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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2021

OR

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

For the transition period from to

Commission File Number: 001-38899

Milestone Pharmaceuticals Inc.

(Exact Name of Registrant as Specified in its Charter)

Quebec	**Not applicable**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1111 Dr. Frederik-Philips Boulevard, Suite 420
Montréal, Québec CA H4M 2X6
(514) 336-0444
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
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. ☒

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

As of August 9th, 2021, the registrant had 29,846,000 common shares, no par value per share, outstanding.

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

- the initiation, timing, progress and results of our current and future clinical trials of etripamil, including our Phase 3 clinical trials of etripamil for the treatment of paroxysmal supraventricular tachycardia, our Phase 2 clinical trial of etripamil for the treatment of atrial fibrillation with rapid ventricular rate, and of our research and development programs;
- uncertain impacts that the COVID-19 pandemic may have on our business, strategy, clinical trial progress and research and development efforts;
- our plans to develop and commercialize etripamil and any future product candidates;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to develop and, if approved by regulatory authorities, commercialize etripamil in China and Taiwan through our license agreement with Ji Xing Pharmaceuticals;
- our ability to establish collaborations or obtain additional funding;
- our ability to obtain regulatory approval of our current and future product candidates;
- our expectations regarding the potential market size and the rate and degree of market acceptance of etripamil and any future product candidates;
- our ability to fund our working capital requirements and expectations regarding the sufficiency of our capital resources;

- the implementation of our business model and strategic plans for our business, etripamil and any future product candidates;
- our intellectual property position and the duration of our patent rights;
- developments or disputes concerning our intellectual property or other proprietary rights;
- our expectations regarding government and third-party payer coverage and reimbursement;
- our ability to compete in the markets we serve;
- the impact of government laws and regulations;
- developments relating to our competitors and our industry; and
- the factors that may impact our financial results.

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

In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report on Form 10-Q, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. You should refer to the section titled "Risk Factors" previously disclosed in Part I, Item 1A. in our Annual Report on Form 10-K, filed with the SEC on March 29, 2021, for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Milestone Pharmaceuticals Inc.
Condensed Consolidated Balance Sheets
(Unaudited)

(in thousands of US dollars, except share data)

	June 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 97,794	$ 72,310
Short-term investment (note 4)	38,000	70,000
Research and development tax credits receivable	903	725
Prepaid expenses	7,447	5,428
Other receivables	242	223
Total current assets	144,386	148,686
Operating lease right-of-use assets	847	980
Property and equipment	262	308
Total assets	$ 145,495	$ 149,974
Liabilities		
Current liabilities		
Accounts payable and accrued liabilities (note 5)	$ 5,069	$ 5,914
Current portion of operating lease liabilities	259	245
Total current liabilities	5,328	6,159
Operating lease liabilities	573	696
Total liabilities	5,901	6,855
Shareholders' Equity (note 6)		
Share capital		
Common shares, no par value, unlimited shares authorized 29,846,000 shares issued and outstanding as of June 30, 2021, 29,827,997 shares issued and outstanding as of December 31, 2020	251,716	251,682
Pre-funded warrants - 12,327,780 issued and outstanding as of June 30, 2021 and 11,417,034 as of December 31, 2020	52,927	48,007
Additional paid-in capital	11,795	8,530
Cumulative translation adjustment	(1,634)	(1,634)
Accumulated deficit	(175,210)	(163,466)
Total shareholders' equity	139,594	143,119
Total liabilities and shareholders' equity	$ 145,495	$ 149,974

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

Milestone Pharmaceuticals Inc.
Condensed Consolidated Statements of Income (Loss)
(Unaudited)

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

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Collaboration revenue (note 3)	$ 15,000	$ —	$ 15,000	$ —
Operating expenses				
Research and development, net of tax credits	$ 9,427	$ 8,622	$ 18,022	$ 20,493
General and administrative	3,018	2,956	5,651	5,659
Commercial	1,843	1,527	3,209	3,710
Income (Loss) from operations	$ 712	$ (13,105)	$ (11,882)	$ (29,862)
Interest income, net of bank charges	58	126	138	540
Net income (loss) for the period	$ 770	$ (12,979)	$ (11,744)	$ (29,322)
Weighted average number of shares and pre-funded warrants outstanding, basic	41,673,370	24,628,049	41,465,961	24,588,413
Net income (loss) per share, basic (note 8)	$ 0.02	$ (0.53)	$ (0.28)	$ (1.20)
Weighted average number of shares and pre-funded warrants outstanding, diluted	44,530,121	24,628,049	41,465,961	24,588,413
Net income (loss) per share, diluted (note 8)	$ 0.02	$ (0.53)	$ (0.28)	$ (1.20)

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

Milestone Pharmaceuticals Inc.
Condensed Consolidated Statements of Shareholders' Equity
(Unaudited)

(thousands of US dollars, except per share data)

	Common Shares		Pre-funded warrants					
	Number of shares	Amount	Number of warrants	Amount	Additional paid-in capital	Cumulative translation adjustment	Accumulated deficit	Total
Balance as of December 31, 2019	24,505,748	$ 226,245	—	$ —	$ 3,805	$ (1,634)	$ (113,499)	$ 114,917
Transactions in three-month period ended March 31, 2020								
Net loss	—	—	—	—	—	—	(16,343)	(16,343)
Exercise of stock options (note 7)	53,722	133	—	—	(56)	—	—	77
Share-based compensation (note 7)	—	—	—	—	981	—	—	981
Balance as of March 31, 2020	24,559,470	$ 226,378	—	$ —	$ 4,730	$ (1,634)	$ (129,842)	$ 99,632
Transactions in three-month period ended June 30, 2020								
Net loss	—	—	—	—	—	—	(12,979)	(12,979)
Exercise of stock options (note 7)	133,483	298	—	—	(126)	—	—	172
Share-based compensation (note 7)	—	—	—	—	1,191	—	—	1,191
Balance as of June 30, 2020	24,692,953	$ 226,676	—	$ —	$ 5,795	$ (1,634)	$ (142,821)	$ 88,016
Balance as of December 31, 2020	29,827,997	$ 251,682	11,417,034	$ 48,007	$ 8,530	$ (1,634)	$ (163,466)	**$** 143,119
Transactions in three-month period ended March 31, 2021								
Net loss	—	—	—	—	—	—	(12,514)	(12,514)
Exercise of stock options (note 7)	18,003	34	—	—	(15)	—	—	19
Share-based compensation (note 7)	—	—	—	—	1,368	—	—	1,368
Balance as of March 31, 2021	29,846,000	$ 251,716	11,417,034	$ 48,007	$ 9,883	$ (1,634)	$ (175,980)	$ 131,992
Transactions in three-month period ended June 30, 2021								
Net income	—	—	—	—	—	—	770	770
Private Placement (note 7)	—	—	910,746	4,920	—	—	—	4,920
Share-based compensation (note 7)	—	—	—	—	1,912	—	—	1,912
Balance as of June 30, 2021	29,846,000	$ 251,716	12,327,780	$ 52,927	$ 11,795	$ (1,634)	$ (175,210)	$ 139,594

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

Milestone Pharmaceuticals Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

(thousands of US dollars)

	Six months ended June 30,	
	2021	**2020**
Cash flows from		
Operating activities		
Net loss for the period	$ (11,744)	$ (29,322)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of property and equipment	46	49
Share-based compensation expense (note 7)	3,280	2,172
Changes in operating assets and liabilities:		
Other receivables	(19)	(60)
Research and development tax credits receivable	(178)	48
Prepaid expenses	(2,019)	(4,287)
Operating lease right of use asset, net	24	(78)
Accounts payable and accrued liabilities	(845)	(3,163)
Net cash used in operating activities	(11,455)	(34,641)
Investing Activities		
Acquisition of short-term investments	—	(32,000)
Redemption of short-term investments	32,000	—
Cash provided by (used in) investing activities	32,000	(32,000)
Financing activities		
Issuance of common shares on exercise of share options (note 7)	19	249
Net proceeds from issuance of pre-funded warrants in a private placement (note 6)	4,920	—
Cash provided by financing activities	4,939	249
Net increase (decrease) in cash and cash equivalents during the period	25,484	(66,392)
Cash and cash equivalents – Beginning of period	72,310	119,818
Cash and cash equivalents – End of period	$ 97,794	$ 53,426

The accompanying notes are an integral part of these interim condensed 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 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 and significant accounting policies

These unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (US GAAP) and on a basis consistent with those accounting principles followed by the Company and disclosed in note 2 of its most recent annual consolidated financial statements. Certain information, in particular the accompanying notes normally included in the annual financial statements prepared in accordance with US GAAP have been omitted or condensed. Accordingly, the unaudited interim condensed consolidated financial statements do not include all the information required for full annual financial statements, and therefore, should be read in conjunction with the annual consolidated financial statements and the notes thereto for the year ended December 31, 2020.

In the opinion of the Company's management, the accompanying unaudited interim condensed consolidated financial statements contain all adjustments, consisting of only normal recurring adjustments, necessary for a fair statement of its balance sheet as of June 30, 2021, and its statements of income (loss), shareholders' equity for the three and six months ended June 30, 2021 and 2020 and its statement of cash flows for the six months ended June 30, 2021.

The condensed consolidated balance sheet as of December 31, 2020, was derived from audited annual consolidated financial statements, but does not contain all the footnote disclosures required by accounting principles generally accepted in the United States of America.

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

The preparation of unaudited interim condensed consolidated financial statements 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 unaudited interim condensed 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, research and development tax credits recoverable, progress of activities performed by the Contract Resource Organizations (CROs) and Contract Manufacturing Organizations (CMOs) which are used to calculate the research and development expense incurred, and share-based compensation. Accordingly, actual results may differ from those estimates and such differences may be material.

The Company's significant accounting policies are described in Note 2—Summary of Significant Accounting Policies, in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020. There has been no material change to the significant accounting policies during the six months ended June 30, 2021, except for the addition of the new policies described below.

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 income (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 income (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 income (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).

Please refer to note 3, “Collaboration Revenue” for additional details regarding the Company’s License and Collaboration Agreement (the License Agreement) with Ji Xing Pharmaceuticals, Limited (Ji Xing).

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 when the license is transferred to the customer and the customer is able to use and benefit from the license.

c) Significant Risks and Uncertainties

The COVID-19 pandemic has had an impact on our business, operations and clinical development timelines. Government orders and restrictions in order to control the spread of the disease have impacted patient recruitment, enrollment and follow-up visits at clinical sites. With the global spread of the ongoing COVID-19 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 evolution of new variants, the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the U.S., Europe and other countries, and the effectiveness of actions taken globally to contain and treat the disease. 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.

d) Recent 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 unaudited condensed consolidated financial statements as a result of future adoption.

e) Sources of Liquidity and Funding Requirements

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.

The Company has incurred operating losses in all periods except the three months ended June 30, 2021 and has experienced negative operating cash flows since its inception with the exception of the three months ended June 30, 2021 and anticipates to continue to incur losses for at least the next several years. As of June 30, 2021, the Company had cash, cash equivalents and short-term investments of $135.8 million and an accumulated deficit of $175.2 million.

3 Collaboration revenue

General

To date, the Company has not generated revenue from product sales. During the quarter ended June 30, 2021, the Company recognized collaboration revenue of $15 million, in the form of a non-refundable upfront cash payment in connection with the License Agreement, explained in more detail below.

Under the License Agreement, the Company could receive the following potential milestone payments in addition to the $15 million recognized during the second quarter of 2021:

	Development Milestones	Sales Milestones
Ji Xing License and Collaboration Agreement	$ 15,500	$ 92,000
Total Potential Milestone Payments	$ 15,500	$ 92,000

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.

Milestone 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.

The Company has determined that the License Agreement is within the scope of ASC 808 as the Company and Ji Xing are both active participants in the development and manufacturing activities and are exposed to significant risks and rewards that are dependent on commercial success of the activities of the arrangement. Further, Milestone determined that Ji Xing is not a customer for goods or services resulting from ordinary activities of the Company. The Company has concluded that the License Agreement is within the scope of ASC 808, which defines collaborative arrangements and addresses the presentation of the transactions between the two parties in the income statement and related disclosures. However, ASC 808 does not provide guidance on the recognition of consideration exchanged or accounting for the obligations that may arise between the parties. The Company has concluded that ASC 606, Revenue from Contracts with Customers, should be applied by analogy.

Management evaluated all of the promised goods or services within the contract and determined which 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 Milestone 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. As of June 30, 2021, the Company has recognized the non-refundable upfront payment as collaboration revenue, for the reasons described in the preceding paragraph.

In conjunction with the License Agreement, Ji Xing acquired $5 million of pre-funded warrants (see note 6). The Company evaluated whether this equity investment should be considered a component of the ASC 606 transaction price, and concluded that the fair value of the shares on a per share basis was equal to the fair value of the shares underlying the warrant, therefore there was no premium paid for the shares and was not included in the transaction price. The Company accounted for the pre-funded warrants as equity and included in earnings per share in the accompanying financial statements. See note 6 for additional details.

For Ji Xing’s 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 Milestone 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 collaboration revenue in the related statement of comprehensive income (loss).

4 Short-term investments

Short-term investments are comprised of term deposits issued in US currency. These short-term investments are in scope of ASC 320, Investments - Debt Securities, since the short-term investments maturity is greater than 90 days but less than one year, they are classified as held to maturity, recorded as current assets and are accounted for at amortized cost.

5 Accounts payable and accrued liabilities

Accounts payable and accrued liabilities are comprised of the following:

	June 30, 2021	December 31, 2020
Trade accounts payable	$ 3,880	$ 4,641
Accrued research and development liabilities	101	152
Other accrued liabilities	348	164
Accrued compensation and benefits payable	740	957
	$ 5,069	$ 5,914

6 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 29,846,000 shares were issued and outstanding as of June 30, 2021.

As of June 30, 2021, there were 822,100 common shares available for issuance under the Employee Stock Purchase Plans and no common shares have been issued under such plan.

Additional paid-in capital

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Opening balance	$ 9,883	$ 4,730	$ 8,530	$ 3,805
Share-based compensation expense	1,912	1191	3,280	2,172
Exercise of stock options	—	(126)	(15)	(182)
Closing balance	$ 11,795	$ 5,795	$ 11,795	$ 5,795

Pre-funded warrants

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 $4.9 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.

7 Shareholders' equity

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 ($1/36^{th}$) of the remaining options vest and are exercisable each month thereafter, such that options are vested in full on four-year anniversary of the grant date.

On January 1, 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 June 30, 2021, there were 4,566,467 shares available for issuance under the 2019 Plan, of which 805,027 shares were available for future grants.

The total outstanding and exercisable options from the 2011 Plan and 2019 Plan as of June 30 were as follows:

	2021				2020			
	Number of shares			Weighted average exercise price	Number of shares			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	2,055,250	—	2,055,250	6.24	1,474,460	—	1,474,460	12.91
Exercised - 2011 Plan	—	(16,753)	(16,753)	0.88	—	(187,205)	(187,205)	1.33
Exercised - 2019 Plan	(1,250)	—	(1,250)	3.74	—	—	—	—
Forfeited - 2011 Plan	—	—	—	—	—	(28,478)	(28,478)	2.57
Forfeited - 2019 Plan	(1,167)	—	(1,167)	21.48	(16,910)	—	(16,910)	21.44
Cancelled - 2019 Plan	(2,833)	—	(2,833)	21.48	—	—	—	—
Outstanding at end of period	3,756,190	2,063,334	5,819,524	$ 6.93	1,677,690	2,148,843	3,826,533	$ 7.34
Outstanding at end of period - Weighted average exercise price	$ 9.55	$ 2.16			$ 13.89	$ 2.22		
Exercisable at end of period	750,626	1,706,309	2,456,935	$ 5.12	44,124	1,363,103	1,407,227	$ 2.11
Exercisable at end of period - Weighted average exercise price	$ 12.07	$ 2.06			$ 7.46	$ 1.94		

The weighted average remaining contractual life was 8.3 and 8.4 years for outstanding options as of June 30, 2021 and 2020, respectively. The weighted average remaining contractual life was 7.0 and 7.2 years for vested options, as of June 30, 2021 and 2020, respectively.

There was $19,381 and $18,873 total unrecognized compensation cost related to non-vested share options as of June 30, 2021 and 2020, respectively. The share options are expected to be recognized over a remaining weighted average vesting period of 2.8 years and 2.5 years as of June 30, 2021 and 2020, respectively.

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 non-vested options as of June 30 were as follows:

	2021				2020			
	Number of options			Weighted average	Number of options			Weighted average
	2019 Plan	2011 Plan	Total	fair value	2019 Plan	2011 Plan	Total	fair value
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	2,055,250	—	2,055,250	4.72	1,474,460	—	1,474,460	7.88
Vested, outstanding 2011 Plan	—	(186,167)	(186,167)	1.61	—	(338,082)	(338,082)	2.23
Vested, outstanding 2019 Plan	(484,879)	—	(484,879)	10.04	(42,959)	—	(42,959)	4.98
Forfeited - 2011 Plan	—	—	—	—	—	(28,478)	(28,478)	1.84
Forfeited - 2019 Plan	(2,833)	—	(2,833)	15.25	(16,910)	—	(16,910)	15.16
Non-vested share options at end of period	3,005,564	357,025	3,362,589	$ 6.02	1,633,566	785,740	2,419,306	$ 6.48
Non-vested share options at end of period - Weighted average fair value	$ 6.51	$ 1.91			$ 6.83	$ 1.74		

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.

The fair value of options granted was estimated using the Black-Scholes option pricing model, resulting in the following weighted average assumptions for the options granted:

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Exercise price	$ 5.56	$ 3.74	$ 6.24	$ 12.91
Share price	$ 5.56	$ 3.74	$ 6.24	$ 12.91
Volatility	92 %	87 %	94 %	84 %
Risk-free interest rate	0.86 %	0.47 %	1.04 %	1.06 %
Expected life	5.32	5.51	6.01	5.89
Dividend	0 %	0 %	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:

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Administration	$ 750	$ 516	$ 1,323	$ 915
Research and development	825	456	1,405	842
Commercial activities	337	219	552	415
	$ 1,912	$ 1,191	$ 3,280	$ 2,172

8 Net income (loss) per share

Basic net income (loss) per common share is determined by dividing net income (loss) applicable to common shareholders by the weighted average number of common shares and pre-funded warrants outstanding during the period.

For the three months ended June 30, 2021 the Company was in a net income position, therefore diluted net income per common share includes dilutive securities. Dilutive net income per common share is determined by dividing net income applicable to common shareholders by the weighted average number of common shares, shares issuable on exercise of pre-funded warrants outstanding during the period and the shares issuable on exercise of options outstanding and in the money during the period. The dilutive securities consisted of 2,856,751 share-based compensation options which were outstanding and in the money.

For the for three months ended June 30, 2020 and the six months ended June 30, 2021 and 2020, the Company was in a net loss position. Dilutive net loss per common share is determined by dividing net loss applicable to common shareholders by the weighted average number of common shares and shares issuable upon exercise of pre-funded warrants outstanding during the period. The following potentially dilutive securities have been excluded from the computation of diluted weighted average shares three months ended June 30, 2020 and the six months ended June 30, 2021 and 2020 outstanding as of June 30 as they would be anti-dilutive:

	2021	2020
Share options	5,819,524	3,826,533

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

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

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the Securities and Exchange Commission, or SEC, on March 29, 2021. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed in "Risk Factors" and in other parts of this Quarterly Report on Form 10-Q.

