. The Company reviews its property and equipment whenever events or changes in circumstances indicate that the carrying value of certain assets might not be recoverable and recognizes an impairment loss when it is probable that an asset's realizable value is less than the carrying value. To date, no such impairment losses have been recorded. Amortization is calculated using the straight-line method over the following estimated useful lives of the assets:

| | |
|--------------------------------|---------------------|
| Computer hardware and software | 3 years |
| Office equipment | 5 years |
| Furniture and fixtures | 5 years |
| Leasehold improvements | over the lease-term |

j) Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and short-term and long-term lease liabilities, as applicable. The Company does not have financing leases.

Operating lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of lease payments over the expected remaining lease term. Right-of-use assets are subsequently accounted for as long-lived assets, including evaluating for indicators of impairment. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate to discount lease payments, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. Prospectively, the Company will adjust the right-of-use assets for straight-line rent expense or any incentives received and remeasure the lease liability at the net present value using the same incremental borrowing rate that was in effect as of the lease commencement or transition date.

The Company has elected not to recognize leases with an original term of one year or less on the balance sheet. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew.

k) Pre-funded Warrants

Pre-funded warrants allow the holder to pay little or no consideration to receive the shares upon exercise of the warrant. The pre-funded warrants do not meet the definition of a derivative under ASC 815 because their fair value at issuance is equal to the fair value of the shares underlying the warrant. As such, they have the characteristics of a prepaid forward sale of equity. As a result, the pre-funded warrants are accounted for as equity instruments.

l) Share Issuance Costs

Share issuance costs applicable to the issuance of equity instruments are recorded as a reduction of the financing equity proceeds.

m) Research and Development and Investment Tax Credits

Research and development costs are charged to expense as costs are incurred in performing research and development activities. The Company's research and development costs consist primarily of salaries and fees paid to contract research organizations (CROs) and to contract manufacturing organizations (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 the Company's trials are being conducted. Direct costs associated with the Company's 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. The Company records expenses for its 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 study in accordance with agreements established with CROs and clinical trial sites. The Company determines 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 the Company as of each consolidated balance sheet date. The actual costs and timing of clinical trials are highly uncertain, subject of risks and may change depending upon a number of factors, including the Company's clinical development plan. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly.

The Company recognizes 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.

n) Income Taxes

The provision for income taxes is computed using the liability method. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities. Deferred tax assets and liabilities are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is recorded to reduce the carrying amount of deferred income tax assets until when it is more likely than not that these assets will be realized. Tax benefits related to tax positions not deemed to meet the "more-likely-than-not" threshold are not permitted to be recognized in the consolidated financial statements.

o) Foreign Currency Translation and Transactions

The functional currency of the Company is the US dollar. Accordingly, transactions denominated in currencies other than the functional currency are measured and recorded in the functional currency at the exchange rate in effect on the date of the transactions. At each consolidated balance sheet date, monetary assets and liabilities denominated in currencies other than the functional currency are remeasured using the exchange rate in effect at that date. Non-monetary assets and liabilities and revenue and expense items denominated in foreign currencies are translated into the functional currency using the exchange rate prevailing at the dates of the respective transactions. Any gains or losses arising on remeasurement are included in the consolidated statement of operations.

p) Share Based Compensation

The Company has a share based compensation plan which is described in detail in note 8 and records all share-based payments, including grants of employee share options, at their fair values. The fair value of share options granted to employees and non-employees is estimated at the date of grant using the Black-Scholes option pricing model. The Company recognizes share based compensation expense over the requisite service period of the individual grants, which equals the vesting period, using the straight-line method. Forfeitures, if any, are recorded as they occur. Any consideration paid by employees on exercising share options and the corresponding portion previously credited to contributed surplus are credited to share capital. The Black-Scholes option pricing model used by the Company to calculate option values was developed to estimate fair value.

The Company approved an employee share purchase plan in April 2019, which became effective on May 8, 2019 and is described in note 8. The plan provides a means by which eligible employees of the Company and certain designated companies may be given an opportunity to purchase common shares. The plan permits the Company to grant a series of purchase rights to eligible employees under an employee stock purchase plan.

q) Recently Adopted Accounting Pronouncements

The Company has considered recent accounting pronouncements and concluded that they are either not applicable to the business or that the effect is not expected to be material to the consolidated financial statements as a result of future adoption.

r) Significant Risks and Uncertainties

The ongoing COVID-19 pandemic has had an impact on our business, operations and clinical development timelines. The pandemic has resulted in many state, local and foreign governments implementing various orders and restrictions in order to control the spread of the disease which has impacted patient recruitment, enrollment and follow-up visits at clinical sites. In light of the ongoing pandemic, the Company has implemented business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on its business. The Company anticipates that the COVID-19 pandemic will continue to have an impact on the development timelines for its clinical programs. The extent to which the COVID-19 pandemic continues to impact its business, its clinical development and regulatory efforts, its corporate development objectives and the value of and market for its common shares will depend on future developments that remain highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, business closure requirements in the U.S., Europe and other countries, the timing and unpredictability of achieving widespread vaccination rates, the effectiveness of any vaccines against new variants, and the timing of the return of the global economy to pre-pandemic levels. The global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic could have a material adverse effect on the Company's business, financial condition, results of operations and growth prospects.

In addition, the Company is subject to other 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 and Russian hostilities in Ukraine and overall fluctuations in the financial markets in the U.S. and abroad.

s) Sources of Liquidity and Funding Requirements

The Company has incurred operating losses and experienced negative operating cash flows since its inception and anticipates to continue to incur losses for at least the next several years. As of December 31, 2021, the Company had cash and cash equivalents of \$114.1 million and an accumulated deficit of \$206.3 million.

