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

FORM 8-K

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

Date of Report (Date of earliest event reported):
May 15, 2021

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
Common Shares

Trading Symbol(s)
MIST

Name of each exchange on which registered
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 1.01. Entry into a Material Definitive Agreement.

License and Collaboration Agreement

On May 15, 2021, Milestone Pharmaceuticals Inc. (the “Company”) entered into a License and Collaboration Agreement (the “License Agreement”) with Ji Xing Pharmaceuticals, Limited (“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 Agreement, the Company will grant 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 (the “Field”) 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 Company’s and Ji Xing’s entry into a supply agreement as contemplated by the License Agreement.

The Company and Ji Xing will establish a Joint Steering Committee to review and discuss the overall strategy for the development and commercialization of the licensed products in the Field in the Territory, provide a forum for the discussion and coordination of the activities under the License Agreement, direct and oversee the operation of other joint subcommittees established pursuant to the License Agreement, and perform such other functions as expressly set forth in the License Agreement or allocated to it by the parties’ written agreement.

The Company will receive an upfront cash payment of \$15 million as well as up to \$107.5 million in total development and sales milestone payments. In addition, the Company will 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.

The License Agreement will remain in effect, unless terminated earlier, until the last to expire royalty term under the License Agreement. Ji Xing may terminate the License Agreement for convenience with at least one hundred eighty (180) days written notice. Each party has the right to terminate the License Agreement for the other party’s material breach of its obligations under the License Agreement, subject to cure rights. Either party may terminate the License Agreement if the other party declares bankruptcy. The Company may also terminate the License Agreement upon notice if Ji Xing or its affiliates challenges the enforceability, validity or scope of any patent rights belonging to the Company, subject to the exceptions set forth in the License Agreement. Upon termination, any license granted by the Company to Ji Xing will terminate, and all sublicenses granted by Ji Xing shall also terminate.

The License Agreement includes customary representations and warranties on behalf of the Company and Ji Xing as are customarily found in transactions of this nature, including representations and operative provisions as to the licensed intellectual property, regulatory matters and compliance with applicable laws. The License Agreement also provides for certain mutual indemnities for breaches of representations, warranties and covenants.

The foregoing description of the material terms of the License Agreement is qualified in its entirety by reference to the complete text of the License Agreement, which the Company intends to file, with confidential terms redacted, with the Securities and Exchange Commission.

Item 3.02 Unregistered Sales of Equity Securities.

Pursuant to the License Agreement, the Company and affiliates of RTW (such entities, the “Purchasers”) , all of whom are accredited investors, will enter into a securities purchase agreement pursuant to which the Company will sell and issue to the Purchasers, in a private placement, pre-funded warrants to purchase up to an aggregate of 910,746 of the Company’s common shares, no par value per share, at a purchase price of \$5.48 per pre-funded warrant (the “Private Placement”). The gross proceeds to the Company from the Private Placement, including proceeds from the exercise price of the warrants, are expected to be approximately \$5.0 million. The Private Placement is expected to close on or about May 21, 2021.

The pre-funded warrants have an initial exercise price of \$0.01 per share, subject to certain adjustments, and no expiration date. The pre-funded warrants will be exercisable immediately. A holder of the pre-funded warrant (together with its affiliates and other attribution parties) may not exercise any portion of a pre-funded warrant to the extent that immediately prior to or after giving effect to such exercise the holder 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 pre-funded warrants.

The foregoing description of the terms of the securities purchase agreement and pre-funded warrants are each qualified in their entirety by reference to the securities purchase agreement and form of pre-funded warrant, which the Company intends to file with the Securities and Exchange Commission.

Item 8.01. Other Events.

On May 17, 2021, the Company issued a press release announcing the License Agreement and the Private Placement. A copy of the press release is attached as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

| Exhibit No. | Description |
|------------------------|---|
| 99.1 | Press release, dated May 17, 2021 |

SIGNATURES

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

MILESTONE PHARMACEUTICALS INC.