Overview

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

Etripamil - Pivotal Clinical Program in PSVT

PSVT is a rapid heart rate condition characterized by episodes of supraventricular tachycardia, or SVT, that start and stop without warning. Episodes of SVT are often experienced by patients with symptoms including palpitations, sweating, chest pressure or pain, shortness of breath, sudden onset of fatigue, lightheadedness or dizziness, fainting and anxiety. Calcium channel blockers have long been approved for the treatment of PSVT as well as other cardiac conditions. Calcium channel blockers available in oral form are frequently used prophylactically to control the frequency and duration of future episodes of SVT. For treatment of episodes of SVT, approved calcium channel blockers are administered intravenously under medical supervision, usually in the emergency department. The combination of convenient nasal-spray delivery, rapid-onset and short duration of action of etripamil has the potential to shift the current treatment paradigm for episodes of SVT away from the burdensome and costly emergency department setting. If approved, we believe that etripamil will be the first self-administered therapy for the rapid termination of episodes of SVT wherever and whenever they occur.

In March 2020, we reported topline results of the first part of the NODE-301 pivotal trial of etripamil for the treatment of PSVT, which is a placebo-controlled Phase 3 safety and efficacy trial. The first part of NODE-301, which enrolled a total of 431 patients across 65 sites in the United States and Canada, did not meet its primary endpoint of time to conversion of SVT to sinus rhythm compared to placebo over the five hour period in which patients wore a cardiac monitor following study drug administration.

In July 2020, we announced that we received guidance from the U.S. Food and Drug Administration, or FDA, on our proposal to alter the size and design of our ongoing RAPID trial as well as the overall program based on the data from the NODE-301 trial. The FDA indicated that the two trials, the RAPID trial and the completed NODE-301 trial, could potentially fulfill the efficacy requirement for our planned NDA for etripamil in patients with PSVT.

Under an updated statistical analysis plan, or SAP, the primary efficacy endpoint for both the RAPID and NODE-301 trials will be defined as time to conversion over the first 30 minutes, with a target p-value of less than 0.05 for each trial. This endpoint supports the desire of patients to rapidly address their PSVT symptoms during an episode and ideally avoid visiting the emergency department. Later and earlier time points will also be assessed as part of secondary analyses to fully characterize the efficacy profile of etripamil.

When employing the updated SAP retrospectively to the NODE-301 data, the analysis results in 54% of etripamil patients vs. 35% of placebo patients converted within 30 minutes (HR 1.87, p=0.02). We also discussed the clinical benefit of 54% conversion rate with the FDA. We believe, based on interactions with PSVT treating physicians and cardiovascular thought leaders, that a 50% conversion rate within 60 minutes is a clinically-meaningful outcome given the symptomatic nature of SVT episodes and the lack of approved at-home treatments.

Based on discussions with the FDA regarding maximizing the treatment effect of etripamil, the RAPID trial will allow for repeat administration of study drug (either 70 mg of etripamil or placebo) for patients who have not experienced symptom relief within ten minutes of the first study drug administration. This repeat dose regimen, which is similar to current PSVT treatment practices in the emergency department setting, is tailored to the pharmacokinetic profile of etripamil to deliver increased exposure over approximately the first 30 minutes following initial administration. We expect that the repeat administration could benefit a broader group of patients, including those with more persistent episodes.

The RAPID study, which was originally designed to collect double-blind data from randomized patients who had not yet experienced an SVT event after the NODE-301 study reached its target number of adjudicated SVT events, will be amended and expanded to serve as a pivotal efficacy and safety study should the RAPID study meet its primary objective. The study will include the 170 patients who are already enrolled, although many of those patients have been enrolled in the study for more than one year without reporting an SVT event. The study will be completed after a total of 180 confirmed SVT events are reached, including those that have already occurred in the study. Additional patients to be enrolled in the RAPID study will be randomized 1:1.

The FDA agreed that the single and repeat administrations of etripamil could be pooled and compared to placebo for the primary analysis, resulting in no increase in the study's sample size.

We initiated the RAPID study in the second half of 2020 and enrolled the first new patient in November of 2020. In the fourth quarter of 2020, we took initiatives to increase the number of clinical trial sites in North America but also planned for more clinical sites in European countries to diversify and better protect the study recruitment against COVID's geographical resurgences. We expect the majority of planned clinical trial sites in Europe will be initiated through the first three quarters of 2021. We continue to monitor enrollment as well as new clinical site activations and expect to report topline data in the second half of 2022.

Etripamil - Safety Studies in PSVT

NODE-302 is our Phase 3 open-label safety extension of the NODE-301 trial. Patients who completed NODE-301 could enroll in NODE-302 and receive up to an additional 11 doses of etripamil. NODE-302 is a multi- center, open label study designed to evaluate the safety of etripamil nasal spray when self-administered by patients without medical supervision for spontaneous episodes of SVT in an outpatient setting. Eligibility was also contingent on satisfying all inclusion and exclusion criteria, including not experiencing a serious adverse event related to the study drug or the study procedure that precludes the self-administration of etripamil. We completed NODE-302 in late 2020 with a data set of 245 episodes with 105 patients dosed at least once out of 169 patients enrolled. Trial results will contribute to the etripamil NDA safety database.

NODE-303 is a Phase 3, multi-center, open-label safety trial, evaluating the safety of etripamil when self-administered without medical supervision, and evaluating the treatment safety and efficacy of etripamil on multiple SVT episodes. We originally designed this trial to enroll enough patients to collect data on 1,000 patients taking etripamil in an at-home setting. With the expanded size of the RAPID trial, we expect the size of the NODE-303 study to be reduced. We will determine a more accurate sizing of the trial following future discussions with the FDA and other regulatory authorities. Based on a review of the NODE-301 safety data available in June 2019, the FDA and multiple European and Latin American regulatory authorities agreed to allow patient enrollment in NODE-303 without an in-office safety test dose, which is required in the NODE-301 trial, and in a broad patient population including patients taking concomitant beta blockers and calcium channel blockers. In a manner similar to that used in starting NODE-303 based on safety data from the NODE-301 trial, we have engaged in discussion with the FDA about introducing, in NODE-303, the etripamil repeat dose regimen (70 mg etripamil administered ten minutes after the initial dose if symptoms persist) currently used in RAPID. Based on a review of the RAPID safety data available until March 2021, the FDA has agreed to allow future patients enrolled in NODE-303 to utilize the repeat dose regimen. We are in the process of implementing the repeat dose regimen in the study.

We have initiated and continue to expand patient access programs that have as their primary objective providing further access to etripamil to patients who have participated in the clinical development registration trials to treat future SVT

episodes. These programs are tailored to meet the regulatory requirements in the territories in which the clinical sites are located.

Etripamil: Atrial Fibrillation with Rapid Ventricular Rate

As with PSVT, calcium channel blockers are also approved for use in intravenous form for the treatment of some episodes of atrial fibrillation in which patients experience rapid ventricular rates. We began enrollment in a Phase 2 proof-of-concept clinical trial, titled ReVeRA, in the first quarter of 2021 to evaluate the ability of etripamil to reduce ventricular rate in AFib-RVR episodes. The Phase 2 double blind, placebo controlled, proof-of-concept study is being conducted in Canada in collaboration with the Montreal Heart Institute and other research centers, and is expected to enroll approximately 50 patients randomized 1:1 to receive either 70 mg of etripamil nasal spray or placebo. The primary endpoint will assess reduction in ventricular rate, with key secondary endpoints including the time to achieve the maximum reduction in rate and the duration of the effect.The trial is being conducted in the hospital or emergency department setting under medical supervision. We anticipate reporting data from this study following disclosure of top line results of the RAPID trial.

Operations Overview

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

While we had net income of $0.8 million in the three months ended June 30, 2021, due to the receipt of a $15 million upfront payment under our License and Collaboration Agreement, or the License Agreement, with Ji Xing Pharmaceuticals, Limited, or Ji Xing, we have incurred significant operating losses since our inception, including a net loss of $11.7 million for the six months ended June 30, 2021. As of June 30, 2021, we had an accumulated deficit of $175.2 million. We expect to continue to incur significant losses for the foreseeable future. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on completing the necessary development activities required for obtaining regulatory approval and preparing for potential commercialization of our product candidates. We had $135.8 million of cash, cash equivalents and short-term investments at June 30, 2021.

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

- continue our ongoing and planned development of etripamil, including our Phase 3 clinical trials of etripamil for the treatment of PSVT and our Phase 2 proof-of-concept clinical trial of etripamil for the treatment of AFib-RVR;
- seek marketing approvals for etripamil for the treatment of PSVT, AFib-RVR and other cardiovascular indications;
- establish a sales, marketing, manufacturing and distribution capability, either directly or indirectly through third parties, to commercialize etripamil or any future product candidate for which we may obtain marketing approval;

- build a portfolio of product candidates through development, or the acquisition or in-license of drugs, product candidates or technologies;
- initiate preclinical studies and clinical trials for etripamil for any additional indications we may pursue, including the clinical trials for the treatment of atrial fibrillation with rapid ventricular rate as well as other areas of unmet medical need, and for any additional product candidates that we may pursue in the future;
- maintain, protect and expand our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting, insurance and other expenses associated with operating as a public company.

COVID-19 Business Update

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 our business, financial condition, results of operations and growth prospects. Our global workforce is utilizing a hybrid remote and office based model and this adjustment may adversely impact our business (see below for discussion on Clinical Development impacts). In addition, working at home policies could increase cybersecurity risk and communication disruptions. Governments have also implemented and continually adjusted restrictions as the spread and severity of the COVID-19 virus has impacted their territories. We continue to closely monitor the COVID-19 situation as we evolve our business continuity plans and response strategy.

Clinical Development

With respect to clinical development, we have taken measures to maintain patient safety and trial continuity and to preserve study integrity. For our clinical development programs, we have experienced disruptions or delays in our ability to initiate trial sites and enroll and assess patients, and such disruptions or delays may continue. Since the filing of our Annual Report on Form 10-K, the COVID-19 pandemic continues to impact patient enrollment rates in our NODE-303 study. While COVID resurgences around the world impact different geographies and clinical sites to varying degrees and at different times, the NODE-303 average overall enrollment rate has stabilized over the first half of 2021. The COVID-19 pandemic has delayed the initiation of many proposed RAPID clinical trial sites as some health care institutions have prioritized their resources for pandemic related activities with some precluding the initiation of new clinical trials. It has also delayed the initiation of enrollment for our ReVeRA trial of etripamil for AFib-RVR due to closures of clinical sites. Given the uncertainty and differing and evolving restrictions applicable to clinical trial sites and participants, additional disruptions and delays are possible. We will continue to monitor the impact of COVID-19 on our planned clinical sites and patient enrollment activities. We could also see an impact on the ability to supply study drug, report trial results, or interact with regulators, ethics committees or other important agencies due to limitations in regulatory authority employee resources or otherwise. In addition, we rely on contract research organizations or other third parties to assist us with clinical trials, and we cannot guarantee that they will continue to perform their contractual duties in a timely and satisfactory manner as a result of the COVID-19 pandemic. If the COVID-19 pandemic continues and persists for an extended period of time, and if phased reopenings stall or are limited due to continued spread of COVID-19, including variants, we could experience further significant disruptions to our clinical development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects.

Corporate Development

On May 15, 2021, we entered into the License Agreement with Ji Xing Pharmaceuticals, Limited, or Ji Xing, which is an entity affiliated with RTW Investments, LP, or RTW, a beneficial owner of approximately 14% of our common shares. Under the Agreement, that we granted Ji Xing exclusive development and commercialization rights to any pharmaceutical product that uses a device to deliver our proprietary calcium channel blocker known as etripamil by nasal spray for all prophylactic and therapeutic uses in humans, or 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, or the Territory. Ji Xing will be responsible for development and regulatory activities in the Territory, and we will remain responsible for certain manufacturing activities in the Territory, subject to our and Ji Xing's entry into a supply agreement as contemplated by the License Agreement.

We and Ji Xing have established 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.

We received an upfront cash payment of $15 million and in the future could receive up to $107.5 million in total development and sales milestone payments. In addition, we 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.

We expect that our current operating plan and existing cash and cash equivalents and short-term investments will be sufficient to fund our operations and we do not envision any events or conditions that may cast substantial doubt on our ability to continue as a going concern for at least the next 12 months.

During the second quarter of 2021, we continued to focus our efforts on the development of etripamil PSVT program, and have expanded our development activities with respect to our etripamil AFib-RVR program. The collaboration and licensing agreement described above will allow us to further expand the etripamil PSVT program. Our operating plan may further change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. Furthermore, the COVID-19 pandemic continues to evolve and has resulted in a significant disruption of global financial markets. It is not possible to reliably estimate the length and severity of this disruption. If the disruption persists and deepens, we could experience an inability to access additional capital, which could in the future negatively affect our operations.

Other Financial and Corporate Impacts

While we expect the COVID-19 pandemic to continue to affect our business operations and financial results, the extent of the impact on our clinical development and regulatory efforts, our corporate development objectives and the value of and market for our common shares, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States, Canada, Europe and other countries, and the effectiveness of actions taken globally to contain and treat the disease.

Components of Results of Operations

Revenues

We have not generated any revenues from product sales to date and we do not expect to generate revenues from product sales in the near future. Our revenues for the current year are from the license and collaboration agreement with Ji Xing and are comprised of upfront payments. For additional information about our revenue recognition policy, see "Note 2—Summary of Significant Accounting Policies."

Research and Development Expenses

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

To date, substantially all of our research and development expenses have been related to the preclinical and clinical development of etripamil. As we advance etripamil or other product candidates for other indications, we expect to allocate our direct external research and development costs across each of the indications or product candidates. Further, while we expect our research and development costs for the development of etripamil in atrial fibrillation with rapid ventricular rate to increase for initiation of the ReVeRA clinical trial as we continue to expand this trial, we expect our research and development expenses related to the development of etripamil for PSVT to remain a very large majority of our total research and development expenses.

We expect our research and development expenses to increase as we continue the development of etripamil and prepare to pursue regulatory approval. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming and is subject to uncertainties and delays, including as a result of the ongoing COVID-19 pandemic. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates, if at all.

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

General and Administrative Expenses

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

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

Commercial Expenses

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

Starting approximately one year before we file our new drug application, or NDA with the FDA, we anticipate our commercial expenses will increase substantially as we invest in the infrastructure, personnel, and operational expenses required to launch our first product in the United States, if approved.

Interest Income

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

Results of Operations

Comparison of the Three Months Ended June 30, 2021 and 2020

The following table summarizes our results of operations and changes:

(in thousands)	Three months ended June 30, 2021	2020	$Change	% Change
Collaboration revenue	$ 15,000	—	$ 15,000	100.0%
Operating expenses				
Research and development, net of tax credits	$ 9,427	$ 8,622	$ 805	9.3%
General and administrative	3,018	2,956	62	2.1%
Commercial	1,843	1,527	316	20.7%
Total operating expenses	14,288	13,105	1,183	9.0%
Income (Loss) from operations	712	(13,105)	13,817	(105.4)%
Interest income, net of bank charges	58	126	(68)	(54.0)%
Net income (loss) and comprehensive income (loss)	$ 770	$ (12,979)	$ 13,749	(105.9)%

Comparison of the Six Months Ended June 30, 2021 and 2020

The following table summarizes our results of operations and changes:

(in thousands)	Six months ended June 30, 2021	2020	$Change	% Change
Collaboration revenue	$ 15,000	—	$ 15,000	100.0%
Operating expenses				
Research and development, net of tax credits	$ 18,022	$ 20,493	$ (2,471)	(12.1)%
General and administrative	5,651	5,659	(8)	(0.1)%
Commercial	3,209	3,710	(501)	(13.5)%
Total operating expenses	26,882	29,862	(2,980)	(10.0)%
Income (Loss) from operations	(11,882)	(29,862)	17,980	(60.2)%
Interest income, net of bank charges	138	540	(402)	(74.4)%
Net income (loss) and comprehensive income (loss)	$ (11,744)	$ (29,322)	$ 17,578	(60.0)%

Collaboration Revenue

We generated revenue of $15 million from upfront payments under the License Agreement during the three months and six months ended June 30, 2021.

Research and Development Expenses

The following table shows our research and development expenses by type of activity for the three and six months ended June 30, 2021 and 2020, respectively.

(in thousands)	Three months ended June 30, 2021	2020	$ Change	% Change	Six months ended June 30, 2021	2020	$ Change	% Change
Clinical	$ 7,677	$ 6,911	$ 766	11.1%	$ 14,466	$ 16,620	$ (2,154)	(13.0)%
Drug manufacturing and formulation	1,237	1,117	120	10.7%	2,653	2,741	(88)	(3.2)%
Regulatory and other costs	600	667	(67)	(10.0)%	1,081	1,310	(229)	(17.5)%
Less: investment tax credits	(87)	(73)	(14)	19.2%	(178)	(178)	—	0.0%
Total R&D expenses	$ 9,427	$ 8,622	$ 805	9.3%	$ 18,022	$ 20,493	$ (2,471)	(12.1)%

Research and development expenses increased by $0.8 million, or 9.3%, for the three months ended June 30, 2021 compared to the three months ended June 30, 2020. The variance is mainly due to the increase in clinical expense of $0.8 million. Spending during both periods in 2021 and 2020 was primarily related to advancing our Phase 3 efficacy and safety trials in etripamil for the treatment of PSVT with the majority of the increase in the three months ended June 30, 2021 compared to the same period in 2020 related to clinical personnel related costs. The increase in clinical personnel cost is related to increased share-based compensation expense due to new grants to clinical employees in the three months ended June 30, 2021 at higher black-scholes valuations resulting from the increase in the Company's stock price compared to prior periods.

Research and development expenses decreased by $2.5 million, or 12.1% for the six months ended June 30, 2021 compared to the six months ended June 30, 2020. The variance is mainly due to the decrease in clinical expense of $2.2 million. Spending during both periods in 2021 and 2020 was primarily related to advancing our Phase 3 efficacy and safety trials in etripamil for the treatment of PSVT with the majority of the decrease due to the fact that the first quarter of 2020 included additional costs related to the effort to complete the first part of the NODE-301 trial. The decrease in

clinical trial expense for the six months ended June 30, 2021 compared to the same period in 2020 was partially offset by an increase of $0.5 million in clinical personnel related costs, including non-cash compensation costs related to share-based compensation expense. The increase in clinical personnel cost is related to increased share-based compensation expense due to new grants to clinical employees in 2021 at higher black-scholes valuations resulting from the increase in the Company's stock price compared to prior periods.

General and Administrative Expenses

General and administrative expenses were relatively stable and decreased by $62 thousand, or 2.1%, for the three months ended June 30, 2021 compared to the three months ended June 30, 2020. Similarly, general and administrative expenses were relatively stable and decreased by $8 thousand, or 0.1%, for the six months ended June 30, 2021 compared to the six months ended June 30, 2020.

Commercial Expenses

Commercial expenses increased by $0.3 million, or 20.7%, for the three months ended June 31, 2021 compared the same period in 2020. During the second quarter of 2020, we reduced commercial costs in order to focus our efforts on an optimized clinical development pathway for etripamil after we issued topline results of the first part of the NODE-301 in March 2020. During the three months ended June 30, 2021, we increased our investment in commercialization activities resulting in higher expenses when compared to the period in 2020.