The Company believes that its cash and cash equivalents as of December 31, 2021 are sufficient for the Company to fund planned operations for at least one year from the issuance date of these consolidated financial statements. The Company has historically financed its operations primarily through the sale of equity securities and, to a lesser extent from cash received pursuant to its license agreement. To date, the Company has not generated any revenue from product sales. Management expects operating losses and negative cash flows from operations to continue for the foreseeable future. The Company currently plans to raise additional funding as required based on the status of its clinical trials and projected cash flows. There can be no assurance that, in the event the Company requires additional financing, such financing will be available at terms acceptable to the Company, if at all. Failure to generate sufficient cash flows from operations, raise additional capital and reduce discretionary spending should additional capital not become available could have a material adverse effect on the Company's ability to achieve its business objectives.

3 Revenue

General

To date, the Company has not generated revenue from product sales. During the year ended December 31, 2021, the Company recognized revenue of \$15 million, in the form of a non-refundable upfront cash payment in connection with the License Agreement.

On May 15, 2021, the Company entered into the License Agreement with Ji Xing, which is an entity affiliated with RTW Investments, LP, (RTW) a beneficial owner of approximately 14% of the Company's common shares. Under the License Agreement, the Company granted Ji Xing exclusive development and commercialization rights to any pharmaceutical product that uses a device to deliver the Company's proprietary calcium channel blocker known as etripamil by nasal spray for all prophylactic and therapeutic uses in humans in the following territories: People's Republic of China, including mainland China, Hong Kong Special Administrative Region, Macau Special Administrative Region, and Taiwan (the Territory). Ji Xing will be responsible for development and regulatory activities in the Territory, and the Company will remain responsible for certain manufacturing activities in the Territory, subject to the supply agreement subsequently entered into by the Company and Ji Xing as contemplated by the License Agreement (the Supply Agreement). The Company received a non-refundable upfront cash payment of \$15 million (see note 3) and the right to future payments of up to \$107.5 million in total development and sales milestone payments. In addition, the Company is entitled to receive tiered royalty payments ranging from a percentage in the low double digits to the high double digits of Net Sales (as defined in the License Agreement) of all products sold in the Territory.

Strategic Partnerships

Ji Xing

Pursuant to the License Agreement, the Company granted Ji Xing exclusive development and commercialization rights to any pharmaceutical product that uses a device to deliver the Company's proprietary calcium channel blocker known as etripamil by nasal spray for all prophylactic and therapeutic uses in humans in the Territory.

Ji Xing will be responsible for development and regulatory activities in the Territory, and the Company will remain responsible for certain manufacturing activities in the Territory, subject to the Supply Agreement.

The Company received a non-refundable upfront cash payment consisting of \$15 million, and the right to receive up to \$107.5 million in future milestone payments and royalties on any sales of etripamil in the Territory.

Management evaluated all of the promised goods or services within the contract and determined that such goods and services were separate performance obligations. The Company determined that the license granted was a separate performance obligation as Ji Xing can benefit from the license granted on its own after the transfer of the license, as it does not require any significant development, regulatory or commercialization activities from Milestone. Ji Xing is responsible for all development, regulatory and commercialization activities in the Territory, including the performance of clinical trials necessary for regulatory approval, and is responsible for all such related costs. Supply of the product can be provided by another entity, as the Company currently uses a CMO for the production of etripamil without subsequent significant modification or customization by the Company, therefore the Company determined the obligation to supply product is a separate and distinct obligation. The Company concluded that the obligation for participation on the various governance committees was distinct as the services could be performed by an outside party, however it was determined to be immaterial after estimating the stand alone cost compared to the License Agreement as a whole. As a result, the Company concluded there were two material and distinct performance obligations to account for under ASC 606 at the inception of the License Agreement.

The Company determined that the transaction price consists of the \$15 million non-refundable upfront cash payment and the constrained variable consideration of the development milestone payments. As the development milestones are contingent on occurrences out of the direct control of the Company, the estimate of the variable consideration is \$0. Variable constraint does not apply to sales- or usage-based royalties derived from the licensing of Intellectual property; rather, consideration from such royalties is only recognized as revenue at the later of when the performance obligation is satisfied or when the uncertainty is resolved (e.g., when subsequent sales or usage occurs), therefore the sales and royalty milestones are not included in the transaction price. The Company will re-evaluate the transaction price at the end of each reporting period and as uncertain events are resolved, or other changes in circumstances occur, adjust its estimate of the transaction price if necessary. For the year ended December 31, 2021, the Company has recognized the non-refundable upfront payment as collaboration revenue, for the reasons described in the preceding paragraph.

Concurrent with the License Agreement, Ji Xing acquired \$5 million of pre-funded warrants (see note 8). The Company considered whether this equity investment should be evaluated as part of the transaction price, and concluded that as the fair value of the company's common shares on a per share basis was equal to the fair value of the pre-funded warrants at the date of the investment, there was no premium or discount on the shares that should be allocated and included in the transaction price. The Company accounted for the issuance of pre-funded warrants as equity and included in basic and diluted loss per share in the accompanying financial statements. See note 8 for additional details.

For any future subsequent purchases of product pursuant to the Supply Agreement, each order will be accounted for as a separate purchase and the order price will be allocated to the products based on the standalone selling price of the products. Under this methodology, the order price will be allocated to the single performance obligation to supply the products. As the Company has not previously licensed a product for a territory, the residual approach was used by deducting the estimated stand-alone selling price of the other obligations from the total transaction price to determine the stand-alone selling price of the remaining goods and services, which consisted of the transfer of intellectual property pursuant to the license. Therefore, the remaining transaction price of \$15 million was allocated to the technology transfer and recognized at a point in time when the technology has been transferred. The technology transfer was completed on June 22, 2021, and the \$15 million was recognized at that point in time as revenue in the related statement of comprehensive loss.