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

Dated: May 17, 2021



Milestone Pharmaceuticals Announces Exclusive License Agreement with Ji Xing Pharmaceuticals to Develop and Commercialize Etripamil for PSVT in Greater China

- Ji Xing Pharmaceuticals to develop and commercialize etripamil for patients with PSVT in Greater China -

- Milestone to receive a \$15 million upfront cash payment and a \$5 million equity investment by RTW Investments, LP -

Montreal and Charlotte, N.C., May 17, 2021 -- Milestone Pharmaceuticals Inc. (Nasdaq: MIST), a biopharmaceutical company focused on the development and commercialization of innovative cardiovascular medicines, today announced an exclusive license and collaboration agreement with Ji Xing Pharmaceuticals (Ji Xing) to develop and, if approved, commercialize the investigational drug etripamil in patients with paroxysmal supraventricular tachycardia (PSVT) and additional cardiovascular conditions in Greater China. Ji Xing is a biotechnology company headquartered in Shanghai and backed by RTW Investments, LP (RTW) focused on advancing innovative medicines in China.

“This agreement marks an important step toward realizing our vision for etripamil to benefit patients living with PSVT globally while strengthening our balance sheet and executional capabilities through partnership,” said Joseph Oliveto, President and Chief Executive Officer of Milestone Pharmaceuticals. “We look forward to partnering with the talented team at Ji Xing to develop and commercialize this promising therapy in the licensed regions.”

“Etripamil has the potential to change the treatment paradigm for PSVT and could serve as a meaningful new therapeutic option for patients,” said Peter Fong, Chief Executive Officer of Ji Xing and Head of Company Creation at RTW. “We are delighted to expand Ji Xing’s cardiovascular focus by partnering with Milestone and look forward to unlocking the full therapeutic potential of etripamil for patients with PSVT in China.”

Under the terms of the agreement, Milestone will grant Ji Xing an exclusive license to develop and, if regulatory approval is obtained, commercialize etripamil in patients with PSVT in Greater China. Milestone will receive an upfront cash payment consisting of \$15 million and a \$5 million equity investment by RTW. In addition, Milestone is eligible to receive up to \$107.5 million in milestone payments and royalties on future sales of etripamil in Greater China. Milestone will supply etripamil and delivery devices to Ji Xing. Ji Xing will be responsible for development and commercialization costs in Greater China.

About Paroxysmal Supraventricular Tachycardia

Paroxysmal supraventricular tachycardia (PSVT) is a rapid heart rate condition characterized by intermittent episodes of supraventricular tachycardia (SVT) that start and stop suddenly and without warning that affects approximately two million Americans. Episodes of SVT 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 calcium channel blockers have long been approved for the treatment of PSVT as well as other cardiac conditions. However, calcium channel blockers approved for the termination of SVT episodes must be administered intravenously under medical supervision, usually in an emergency department or other acute care setting.

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 the at-home 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 is now underway in patients with atrial fibrillation and rapid ventricular rate (AFib-RVR).

About Ji Xing Pharmaceuticals

Backed by RTW Investments, LP, Ji Xing is a privately held, leading biotechnology company headquartered in Shanghai committed to bringing innovative science and medicines to underserved Chinese patients with serious and life-threatening diseases.

About RTW Investments

RTW Investments, LP ("RTW") is a New York-based, global, full life-cycle investment firm that focuses on identifying transformational and disruptive innovations across the biopharmaceutical and medical technologies sectors. As a leading partner of industry and academia, RTW combines deep scientific expertise with a solution-oriented investment approach to support emerging medical therapies and the companies and/or academics developing them.

For further information about RTW, please visit www.RTWfunds.com.

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 and 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 "may," "will," "expect," "plan," "anticipate," "estimate," "potential," "intend" 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 as a promising therapy for PSVT patients, and Milestone's and Ji Xing's intention and ability to develop and commercialize etripamil in China. 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 COVID-19, 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 quarterly report on Form 10-K for the year ended December 31, 2020, under the caption "Risk Factors." 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.

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