Commercial expenses decreased by $0.5 million, or 13.5%, for the six months ended June 31, 2020, compared the same period in 2020. This decrease is mostly due to the fact that spending before we issued topline results of the first part of the NODE-301 in March 2020 was significantly higher compared to the same period in 2021.

Interest Income, Net

Interest income, net of bank charges, was $0.1 million for both the three-month periods ended June 30, 2021 and 2020. Interest income, net of bank charges, was $0.1 million and $0.5 million for the six-month periods ended June 30, 2021 and 2020, respectively. The reduction in interest income was due to lower interest rates earned on investments in 2021 when compared to 2020.

Net Income (Loss)

We had net income of $0.8 million and a net loss of $13.0 million for the three months ended June 30, 2021 and 2020, respectively. We had net losses of $11.7 and $29.3 million for the six months ended June 30, 2021 and 2020, respectively. The net income in the second quarter of 2021 and the decrease in net loss for the for the six months ended June 30, 2021 compared to the six months ended June 30, 2020 is due to the upfront payment received from the License Agreement, which was recognized as collaboration revenue.

Liquidity and Capital Resources

Sources of Liquidity

Except for the three months ended June 30, 2021, we have incurred operating losses and experienced negative operating cash flows since our inception, and we anticipate continuing to incur losses for at least the next several years. As of June 30, 2021, we had cash, cash equivalents and short-term investments of $135.8 million and an accumulated deficit of $176.0 million.

Pursuant to the License agreement, we received an upfront cash payment of $15 million (see note 3 of our unaudited interim condensed consolidated financial statement) during the three months ended June 30, 2021, and in the future could receive up to $107.5 million in total development and sales milestone payments. In addition, under the License Agreement, we 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.

Pursuant to the License Agreement, we and affiliates of RTW, or the Purchasers, entered into a securities purchase agreement pursuant to which we issued to the Purchasers, in a private placement, pre-funded warrants to purchase up to an aggregate of 910,746 of our common shares at a purchase price of $5.48 per pre-funded warrant, or the Private Placement. The gross proceeds to us from the Private Placement, excluding proceeds from the exercise price of the warrants, were approximately $4.9 million.

On July 29, 2020, we entered into an Open Market Sale Agreement℠, or the Sales Agreement, with Jefferies LLC, or Jefferies, with respect to an at-the-market offering program, or the ATM Program, under which we may issue and sell our common shares having an aggregate offering price of up to $50 million through Jefferies as our sales agent or principal. The common shares to be sold under the Sales Agreement, if any, will be offered and sold pursuant to our shelf registration statement on Form S-3 (File No. 333-239318), which was declared effective by the Securities and Exchange Commission on July 6, 2020. We have not sold shares under the ATM program as of the date of this filing.

We have evaluated whether material uncertainties exist relating to clinical trials, the COVID-19 pandemic and the impact on market conditions. The COVID-19 pandemic has had an impact on our business, operations and clinical development timelines. Government orders and restrictions in order to control the spread of the disease have impacted patient recruitment, enrollment and follow-up visits at clinical sites. At the date of the publication of our quarterly report, it is not possible to reliably estimate the length and severity of these developments. We expect that our current operating plan, existing cash, cash equivalents, short-term investments and access to financing sources to be sufficient to fund our operations and determined that there are no events or conditions that may cast substantial doubt on our ability to continue as a going concern for at least the next 12 months from the date of this filing. Based on our cash, cash equivalents and short-term-investments as of June 30, 2021, including the upfront payment from Ji Xing and proceeds from the equity investment from the Purchasers, we expect to be able to support our ongoing operations into mid-2023.

Funding Requirements

We use our cash primarily to fund research and development expenditures. We expect our research and development expenses to increase as we continue the development of etripamil and prepare to pursue regulatory approval. We expect to incur an increase in general and administrative expenses, and a continued increase in expenses related to commercial activities in 2021 as we focus our efforts on the clinical pathway and potential commercialization of etripamil. We expect to incur increasing operating losses for the foreseeable future as we continue the clinical development of our product candidate. At this time, due to the inherently unpredictable nature of clinical development, we cannot reasonably estimate the costs we will incur and the timelines that will be required to complete development, obtain marketing approval, and commercialize etripamil or any future product candidates, if at all. For the same reasons, we are also unable to predict when, if ever, we will generate revenue from product sales or whether, or when, if ever, we may achieve profitability. Clinical and preclinical development timelines, the probability of success, and development costs can differ materially from expectations.

In addition, we have exclusive development and commercialization rights for etripamil for all indications that we may pursue outside the Territory under the License Agreement, and as such have the potential to license development and or commercialization rights for etripamil to other potential partners. We plan to establish commercialization and marketing capabilities using a direct sales force to commercialize etripamil in the United States. Outside of the United States and the Territory, we are considering commercialization strategies that may include collaborations with other companies. In the case of either in-licensing or out-licensing, we cannot forecast when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development and commercialization plans and capital requirements.

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

- the timing, progress and results of our ongoing and planned clinical trials and other development activities of etripamil in PSVT, AFib-RVR and other cardiovascular indications;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials of etripamil for additional indications or any future product candidates that we may pursue;

- our ability to establish collaborations on favorable terms, if at all;
- the ability of vendors and third-party service providers to accurately forecast expenses and deliver on expectations;
- the costs, timing and outcome of regulatory review of etripamil and any future product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for etripamil and any future product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of etripamil and any future product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the extent to which we acquire or in-license other product candidates and technologies.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to fund our operations and capital funding needs through equity and/or debt financing and existing collaborations. We may also consider entering into additional collaboration arrangements or selectively partnering for clinical development and commercialization. The sale of additional equity would result in additional dilution to our shareholders. The incurrence of debt financing would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that restrict our operations or our ability to incur additional indebtedness or pay dividends, among other items. In addition, the COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital, which could in the future negatively affect our operations. If we are not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially and adversely affect our business, financial condition, results of operations and prospects.

Cash Flows

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

	Six months ended June 30,			
(in thousands)	**2021**	**2020**	**$ Change**	**% Change**
Net cash (used in) provided by:				
Operating activities	$ (11,455)	$ (34,641)	23,186	(66.93)%
Investing activities	32,000	(32,000)	64,000	(200.00)%
Financing activities	4,939	249	4,690	1,883.53 %
Net increase (decrease) in cash and cash equivalents during the period	$ 25,484	$ (66,392)	91,876	

Operating Activities

In the six months ended June 30, 2021, we used $11.5 million of cash in operating activities, which consisted of a net loss of $11.7 million and a net change of $3.0 million in our net operating liabilities and non-cash charges of $3.3 million related to share-based compensation expense for grants to employees, board directors and consultants. The change in our net operating assets and liabilities was mainly due to a decrease of $0.8 million for accounts payable and accrued liabilities and an increase of $2.0 million for prepaid expenses.

In the six months ended June 30, 2020, we used $34.6 million of cash in operating activities, which consisted of a net loss of $29.3 million and a net change of $7.5 million in our net operating liabilities and non-cash charges of $2.2 million related to share-based compensation expense for grants to employees, board directors and consultants. The change in our net operating assets and liabilities was mainly due to a decrease of $3.2 million for accounts payable and accrued liabilities and a increase of $4.2 million for prepaid expenses.

Investing Activities

In the six months ended June 30, 2021, we received $32.0 million of cash for the redemption of short-term investments compared to the same period in 2020 where we used $32.0 million of cash for the acquisition of short-term investments.

Financing Activities

In the six months ended June 30, 2021, our financing activities provided $4.9 million, consisting of net proceeds from the Private Placement and a de minimis amount of proceeds from the exercise of share options. In the six months ended June 30, 2020, our financing activities provided $249 thousand, which consisted of proceeds from the exercise of share options.

We have not entered into off-balance sheet arrangements.

Contractual Obligations

During the six months ended June 30, 2021, there were no material changes to our contractual obligations and commitments described under "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K, filed with the SEC on March 29, 2021.

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our unaudited interim consolidated financial statements as of June 30, 2021, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP and on a basis consistent with those accounting principles followed by us and disclosed in Note 2 to our most recent annual audited consolidated financial statements.

The preparation of these unaudited interim condensed consolidated financial statements requires our management to make judgments and estimates that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Significant estimates and judgments include, but are not limited to, research and development tax credits recoverable, research and development expenses, and share-based compensation. Accordingly, actual results may differ from these judgments and estimates under different assumptions or conditions and any such differences may be material. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management’s judgments and estimates.

We anticipate that the COVID-19 pandemic will have an impact on the development timelines of our 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 financial statements, we are not aware of any specific event or circumstance that would require the update of our 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 our financial statements.

Other than as described under Note 2 of our unaudited interim condensed consolidated financial statements, there have been no material changes to our significant accounting policies from those described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” included in our most recent annual consolidated financial statements.

Recent Accounting Pronouncements

Refer to Note 2, “Summary of Significant Accounting Policies”, for a discussion of recent accounting pronouncements and to the notes to our audited consolidated financial statements as of December 31, 2020 appearing in our Annual Report on Form 10-K, filed with the SEC on March 29, 2021.

Emerging Growth Company Status

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rate risks. We had cash, cash equivalents and short-term investments of $135.8 million as of June 30, 2021, which consist primarily of bank deposits and guaranteed investment certificates. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our investment portfolio, we do not believe an immediate 10% increase or decrease in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

We undertake certain transactions in Canadian dollars and as such are subject to risk due to fluctuations in exchange rates. Canadian dollar denominated payables are paid at the converted rate as due. We do not use derivative instruments to hedge exposure to foreign exchange rate risk due to the low volume of transactions denominated in foreign currencies. On June 30, 2021, our net monetary exposure denominated in Canadian dollars was $0.9 million.

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

We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein. We do not have a formal hedging program with respect to foreign currency. A 10% increase or decrease in current exchange rates would not have a material effect on our consolidated financial results.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures.

We maintain “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed

and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2021. Based upon the evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting.

There were no changes in our internal control over financial reporting during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal controls over financial reporting despite the fact that our employees have worked remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation on our internal controls to minimize the impact on their design and operating effectiveness.

Inherent Limitations on Effectiveness of Controls.

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

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors

There have been no material changes from the risk factors previously disclosed in Part I, Item 1A. in our Annual Report on Form 10-K, filed with the SEC on March 29, 2021.

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

Recent Sales of Unregistered Equity Securities

None

Use of Proceeds from the IPO

On May 13, 2019, we completed the IPO and issued 6,325,000 common shares at an initial offering price of $15.00 per share (inclusive of 825,000 common shares pursuant to the full exercise of an overallotment option granted to the underwriters in connection with the offering). We received net proceeds from the IPO of $85.4 million, after deducting underwriting discounts and commissions. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates. Jefferies LLC, Cowen and Company, LLC and Piper Jaffray & Co. acted as lead book-running managers. Oppenheimer & Co. Inc. acted as lead manager for the IPO.

Our common shares began trading on The Nasdaq Global Select Market on May 9, 2019. The offer and sale of the shares were registered under the Securities Act on Registration Statement on Form S-1 (Registration No. 333-230846), which was declared effective on May 8, 2019.

There has been no material change in the planned use of proceeds from the IPO as described in the prospectus used in connection therewith. We invested the funds received in cash equivalents and other short-term investments in accordance with our investment policy. In July 2020, we started to use proceeds from the IPO for the development of etripamil and to pursue regulatory approval.

Item 3. Defaults Upon Senior Securities.

Not applicable

Item 4. Mine Safety Disclosures.

Not applicable

Item 5. Other Information.

Not applicable

Item 6. Exhibits.

Exhibit Number		Description
3.1		Amended Articles of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38899), filed with the SEC on May 15, 2019).
3.2		Amended and Restated Bylaws of the Company (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-38899), filed with the SEC on May 15, 2019).
4.1		Form of Pre-Funded Warrants to Purchase Common Shares
10.1+		License and Collaboration Agreement by and among the Company and Ji Xing Pharmaceuticals, Limited, dated May 15, 2021
31.1		Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2		Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*		Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS		Inline XBRL Instance Document
101.SCH		Inline XBRL Taxonomy Extension Schema Document
101.CAL		Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF		Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB		Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE		Inline XBRL Taxonomy Extension Presentation Linkbase Document
104		The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, formatted in Inline XBRL.

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

\+ Certain portions of this exhibit have been omitted pursuant to Item 601(b)(10) of Regulation S-K. The Registrant hereby undertakes to furnish to the SEC, upon request, copies of any such instruments.

SIGNATURES

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

MILESTONE PHARMACEUTICALS INC.

Date: August 11, 2021

By: /s/ Joseph Oliveto
Joseph Oliveto
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 11, 2021

By: /s/ Amit Hasija
Amit Hasija
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

NEITHER THIS SECURITY NOR THE SECURITIES FOR WHICH THIS SECURITY IS EXERCISABLE HAVE BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS. THIS SECURITY AND THE SECURITIESISSUABLE UPON EXERCISE OF THIS SECURITY MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT OR OTHER LOAN SECURED BY SUCH SECURITIES.

UNLESS PERMITTED UNDER SECURITIES LEGISLATION, THE HOLDER OF THIS SECURITY MUST NOT TRADE THE SECURITY BEFORE SEPTEMBER [●], 2021.

MILESTONE PHARMACEUTICALS INC.

FORM OF PRE-FUNDED WARRANT TO PURCHASE COMMON SHARES

Number of Shares: [●] (subject to adjustment)

Warrant No. PFW2021 - [ ] Original Issue Date: May [●], 2021

Milestone Pharmaceuticals Inc., an exempted company incorporated and existing under the laws of the Province of Québec, Canada (the "**Company**"), hereby certifies that, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, [ ] or its registered assigns (the "**Holder**"), is entitled, subject to the terms set forth below, to purchase from the Company up to a total of [●] common shares, no par value per share (the "**Common Shares**"), of the Company (each such share, a "**Warrant Share**" and all such shares, the "**Warrant Shares**") at an exercise price per share equal to $0.01 per share (as adjusted from time to time as provided in Section 9 herein, the "**Exercise Price**") upon surrender of this Warrant to Purchase Common Shares (including any Warrants to Purchase Common Shares issued in exchange, transfer or replacement hereof, the "**Warrant**") at any time and from time to time on or after the date hereof (the "**Original Issue Date**") until the Warrant has been exercised in full, subject to the following terms and conditions:

1. *Definitions*. For purposes of this Warrant, the following terms shall have the following meanings:

(a) "**Affiliate**" means any Person directly or indirectly controlled by, controlling or under common control with, a Holder, as such terms are used in and construed under Rule 405 under the Securities Act, but only for so long as such control shall continue.

(b) "**Commission**" means the United States Securities and Exchange Commission.

(c) "**Closing Sale Price**" means, for any security as of any date, the last trade price for such security on the Principal Trading Market for such security, as reported by Bloomberg L.P., or, if such Principal Trading Market begins to operate on an extended hours basis and does not designate the last trade price, then the last trade price of such security prior to 4:00 P.M., New York City time, as reported by Bloomberg L.P., or if the security is not listed for trading on a national securities exchange or other trading market on the relevant date, the last quoted bid price for the security in the over-the-counter market on the relevant date as reported by OTC Markets Group Inc. (or a similar organization or agency succeeding to its functions of reporting prices). If the Closing Sale Price cannot be calculated for a security on a particular date on any of the foregoing bases, the Closing Sale Price of such security on such date shall be the fair market value as mutually determined in good faith by the Company and the Holder. All such determinations shall be appropriately adjusted for any share dividend, share split, share combination or other similar transaction during the applicable calculation period.

(d) "**Principal Trading Market**" means the national securities exchange or other trading market on which the Common Shares are primarily listed on and quoted for trading, which, as of the Original Issue Date, shall be the Nasdaq Global Select Market.

(e) "**Securities Act**" means the Securities Act of 1933, as amended.

(f) "**Trading Day**" means any weekday on which the Principal Trading Market is open for trading. If the Common Shares are not listed or admitted for trading, "Trading Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in New York City are authorized or required by law or other governmental action to close.

(g) "**Transfer Agent**" means Computershare Investor Services Inc. and Computershare Trust Company, N.A., collectively, the Company's transfer agent and registrar for the Common Share, and any successor appointed in such capacity.

2. *Warrant Register*. The Company shall register ownership of this Warrant, upon records to be maintained by the Company for that purpose (the "**Warrant Register**"), in the name of the record Holder (which shall include the initial Holder or, as the case may be, any assignee to which this Warrant is assigned hereunder) from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

3. *Registration of Transfers*. Subject to compliance with all applicable securities laws, the Company shall, or will cause its Transfer Agent to, register the transfer of all or any portion of this Warrant in the Warrant Register, upon surrender of this Warrant, and payment for all applicable transfer taxes (if any). Upon any such registration or transfer, a new warrant to purchase Common Shares in substantially the form of this Warrant (any such new warrant, a "**New Warrant**") evidencing the portion of this Warrant so transferred shall be issued to the transferee, and a New Warrant evidencing the remaining portion of this Warrant not so transferred, if any, shall be issued to the transferring Holder. The acceptance of the New Warrant by the transferee thereof shall be deemed the acceptance by such transferee of allof the rights and obligations in respect of the New Warrant that the Holder has in respect of this Warrant. The Company shall, or will cause its Transfer Agent to, prepare, issue and deliver at the Company's own expense any New Warrant under this Section 3. Until due presentment for registration of transfer, the Company may treat the registered Holder hereof as the owner and holder for all purposes, and the Company shall not be affected by any notice to the contrary.

4. *Exercise and Duration of Warrants*.

(a) All or any part of this Warrant shall be exercisable by the registered Holder in the manner set forth in Section 4(b) at any time and from time to time on or after the Original Issue Date subject to the limitations set forth in Section 11.

(b) The Holder may exercise this Warrant by delivering to the Company (i) an exercise notice, in the form attached as Schedule 1 hereto (the "**Exercise Notice**"), completed and duly signed, and (ii) payment of the Exercise Price (if applicable) in cash or immediately available funds (or pursuant to cashless exercise provisions in accordance herewith and with Section 10) for the number of Warrant Shares as to which this Warrant is being exercised. The date on which such Exercise Notice is delivered to the Company (as determined in accordance with the notice provisions hereof) is an **"Exercise Date**." The Holder shall not be required to deliver the original Warrant in order to effect an exercise hereunder. Execution and delivery of the Exercise Notice shall have the same effect as cancellation of the original Warrant and issuance of a New Warrant evidencing the right to purchase the remaining number of Warrant Shares, if any. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

5. *Delivery of Warrant Shares*.

(a) The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company ("**DTC**") through its Deposit or Withdrawal at Custodian system ("**DWAC**") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by the Holder or (B) the Warrant Shares are eligible for resale by the Holder without volume or manner-of-sale limitations pursuant to Rule 144 (assuming cashless exercise of the Warrants), and otherwise by issuing such Warrant Shares in the name of the Holder or its designee in restricted book-entry form in

the Company's share register, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise by the date that is two (2) Trading Days after the delivery to the Company of the Notice of Exercise and delivery of the aggregate Exercise Price (if applicable) to the Company. The Holder, or any natural person or legal entity (each, a "**Person**") so designated by the Holder to receive Warrant Shares, shall be deemed to have become the holder of record of such Warrant Shares as of the Exercise Date, irrespective of the date such Warrant Shares are credited to the Holder's DTC account or the date of restricted book-entry evidencing such Warrant Shares, as the case may be.