4 Short-term Investments

The Company had no short-term investments as at December 31, 2021. For the year ended December 31, 2020, the short-term investments were comprised of term deposits issued in US currency, earning interest between 0.30% and 0.86%, maturing between January 29, 2021 and August 16, 2021. These short-term investments were in scope of ASC 320, Investments - Debt Securities. The short-term investments maturity is greater than 90 days but less than one year, and they were classified as held to maturity, recorded as current assets and were accounted for at amortized cost.

5 Leases

On June 3, 2019, the Company entered into a new lease arrangement for a three-year term for its office located in Charlotte, NC. The Company recognized the operating lease right-of-use asset and operating lease liabilities at the lease commencement date on September 10, 2019. The interest rate implicit in lease contracts is not readily determinable and the Company does not have a public credit rating and carries no debt. As such, several factors were considered in the determination of the Company's incremental borrowing rate used in determining the present value of lease payments. The Company's examined credit ratings for similar companies, assumed equivalency between the Canadian and U.S. markets for collateralized debt and used rates over the 36-month period. This resulted in an incremental borrowing rate of 8%. Lease expenses are recognized on a straight-line basis over the lease term, which is accomplished by increasing the amortization of the right-of-use asset as interest expense on the lease liability declines over the lease term. The company was not reasonably certain of renewing the lease following the initial term and recognized the right-of-use asset and operating lease liabilities over the 36-month period ending September 30, 2022.

On July 1, 2020, the Company entered into an arrangement for the lease renewal for its headquarters located in Ville Saint-Laurent, Quebec. The 5-year lease term is from December 1, 2020 expiring on November 30, 2025. The Company revalued the operating lease right-of-use asset and operating lease liabilities at the effective lease arrangement date of July 1, 2020. The Company's examined credit ratings for similar companies, assumed equivalency between the Canadian and U.S. markets for collateralized debt and used rates for the remaining lease term of 65 months. This resulted in an incremental borrowing rate of 5.26%. Lease expenses are recognized on a straight-line basis over the lease term, which is accomplished by increasing the amortization of the right-of-use asset as interest expense on the lease liability declines over the lease term. The Company is not reasonably certain of renewing the lease following the current renewal option and recognized the right-of-use asset and operating lease liabilities to November 30, 2025.

The Company's two operating office leases right-of-use assets as at December 31 were as follows:

| | 2021 | 2020 |
|---|---------------|---------------|
| Opening balance | \$ 980 | \$ 524 |
| Right-of-use adjustment renewal on July 1, 2020 | — | 735 |
| Amortization of right-of-use asset | (269) | (279) |
| Closing balance | <u>\$ 711</u> | <u>\$ 980</u> |

Operating lease expenses of \$314 and \$318 are included in general and administrative operating expenses in the consolidated statement loss and comprehensive loss, and within operating activities in the statement of cash flows for the year ended December 31, 2021 and 2020, respectively and are comprised of two operating lease right-of-use assets and one operating lease of less than 12 months.

The following table summarizes the future minimum lease payments of right-of-use assets operating lease as at December 31, 2021:

| | | |
|--------------------------------------|----|------------|
| January 1, 2022 to December 31, 2022 | \$ | 243 |
| January 1, 2023 to December 31, 2023 | | 176 |
| January 1, 2024 to December 31, 2024 | | 176 |
| January 1, 2025 to November 30, 2025 | | 160 |
| | | <u>755</u> |
| Less interest | | (68) |
| | \$ | <u>687</u> |

6 Property and equipment

Property and equipment consist of the following at December 31:

| | 2021 | 2020 |
|--------------------------------|---------------|---------------|
| Computer hardware and software | \$ 22 | \$ 22 |
| Office equipment | 406 | 406 |
| Leasehold improvements | 26 | 26 |
| Total | \$ 454 | \$ 454 |
| Less accumulated depreciation | (239) | (146) |
| Property and equipment, net | <u>\$ 215</u> | <u>\$ 308</u> |

During the year ended December 31, 2021 and December 31, 2020, the Company did not record any write off. For the year ended December 31, 2021 and 2020, amortization expense was \$93 and \$97, respectively and was included in research and development expense.

7 Accounts payable and accrued liabilities

Accounts payable and accrued liabilities comprised the following as of December 31:

| | 2021 | 2020 |
|--|-----------------|-----------------|
| Trade accounts payable | \$ 4,384 | \$ 4,641 |
| Accrued compensation and benefits payable | 1,458 | 957 |
| Accrued research and development liabilities | 272 | 152 |
| Other accrued liabilities | 437 | 164 |
| | <u>\$ 6,551</u> | <u>\$ 5,914</u> |

8 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 29,897,559 shares were issued and outstanding as of December 31, 2021.

As of December 31, 2021, there were 827,187 common shares available for issuance under the Employee Stock Purchase Plans and no common shares have been issued under such plan.

Shelf Registration

On November 12, 2021, the company entered into an agreement and the company may sell any combination of the securities described in this prospectus in one or more offerings up to a total aggregate offering price of \$250,000,000.

Pre-funded Warrants – Private Placement

On May 15, 2021, the Company entered into a securities purchase agreement to sell and issue in a private placement pre-funded warrants to purchase up to 910,746 of the Company's common shares, at a purchase price of \$5.48 per pre-funded warrant pursuant to the License Agreement for aggregate net proceeds of \$5.0 million (the Private Placement). The Private Placement closed on May 21, 2021. Each pre-funded warrant is exercisable for one of the Company's common shares at an exercise price of \$0.01 per share, has no expiration date, and is immediately exercisable, subject to certain beneficial ownership limitations. The pre-funded warrants are classified and accounted for as equity.