(b) If by the close of the second (2nd) Trading Day after the Exercise Date, the Company fails to deliver to the Holder the required number of Warrant Shares in the manner required pursuant to Section 5(a) or fails to credit the Holder's DTC account for such number of Warrant Shares to which the Holder is entitled, and if after such third (3rd) Trading Day and prior to the receipt of such Warrant Shares, the Holder purchases (in an open market transaction or otherwise) Common Shares to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "**Buy-In**"), then the Company shall, within two (2) Trading Days after the Holder's request promptly honor its obligation to deliver to the Holder such Warrant Shares and pay cash to the Holder in an amount equal to the excess (if any) of Holder's total purchase price (including brokerage commissions, if any) for the Common Shares so purchased in the Buy-In less the product of (A) the number of Common Shares purchased in the Buy-In, times (B) the Closing Sale Price of a Common Share on the Exercise Date.

(c) To the extent permitted by law and subject to Section 5(b), the Company's obligations to issue and deliver Warrant Shares in accordance with and subject to the terms hereof (including the limitations set forth in Section 11 below) are absolute and unconditional, irrespective of any action or inaction by the Holder to enforce the same, any waiver or consent with respect to any provision hereof, the recovery of any judgment against any Person or any action to enforce the same, or any setoff, counterclaim, recoupment, limitation or termination, or any breach or alleged breach by the Holder or any other Person of any obligation to the Company or any violation or alleged violation of law by the Holder or any other Person, and irrespective of any other circumstance that might otherwise limit such obligation of the Company to the Holder in connection with the issuance of Warrant Shares. Subject to Section 5(b), nothing herein shall limit the Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver Common Shares upon exercise of the Warrant as required pursuant to the terms hereof.

6. *Charges, Taxes and Expenses*. Issuance and delivery of Common Shares upon exercise of this Warrant shall be made without charge to the Holder for any issue or transfer tax, transfer agent fee or other incidental tax or expense (excluding any applicable stamp duties) in respect of the issuance of such shares, all of which taxes and expenses shall be paid by the Company; *provided*, *however*, that the Company shall not be required to pay any tax that may be payable in respect of any transfer involved in the registration of any Warrant Shares or the Warrants in a name other than that of the Holder or an Affiliate thereof. The Holder shall be responsible for all other tax liability that may arise as a result of holding or transferring this Warrant or receiving Warrant Shares upon exercise hereof.

7. *Replacement of Warrant*. If this Warrant is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation hereof, or in lieu of and substitution for this Warrant, a New Warrant, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction (in such case) and, in each case, a customary and reasonable indemnity and surety bond, if requested by the Company. Applicants for a New Warrant under such circumstances shall also comply with such other reasonable regulations and procedures and pay such other reasonable third-party costs as the Company may prescribe. If a New Warrant is requested as a result of a mutilation of this Warrant, then the Holder shall deliver such mutilated Warrant to the Company as a condition precedent to the Company's obligation to issue the New Warrant.

8. *No Pre-Emptive Rights; Duly Issued Warrant Shares*. The Company covenants that all Warrant Shares issuable and deliverable upon exercise in full of this Warrant shall, upon issuance and the payment of the applicable Exercise Price in accordance with the terms hereof, be duly and validly authorized, issued and fully paid and non-assessable. The Company will take all such action as may be reasonably necessary to assure that such Common Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of any securities exchange or automated quotation system upon which the Common Shares may be listed.

9. *Certain Adjustments*. The Exercise Price and number of Warrant Shares issuable upon exercise of this Warrant are

subject to adjustment from time to time as set forth in this Section 9.

(a) Share Dividends and Splits. If the Company, at any time while this Warrant is issued and outstanding, (i) pays a share dividend on its Common Shares or otherwise makes a distribution on any class of capital shares issued and outstanding on the Original Issue Date and in accordance with the terms of such shares on the Original Issue Date or as amended, that is payable in Common Shares, (ii) subdivides its issued and outstanding Common Shares into a larger number of Common Shares, (iii) combines its issued and outstanding Common Shares into a smaller number of Common Shares or (iv) issues by reclassification of capital shares any additional Common Shares of the Company, then in each such case the Exercise Price shall be multiplied by a fraction, the numerator of which shall be the number of Common Shares issued and outstanding immediately before such event and the denominator of which shall be the number of Common Shares issued and outstanding immediately after such event. Any adjustment made pursuant to clause (i) of this paragraph shall become effective immediately after the record date for the determination of shareholders entitled to receive such dividend or distribution, provided, however, that if such record date shall have been fixed and such dividend is not fully paid on the date fixed therefor, the Exercise Price shall be recomputed accordingly as of the close of business on such record date and thereafter the Exercise Price shall be adjusted pursuant to this paragraph as of the time of actual payment of such dividends. Any adjustment pursuant to clause (ii) or (iii) of this paragraph shall become effective immediately after the effective date of such subdivision or combination.

(b) Pro Rata Distributions. If the Company, at any time while this Warrant is issued and outstanding, distributes to all holders of Common Shares for no consideration (i) evidences of its indebtedness, (ii) any security (other than a distribution of Common Shares covered by the preceding paragraph), (iii) rights or warrants to subscribe for or purchase any security, or (iv) cash or any other asset (in each case, a "**Distribution**"), other than a reclassification as to which Section 9(c) applies, then in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of Common Shares acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the ownership limitation set forth in Section 11(a) hereof) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of Common Shares are to be determined for the participation in such Distribution (provided, however, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the ownership limitation set forth in Section 11(a) hereof, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any Common Shares as a result of such Distribution to such extent)) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until the earlier of (i) such time, if ever, as the delivery to such Holder of such portion would not result in the Holder exceeding the ownership limitation set forth in Section 11(a) hereof and (ii) such time as the Holder has exercised this Warrant.

(c) Fundamental Transactions. If, at any time while this Warrant is issued and outstanding (i) the Company effects any amalgamation, merger or consolidation of the Company with or into another Person, in which the Company is not the surviving entity and in which the shareholders of the Company immediately prior to such amalgamation, merger or consolidation do not own, directly or indirectly, at least 50% of the voting power of the surviving entity immediately after such amalgamation, merger or consolidation, (ii) the Company effects any sale to another Person of all or substantially all of its assets in one transaction or a series of related transactions, (iii) pursuant to any tender offer or exchange offer (whether by the Company or another Person), holders of share capital tender shares representing more than 50% of the voting power of the capital shares of the Company and the Company or such other Person, as applicable, accepts such tender for payment, (iv) the Company consummates a share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person whereby such other Person acquires more than the 50% of the voting power of the capital shares of the Company (except for any such transaction in which the shareholders of the Company immediately prior to such transaction maintain, in substantially the same proportions, the voting power of such Person immediately after the transaction) or (v) the Company effects any reclassification of the Common Shares or any compulsory share exchange pursuant to which the Common Shares are effectively converted into or exchanged for other securities, cash or property (other than as a result of a subdivision or combination of Common Shares covered by Section 9(a) above) (in any such case, a "**Fundamental Transaction**"), then following such Fundamental Transaction the Holder shall have the right to receive, upon exercise of this Warrant, the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of Warrant Shares then issuable upon exercise in full of this Warrant without regard to any limitations on exercise contained herein (the "**Alternate Consideration**"). The

Company shall not effect any Fundamental Transaction in which the Company is not the surviving entity or the Alternate Consideration includes securities of another Person unless (i) the Alternate Consideration is solely cash and the Company provides for the simultaneous "cashless exercise" of this Warrant pursuant to Section 10 below or (ii) prior to or simultaneously with the consummation thereof, any successor to the Company, surviving entity or other Person (including any purchaser of assets of the Company) shall assume the obligation to deliver to the Holder such Alternate Consideration as, in accordance with the foregoing provisions, the Holder may be entitled to receive, and the other obligations under this Warrant. The provisions of this paragraph (c) shall similarly apply to subsequent transactions analogous of a Fundamental Transaction type.

(d) Number of Warrant Shares. Simultaneously with any adjustment to the Exercise Price pursuant to Section 9 (including any adjustment to the Exercise Price that would have been effected but for the final sentence in this paragraph (d)), the number of Warrant Shares that may be purchased upon exercise of this Warrant shall be increased or decreased proportionately, so that after such adjustment the aggregate Exercise Price (if applicable) payable hereunder for the increased or decreased number of Warrant Shares shall be the same as the aggregate Exercise Price in effect immediately prior to such adjustment.

(e) Calculations. All calculations under this Section 9 shall be made to the nearest one-millionth of one cent or the nearest share, as applicable.

(f) Notice of Adjustments. Upon the occurrence of each adjustment pursuant to this Section 9, the Company at its expense will, at the written request of the Holder, promptly compute such adjustment, in good faith, in accordance with the terms of this Warrant and prepare a certificate setting forth such adjustment, including a statement of the adjusted Exercise Price and adjusted number or type of Warrant Shares or other securities issuable upon exercise of this Warrant (as applicable), describing the transactions giving rise to such adjustments and showing in detail the facts upon which such adjustment is based. Upon written request, the Company will promptly deliver a copy of each such certificate to the Holder and to the Company's transfer agent.

(g) Notice of Corporate Events. If, while this Warrant is issued and outstanding, the Company (i) declares a dividend or any other distribution of cash, securities or other property in respect of its Common Shares, including, without limitation, any granting of rights or warrants to subscribe for or purchase any capital shares of the Company or any subsidiary, (ii) authorizes or approves, enters into any agreement contemplating or solicits shareholder approval for any Fundamental Transaction or (iii) authorizes the voluntary dissolution, liquidation or winding up of the affairs of the Company, then, except if such notice and the contents thereof shall be deemed to constitute material non-public information, the Company shall deliver to the Holder a notice of such transaction at least ten (10) days prior to the applicable record or effective date on which a Person would need to hold Common Shares in order to participate in or vote with respect to such transaction; provided, however, that the failure to deliver such notice or any defect therein shall not affect the validity of the corporate action required to be described in such notice. In addition, if while this Warrant is issued and outstanding, the Company authorizes or approves, enters into any agreement contemplating or solicits shareholder approval for any Fundamental Transaction contemplated by Section 9(c), other than a Fundamental Transaction under clause (iii) of Section 9(c), then, except if such notice and the contents thereof shall be deemed to constitute material non-public information, the Company shall deliver to the Holder a notice of such Fundamental Transaction at least ten (10) days prior to the date such Fundamental Transaction is consummated.

10. *Payment of Cashless Exercise Price*. Upon the cashless exercise of this Warrant pursuant to Section 4(b) or Section 9(c) hereof, the Company shall issue to the Holder the number of Warrant Shares in an exchange of securities effected pursuant to Section 3(a)(9) of the Securities Act as determined as follows:

$X = Y [(A-B)/A]$

where:

"X" equals the number of Warrant Shares to be issued to the Holder;

"Y" equals the total number of Warrant Shares with respect to which this Warrant is then being exercised;

"A" equals the Closing Sale Price per Common Share as of the Trading Day on the date immediately preceding the Exercise Date; and

"B" equals the Exercise Price per Warrant Share then in effect on the Exercise Date.

For purposes of Rule 144 promulgated under the Securities Act, it is intended, understood and acknowledged that the Warrant Shares issued in such a "cashless exercise" transaction pursuant to Section 9(c) hereof shall be deemed to have been acquired by the Holder, and the holding period for the Warrant Shares shall be deemed to have commenced, on the date this Warrant was originally issued (provided that the Commission continues to take the position that suchtreatment is proper at the time of such exercise).

For the avoidance of doubt, any exercise of this Warrant pursuant to Section 4 hereof shall only be settled in cash.

11. *Limitations on Exercise*.

(a) Notwithstanding anything to the contrary contained herein, the Company shall not effect any exercise of this Warrant, and the Holder shall not be entitled to exercise this Warrant for a number of Warrant Shares in excess of that number of Warrant Shares which, upon giving effect or immediately prior to such exercise, would cause (i) the aggregate number of Common Shares beneficially owned by the Holder, its Affiliates and any other Persons whose beneficial ownership of Common Shares would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act (such as any other members of a Section 13(d) "group") to exceed 9.99% (the "**Maximum Percentage**") of the total number of issued and outstanding Common Shares of the Company following such exercise, or (ii) the combined voting power of the securities of the Company beneficially owned by the Holder and its Affiliates and any other Persons whose beneficial ownership of Common Shares would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act (such as any other members of a Section 13(d) "group") to exceed 9.99% of the combined voting power of all of the securities of the Company then outstanding following such exercise.For purposes of this Warrant, in determining the number of outstanding Common Shares, the Holder may rely on the number of outstanding Common Shares as reflected in (x) the Company's most recent Form 10-Q or Form 10-K, as the case may be, filed with the Commission prior to the date hereof, (y) a more recent public announcement by the Company or (z) any other notice by the Company or its transfer agent setting forth the number of Common Shares outstanding. Upon the written request of the Holder, the Company shall within two (2) Trading Days confirm in writing or by electronic mail to the Holder the number of Common Shares then outstanding. In any case, the number of outstanding Common Shares shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder since the date as of which such number of outstanding Common Shares was reported. By written notice to the Company, the Holder may from time to time increase or decrease the Maximum Percentage to any other percentage specified not in excess of 9.99% as specified in such notice; provided that any such increase will not be effective until the sixty-first (61st) day after such notice is delivered to the Company. For purposes of this Section 11(a), the aggregate number of Common Shares or voting securities beneficially owned by the Holder and its Affiliates and any other Persons whose beneficial ownership of Common Shares would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act (such as any other members of a Section 13(d) "group") shall include the Common Shares issuable upon the exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of Common Shares which would be issuable upon (x) exercise of the remaining unexercised and non-cancelled portion of this Warrant by the Holder and (y) exercise or conversion of the unexercised, non-converted or non-cancelled portion of any other securities of the Company that do not have voting power (including without limitation any securities of the Company which would entitle the holder thereof to acquire at any time Common Shares, including without limitation any debt, preferred share, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Shares), is subject to a limitation on conversion or exercise analogous to the limitation contained herein and is beneficially owned by the Holder or any of its Affiliates and other Persons whose beneficial ownership of Common Shares would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act (such as any other members of a Section 13(d) "group").

(b) This Section 11 shall not restrict the number of Common Shares that a Holder may receive or beneficially own in order to determine the amount of securities or other consideration that such Holder may receive in the event of a Fundamental Transaction as contemplated in Section 9(c) of this Warrant.

12. *No Fractional Shares*. No fractional Warrant Shares will be issued in connection with any exercise of this Warrant. In lieu of any fractional shares that would otherwise be issuable, the number of Warrant Shares to be issued shall be rounded down to the next whole number and the Company shall pay the Holder in cash the fair market value (based

on the Closing Sale Price) for any such fractional shares.

13. *Notices*. Any and all notices or other communications or deliveries hereunder (including, without limitation, any Exercise Notice) shall be in writing and shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via confirmed e-mail prior to 5:30 P.M., New York City time, on a Trading Day, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via confirmed e-mail on a day that is not a Trading Day or later than 5:30 P.M., New York City time, on any Trading Day, (iii) the Trading Day following the date of mailing, if sent by nationally recognized overnight courier service specifying next business day delivery, or (iv) upon actual receipt by the Person to whom such notice is required to be given, if by hand delivery. The addresses and e-mail addresses for such communications shall be:

If to the Company:

Attention: Amit Hasija, Chief Financial OfficerMilestone
Pharmaceuticals Inc.
1111 Dr. Frederik-Philips Blvd., Suite 420
Montréal, Québec H4M 2X6
Email: ahasija@milestonepharma.com

with copies (which shall not constitute notice) to:

Attention: Ryan SansomCooley
LLP
500 Boylston Street, 14th Floor
Boston, Massachusetts 02116
Facsimile: (617) 937-2400
Email: rsansom@cooley.com

If to the Holder, to its address or e-mail address set forth herein or on the books and records of the Company.

Or, in each of the above instances, to such other address or e-mail address as the recipient party has specified by written notice given to each other party at least five (5) days prior to the effectiveness of such change.

14. *Warrant Agent*. The Company shall initially serve as warrant agent under this Warrant. Upon ten (10) days' notice to the Holder, the Company may appoint a new warrant agent. Any corporation into which the Company or any new warrant agent may be merged or any corporation resulting from any consolidation or amalgamation to which the Company or any new warrant agent shall be a party or any corporation to which the Company or any new warrant agent transfers substantially all of its corporate trust or shareholders services business shall be a successor warrant agent under this Warrant without any further act. Any such successor warrant agent shall promptly cause notice of its succession as warrant agent to be mailed (by first class mail, postage prepaid) to the Holder at the Holder's last address as shown on the Warrant Register.

15. *Miscellaneous*.

(a) No Rights as a Shareholder. The Holder, solely in such Person's capacity as a holder of this Warrant, shall not be entitled to vote or receive dividends or be deemed the holder of share capital of the Company for any purpose, nor shall anything contained in this Warrant be construed to confer upon the Holder, solely in such Person's capacity as the Holder of this Warrant, any of the rights of a shareholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of shares, reclassification of shares, consolidation, merger, amalgamation, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights, or otherwise, prior to the issuance to the Holder of the Warrant Shares which such Person is then entitled to receive upon the due exercise of this Warrant. In addition, nothing contained in this Warrant shall be construed as imposing any liabilities on the Holder to purchase any securities (upon exercise of this Warrant or otherwise) or as a shareholder of the Company, whether such liabilities are asserted by the Company or by creditors of the Company.

(b) Successors and Assigns. Subject to compliance with applicable securities laws, this Warrant may be assigned by the Holder. This Warrant may not be assigned by the Company without the written consent of the Holder, except to a successor in the event of a Fundamental Transaction. This Warrant shall be binding on and inure to the benefit of the Company and the Holder and their respective successors and assigns. Subject to the preceding sentence, nothing in this Warrant shall be construed to give to any Person other than the Company and the Holder any legal or equitable right, remedy or cause of action under this Warrant. This Warrant may be amended only in writing signed by the Company and the Holder, or their successors and assigns.

(c) Amendment and Waiver. Except as otherwise provided herein, this Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder.

(d) Acceptance. Receipt of this Warrant by the Holder shall constitute acceptance of and agreement to all of the terms and conditions contained herein.