On July 23, 2020, the Company entered into a securities purchase agreement to sell and issue in a private placement pre-funded warrants of 6,655,131 of the Company's common shares, at a purchase price of \$3.7465 per pre-funded warrant for aggregate net proceeds of \$24.8 million (the Private Placement). The Private Placement closed on July 24, 2020. Each pre-funded warrant is exercisable for one of the Company's common shares at an exercise price of \$0.01 per share, has no expiration date, and is immediately exercisable, subject to certain beneficial ownership limitations. The pre-funded warrants are classified and accounted for as equity.

Open Market Sale Agreement

On July 29, 2020, the Company entered into an Open Market Sale AgreementSM with respect to an at-the-market offering program (ATM Program) under which the Company may issue and sell its common shares having an aggregate offering price of up to \$50 million. The Company has not sold shares under the ATM program as of the date of this filing.

Pre-funded Warrants and Common Shares – Public Offering

On October 22, 2020, the Company issued (i) 5,095,897 common shares, without par value, at a price to the public of \$5.25 per share, and (ii) pre-funded warrants to purchase 4,761,903 common shares at an exercise price equal to \$0.01 per share, at a price to the public of \$5.24 per common share underlying the pre-funded warrants (the Offering). The net proceeds to the Company from the Offering were \$48.2 million. The pre-funded warrants are classified and accounted for as equity.

Additional Paid-in Capital

| | 2021 | 2020 |
|----------------------------------|------------------|-----------------|
| Opening balance | \$ 8,530 | \$ 3,805 |
| Share-based compensation expense | 7,279 | 4,945 |
| Exercise of stock options | (98) | (220) |
| Closing balance | <u>\$ 15,711</u> | <u>\$ 8,530</u> |

9 Share Based Compensation

Under the Company's 2019 Equity Incentive Plan (the 2019 Plan) and the Company's Stock Option Plan (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 November 10th, 2021, the Company established an 2021 Inducement Plan under Nasdaq Marketplace Rules 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. There were no options granted under the 2021 Inducement Plan for the year ended December 31 2021.

On January 1, 2021, the number of the Company's common shares reserved for issuance under the 2019 Plan increased by 1,193,119 common shares. In addition, 72,186 options have been forfeited under the 2011 Plan after adoption of the 2019 Plan and became available for issuance under the 2019 Plan. As of December 31, 2021, there were 4,596,021 shares available for issuance under the 2019 Plan, of which 827,187 shares were available for future grants.

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

| | 2021 | | | Weighted average exercise price | 2020 | | | Weighted average exercise price |
|--|------------------|------------------|------------------|---------------------------------|------------------|------------------|------------------|---------------------------------|
| | 2019 Plan | 2011 Plan | Total | | 2019 Plan | 2011 Plan | Total | |
| Outstanding at beginning of year - 2011 Plan | — | 2,080,087 | 2,080,087 | \$ 2.15 | — | 2,364,526 | 2,364,526 | \$ 2.15 |
| Outstanding at beginning of year - 2019 Plan | 1,706,190 | — | 1,706,190 | 13.55 | 220,140 | — | 220,140 | 20.78 |
| Granted - 2019 Plan | 2,137,250 | — | 2,137,250 | 6.22 | 1,534,460 | — | 1,534,460 | 12.68 |
| Exercised - 2011 Plan | — | (50,562) | (50,562) | 0.98 | — | — | — | — |
| Exercised - 2019 Plan | (19,000) | — | (19,000) | 3.74 | — | (226,352) | (226,352) | 1.23 |
| Forfeited - 2011 Plan | — | (8,812) | (8,812) | 9.42 | — | (58,087) | (58,087) | 5.94 |
| Forfeited - 2019 Plan | (63,303) | — | (63,303) | 8.64 | (45,413) | — | (45,413) | 18.53 |
| Cancelled - 2011 Plan | — | (23,029) | (23,029) | 9.42 | — | — | — | — |
| Cancelled - 2019 Plan | (11,303) | — | (11,303) | 9.22 | (2,997) | — | (2,997) | 21.48 |
| Expired - 2011 Plan | — | (1,713) | (1,713) | 0.70 | — | — | — | — |
| Outstanding at end of period | <u>3,749,834</u> | <u>1,995,971</u> | <u>5,745,805</u> | <u>\$ 6.93</u> | <u>1,706,190</u> | <u>2,080,087</u> | <u>3,786,277</u> | <u>\$ 7.29</u> |
| Outstanding at end of period - Weighted average exercise price | <u>\$ 9.52</u> | <u>\$ 2.07</u> | | | <u>\$ 13.55</u> | <u>\$ 2.15</u> | | |
| Exercisable at end of period | <u>1,094,316</u> | <u>1,795,332</u> | <u>2,889,648</u> | <u>\$ 5.60</u> | <u>268,164</u> | <u>1,536,895</u> | <u>1,805,059</u> | <u>\$ 2.94</u> |
| Exercisable at end of period - Weighted average exercise price | <u>\$ 11.48</u> | <u>\$ 2.01</u> | | | <u>\$ 8.23</u> | <u>\$ 2.02</u> | | |

The weighted average remaining contractual life was 7.81 and 7.86 years for outstanding options as of December 31, 2021 and 2020, respectively. The weighted average remaining contractual life was 6.80 and 6.91 years for vested options, as of December 31, 2021 and 2020, respectively.

There was \$15,324 and \$13,012 total unrecognized compensation cost related to non-vested share options as of December 31, 2021 and 2020, respectively. The share options are expected to be recognized over a remaining weighted average vesting period of 2.42 years and 2.67 years as of December 31, 2021 and 2020, respectively.

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

| | 2021 | | | | 2020 | | | |
|---|-------------------|-----------|-----------|-----------------------------|-------------------|-----------|-----------|-----------------------------|
| | Number of options | | Total | Weighted average fair value | Number of options | | Total | Weighted average fair value |
| 2019 Plan | 2011 Plan | 2019 Plan | | | 2011 Plan | | | |
| Non-vested share options at beginning of year - 2011 Plan | — | 543,192 | 543,192 | \$ 1.81 | — | 1,152,300 | 1,152,300 | \$ 1.88 |
| Non-vested share options at beginning of year - 2019 Plan | 1,438,026 | — | 1,438,026 | \$ 10.28 | 218,975 | — | 218,975 | \$ 14.44 |
| Granted - 2019 Plan | 2,137,250 | — | 2,137,250 | 4.70 | 1,534,460 | — | 1,534,460 | 8.98 |
| Vested, outstanding 2011 Plan | — | (333,741) | (333,741) | 1.65 | — | (551,026) | (551,026) | 1.70 |
| Vested, outstanding 2019 Plan | (856,455) | — | (856,455) | 8.69 | (269,996) | — | (269,996) | 5.80 |
| Forfeited - 2011 Plan | — | (8,812) | (8,812) | 6.66 | — | (58,082) | (58,082) | 4.32 |
| Forfeited - 2019 Plan | (63,303) | — | (63,303) | 6.28 | (45,413) | — | (45,413) | 13.03 |
| Non-vested share options at end of period | 2,655,518 | 200,639 | 2,856,157 | \$ 6.08 | 1,438,026 | 543,192 | 1,981,218 | \$ 7.96 |
| Non-vested share options at end of period - Weighted average fair value | \$ 6.40 | \$ 1.86 | | | \$ 10.28 | \$ 1.81 | | |

Options granted are valued using the Black-Scholes option pricing model. 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 following table summarizes information with respect to share options outstanding as of December 31, 2021:

| Exercise price | Options outstanding | | | Options exercisable | | |
|-----------------|---------------------|---|---------------------------------|---------------------|---|---------------------------------|
| | Number of options | Weighted average remaining contractual life (years) | Weighted average exercise price | Number of options | Weighted average remaining contractual life (years) | Weighted average exercise price |
| \$0.84-\$1.00 | 73,629 | 2.36 | \$ 0.89 | 73,629 | 2.36 | \$ 0.89 |
| \$1.01-\$2.00 | 1,202,193 | 5.61 | \$ 1.48 | 1,120,697 | 5.57 | \$ 1.47 |
| \$2.01-\$4.00 | 1,321,374 | 7.64 | \$ 3.20 | 1,066,458 | 7.61 | \$ 3.18 |
| \$4.01-\$10.00 | 2,221,317 | 9.20 | \$ 6.32 | 157,524 | 8.69 | \$ 6.86 |
| \$15.01-\$20.00 | 80,380 | 7.82 | \$ 17.20 | 50,592 | 7.81 | \$ 17.24 |
| \$20.01-\$22.45 | 846,912 | 8.00 | \$ 21.65 | 420,748 | 7.99 | \$ 21.67 |
| Total | 5,745,805 | 7.81 | \$ 6.93 | 2,889,648 | 6.80 | \$ 5.60 |

The intrinsic value of all outstanding options as of December 31, 2021 was \$11.7 million, based on the fair value of our common shares of \$6.55 per share at December 31, 2021, of which \$9.8 million related to vested options and \$1.9 million related to unvested options.

The fair value of share-based payment transaction is measured using Black-Scholes valuation model. This model also requires assumptions, including expected option life, volatility, risk-free interest rate and dividend yield, which greatly affect the calculated values:

| | 2021 | 2020 |
|-------------------------|------------|------------|
| Exercise price | \$ 6.22 | \$ 12.68 |
| Share price | \$ 6.22 | \$ 12.68 |
| Volatility | 93% | 85% |
| Risk-free interest rate | 1.05% | 1.03% |
| Expected life | 6.01 years | 5.88 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.

The Company recognized share-based compensation expense as follows for the year ended December 31:

| | 2021 | 2020 |
|--------------------------|-----------------|-----------------|
| Administration | \$ 3,011 | \$ 2,007 |
| Research and development | 3,046 | 2,055 |
| Commercial activities | 1,222 | 883 |
| | <u>\$ 7,279</u> | <u>\$ 4,945</u> |

10 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. Share-based compensation shares have been excluded from the calculation because their effects would be anti-dilutive. Therefore, the weighted average number of shares used to calculate both basic and diluted loss per share are the same.

The following potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding as of December 31, 2021 and 2020, as they would be anti-dilutive:

| | 2021 | 2020 |
|---------------|-----------|-----------|
| Share options | 5,745,805 | 3,786,277 |

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

11 Income taxes

A reconciliation between tax expense and the product of accounting income multiplied by the basic income tax rate for the years ended December 31, 2021 and 2020 is as follows:

| | 2021 | 2020 |
|--|----------|-------------|
| Loss before income taxes | (42,853) | \$ (49,984) |
| Basic income tax rate | 26.19% | 26.33% |
| Computed income tax recovery | (11,221) | (13,161) |
| Effect on income tax rate resulting from | | |
| Accounting charges not deductible for tax purposes | 18 | 7 |
| Non-deductible share-based compensation | 1,929 | 1,310 |
| Share issue costs | 15 | (984) |
| Tax benefits of current period losses and other tax assets | 9,536 | 12,715 |
| Valuation allowance for prior year adjustment | (276) | 108 |
| Other | (1) | (12) |
| Income tax expense recovery reported in the consolidated statements of loss and comprehensive loss | \$ — | \$ (17) |

The Company has incurred Canadian federal and provincial net operating losses (NOLs) from inception. As of December 31, 2021, the Company has NOL carry-forwards of approximately \$149,012 and \$146,652, respectively, for Canadian federal and Québec purposes, available to reduce future taxable income, which expire beginning in 2027 through 2041. The Company also has scientific research and experimental development expenditures of approximately \$18,051 and \$22,185, respectively, for Canadian federal and Québec income tax purposes, which have not been deducted. These expenditures are available to reduce future taxable income and have an unlimited carry-forward period. Research and development tax credits and expenditures are subject to verification by the tax authorities, and, accordingly, these amounts may vary.