(e) Governing Law; Jurisdiction. ALL QUESTIONS CONCERNING THE CONSTRUCTION, VALIDITY, ENFORCEMENT AND INTERPRETATION OF THIS WARRANT SHALL BE GOVERNED BY AND CONSTRUED AND ENFORCED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK WITHOUT REGARD TO THE PRINCIPLES OF CONFLICTS OF LAW THEREOF. EACH OF THE COMPANY AND THE HOLDER HEREBY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF THE STATE AND FEDERAL COURTS SITTING IN THE CITY OF NEW YORK, BOROUGH OF MANHATTAN, FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION HEREWITH OR WITH ANY TRANSACTION CONTEMPLATED HEREBY OR DISCUSSED HEREIN (INCLUDING WITH RESPECTTO THE ENFORCEMENT OF ANY OF THE TRANSACTION DOCUMENTS), AND HEREBY IRREVOCABLY WAIVES, AND AGREES NOT TO ASSERT IN ANY SUIT, ACTION OR PROCEEDING, ANY CLAIM THAT IT IS NOT PERSONALLY SUBJECT TO THE JURISDICTION OF ANY SUCH COURT. EACH OF THE COMPANY AND THE HOLDER HEREBY IRREVOCABLY WAIVES PERSONAL SERVICE OF PROCESS AND CONSENTS TO PROCESS BEING SERVED IN ANY SUCH SUIT, ACTION OR PROCEEDING BY MAILING A COPY THEREOF VIA REGISTERED OR CERTIFIED MAIL OR OVERNIGHT DELIVERY (WITH EVIDENCE OF DELIVERY) TO SUCH PERSON AT THE ADDRESS IN EFFECT FOR NOTICES TO IT AND AGREES THAT SUCH SERVICE SHALL CONSTITUTE GOOD AND SUFFICIENT SERVICE OF PROCESS AND NOTICE THEREOF. NOTHING CONTAINED HEREIN SHALL BE DEEMED TO LIMIT IN ANY WAY ANY RIGHT TO SERVE PROCESS IN ANY MANNER PERMITTED BY LAW. EACH OF THE COMPANY AND THE HOLDER HEREBY WAIVES ALL RIGHTS TO A TRIAL BY JURY.

(f) Headings. The headings herein are for convenience only, do not constitute a part of this Warrant and shall not be deemed to limit or affect any of the provisions hereof.

(g) Severability. In case any one or more of the provisions of this Warrant shall be invalid or unenforceable in any respect, the validity and enforceability of the remaining terms and provisions of this Warrant shall not in any way be affected or impaired thereby, and the Company and the Holder will attempt in good faith to agree upon a valid and enforceable provision which shall be a commercially reasonable substitute therefor, and upon so agreeing, shall incorporate such substitute provision in this Warrant.

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IN WITNESS WHEREOF, the Company has caused this Warrant to be duly executed by its authorized officer asof the date first indicated above.

MILESTONE PHARMACEUTICALS INC.

By: _____

Name: Joseph G. Oliveto

Title: President and CEO

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Exhibit 10.1

LICENSE AND COLLABORATION AGREEMENT

This **License and Collaboration Agreement** (this "**Agreement**") is entered into as of May 15, 2021 (the "**Effective Date**") by and between:

Milestone Pharmaceuticals, Inc., a Quebec corporation with a place of business at 1111 Dr.-Frederik-Philips Blvd., Ste. 420, Montreal, (Quebec), H4M 2X6 Canada ("**MIST**"), and

Ji Xing Pharmaceuticals Limited, a limited liability company organized and existing under the laws of Hong Kong, with a business address located at Room 1902, 19/F, Lee Garden One, 33 Hysan Avenue, causeway Bay, Hong Kong Special Administrative Region ("**Ji Xing**").

MIST and Ji Xing are referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**."

Recitals

Whereas, MIST, a biopharmaceutical company, is developing etripamil, a novel calcium channel blocker in the form of a nasal spray, for the acute treatment of patients with Paroxysmal Supraventricular Tachycardia and other episodic cardiovascular conditions;

Whereas, Ji Xing is a pharmaceutical company organized to develop and commercialize pharmaceutical products in the greater China region; and

Whereas, Ji Xing wishes to obtain an exclusive license from MIST to develop, import and commercialize such product in the Territory, and MIST is willing to grant such a license and to supply such product to Ji Xing for development and commercial use in the Territory, all in accordance with the terms and conditions set forth herein.

Agreement

Now, Therefore, in consideration of the foregoing premises and the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1
DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

1.1 "**Active Ingredient**" means any clinically active material that provides pharmacological activity in a pharmaceutical product (excluding formulation components such as coatings, stabilizers, excipients or solvents, adjuvants or controlled release technologies).

1.2 "**Affiliate**" means, with respect to a Party, any person or entity that directly or indirectly controls, is controlled by or is under common control with such Party. As used in this

definition, "**control**" (and, with correlative meanings, the terms "**controlled by**" and "**under common control with**") means, in the case of a corporation, the ownership of fifty percent (50%) or more of the outstanding voting securities thereof or, an interest that results in the ability to direct or cause the direction of the management and policies of such party or the power to appoint fifty percent (50%) or more of the members of the governing body of the party. Notwithstanding the foregoing or any provision to the contrary set forth in this Agreement, Affiliates of Ji Xing will exclude [*].

1.3 "**Applicable Laws**" means all statutes, ordinances, regulations, rules or orders of any kind whatsoever of any Governmental Authority that may be in effect from time to time and applicable to the activities contemplated by this Agreement.

1.4 "**Arising Product IP**" means [*].

1.5 "**Business Day**" means a day other than Saturday, Sunday or any day on which banks located in San Francisco, U.S. or Beijing, China are authorized or obligated to close. Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days are specified.

1.6 "**Calendar Quarter**" means the period commencing on January 1 of each Calendar Year and ending on March 31 of the same Calendar Year, the period commencing on April 1 of each Calendar Year and ending on June 30 of the same Calendar Year, the period commencing on July 1 of each Calendar Year and ending on September 30 of the same Calendar Year and the period commencing on October 1 of each Calendar year and ending on December 31 of the same Calendar Year, as the context shall require.

1.7 "**Calendar Year**" means each twelve (12) month period commencing on January 1 and ending on December 31.

1.8 "**cGMP**" means, in respect of MIST's obligations under this Agreement, all applicable current Good Manufacturing Practices as set forth in 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, and in respect of Ji Xing's obligations under this Agreement, the equivalent Applicable Laws in any relevant country or region in the Territory, each as may be amended and applicable from time to time.

1.9 "**Change of Control**" means, with respect to a Party, (a) a merger, reorganization, consolidation or other transaction involving such Party and any entity that is not an Affiliate of such Party as of the Effective Date, which results in the voting securities of such Party outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization, consolidation or other transaction, or (b) any entity that is not an Affiliate of such Party as of the Effective Date becoming the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party, or (c) any entity that is not an Affiliate of such Party as of the Effective Date acquiring the power (whether through ownership interest, contractual right, or otherwise, including the result of any government action) to direct or cause the direction of the management and policies of such Party.

1.10 "**Clinical Trial**" means any clinical testing of the Product in human subjects.

1.11 "**CMO**" means any Third Party contract manufacturing organization.

1.12 "**Commercialization**" or "**Commercialize**" means all activities directed to commercializing, promoting, selling, offering for sale and related importing and exporting activities, but excluding Manufacturing.

1.13 "**Committee**" means the JSC, JDC, JCC or any subcommittee established by the JSC, as applicable.

1.14 "**Compound**" means MIST's proprietary calcium channel blocker known as etripamil, having chemical structure set forth in **Exhibit A** attached hereto, and including any [*].

1.15 "**Confidential Information**" of a Party means all Know-How, unpublished patent applications and other proprietary and confidential information and data of a financial, commercial, business, scientific or technical nature of such Party that is (a) disclosed by or on behalf of such Party or any of its Affiliates or agents, or is otherwise made available to the other Party or any of its Affiliates, whether made available orally, in writing or in electronic form; or (b) learned by the other Party or come to the attention of the other Party in connection with the performance of this Agreement by either Party.

1.16 "**Control**" or "**Controlled**" means, with respect to any Know-How, Patents or other intellectual property rights, that a Party has the legal authority or right (whether by ownership, license or otherwise) to grant to the other Party a license, sublicense, access or other right (as applicable) under such Know-How, Patents, or other intellectual property rights, on the terms and conditions set forth herein, in each case without breaching the terms of any agreement with a Third Party.

1.17 "**Development**" or "**Develop**" means all development activities to obtain and maintain Regulatory Approval for the Product, including all pre-clinical studies and Clinical Trials of the Product, distribution of Product for use in Clinical Trials (including placebos and comparators), statistical analyses, the preparation of regulatory filings and all regulatory affairs related to any of the foregoing, but excluding Manufacturing.

1.18 "**Diligent Efforts**" means [*].

1.19 "**Device**" means any device for the delivery of the Compound by nasal spray, including the device as set forth in **Exhibit A**.

1.20 "**Dollars**" or "**$**" means U.S. dollars, the lawful currency of the U.S.

1.21 "**FDA**" means the U.S. Food and Drug Administration or its successor.

1.22 "**Field**" means all prophylactic and therapeutic uses in humans.

1.23 "**First Commercial Sale**" means, with respect to a Product in any country or jurisdiction, the first sale of such Product to a Third Party for distribution, use or consumption in such country or jurisdiction after the Regulatory Approvals have been obtained for such Product in such country or jurisdiction. For clarity, First Commercial Sale shall not include any sale or transfer of the Product prior to receipt of Regulatory Approval, such as so-called "treatment IND sales," "named patient sales" and "compassionate use sales."

1.24 "**GAAP**" means, with respect to a person or entity's accounting standard in a country or jurisdiction, (a) if in regards to the U.S., U.S. generally accepted accounting principles, (b) if in regards to mainland China, the PRC generally accepted accounting principles, (c) if in regard to any country or jurisdiction other than the U.S. and mainland China, either (i) the International Financial Reporting Standards issued by the International Financial Reporting Standards Foundation and the International Accounting Standards Board, or (ii) the applicable accounting standards as published by the preeminent accounting society for that country or jurisdiction and followed by such person or entity, in each case of (a), (b) and (c), consistently applied and that provide for, among other things, assurance that the accounting and reported results are credible and accurate.

1.25 "**GCP**" means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including, as applicable, (a) as set forth in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products in the Territory, (b) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) 21 C.F.R. Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), as may be amended from time to time, and (d) the equivalent Applicable Laws in the Territory, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.26 "**Generic Product**" means, with respect to a Product in a particular Region in the Territory, any pharmaceutical product that (a) contains the same [*] Active Ingredients as such Product [*]; (b) [*] in such Region ([*] in such Region) [*] in such Region; (c) is [*] the Product, as determined by [*]; and (d) is sold in such Region by a Third Party that is not a sublicensee of Ji Xing or its Affiliates and did not purchase such product in a chain of distribution that included any of Ji Xing or its Affiliates or sublicensees.

1.27 "**GLP**" means all applicable Good Laboratory Practice standards, including, as applicable, as set forth in the then current good laboratory practice standards promulgated or endorsed by the U.S. Food and Drug Administration as defined in 21 C.F.R. Part 58, or the equivalent Applicable Laws in the region in the Territory, each as may be amended and applicable from time to time.

1.28 "**Governmental Authority**" means any court, commission, authority, department, ministry, official or other instrumentality of, or being vested with public authority under any law of, any country, region, state or local authority or any political subdivision thereof, or any association of countries.

1.29 "**IND**" means any investigational new drug application, clinical trial application, clinical trial exemption or similar or equivalent application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

1.30 "**Know-How**" means any proprietary scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including databases, safety information, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, skill, experience, test data including pharmacological, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures, and manufacturing process and development information, results and data.

1.31 "**Licensed IP**" means Licensed Know-How and Licensed Patents.

1.32 "**Licensed Know-How**" means all Know-How Controlled by MIST or its Affiliates as of the Effective Date or at any time during the Term that is necessary or reasonably useful for the Development, Manufacture or Commercialization of the Product in the Field in the Territory; provided, however, that Licensed Know-How shall exclude [*].

1.33 "**Licensed Patents**" means all Patents in the Territory Controlled by MIST or its Affiliates as of the Effective Date or at any time during the Term that are necessary or reasonably useful for the Development, Manufacture or Commercialization of the Product in the Field in the Territory; provided, however, that Licensed Patents shall exclude [*]. Licensed Patents existing as of the Effective Date are set forth in **Exhibit B**.

1.34 "**Manufacture**" and "**Manufacturing**" mean activities directed to manufacturing, processing, filling, finishing, packaging, labeling, quality control, quality assurance testing and release, post-marketing validation testing, inventory control and management, storing and transporting the Product.

1.35 "**Manufacturing Cost**" means, with respect to the Compound, Device or Product supplied by MIST to Ji Xing hereunder:

(a) if the Compound, Device or Product [*]; and

(b) if the Compound, Device or Product [*].

1.36 "**MIST Licensees**" means any and all licensees and sublicensees of MIST or a MIST's Affiliate for the Product (other than Ji Xing, Ji Xing's Affiliates and sublicensees).

1.37 "**NDA**" means a New Drug Application, as defined by the FDA, or equivalent application for approval (but not including pricing and reimbursement approvals) to market a pharmaceutical product in a country or jurisdiction outside the U.S.

1.38 "**Net Sales**" means the [*] on sales of the Product by Ji Xing, its Affiliates, or sublicensees for sale of the Product to a Third Party in the Territory, less following deductions, to the extent reasonable, customary and allocable to such Product:

(a) [*];

(b) [*];

(c) [*];

(d) [*];

(e) [*]; and

(f) [*]

Each of the amounts set forth above shall be determined from the books and records of Ji Xing, its Affiliate or sublicensee, maintained in accordance with GAAP consistently applied. For the avoidance of doubt, if a single item falls into more than one of the categories set forth in clauses (a)-(f) above, such item may not be deducted more than once.

With respect to any sale of the Product [*].

Sales between Ji Xing and its Affiliates and sublicensees shall be disregarded for purposes of calculating Net Sales except if such purchaser is an end user. Net Sales also exclude any sale or transfer of the Product for free or below cost in early access, compassionate use or named patient programs.

Notwithstanding the foregoing, Net Sales shall not include amounts (whether actually existing or deemed to exist for purposes of calculation) for Product distributed for use in Clinical Trials.

1.39 "**NMPA**" means National Medicine Products Administration of China (formerly known as the China Food and Drug Administration), or its successor.

1.40 "**Patents**" means all national, regional and international patents and patent applications, including divisions, continuations, continuations-in-part, additions, re-issues, renewals, extensions, substitutions, re-examinations or restorations, registrations and revalidations, and supplementary protection certificates and equivalents to any of the foregoing.

1.41 "**Person**" means any natural person, corporation, general partnership, limited partnership, joint venture, proprietorship or other business organization or a Governmental Authority.

1.42 "**Phase 1 Clinical Trial**" means any human clinical trial of the Product that would satisfy the requirements of 21 § CFR 312.21(a) or corresponding foreign regulations.

1.43 "**Phase 2 Clinical Trial**" means any human clinical trial of the Product that would satisfy the requirements of 21 § CFR 312.21(b) or corresponding foreign regulations.

1.44 "**Phase 3 Clinical Trial**" means any human clinical trial of the Product that would satisfy the requirements of 21 § CFR 312.21(c) or corresponding foreign regulations.

1.45 "**Pivotal Clinical Trial**" means any human clinical trial of the Product that is intended (as of the time of Initiation of such clinical trial) to obtain the results and data to support the filing of an NDA (including label expansion but excluding the data that may be necessary to support the pricing and/or reimbursement approval), including so called Phase 2/3 trials and any human clinical trial that would satisfy the requirements of 21 § CFR 312.21(c) or corresponding foreign regulations. [*]

1.46 "**Product**" means any pharmaceutical product that uses a Device to deliver the Compound (as the sole Active Ingredient) by nasal spray.

1.47 "**PSVT**" means Paroxysmal Supraventricular Tachycardia.

1.48 "**Regulatory Approval**" means, with respect to the Product in a country or jurisdiction, all approvals from the Regulatory Authorities necessary to market and sell the Product in such country or jurisdiction, including pricing and reimbursement approval.

1.49 "**Regulatory Authority**" means any applicable Governmental Authority responsible for granting Regulatory Approvals for Product, including the FDA, NMPA, and any corresponding national or regional regulatory authorities.

1.50 "**Regulatory Exclusivity**" means any exclusive marketing rights or data exclusivity rights (other than Patents) conferred by any Regulatory Authority with respect to a pharmaceutical or medical product, including without limitation [*].

1.51 "**Regulatory Materials**" means any regulatory application, submission, notification, communication, correspondence, registration, approval and other filings made to, received from or otherwise conducted with a Regulatory Authority regarding the Product, including any NDA and Regulatory Approval.

1.52 "**Territory**" means the People's Republic of China, including mainland China, Hong Kong Special Administrative Region, Macau Special Administrative Region, and Taiwan, each of which shall be referred to as a "**Region**".

1.53 "**Third Party**" means an entity other than MIST, Ji Xing and Affiliates of either of them.

1.54 "**U.S.**" means United States of America, including all possession and territories thereof.

1.55 "**Upstream Licenses**" means any and all agreements between MIST or any of its Affiliates, on the one hand, and any Third Party (the "**Upstream Licensor**"), on the other hand, pursuant to which MIST has (a) in-licensed any Patent or Know-How owned or Controlled by such Third Party that are included as part of the Licensed Patents or Licensed Know-How or (b) agreed to provisions that would require Ji Xing to make any payments (including royalties) to any Third Party or to undertake or observe any restrictions or obligations with respect to the Development, Manufacture or Commercialization of Compound, Device, or Product in the Field.

1.56 "**Valid Claim**" means a claim of a pending patent application or an issued and unexpired Patent (as may be extended through supplementary protection certificate or patent term extension or the like) that has not been revoked, held invalid or unenforceable by a patent office, court or other Governmental Authority of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period) and which claim has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise; provided that [*].

1.57 Additional Definitions. The following table identifies the location of definitions set forth in various Sections of the Agreement:

Defined Terms	**Section**
Agreed Percentage	Section 8.9(b)
Agreement	Preamble
Alliance Manager	Section 3.1
Assigning Party	Section 8.9(c)
Commercialization Plan	Section 7.3
Competing Product	Section 2.7(b)
Development Plan	Section 4.3
Effective Date	Preamble
Executive Officers	Section 3.2
FCPA	Section 15.7(a)
FCPA Covered Person	Section 15.7(a)
ICC	Section 14.3(a)
Incremental Taxes	Section 8.9(c)
Indemnified Party	Section 12.3
Indemnifying Party	Section 12.3
Initiation	Section 8.3(b)(iii)
JCC	Section 3.4
JDC	Section 3.3
Ji Xing	Preamble
Ji Xing Indemnitee(s)	Section 12.2
Joint Commercialization Committee	Section 3.4
Joint Development Committee	Section 3.3

Defined Terms	Section
Joint Steering Committee	Section 3.2
JSC	Section 3.2
Losses	Section 12.1
MIST	Preamble
MIST Indemnitee(s)	Section 12.1
MIST Trademarks	Section 9.6(b)
Non-Compete Period	Section 2.6
Other Product	Section 2.7(a)
Parties	Preamble
Party	Preamble
Pharmacovigilance Agreement	Section 5.6
Phase 1 Waiver	Section 8.3(a)
Phase 3 Waiver	Section 8.3(a)
Prior CDA	Section 10.6
Product Infringement	Section 9.3(b)
Product Marks	Section 9.6(a)
Region	Section 1.52
Remedial Action	Section 5.9
ROFN	Section 2.7(b)
Royalty Term	Section 8.5(b)
[*]	[*]
SEC	Section 10.5(b)
Successful completion	Section 8.3(b)(iii)
Supply Agreement	Section 6.1
Technology Transfer Plan	Section 4.4(a)
Term	Section 13.1(a)
Upstream Licensor	Section 1.55

ARTICLE 2
LICENSES

2.1 License Grant to Ji Xing. Subject to the terms and conditions of this Agreement, MIST hereby grants to Ji Xing:

(a) an exclusive (even as to MIST but subject to MIST's retained rights as set forth in Section 2.3) royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.2, under the Licensed IP to Develop, use, import, sell, offer for sale and otherwise Commercialize the Product in the Field in the Territory,

(b) a non-exclusive license, with the right to grant sublicenses solely in accordance with Section 2.2, under the Licensed IP to Manufacture the Product in the Territory using the Compound and Device supplied by MIST solely for the purposes set forth in Section 2.1(a), and

(c) upon MIST's written consent that Ji Xing may Manufacture the Compound in the Territory, a non-exclusive license, with the right to grant sublicenses solely in accordance with Section 2.2, under the Licensed IP to Manufacture the Compound and the Product in the Territory using the Device supplied by MIST solely for the purposes set forth in Section 2.1(a).