The Company has incurred NOLs for U.S. tax purposes. As of December 31, 2021, the Company has carry-forwards of approximately \$26,347 related to U.S. NOLs that may be carried forward indefinitely and are available to reduce future taxable income.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The net deferred tax assets have not been recognized in these financial statements because the criteria for recognition of these assets were not met.

The Company's deferred tax assets consist of the following for the years ended December 31, 2021 and 2020:

| | 2021 | 2020 |
|--|----------|----------|
| Net operating loss carry-forwards | 45,756 | 36,951 |
| Tax basis of property and equipment in excess of carrying values | 103 | 100 |
| Federal SR&ED investment tax credits | 709 | 496 |
| Taxation of federal SR&ED investment tax credits | (108) | (132) |
| Research and development expenditures | 5,259 | 3,929 |
| Financing costs | 1,726 | 2,583 |
| Change in tax rates | 51 | 25 |
| Others | 26 | 34 |
| Total gross deferred tax assets | 53,522 | 43,986 |
| Valuation allowance | (53,522) | (43,986) |
| Net deferred tax assets | — | — |

The Company files income tax returns in Canada and in the United States. The Company is subject to Canada Revenue Agency and Revenu Québec examination for fiscal years 2016 to 2021 due to unexpired statute of limitation periods and is subject to US Federal and state income tax examination for fiscal years 2018 to 2021.

12 Government assistance

The Company incurred research and development expenditures that are eligible for investment tax credits. The investment tax credits recorded are based on management's estimates of amounts expected to be recovered and are subject to audit by the taxation authorities. These amounts (expressed in thousands of US dollars) have been recorded as a reduction of research and development expenditures the year ended December 31, 2021 and 2020 for an amount of \$458 and \$373, respectively.

13 Commitments

In the normal course of business, the Company enters into contracts with clinical research organizations, drug manufacturers and other vendors for preclinical and clinical research studies, research and development supplies and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore are cancellable contracts. Therefore, as at December 31, 2021 there are no contractual commitments, except for office leases (see note 5).

14 Currency risk

The Company is exposed to the financial risk related to the fluctuation of foreign exchange rates and the degree of volatility of those rates. The foreign currency risk is limited to the portion of the Company's business transactions denominated in currency other than US dollars. The following table provides an indication of the Company's exposure to the Canadian dollar, which is expressed in US dollars as of December 31:

| | 2021 | 2020 |
|--|-----------------|---------------|
| Cash | \$ 2,049 | \$ 426 |
| Other receivables | 106 | — |
| Operating lease assets | 605 | — |
| Accounts payable and accrued liabilities | 998 | 675 |
| Operating lease liabilities | 622 | — |
| Net financial position exposure | <u>\$ 1,140</u> | <u>\$ 249</u> |

The Company does not enter into arrangements to hedge its currency risk exposure.

15 Fair value of financial instruments

Pursuant to the accounting guidance for fair value measurement and its subsequent updates, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e. the exit price) in an orderly transaction between market participants at the measurement date. The accounting guidance establishes a hierarchy for inputs used in measuring fair value that minimizes the use of unobservable inputs by requiring the use of observable market data when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on active market data. Unobservable inputs are inputs that reflect the assumptions market participants would use in pricing the asset or liability based on the best information available in the circumstances.

The fair value hierarchy is broken down into the three input levels summarized below:

Level 1— Valuations are based on quoted prices in active markets for identical assets or liabilities and readily accessible by the Company at the reporting date.

Level 2— Valuations based on inputs other than the quoted prices in active markets that are observable either directly or indirectly in active markets.

Level 3— Valuations based on unobservable inputs in which there is little or no market data, which requires the Company to develop its own assumptions.

The Company's fair value hierarchy for all its financial assets (by major security type measured at fair value on a recurring basis) for the year ended December 31, 2021 is nil, as there was no financial instruments measured at fair value on a recurring basis as of that date. For the year ended December 31, 2020, the Company held a Guaranteed investment certificate at Level 1 with a fair value of \$70 million.



Milestone Pharmaceuticals Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Clinical and Corporate Update

- *RAPID topline data readout expected in the second half 2022*

Montreal and Charlotte, N.C., Mar. 24, 2021 -- Milestone Pharmaceuticals Inc. (Nasdaq: MIST), a biopharmaceutical company focused on the development and commercialization of innovative cardiovascular medicines, today reported financial results for the fourth quarter and year ended December 31, 2021, and provided a clinical and corporate update.

“2021 was a year of focused execution across our ongoing clinical programs which are evaluating etripamil in patients with PSVT and AFib-RVR,” said Joseph Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. “We are well-positioned for a transformative 2022, with topline data from the pivotal Phase 3 RAPID trial on track for the second half of the year. We are committed to unlocking the full potential of etripamil, if approved, to serve as a meaningful therapeutic option for patients with episodic cardiovascular conditions. We look forward to providing updates on our progress throughout the coming quarters.”