For clarity, the foregoing license does not include any right for Ji Xing to Manufacture the Compound (except with MIST's written consent and in accordance with Section 2.1(c)) or Device, or Develop, use, import, sell, offer for sale and otherwise Commercialize a generic version of the Product.

2.2 Right to Sublicense.

(a) Subject to the terms and conditions of this Agreement, Ji Xing shall have the right to grant sublicenses of the license granted to it under Section 2.1: (i) to any Affiliate [*], which shall require [*], provided [*]; and (ii) from [*] to Third Parties, which shall require [*].

(b) Each sublicense under the Licensed IP shall be subject to a written agreement that is consistent with the terms and conditions of this Agreement. [*].

(c) Ji Xing shall provide a copy of each sublicense agreement to MIST within [*] after the grant of a sublicense, provided that Ji Xing shall be permitted to redact sensitive or proprietary information from any such agreement which terms are not necessary for MIST to confirm Ji Xing's compliance with its obligations hereunder, and such sublicense agreement shall be treated as Ji Xing's Confidential Information. Ji Xing shall remain directly responsible for all of its obligations under this Agreement that have been delegated or sublicensed to any sublicensee. [*]. Ji Xing shall not grant a sublicense to any sublicensee that has been debarred or disqualified by a Regulatory Authority.

2.3 MIST Retained Rights. Notwithstanding the exclusive license granted to Ji Xing under Section 2.1(a), MIST hereby expressly retains the rights to use the Licensed IP in the Field in the Territory to (a) perform its obligations under this Agreement, and (b)[*]. For clarity, MIST retains the exclusive right to practice, license and otherwise exploit the Licensed IP outside the scope of the license granted to Ji Xing under Section 2.1, including the exclusive right to Develop, Manufacture and Commercialize the Product outside the Territory and to Manufacture and have Manufactured the Compound and Device anywhere in the world. MIST also retains the non-exclusive right to Manufacture and have Manufactured the Product in the Territory.

2.4 No Implied Licenses; Negative Covenant. Except as set forth herein, neither Party shall acquire any license or other right or interest, by implication or otherwise, under any Know-How, Patent or other intellectual property of the other Party. Ji Xing shall not, and shall not permit any of its Affiliates or sublicensees to, practice any Licensed IP outside the scope of the license granted by MIST to Ji Xing under Section 2.1 of this Agreement.

2.5 No Diversion. Each Party hereby covenants and agrees that it shall not, and shall ensure that its Affiliates and sublicensees shall not, either directly or indirectly, promote, market, distribute, import, sell or have sold any Product, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like in the other Party's territory or to any Third Party that such Party knows (or reasonably should know after due inquiry) has previously exported or is likely to export the Product to the other Party's territory. Neither Party shall engage, nor permit its Affiliates and sublicensees to engage, in any advertising or promotional activities relating to any Product for use directed primarily to customers or other buyers or users of the Product located in any country or jurisdiction in the other Party's territory, or solicit orders from any prospective purchaser located in any country or jurisdiction in the other Party's territory. If a Party or its Affiliates or sublicensees receive any order for the Product from a prospective purchaser located in a country or jurisdiction in the other Party's territory, such Party shall immediately refer that order to such other Party and shall not accept any such orders. Neither Party shall, nor permit its Affiliates and sublicensees to, deliver or tender (or cause to be delivered or tendered) any Product to any Third Party for use in or distribution into the other Party's territory[*].

2.6 Non-Compete. During the time period after the Effective Date and until [*] (the "**Non-Compete Period**"), neither Ji Xing nor any of its Affiliates shall[*].

2.7 MIST Obligations.

(a) Right of First Refusal. MIST hereby grants to Ji Xing a right of first refusal to obtain a license to develop and commercialize in the Field in the Territory any [*] (an "**Other Product**") as follows. If, during the Term, MIST intends to develop or commercialize any Other Product in the Territory either by itself or through its Affiliate(s) or through a partner [*], MIST shall notify Ji Xing before [*] or entering into such agreement with any Third Party with respect to such a license, as the case may be, and in good faith provide Ji Xing the opportunity to negotiate a license (if MIST is conducting such development without a Third Party) or match any bona fide terms offered by a Third Party. If Ji Xing chooses not to negotiate such license or match such terms, then MIST shall have the right to develop and commercialize such Other Product in the Territory by itself or through its Affiliate(s), or enter into an agreement with such Third Party to grant such a license to any Third Party, without any further obligations to Ji Xing.

(b) Right of First Negotiation. MIST hereby grants to Ji Xing a right of negotiation (the "**ROFN**") to obtain a license to develop and commercialize in the Field in the Territory any [*] (a "**Competing Product**") as follows. If during the Non-Compete Period, MIST intends to, either by itself or any of its Affiliates or in collaboration with a Third Party, develop or commercialize any Competing Product in the Territory [*], MIST shall notify Ji Xing of such intention in writing about the Competing Product prior to develop or commercialize such Competing Product in the Territory or commencing discussions or negotiations with any Third Party regarding the Competing Product in the Territory. Ji Xing may exercise the ROFN by notifying MIST's its intention within [*] after receiving MIST's notice, and upon Ji Xing's exercise of ROFN, MIST will exclusively negotiate in good faith with Ji Xing for [*] the terms of a binding written agreement that grants Ji Xing the right to develop and commercialize such Other Product in the Field in the Territory. If Ji Xing does not exercise the ROFN, or the Parties fail to

reach a binding agreement during such [*] period, the ROFN with respect to such Competing Product will expire. For clarity, if MIST and Ji Xing enter into a binding written agreement that grants Ji Xing the right to develop and commercialize a Competing Product in the Field in the Territory, then such Competing Product shall be [*].

2.8 Performance by Subcontractors. Subject to the terms and conditions of this Agreement, Ji Xing may, without MIST's consent or approval, engage subcontractors for purposes of conducting Development, Manufacturing, Commercialization and other activities for Ji Xing under this Agreement, provided that [*], and further provided that [*]; (c) any subcontractor shall be bound by a written agreement that is consistent with the terms and conditions of this Agreement. Ji Xing will remain directly responsible for any obligations under this Agreement that have been delegated or subcontracted to any subcontractor, and will be directly responsible for the performance of its subcontractors.

ARTICLE 3
GOVERNANCE

3.1 Alliance Managers. Within [*] after the Effective Date, each Party shall appoint (and notify the other Party of the identity of) a representative having the appropriate qualifications (including a general understanding of pharmaceutical development, manufacture and commercialization issues) to act as its alliance manager under this Agreement (the "**Alliance Manager**"). The Alliance Managers shall facilitate the flow of information and otherwise promote communication, coordination and collaboration between the Parties and raise cross-Party and/or cross-functional issues in a timely manner. Each Party may replace its Alliance Manager by written notice to the other Party.

3.2 Joint Steering Committee. The Parties hereby establish a joint steering committee (the "**Joint Steering Committee**" or the "**JSC**") to manage the overall collaboration of the Parties under this Agreement, which committee shall include the Chief Executive Officer of MIST and the Chairman of Ji Xing (the "**Executive Officers**"). The JSC shall in particular (a) review and discuss the overall strategy for the Development and Commercialization of the Product in the Field in the Territory; (b) provide a forum for the discussion and coordination of the Parties' activities under this Agreement; (c) direct and oversee the operation of the JDC, JCC and any other joint subcommittee established by JSC, including resolving any disputed matter of the JDC, JCC and other joint subcommittees; (d) establish other joint subcommittees as necessary or advisable to further the purpose of this Agreement; and (e) perform such other functions as expressly set forth in this Agreement or allocated to it by the Parties' written agreement.

3.3 Joint Development Committee. The Parties hereby establish a joint development committee (the "**Joint Development Committee**" or the "**JDC**") to oversee the Development of the Product in the Field in the Territory under this Agreement, which committee shall be comprised of [*] representatives from each Party. Each Party shall appoint its JDC representatives within [*] after the Effective Date. The JDC shall in particular: (a) review, discuss and approve the Development Plan and amendment thereto; (b) review and discuss the progress and results of the Development of the Product in the Field in the Territory; (c) provide a forum for and facilitate communications between the Parties with respect to the Development of the Product; (d) provide

updates on the Manufacture and supply of the Compound, Drug and Product by MIST to Ji Xing; (e) [*], and (f) perform such other functions as may be appropriate to further the purposes of this Agreement with respect to the Development of the Product, as directed by the JSC.

3.4 Joint Commercialization Committee. At a time to be determined by the JSC (but no later than [*]), the Parties shall establish a joint Commercialization committee (the "**Joint Commercialization Committee**" or the "**JCC**") to oversee the Commercialization of the Product in the Field in the Territory under this Agreement, which committee shall be comprised of [*] representatives from each Party. The JCC shall in particular: (a) review and discuss the Commercialization Plan and amendment thereto; (b) review and discuss the progress and results of the Commercialization of the Product in the Field in the Territory; (c) provide a forum for and facilitate communications between the Parties with respect to the Commercialization of the Product; and (d) perform such other functions as may be appropriate to further the purposes of this Agreement with respect to the Commercialization of the Product, as directed by the JSC.

3.5 Limitation of Authority. Each Committee shall only have the powers expressly assigned to it in this Article 3 and elsewhere in this Agreement and shall not have the authority to (a) modify or amend the terms and conditions of this Agreement; (b) waive either Party's compliance with the terms and conditions of this Agreement; or (c) determine any such issue in a manner that would conflict with the express terms and conditions of this Agreement.

3.6 Committee Members. Each Party's representatives on the Committees shall be an officer or employee of the applicable Party having sufficient seniority within such Party to make decisions arising within the scope of the applicable Committee's responsibilities. Each Party may replace its representatives on any Committee upon written notice to the other Party. Each Party shall appoint one of its representatives on each Committee to act as a co-chairperson of such Committee.

3.7 Meetings. Each Committee shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than [*]. Each Party may call additional ad hoc Committee meetings as the needs arise with reasonable advance notice to the other Party. Meetings of any Committee may be held in person, by audio or video teleconference. In-person Committee meetings shall be held at locations selected alternatively by the Parties. The co-chairpersons of the applicable Committee shall jointly prepare the agenda and minutes for each Committee meeting. Each Party shall be responsible for all of its own expenses of participating in the Committee meetings. No action taken at any Committee meeting shall be effective unless at least [*] of each Party is participating in such Committee meeting.

3.8 Non-Member Attendance. Each Party may from time to time invite a reasonable number of participants, in addition to its representatives, to attend any Committee meeting in a non-voting capacity; provided that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide prior written notice to the other Party. Such Party shall also ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

3.9 Decision-Making. All decisions of each Committee shall be made by unanimous vote, with each Party's representatives collectively having one vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JDC, JCC or any subcommittee established by the JSC, the representatives of the Parties on such Committee cannot reach an unanimous decision as to such matter within [*] after a Party has requested resolution of such matter by such Committee, such matter shall be referred to the JSC for resolution. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JSC (including matter referred to the JSC by JDC, JCC or any subcommittee established by the JSC), the representatives of the Parties on the JSC cannot reach an unanimous decision as to such matter within [*] after a Party has requested resolution of such matter by the JSC, then:

(a) [*]; and

(b) [*].

3.10 Discontinuation of Committees. The activities to be performed by each Committee shall solely relate to governance under this Agreement, and are not intended to be or involve the delivery of services. Each Committee shall continue to exist until the first to occur of (a) the Parties mutually agreeing to disband such Committee; or (b) MIST providing written notice to Ji Xing of its intention to disband and no longer participate in such Committee. Once the Parties mutually agree or MIST has provided written notice to disband any Committee, such Committee shall have no further obligations under this Agreement and, thereafter, the Alliance Managers shall be the contact persons for the exchange of information under this Agreement, and decisions of such Committee shall be decisions as between the Parties, subject to the same respective decision-making rights and limitations set forth in Section 3.9 and other terms and conditions of this Agreement.

ARTICLE 4
DEVELOPMENT

4.1 General. Subject to the terms and conditions of this Agreement, Ji Xing shall be responsible for the Development of the Product in the Field in the Territory, including the performance of Clinical Trials of the Product in the Field in the Territory necessary for Regulatory Approval.

4.2 Development Diligence. Ji Xing shall use Diligent Efforts to Develop the Product and obtain and maintain Regulatory Approval of the Product in the Field in the Territory.

4.3 Development Plan. All Development of the Product by or on behalf of Ji Xing under this Agreement shall be conducted pursuant to a written Development plan that sets forth the timeline, budget and other aspects of all clinical and regulatory activities to be conducted by or on behalf of Ji Xing to obtain Regulatory Approval of the Product in the Field in each Region in the Territory (the "**Development Plan**"). As of the Effective Date, the Parties have agreed to the initial Development Plan, which is attached hereto as **Exhibit C**. From time to time, but at least once every [*], Ji Xing shall propose updates or amendments to the Development Plan in consultation with MIST and submit such proposed updated or amended plan to the JSC for review,

discussion, and approval. Once approved by the JSC, the updated or amended Development Plan shall become effective.

4.4 Technology Transfer.

(a) As of the Effective Date, the Parties have agreed to a technology transfer plan (the "**Technology Transfer Plan**", which is attached hereto as **Exhibit D**) for MIST to provide Ji Xing with access to the Licensed Know-How (including clinical data but for clarity excluding Manufacturing related Licensed Know-How) that is [*]. Within [*] after the Effective Date, MIST shall provide Ji Xing with access to such Licensed Know-How in accordance with the Technology Transfer Plan and, if specified, in a form set forth in the Technology Transfer Plan. MIST shall provide the Licensed Know-How only in the English language, and Ji Xing shall be responsible for the translation of the Licensed Know-How into the Chinese language at Ji Xing's own cost and expense. Ji Xing may request MIST to provide additional information to Ji Xing regarding such Licensed Know-How that is encompassed in the Technology Transfer Plan that Ji Xing reasonably believes is missing or is otherwise necessary or reasonably useful for Ji Xing's exploitation of the disclosed Licensed Know-How, and MIST shall provide such additional information as promptly as practicable but in any event within [*] after the receipt of such request. The initial technology transfer shall be deemed completed [*].

(b) In addition to the technology transfer obligation under Section 4.4(a), at any time, if either Party becomes aware that MIST is in possession of Licensed Know-How existing as of the Effective Date that is not set forth in the Technology Transfer Plan and is not provided in response to Ji Xing's request for additional information under Section 4.4(a), such Party shall notify the other Party in writing, and MIST shall promptly provide Ji Xing with such Licensed Know-How. MIST shall periodically notify Ji Xing if any additional Licensed Know-How comes into MIST's Control during the Term of this Agreement (including any data resulting from the Development of the Product conducted by MIST outside the Territory) and promptly provide Ji Xing with access to such additional Licensed Know-How. The transfer of any addition Licensed Know-How under this Section 4.4(b) shall not be deemed part of the "initial technology transfer" for the purpose of Section 8.1(b) no matter when such transfer occurs.

(c) In connection with the transfer of Licensed Know-How to Ji Xing, MIST shall also provide Ji Xing with reasonable technical assistance to help Ji Xing to understand and use such Licensed Know-How in connection with the Development of the Product, including reasonable access to MIST's technical personnel involved in the research and Development of the Product. Ji Xing shall reimburse MIST for both out-of-pocket cost and internal cost incurred by MIST to provide such technical assistance, except for the internal cost of the first [*] FTE hours of assistance, which shall be provided at MIST's cost. MIST's internal costs shall be reimbursed at a rate of [*].

4.5 Development Collaboration. [*]. MIST shall [*], shall coordinate with Ji Xing with respect to such Development work, and shall keep Ji Xing reasonably informed on the progress and result of such Development work. [*].

4.6 Development Cost. Ji Xing shall be solely responsible for all the costs and expenses it incurs to Develop the Product in the Territory.

4.7 Data Exchange and Use. In addition to its adverse event and safety data reporting obligations pursuant to Section 5.6, each Party shall promptly provide the other Party with copies of all data and results and all supporting documentation (e.g. protocols, CRFs, analysis plans) generated from its Development of the Product. Ji Xing shall have the right to use the data provided by MIST for the purpose of obtaining and maintaining Regulatory Approval for and Commercializing the Product in the Field in the Territory. MIST shall have the right to use the data provided by Ji Xing for the purpose of obtaining and maintaining Regulatory Approval for and Commercializing the Product outside the Territory.

4.8 Development Records. Ji Xing shall maintain complete, current and accurate records of all Development activities conducted by or on behalf of Ji Xing hereunder, and all data and other information resulting from such activities. Such records shall fully and properly reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory and patent purposes. Ji Xing shall document all non-clinical studies and Clinical Trials in formal written study reports according to Applicable Laws and national and international guidelines (e.g., ICH, GCP, GLP, and cGMP). MIST shall have the right to review and copy such records maintained by Ji Xing at reasonable times and to use such records and obtain access to the original for its research and development activities and regulatory and patent purposes or for other legal proceedings.

4.9 Development Reports. Ji Xing shall keep MIST reasonably informed as to the progress and results of its and its Affiliates' and sublicensees' Development of the Product. Without limiting the foregoing, the status, progress and results of the Development of the Product in the Territory shall be discussed at meetings of the JDC. At least [*] before each regularly scheduled JDC meeting, Ji Xing shall provide the JDC with a written report summarizing its Development activities and the results thereof, covering subject matter at a level of detail reasonably required by MIST and sufficient to enable MIST to determine Ji Xing's compliance with its diligence obligations pursuant to Section 4.2. In addition, Ji Xing shall make available to MIST such additional information about its Development activities as may be reasonably requested by MIST from time to time.

ARTICLE 5
REGULATORY

5.1 General. The Development Plan shall set forth the regulatory strategy for seeking Regulatory Approvals of the Product in the Field in each Region in the Territory. Ji Xing shall be responsible for all regulatory activities necessary for obtaining and maintaining Regulatory Approvals of the Product in the Field in the Territory, which regulatory activities shall be performed at Ji Xing's own cost and expense and in accordance with the regulatory strategy set forth in the Development Plan. Through the JDC, Ji Xing shall keep MIST informed of regulatory developments related to the Product in the Territory, including any decision by any Regulatory Authority in the Territory regarding the Product.

5.2 Regulatory Approval Holder. Subject to Applicable Laws, Ji Xing shall apply for Regulatory Approvals of the Product in the Field in each Region in the Territory in its own name, and Ji Xing (or an Affiliate or a permitted sublicensee of Ji Xing) shall be named as the holder of such Regulatory Approvals in the Territory. MIST will reasonably cooperate with Ji Xing, at Ji Xing's expense, to enable Ji Xing (or an Affiliate or a sublicensee of Ji Xing) to acquire and hold any or all such Regulatory Approvals and Regulatory Materials in the Territory, provided, however, that if Applicable Laws in the Territory do not allow Ji Xing (or an Affiliate or a permitted sublicensee of Ji Xing) to hold Regulatory Approvals or Regulatory Materials for the Product in the Field in the Territory, then [*].

5.3 Regulatory Materials. Ji Xing shall provide MIST with drafts in English of all material Regulatory Materials a reasonable time (to the extent reasonably practicable, no less than [*]) prior to submission for review and comment, and shall consider in good faith reasonable comments received from MIST no later than [*] prior to submission. [*] In addition, Ji Xing shall notify MIST of any material Regulatory Materials submitted to or received from any Regulatory Authority in the Territory and shall provide MIST with copies thereof within [*] after submission or receipt, and shall notify MIST of any other material communication with any Regulatory Authority in the Territory within [*] after such communication. [*] Upon Ji Xing's request and at Ji Xing's cost, MIST shall assist Ji Xing in addressing any additional requirements requested by any Regulatory Authority in the Territory within a reasonable time (depending on the events), including providing existing supplementary data or documentation.

5.4 Regulatory Meetings. Ji Xing shall provide MIST with reasonable (to the extent reasonably practicable, no less than [*]) advance notice of any meeting or discussion with any Regulatory Authority in the Territory related to the Product. Ji Xing shall lead such meeting or discussion; provided, however, that if permissible under Applicable Laws and permitted by the Regulatory Authority, MIST or its designee shall have the right, but not the obligation, to attend and participate in such meeting or discussion. If MIST elects not to attend such meeting or discussion, Ji Xing shall promptly provide MIST with a written English summary of such meeting or discussion.

5.5 Right of Reference. Each Party hereby grants to the other Party the right of reference to all Regulatory Materials pertaining to the Product submitted by or on behalf of such Party. Ji Xing may use such right of reference to MIST's Regulatory Materials for the purpose of obtaining and maintaining Regulatory Approval of the Product in the Field in the Territory. MIST may use such right of reference to Ji Xing's Regulatory Materials for the purpose of obtaining and maintaining Regulatory Approval of the Product outside the Territory.

5.6 Adverse Events Reporting; Quality. Promptly following the Effective Date, but in any event no later than [*], the Parties shall enter into a pharmacovigilance and adverse event reporting agreement setting forth the worldwide pharmacovigilance procedures for the Parties with respect to the Product, such as safety data sharing, adverse events reporting and prescription events monitoring (the "**Pharmacovigilance Agreement**"). Such procedures shall be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting obligations under Applicable Laws. MIST shall establish and maintain the global safety database for the Product. Each Party shall hold the primary responsibility for reporting quality complaints, adverse events

and safety data related to the Product in its territory to such database and to the applicable Regulatory Authorities in its territory, as well as responding to safety issues and to all requests of Regulatory Authorities in its territory related to the Product, in each case at its own cost and to the extent required by the Applicable Laws. Each Party agrees to comply with its respective obligations under the Pharmacovigilance Agreement and to cause its Affiliates, licensees and sublicensees to comply with such obligations.

5.7 Regulatory Audits and Inspection. Upon reasonable advance notice (at least [*] in advance), MIST or its representatives acceptable to Ji Xing (such acceptance not to be unreasonably withheld, delayed or conditioned) shall have the right to audit [*]. Such audit may not be conducted [*] and will take place during regular business hours of the audited party and shall be conducted under obligations of confidentiality. [*] Ji Xing shall also permit the Regulatory Authorities outside the Territory to conduct audits and inspections of Ji Xing, its Affiliates, sublicensees or subcontractors relating to the Product, and shall [*].

5.8 No Harmful Actions. If MIST believes that Ji Xing is taking or intends to take any action with respect to the Product that could have a material adverse impact upon the regulatory status of the Product outside the Territory, MIST shall have the right to bring the matter to the attention of the JDC, and the Parties shall promptly meet to discuss in good faith to resolve such concern. Without limiting the foregoing, unless the Parties otherwise agree, (a) Ji Xing shall not communicate with any Regulatory Authority outside the Territory regarding the Product, unless so ordered by such Regulatory Authority, in which case Ji Xing shall immediately notify MIST of such order; and (b) Ji Xing shall not submit any Regulatory Materials or seek Regulatory Approvals for the Product outside the Territory.

5.9 Remedial Actions. Each Party shall notify the other immediately, and promptly confirm such notice in writing, if it obtains information indicating that any Product may be subject to any recall, corrective action or other regulatory action by any Governmental Authority or Regulatory Authority (a "**Remedial Action**"). The Parties shall assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. Ji Xing shall have sole discretion with respect to any matters relating to any Remedial Action in the Territory, including the decision to commence such Remedial Action and the control over such Remedial Action. The cost and expenses of any Remedial Action in the Territory shall be borne solely by Ji Xing. Ji Xing shall, and shall ensure that its Affiliates and sublicensees will, maintain adequate records to permit Ji Xing to trace the distribution, sale and use of the Product in the Territory.

ARTICLE 6
MANUFACTURE AND SUPPLY

6.1 Promptly after the execution of this Agreement, the Parties shall enter into a supply agreement (the "**Supply Agreement**"), pursuant to which MIST shall, either by itself or through its Affiliates or Third Party contract manufacturers, Manufacture and supply, and Ji Xing shall purchase from MIST, all of Ji Xing's and its Affiliates', sublicensees' and sub-distributors' requirements of the Compound and Device for Development and Commercialization use in the Field in the Territory. If the Parties mutually agree, MIST may also Manufacture and supply the

Product to Ji Xing for Development and Commercialization use in the Field in the Territory. For clarity, Ji Xing shall not have the right to Manufacture the Compound, unless with MIST consent as described in 2.1(c), or the Device.

6.2 Ji Xing shall pay for the Compound, Device and Product supplied by MIST at a price equal to (i) the Manufacturing Cost plus [*] mark up, for Compound, Device and Product supplied to Ji Xing [*]; and (ii) the Manufacturing Cost plus [*] mark up, for Compound, Device and Product supplied [*]. This price does not include any sales, use, excise, value added, transfer or other taxes or duties levied or assessed by any Governmental Authority on the transfer and sale of the Compound, Device and Product to Ji Xing, all of which shall be borne and paid by Ji Xing.

6.3 Audit by Ji Xing. MIST shall (and shall ensure its MIST's Third Party contract manufacturer to) keep complete and accurate records in accordance with GAAP and in sufficient detail relating to the Manufacture of the Compound, Device and Products supplied to Ji Xing [*]. Upon no less than [*] prior notice, Ji Xing will have the right to have an independent certified public accountant, selected by Ji Xing and reasonably acceptable to MIST to inspect such records for the purpose of determining the accuracy of the Manufacturing Cost due within the prior [*] period. Such audit may not be conducted more than [*] unless [*] and will take place at the location(s) where such records, materials, documents are maintained by MIST upon reasonable prior written notice, during regular business hours and under obligations of confidentiality. If it is determined that any amounts were overpaid or underpaid during such period, MIST will pay Ji Xing such overpaid amounts or Ji Xing will pay MIST the underpaid amounts within [*] of the date the independent certified public accountant's written report. The fees charged by such independent certified public accountant will be paid by Ji Xing, unless it is determined that any overpaid amounts exceed [*] of the total amount payable by Ji Xing to MIST for the period then being audited, in which case MIST will be responsible for the fees charged by such independent certified public accountant.

6.4 Manufacture Technology Transfer Option. Upon MIST's consent that Ji Xing may, Manufacture (by itself, or through Affiliates or a CMO) the Compound and the Product (but not the Device) in the PRC, the Parties will discuss in good faith a manufacturing technology transfer plan, pursuant to which MIST will, at Ji Xing's cost, provide access to and transfer to Ji Xing, or an Affiliate or a CMO [*], all Licensed Know-How that is necessary or reasonably useful for Ji Xing, or an Affiliate or the CMO [*] to Manufacture the Compound and the Products (but not the Device) in the Territory. Upon reasonable request from Ji Xing and at Ji Xing's cost, MIST will also provide to Ji Xing all necessary assistance and services to enable Ji Xing, or an Affiliate or the CMO [*], to Manufacture the Compound and the Product (but not the Device) in substantially the same manner as MIST, its Affiliate or MIST's Third Party contracting manufacturer Manufactures the Compound and the Product (but not the Device) for Ji Xing.

ARTICLE 7
COMMERCIALIZATION

7.1 General. Subject to the terms and conditions of this Agreement, Ji Xing shall, either by itself or through its Affiliates, sublicensees or Third Party contractor(s), be solely responsible for the Commercialization of the Product in the Field in the Territory, at Ji Xing's own

cost and expense, including developing and executing a commercial launch plan, product marketing and promotion, marketing access and pricing strategy, negotiating with applicable Governmental Authorities regarding the price and reimbursement mechanisms, booking sales, product distribution, providing customer support (including handling medical queries), and performing other related functions, subject to the terms of this Agreement, including Section 7.6.

7.2 Commercialization Diligence. Ji Xing shall use Diligent Efforts to Commercialize the Product in the Field in each Region in the Territory in which it receives Regulatory Approval. Without limiting the foregoing, Ji Xing shall achieve [*].

7.3 Commercialization Plan. No later than [*], Ji Xing shall submit to the JCC for review and discussion a written Commercialization plan that sets the timeline and details of all major Commercialization activities planned for the Product in the Territory (the "**Commercialization Plan**"). Thereafter, from time to time, but at least [*], Ji Xing shall prepare updates or amendments to the Commercialization Plan to reflect changes in such plans, including [*], and submit such updated or amended plan to JCC for review and discussion before adopting such update or amendment. For clarity, [*]. The Commercialization of the Product in the Territory shall be conducted in accordance with the Commercialization Plan.

7.4 Coordination of Commercialization Activities. The Parties recognize that they may benefit from the coordination of certain activities in support of the Commercialization of the Product across their territories. As such, the Parties may coordinate such activities where appropriate, including scientific and medical communication and product positioning. If the Parties agree to jointly conduct any specific Commercialization activities for the benefit of the Product in both Parties' territories, the Parties shall negotiate and agree on the details of such activities, including allocation of responsibilities, budget and cost sharing.

7.5 Marketing Materials. Upon Ji Xing's reasonable request, MIST shall provide Ji Xing with copies of marketing, promotion and commercialization materials Controlled by MIST and pertaining to the Commercialization of Product. Subject to the terms and conditions of this Agreement, Ji Xing shall have the right to use such materials in connection with the Commercialization of the Product in the Field in the Territory, but Ji Xing shall be responsible for the translation of such materials into the Chinese language at Ji Xing's own cost and expense. Ji Xing shall Commercialize the Product, including conducting marketing and advertisement activities, in accordance with Applicable Laws and shall not [*] that are (a) [*], and (b) [*].

7.6 Pricing. Ji Xing shall advise the JSC of its proposed pricing for the Product in each Region in advance of commencing price discussions with Regulatory Authorities or other parties involved in reimbursement decisions. Ji Xing shall consider in good faith any comments received from MIST with respect to pricing of the Product and shall keep MIST informed on the status of any application for pricing or reimbursement approval for the Product in any Region in the Territory, including any discussion with Regulatory Authority with respect thereto. [*], Ji Xing shall [*]; provided, however, that Ji Xing shall not [*], and further provided that, in the event [*], then the Parties will discuss in good faith [*].

7.7 Commercialization Reports. Ji Xing shall keep MIST reasonably informed of its, its Affiliates' and sublicensees' Commercialization activities with respect to the Product. Without limiting the foregoing, Ji Xing shall update the JCC at each regularly scheduled JCC meeting regarding the Commercialization activities with respect to the Product in the Territory. Each such update shall be in a form to be agreed by the JCC and shall summarize Ji Xing's, its Affiliates' and sublicensees' significant Commercialization activities with respect to the Product in the Territory, covering subject matter at a level of detail reasonably required by MIST and sufficient to enable MIST to determine Ji Xing's compliance with its diligence obligations pursuant to Section 7.2. In addition, Ji Xing shall make available to MIST such additional information about its Commercialization activities as may be reasonably requested by MIST from time to time.

ARTICLE 8
PAYMENTS AND MILESTONES

8.1 Upfront Payment. In partial consideration of the rights granted by MIST to Ji Xing hereunder, Ji Xing shall pay to MIST a one-time, non-refundable and non-creditable upfront payment of fifteen million Dollars ($15,000,000), which shall be paid in two installments as follows: (a) ten million Dollars ($10,000,000) within [*] after the Effective Date; and (b) five million Dollars ($5,000,000) within [*] after the [*].

8.2 Equity Investment. [*] following the execution of this Agreement, MIST, RTW Master Fund, Ltd., RTW Innovation Master Fund, Ltd. and RTW Venture Fund Limited, shall enter into the Securities Purchase Agreement set forth on **Exhibit E** hereto, pursuant to which RTW Master Fund, Ltd., RTW Innovation Master Fund, Ltd. and RTW Venture Fund Limited, will purchase pre-funded warrants issued by MIST for an aggregate purchase price of Five Million Dollars ($5,000,000). Such warrants shall be exercisable for such number of MIST common shares as is equal to (a) Five Million Dollars ($5,000,000) divided by (b) [*] each at an exercise price equal to $0.01 per share.

8.3 Development Milestones Payments.

(a) Milestone Events. Subject to the remainder of this Section 8.3, Ji Xing shall pay to MIST the following one-time, non-refundable and non-creditable Development milestone payments set forth in the table below upon the first achievement of the corresponding milestone event:

Development Milestone Event	Milestone Payment
1) [*]	[*]
2) [*]	[*]
3) [*]	[*]
4) [*]	[*]
5) [*]	[*]
6) [*]	[*]

7) [*]	[*]
Total	**$[*]**

(b) Milestone Conditions.

(i) Each milestone payment set forth above shall be due and payable only once, regardless of how many times such milestone event is achieved and/or the number of Products that achieves such milestone event. The aggregate milestone payments under this Section 8.3 shall not exceed [*].

(ii) Each milestone payment set forth above shall be due and payable irrespective of whether such milestone event is achieved by MIST, Ji Xing, their Affiliates, licensee or sublicensee.

(iii) As used herein, [*] of a Clinical Trial means [*], and [*] of a Clinical Trial means [*].

(iv) If [*], then milestone [*] shall be deemed achieved upon [*].

(v) In the event that any milestone events have not been achieved at the time of achievement of a milestone event having a higher number than the skipped milestone event, and such higher number milestone event is for the same indication and same country or region as the skipped milestone, then the skipped milestone event shall be deemed achieved at the time of achievement of the higher number milestone event.

(c) Notice and Payment. For milestones set forth above to be achieved [*], [*] shall notify [*] in writing within [*] after the first achievement of such milestone. For milestones set forth above to be achieved [*], [*] shall notify [*] in writing within [*] after the first achievement of such milestone; provided, however, that in each case, failure to notify a Party shall be without prejudice to any milestone payment obligation once achievement of such milestone is notified. MIST will invoice Ji Xing for the corresponding milestone payments promptly after it becomes aware of the achievement of such milestone, and Ji Xing shall pay to MIST the corresponding milestone payment within [*] after the achievement of such milestone and the receipt of a corresponding invoice from MIST.

8.4 Sales Milestone Payments.

(a) Milestone Events. Subject to the remainder of this Section 8.4, Ji Xing shall pay to MIST the following one-time, non-refundable and non-creditable sales milestone payments set forth in the table below when the aggregated annual Net Sales of all Products sold in the Territory first reach the corresponding threshold value indicated below.

Aggregate annual Net Sale of all Products in the Territory	**Milestone Payment**
1. [*]	[*]

2. [*]	[*]
3. [*]	[*]
4. [*]	[*]
5. [*]	[*]
6. [*]	[*]
Total	**[*]**

(b) Milestone Conditions. Each sales milestone payment set forth above shall be due and payable only once, regardless of how many times such milestone event is achieved. The aggregate milestone payments under this Section 8.4 shall not exceed [*]. For clarity, the sales milestone payments in this Section 8.4 are additive, such that if more than one sales milestone set forth above is achieved in the same time period, then the milestone payments for all such sales milestones shall be payable.

(c) Notice and Payment. As part of the royalty report in Section 8.5(d), Ji Xing shall provide written notice to MIST if the aggregated annual Net Sales of the Product in the Territory first reaches any threshold value set forth in Section 8.4(a) above during the time period to which such report pertains. Promptly following the delivery of the applicable quarterly report stating a sales milestone has been achieved, MIST will invoice Ji Xing for the corresponding milestone payments, and Ji Xing shall pay to MIST the corresponding milestone payments within [*] after Ji Xing receives such invoice.

8.5 Royalty Payments.

(a) Royalty Rates. Subject to the remainder of this Section 8.5, Ji Xing shall make quarterly non-refundable royalty payments to MIST on the Net Sales of all Products sold in the Territory, as calculated by multiplying the applicable royalty rate set forth in the table below by the corresponding amount of incremental, aggregated annual Net Sales of all Products sold in the Territory in the applicable Calendar Year.

For that portion of annual Net Sale of the Product in the Territory	**Royalty Rate**
1) less than or equal to [*]	[*]
2) greater than [*] but less than or equal to [*]	[*]
3) greater than [*] but less than or equal to [*]	[*]
4) greater than [*] but less than or equal to [*]	[*]
5) greater than [*]	[*]

(b) Royalty Term. Ji Xing's obligation to pay royalties pursuant to this Section 8.5 shall continue, on a Product-by-Product and Region-by-Region basis, until the latest of (i) [*]; (ii) [*]; and (iii) [*] (the "**Royalty Term**").

(c) Royalty Reductions.

(i) If a Product is generating Net Sales in a Region in a Calendar Quarter during the applicable Royalty Term at a time when there is no Valid Claim in the Licensed Patent in such Region that claims such Product, including [*], then, subject to Section 8.5(c)(iii), the royalty rate applicable to Net Sales of such Product in such Region in such Calendar Quarter shall be reduced to [*] of the average royalty rate otherwise applicable to all Net Sales of the Product in the Territory in such Calendar Quarter under Section 8.5(a).

(ii) If a Product is generating Net Sales in a Region in a Calendar Quarter during the applicable Royalty Term at a time when a Generic Product with respect to such Product is being sold in such Region, and the Net Sales of such Product in such Calendar Quarter is less than [*] of the average Net Sales of such Product in the [*] immediately before the launch of the Generic Product in such Region, then, subject to Section 8.5(c)(iii), the royalty rate applicable to Net Sales of such Product in such Region in such Calendar Quarter shall be reduced to [*] of the average royalty rate otherwise applicable to all Net Sales of the Product in the Territory in such Calendar Quarter under Section 8.5(a).

(iii) Notwithstanding the foregoing, in no event shall the operation of Section 8.5(c)(i) or (ii), individually or in combination, reduce the royalties paid to MIST with respect to the Net Sales of any Product in any Region in the Territory in any Calendar Quarter to less than [*] of the amount that would otherwise have been due pursuant to Section 8.5(a) with respect to such Net Sales.

(d) Royalty Report and Payment. Within [*] after the end of each Calendar Quarter, commencing with the first Calendar Quarter in which there is any Net Sale of the Product anywhere in the Territory, Ji Xing shall provide MIST with a report that contains the following information for the applicable Calendar Quarter, on a Product-by-Product and Region-by-Region basis: [*] a calculation of the royalty payment due on such sales in Dollars, including the exchange rate and any reduction under Section 8.5(c)[*]. Promptly following the delivery of the applicable quarterly report, MIST will invoice Ji Xing for the royalties due to MIST with respect to Net Sales for such Calendar Quarter and Ji Xing shall pay such amounts to MIST within [*] following Ji Xing's receipt of such invoice.