Recent Updates

- **Company Expects to Report Topline Data in the second half 2022.** The RAPID trial, which is targeting a total of 180 confirmed PSVT events, is expected to randomize approximately 500 patients 1:1 to receive either etripamil or placebo. To maximize the potential treatment effect of etripamil, patients will be directed to administer a repeat dose of study drug if they do not experience symptom relief within 10 minutes of the first study drug administration. The primary efficacy analysis for both the RAPID trial and the completed NODE-301 trial will be time to conversion of supraventricular tachycardia (SVT) over the first 30 minutes following initial study drug administration, with a target p-value of less than 0.05 for each trial. The RAPID and NODE-301 trials could potentially serve to fulfill the efficacy requirement for a future New Drug Application (NDA) submission for etripamil in patients with PSVT.
 - **New Clinical Analysis Evaluating the Drug Characteristics and Safety of Etripamil to be Presented at the American College of Cardiology (ACC) 71st Annual Scientific Session and Expo.** New analyses on the safety, tolerability, pharmacokinetics and pharmacodynamics of etripamil will be presented at the upcoming ACC 71st Annual Scientific Session and Expo taking place from April 2-4, 2022, in Washington D.C. The presentation, titled "Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Intranasal Etripamil in Healthy Japanese and Non-Japanese Adults", will be featured during a poster session on April 4, 2022 at 12:15 p.m. ET.
 - **Appointment of David Bharucha, M.D., Ph.D., as Chief Medical Officer.** In February 2022, Milestone announced the appointment of Dr. David Bharucha as Chief Medical Officer. Dr. Bharucha is a cardiac electrophysiologist who brings to Milestone over thirty years of global drug development and clinical experience across a range of therapeutic areas, with a focus on cardiovascular medicine.
 - **Heart Rate Data from NODE-301 Study Presented at the American Heart Association (AHA) Scientific Sessions 2021.** In November 2021, new data from a post-hoc analysis of the Phase 3, randomized, double-blind, placebo-controlled NODE-301 trial were presented during an e-poster session at the AHA Scientific Sessions 2021 meeting. The data demonstrated that etripamil significantly decreased heart rate prior to conversion to sinus rhythm. A copy of the presentation, titled “Etripamil Nasal Spray Reduces Heart Rate in Patients with Paroxysmal Supraventricular Tachycardia Prior to Conversion to Sinus Rhythm”, is available on the Publications page of the Milestone website.
 - **Recruitment Continues in the ReVeRA Phase 2 Proof-of-Concept Trial in Patients Experiencing Atrial Fibrillation with Rapid Ventricular Rate (AFib-RVR).** Enrollment continues in ReVeRA, Milestone’s Phase 2 double-blind, placebo-controlled, proof-of-concept in-patient study of etripamil nasal spray in patients experiencing AFib-RVR. The study, in which patients are randomized 1:1 to receive either 70 mg of etripamil or placebo, is designed to assess the safety and efficacy of etripamil nasal spray to reduce the ventricular rate in patients with AFib-RVR. The trial is being conducted in Canada in collaboration with the Montreal Heart Institute and other research centers. The primary endpoint will assess reduction in ventricular rate, with key secondary endpoints including the time to achieve the maximum reduction in rate and duration of the effect.
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Fourth Quarter and Full Year 2021 Financial Results

- As of December 31, 2021, Milestone had cash, cash equivalents, and short-term investments of \$114.1 million, compared to \$142.3 million as of December 31, 2020, and 29.9 million common shares and 12.3 million common shares issuable upon exercise of pre-funded warrants outstanding.
- Research and development expense for the fourth quarter of 2021 was \$10.9 million, compared with \$5.8 million for the prior year period. For the full year ended December 31, 2021, research and development expense was \$38.7 million, compared with \$34.5 million for the prior year. The increase of research and development expense is due to personnel-related costs, higher clinical consulting fees and CRO costs due to advancing RAPID Phase 3 efficacy and NODE-303 safety trials in etripamil for the treatment of PSVT along with an increase in non-cash compensation costs related to share-based compensation expense.
- General and administrative expense for the fourth quarter of 2021 was \$3.8 million, compared with \$1.7 million for the prior year period. For the full year ended December 31, 2021, general and administrative expense was \$12.4 million, compared with \$10.3 million for the prior year. The increase of general and administrative expense is due to an increase in share-based compensation expense.
- Commercial expense for the fourth quarter of 2021 was \$2.2 million, compared with \$1.3 million for the prior year period. For the full year ended December 31, 2021, commercial expense was \$7.0 million, compared with \$5.9 million for the prior year. The increase of commercial expense is due increase in personnel related costs and marketing activities.
- For the fourth quarter of 2021, operating loss was \$16.9 million, compared to \$8.8 million for the prior year period. For the full year ended December 31, 2021, Milestone's operating loss was \$42.9 million, compared to \$50.0 million for the prior year.

About Paroxysmal Supraventricular Tachycardia

Paroxysmal supraventricular tachycardia (PSVT) is a condition characterized by intermittent episodes of rapid heartbeat that starts and stops suddenly and without warning that affects approximately two million Americans. Episodes of PSVT are often associated with symptoms including palpitations, sweating, chest pressure or pain, shortness of breath, sudden onset of fatigue, lightheadedness or dizziness, fainting, and anxiety. Certain intravenous medications, including adenosine, beta-blockers and calcium channel blockers, have long been used for the acute treatment of PSVT. However, these medications must be administered under medical supervision, usually in an emergency department or other acute care setting.

About Atrial Fibrillation with Rapid Ventricular Rate

Atrial fibrillation (AFib) is a common arrhythmia marked by an irregular and often rapid heartbeat. AFib is estimated to affect five million patients in the United States, a prevalence projected by the Centers for Disease Control to increase to twelve million patients within the next 10 years. Atrial fibrillation with rapid ventricular rate (AFib-RVR) is a condition that some patients with AFib experience and includes episodes of abnormally high heart rate, often with symptoms such as palpitations, shortness of breath, dizziness and weakness. Oral calcium channel blockers and/or beta blockers are commonly used to manage the heart rate in this condition. When AFib-RVR episodes occur, symptoms often cause patients to seek acute care in settings such as the emergency department, where standard of care procedures include intravenous administration of calcium channel blockers or beta blockers under medical supervision. Milestone's market research indicates that 30-40% of patients with AFib experience one or more symptomatic episodes of AFib-RVR per year that require treatment, suggesting a target addressable market in 2030 for etripamil in patients with AFib of approximately three to four million patients.

About Etripamil

Etripamil, Milestone's lead investigational product, is a novel calcium channel blocker designed to be a rapid-response therapy for episodic cardiovascular conditions. As a nasal spray that is self-administered by the patient, etripamil has the potential to shift the current treatment experience for many patients from the emergency department to a medically-unsupervised setting. Milestone is conducting a comprehensive development program for etripamil, with Phase 3 trials ongoing in paroxysmal supraventricular tachycardia (PSVT) and a Phase 2 proof-of-concept trial underway in patients with atrial fibrillation with rapid ventricular rate (AFib-RVR).

About Milestone Pharmaceuticals

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

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believe," "will," "expect," "continue," "estimate," "potential," "progress" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Milestone's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include statements regarding the potential of etripamil to serve as a promising therapy for PSVT patients, the design, progress, timing, scope and results of the RAPID and ReVeRA trials; Milestone's ability to execute on the remainder of the PSVT program, Milestone's ongoing plans to study etripamil in atrial fibrillation patients, the sufficiency of Milestone's current cash resources to support its operations, and estimates about the addressable market and commercial potential for treatments of atrial fibrillation with rapid ventricular rate. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, but are not limited to, the risks inherent in biopharmaceutical product development and clinical trials, including the lengthy and uncertain regulatory approval process, uncertainties related to the timing of initiation, enrollment, completion and evaluation of clinical trials, and whether the clinical trials will validate the safety and efficacy of etripamil for PSVT or other indications, among others, as well as risks related to pandemics and public health emergencies, including those related to the ongoing COVID-19 pandemic, and risks related to the sufficiency of Milestone's capital resources and its ability to raise additional capital. These and other risks are set forth in Milestone's filings with the U.S. Securities and Exchange Commission, including in its annual report on Form 10-K for the year ended December 31, 2020, under the caption "Risk Factors," as such discussion may be updated from time to time by subsequent filings we may make with the U.S. Securities & Exchange Commission. Except as required by law, Milestone assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

CONSOLIDATED STATEMENTS OF LOSS

(Unaudited, in thousands of US dollars, except share and per share data)

| | Three months ended December 31, | | Year ended December 31, | |
|---|---------------------------------|-------------------|-------------------------|--------------------|
| | 2021 | 2020 | 2021 | 2020 |
| Revenue | \$ — | \$ — | \$ 15,000 | \$ — |
| Operating expenses | | | | |
| Research and development, net of tax credits | 10,916 | 5,766 | 38,671 | 34,488 |
| General and administrative | 3,787 | 1,674 | 12,399 | 10,285 |
| Commercial | 2,215 | 1,322 | 7,003 | 5,937 |
| Loss from operations | (16,918) | (8,762) | (43,073) | (50,710) |
| Interest income, net | 34 | 96 | 220 | 726 |
| Loss before income taxes | (16,884) | (8,666) | (42,853) | (49,984) |
| Income tax benefit | — | — | — | 17 |
| Net loss | \$ (16,884) | \$ (8,666) | \$ (42,853) | \$ (49,967) |
| Weighted average number of shares and pre-funded warrants outstanding, basic & diluted | 42,208,636 | 38,424,384 | 41,833,861 | 29,344,993 |
| Net loss per share, basic and diluted | \$ (0.40) | \$ (0.23) | \$ (1.02) | \$ (1.70) |

CONSOLIDATED BALANCE SHEETS
(Unaudited, in thousands of US dollars, except share data)

| | <u>December 31, 2021</u> | <u>December 31, 2020</u> |
|---|--------------------------|--------------------------|
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | \$ 114,141 | \$ 72,310 |
| Short-term investment | — | 70,000 |
| Research and development tax credits receivable | 356 | 725 |
| Prepaid expenses | 4,299 | 5,428 |
| Other receivables | 127 | 223 |
| Total current assets | <u>118,923</u> | <u>148,686</u> |
| Operating lease assets | 711 | 980 |
| Property and equipment | 215 | 308 |
| Total assets | <u>\$ 119,849</u> | <u>\$ 149,974</u> |
| Liabilities, and Shareholders' Equity | | |
| Current liabilities | | |
| Accounts payable and accrued liabilities | \$ 6,551 | \$ 5,914 |
| Operating lease liabilities | 224 | 245 |
| Total current liabilities | <u>6,775</u> | <u>6,159</u> |
| Operating lease liabilities (net of current portion) | 474 | 696 |
| Total liabilities | <u>7,249</u> | <u>6,855</u> |
| Shareholders' Equity | | |
| Common shares, no par value, unlimited shares authorized 29,897,559 shares issued and outstanding as of December 31, 2021, 29,827,997 shares issued and outstanding as of December 31, 2020 | 251,901 | 251,682 |
| Pre-funded warrants - 12,327,780 issued and outstanding as of December 31, 2021 and 11,417,034 as of December 31, 2020 | 52,941 | 48,007 |
| Additional paid-in capital | 15,711 | 8,530 |
| Cumulative translation adjustment | (1,634) | (1,634) |
| Accumulated deficit | (206,319) | (163,466) |
| Total shareholders' equity | <u>112,600</u> | <u>143,119</u> |
| Total liabilities and shareholders' equity | <u>\$ 119,849</u> | <u>\$ 149,974</u> |

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