8.6 Currency; Exchange Rate. All payments to be made by Ji Xing to MIST under this Agreement shall be made in Dollars by bank wire transfer in immediately available funds to a bank account designated by written notice from MIST. The rate of exchange to be used in computing the amount of currency equivalent in Dollars shall be made at the average of the closing exchange rates reported in *The Wall Street Journal* (U.S., Eastern Edition) for the first, middle and last business days of the applicable reporting period for the payment due.

8.7 Late Payments. Time is of the essence in respect of all payment obligations of Ji Xing under this Agreement. In addition, if either Party does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due to such Party from the due date until the date of payment at a per-annum rate of [*] or the maximum rate allowable by Applicable Laws, whichever is less.

8.8 Financial Records and Audits. Ji Xing shall (and shall ensure that its Affiliates and sublicensees will) maintain complete and accurate records in accordance with GAAP and in sufficient detail to permit MIST to confirm the accuracy of Net Sales reported by Ji Xing and amounts payable under this Agreement. Upon no less than [*] prior notice, such records shall be open for examination, during regular business hours, for a period of [*] from the creation of individual records, and not more often than [*], by an independent certified public accountant selected by MIST and reasonably acceptable to Ji Xing, for the sole purpose of verifying for MIST the accuracy of the Net Sales and royalty reports provided by Ji Xing under this Agreement. MIST shall bear the cost of such audit unless such audit reveals an underpayment by Ji Xing of more than [*] of the amount actually due for the time period being audited, in which case Ji Xing shall reimburse MIST for the costs of such audit. Ji Xing shall pay to MIST any underpayment discovered by such audit within [*] after the accountant's report, plus interest (as set forth in Section 8.7) from the original due date. [*].

8.9 Taxes.

(a) [*]. In the event that Ji Xing is required, under Applicable Laws, to withhold any deduction or tax from any payment due to MIST under this Agreement, [*]; provided, however, that [*]. Ji Xing shall promptly furnish MIST, as applicable, [*]. Each Party agrees to cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time to time in effect.

(b) Notwithstanding the foregoing, if any withholding taxes or value added taxes are imposed with respect to any payment contemplated under this Agreement as a result of a (sub)license, an assignment or other transfer by a Party of its rights or obligations hereunder to another entity (including its Affiliate), or as a result of a subsequent (sub)license, assignment or transfer following such (sub)license, assignment or transfer (such Party, the "**Assigning Party**"), in each case, pursuant to Section 15.2 or Section 2.2, and such withholding taxes or value added taxes would not have been imposed with respect to such payment under then-applicable tax laws if such Party had not (sub)licensed, assigned or transferred its rights or obligations hereunder (or had such subsequent transfer not occurred) (such incremental withholding taxes and/or value added taxes, "**Incremental Taxes**"), then the Assigning Party (or its successor or assignee) shall bear all such Incremental Taxes without increasing the other Party's tax obligations.

ARTICLE 9
INTELLECTUAL PROPERTY

9.1 Arising Product IP.

(a) To the extent permissible under the Applicable Laws, MIST shall solely own all Arising Product IP, regardless of inventorship, and Ji Xing shall and hereby does assign

to MIST all the right, title and interest in and to all Arising Product IP invented or generated by or on behalf of Ji Xing, its Affiliates or sublicensees, and agrees to execute such instrument and take such further action requested by MIST to evidence and perfect such assignment and to obtain and maintain patent and other intellectual property protection for such Arising Product IP.

(b) To the extent the assignment of any Arising Product IP by Ji Xing to MIST is not permissible under the Applicable Laws, Ji Xing shall and hereby does grant to MIST an exclusive (even as to Ji Xing but subject to the license granted by MIST back to Ji Xing as part of Licensed IP), worldwide, sublicensable (through multiple tiers), royalty free, fully paid, worldwide, perpetual and irrevocable license under such Arising Product IP for any and all uses.

(c) All Arising Product IP (regardless of whether invented or developed by MIST itself, assigned by Ji Xing to MIST under Section 9.1(a), or exclusively licensed by Ji Xing to MIST under Section 9.1(b) above) shall be deemed Confidential Information of MIST and shall be included in the Licensed IP and licensed to Ji Xing under the terms and conditions of this Agreement.

(d) Each Party shall promptly disclose to the other Party all Arising Product IP invented or generated by or on behalf of such Party under this Agreement, including any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing such Arising Product IP, and shall promptly respond to reasonable request from the other Party for additional information relating to such Arising Product IP.

(e) Each Party shall promptly disclose to the other Party all Arising Product IP invented or generated by or on behalf of such Party under this Agreement, including any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing such Arising Product IP, and shall promptly respond to reasonable request from the other Party for additional information relating to such Arising Product IP.

(f) Other than the Arising Product IP, the ownership of all intellectual property rights generated from the Parties' activities under this Agreement will be determined based on the principles of inventorship in accordance with the laws where such intellectual property rights are generated.

9.2 Patent Prosecution.

(a) As between the Parties, MIST shall have the first right (but not the obligation) to file, prosecute and maintain all Licensed Patents (including Patents claiming Arising Product IP) throughout the world. Ji Xing shall reimburse MIST for the reasonable and documented cost and expense incurred specifically to file, prosecute and maintain the Licensed Patents in the Territory within [*] after the receipt of invoice from MIST.

(b) MIST shall consult with Ji Xing and keep Ji Xing reasonably informed of the status of the Licensed Patents in the Territory and shall promptly provide Ji Xing with all material correspondence received from any patent authority in the Territory in connection therewith. In addition, MIST shall promptly (at least [*] prior to the intended submission) provide Ji Xing with drafts of all proposed material filings and correspondence to any patent authority in

the Territory with respect to the Licensed Patents for Ji Xing's review and comment prior to submission. MIST shall confer with Ji Xing and consider in good faith Ji Xing's comments prior to submitting such filings and correspondences in the Territory, provided that Ji Xing shall provide such comments within [*] (or a shorter period reasonably designated by MIST if [*] is not practicable given the filing deadline through no delay of MIST) of receiving the draft filings and correspondences from MIST.

(c) MIST shall notify Ji Xing of any decision to cease prosecution and/or maintenance of any Licensed Patents in any Region in the Territory. MIST shall provide such notice at least [*] prior to any filing or payment due date, or any other due date that requires action in order to avoid loss of rights, in connection with such Licensed Patent in such Region. In such event, MIST shall permit Ji Xing, at Ji Xing's discretion and expense, to continue the prosecution and maintenance of such Licensed Patent in such Region in the Territory.

(d) Each Party shall provide the other Party all reasonable assistance and cooperation in the patent prosecution efforts under this Section 9.2, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

9.3 Patent Enforcement.

(a) Each Party shall promptly notify the other Party if it becomes aware of any alleged or threatened infringement by a Third Party of any of the Licensed Patents in the Territory, and any related declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability or non-infringement of any of the Licensed Patents in the Territory.

(b) As between the Parties, Ji Xing shall have the first right (but not the obligation) to bring and control any legal action in connection with any infringement of the Licensed Patents in the Territory that [*] in the Field in the Territory (a "**Product Infringement**"), at Ji Xing's own expense as it reasonably determines appropriate. If Ji Xing does not bring such legal action within [*] after the notice provided pursuant to Section 9.3(a), MIST shall have the right (but not the obligation) to bring and control any legal action in connection with such Product Infringement in the Territory, at MIST's own expense as it reasonably determines appropriate.

(c) At the request and expense of the Party bringing an action under Section 9.3(b) above, the other Party shall provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action if required by Applicable Laws to pursue such action. In connection with any such enforcement action, the enforcing Party shall keep the other Party reasonably informed on the status of such action and shall not enter into any settlement admitting the invalidity or non-infringement of, or otherwise impairing the other Party's rights in the Licensed Patents without the prior written consent of the other Party. The non-enforcing Party shall be entitled to separate representation in such enforcement action by counsel of its own choice and at its own expense.

(d) Any recoveries resulting from enforcement action relating to a claim of Product Infringement in the Territory shall be first applied against payment of each Party's costs

and expenses in connection therewith. Any such recoveries in excess of such costs and expenses shall be retained by the enforcing Party, provided that if Ji Xing is the enforcing Party, then such excess recoveries shall be [*].

(e) MIST shall have the exclusive right to bring and control any legal action to enforce the Licensed Patents against any infringement that is not a Product Infringement, at MIST's own expense and as it reasonably determines appropriate, and shall have the right to retain all recoveries.

9.4 Infringement of Third Party Rights.

(a) Each Party shall notify the other Party of any allegations it receives from a Third Party that the Development, Manufacture or Commercialization of any Product in the Field in the Territory under this Agreement infringes the intellectual property rights of such Third Party. Such notice shall be provided promptly, but in no event after more than [*] following receipt of such allegations. Such notice shall include a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing. Thereafter, the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action and may, if appropriate, agree on and enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. Each Party shall assert and not waive the joint defense privilege with respect to all communications between the Parties.

(b) Ji Xing shall be solely responsible for the defense of any such infringement claims brought against Ji Xing, at Ji Xing's own cost and expense; provided, however, that the provisions of Section 9.3 shall govern the right of Ji Xing to assert a counterclaim of infringement of any Licensed Patents; and provided further that Ji Xing shall [*]. Ji Xing shall keep MIST informed on the status of such defense action, and MIST shall have the right, but not the obligation, to participate and be separately represented in such defense action at its sole option and at its own expense. MIST shall also have the right to control the defense of any infringement claim brought against MIST, at MIST's own cost and expense, provided that [*].

9.5 Patent Marking. Ji Xing shall mark the Product sold in the Territory in accordance with the applicable patent marking laws, and shall require all of its Affiliates and sublicensees to do the same. To the extent permitted by Applicable Laws, Ji Xing shall indicate on the product packaging, advertisement and promotional materials that the Product is in-licensed from MIST.

9.6 Trademarks.

(a) Subject to Sections 9.6 (b) and 9.6(c) below, Ji Xing shall have the right to brand the Product sold in the Territory using any trademarks and trade names it determines appropriate for the Product, which may vary by Region or within a Region (the "**Product Marks**"); provided that Ji Xing shall not select any mark or China-approved drug name that is confusingly similar to any MIST Trademarks as a Product Mark. Ji Xing shall own all rights in the Product Marks in the Territory and shall register and maintain the Product Marks in the Territory that it determines reasonably necessary, at Ji Xing's own cost and expense.

(b) Ji Xing acknowledges that MIST may develop a global branding strategy for the Product and adopt the key distinctive colors, logos, images, symbols, and trademarks to be used in connection with the Commercialization of the Product throughout the world (collectively and including any Chinese language versions thereof, the "**MIST Trademarks**"). MIST shall own all rights in the MIST Trademarks and shall have the sole right (but not the obligation) to register, maintain and enforce the MIST Trademarks in any country in the world as it determines appropriate, at MIST's own cost and expense.

(c) Subject to the terms and conditions of this Agreement and for no additional considerations, MIST hereby grants to Ji Xing an exclusive license to use the MIST Trademarks solely in connection with the Commercialization of the Product in the Field in the Territory during the Term of this Agreement, and if Ji Xing elects to Commercialize the Product in the Territory using the MIST Trademarks, Ji Xing shall do so in a manner consistent with MIST's global branding strategy for the Product.

ARTICLE 10
CONFIDENTIALITY

10.1 Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that, for the Term and for a period of [*] thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any Confidential Information of the other Party pursuant to this Agreement.

10.2 Exceptions. The foregoing confidentiality and non-use obligations shall not apply to any portion of the Confidential Information that the receiving Party can demonstrate by competent written proof:

(a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) is subsequently disclosed to the receiving Party by a Third Party who has a legal right to make such disclosure; or

(e) is subsequently independently discovered or developed by the receiving Party without the aid, application, or use of the disclosing Party's Confidential Information, as evidenced by a contemporaneous writing.

10.3 Authorized Disclosure. Notwithstanding the obligations set forth in Section 10.1, a Party may disclose the other Party's Confidential Information and the terms of this Agreement to the extent:

(a) such disclosure is reasonably necessary (i) for the filing or prosecution of Patents as contemplated by this Agreement; (ii) in connection with regulatory filings for the Product; or (iii) for the prosecuting or defending litigation as contemplated by this Agreement;

(b) such disclosure is reasonably necessary: (i) to such Party's directors, attorneys, independent accountants or financial advisors for the sole purpose of enabling such directors, attorneys, independent accountants or financial advisors to provide advice to the receiving Party, provided that in each such case on the condition that such directors, attorneys, independent accountants and financial advisors are bound by confidentiality and non-use obligations consistent with those contained in this Agreement; or (ii) to actual or potential investors, acquirors, licensors, licensees, collaborators or other business or financial partners (including royalty financing partners) solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, license, collaboration, financing or other business transaction; provided that in each such case on the condition that such disclosees are bound by confidentiality and non-use obligations consistent with those contained in the Agreement; or

(c) such disclosure is required by judicial or administrative process, provided that in such event such Party shall promptly inform the other Party of such required disclosure and provide the other Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed by judicial or administrative process shall remain otherwise subject to the confidentiality and non-use provisions of this Article 10, and the Party disclosing Confidential Information pursuant to law or court order shall take all steps reasonably necessary, including seeking of confidential treatment or a protective order, to ensure the continued confidential treatment of such Confidential Information.

10.4 Scientific Publication. Except to the extent required by Applicable Laws, Ji Xing shall not publish [*], without MIST's review and approval, which shall not be unreasonably withheld or delayed. Ji Xing shall deliver to MIST for review and approval a copy of [*] at least [*] before its intended submission for publication. MIST shall have the right to require modifications of the proposed publication or presentation to protect MIST's Confidential Information and for trade secret reasons [*]. MIST may also delay the submission of the proposed publication or presentation for an additional [*] as may be reasonably necessary to seek patent protection for the information disclosed in such proposed publication or presentation. Ji Xing agrees to acknowledge the contribution of MIST and MIST's employees in all publications relating to the Product as scientifically appropriate.

10.5 Publicity.

(a) The Parties have agreed on language of a joint press release announcing this Agreement, which is attached hereto as **Exhibit F**, to be issued by the Parties promptly after the Effective Date. Subject to the rest of this Section 10.5, no disclosure of the terms of this Agreement may be made by either Party, and no Party shall use the name, trademark, trade name or logo of

the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by Applicable Laws. Following the initial joint press release announcing this Agreement, either Party shall be free to disclose or publicize, without the other Party's prior written consent, the existence of this Agreement, the identity of the other Party, and those terms of this Agreement that have already been publicly disclosed in accordance herewith.

(b) A Party may disclose this Agreement and its terms in securities filings with the U.S. Securities Exchange Commission (or equivalent foreign agency) ("**SEC**") to the extent required by Applicable Laws after complying with the procedure set forth in this Section 10.5. In such event, the Party seeking such disclosure will prepare a draft confidential treatment request and proposed redacted version of this Agreement to request confidential treatment for this Agreement, and the other Party agrees to promptly (and in any event, no less than [*] after receipt of such confidential treatment request and proposed redactions) give its input in a reasonable manner in order to allow the Party seeking disclosure to file its request within the time lines prescribed by applicable SEC regulations. The Party seeking such disclosure shall exercise commercially reasonable efforts to obtain confidential treatment of this Agreement from the SEC as represented by the redacted version reviewed by the other Party.

(c) Each Party acknowledges that the other Party may be legally required to make public disclosures (including in filings with the SEC or other agency) of certain material developments or material information generated under this Agreement and agrees that each Party may make such disclosures as required by Applicable Laws, *provided* that the Party seeking such disclosure first provides the other Party a copy of the proposed disclosure, and provided further that (except to the extent that the Party seeking disclosure is required to disclose such information to comply with Applicable Laws) if the other Party demonstrates to the reasonable satisfaction of the Party seeking disclosure, within [*] of such Party's providing the copy, that the public disclosure of previously undisclosed information will materially adversely affect the development and/or commercialization of a Product being developed and/or commercialized, the Party seeking disclosure will remove from the disclosure such specific previously undisclosed information as the other Party shall reasonably request to be removed.

10.6 Prior CDA. This Agreement supersedes the Confidentiality Agreement between the Parties dated [*] (the "**Prior CDA**") with respect to information disclosed thereunder. All information exchanged between the Parties under the Prior CDA shall be deemed Confidential Information of the disclosing Party and shall be subject to the terms of this Article 10.

10.7 Equitable Relief. Each Party acknowledges that a breach of this Article 10 may not reasonably or adequately be compensated by damages in an action at law and that such a breach may cause the other Party irreparable injury and damage. By reason thereof, each Party agrees that the other Party shall be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to preliminary and permanent injunctive and other equitable relief to prevent or curtail any breach of the obligations relating to Confidential Information set forth herein.

10.8 Attorney-Client Privilege. Neither Party is waiving, nor shall be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges or the like, as a result of disclosing information pursuant to this Agreement, or any of its Confidential Information (including Confidential Information related to pending or threatened litigation) to the other Party, regardless of whether the disclosing Party has asserted, or is or may be entitled to assert, such privileges and protections. The Parties: (a) share a common legal and commercial interest in such disclosure that is subject to such privileges and protections; (b) are or may become joint defendants in proceedings to which the information covered by such protections and privileges relates; (c) intend that such privileges and protections remain intact should either Party become subject to any actual or threatened proceeding to which the disclosing Party's Confidential Information covered by such protections and privileges relates; and (d) intend that after the Effective Date, both the receiving Party and the disclosing Party shall have the right to assert such protections and privileges.

ARTICLE 11
REPRESENTATIONS AND WARRANTIES

11.1 Representations and Warranties of Each Party. Each Party represents, warrants, and covenants (as applicable) to the other Party that:

(a) it is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement;

(b) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder, and this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and similar laws affecting creditors' rights and remedies generally;

(c) it is not a party to, and will not enter into during the Term, any agreement that would prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under the Agreement; and

(d) in the course of performing its obligations or exercising its rights under this Agreement, it shall comply with all Applicable Laws, including as applicable, cGMP, GCP, and GLP standards, and shall not employ or engage any person or entity who has been debarred by any Regulatory Authority, or, to such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority.

11.2 Representations and Warranties of MIST. MIST represents, warrants, and covenants (as applicable) to Ji Xing that:

(a) it has the right under the Licensed IP to grant the licenses to Ji Xing as purported to be granted under Section 2.1 of this Agreement;

(b) it has not granted, and will not grant during the Term, any license or other right under the Licensed IP that is inconsistent with the license granted to Ji Xing under Section 2.1;

(c) **Exhibit B** includes all Licensed Patents as of the Effective Date. MIST is the sole and exclusive owner of the Licensed Patents, all of which are free and clear of any claims, liens, charges or encumbrances. All Licensed Patents are (i) subsisting and in good standing and (ii) being diligently prosecuted in the respective patent offices in accordance with Applicable Laws, and all applicable fees have been paid on or before the due date for payment. To its knowledge, all Licensed Patents and have been filed and maintained properly and correctly and all issued Licensed Patents are valid;

(d) it has not received any written notice from any Third Party asserting or alleging that the Development of the Product prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party;

(e) there are no pending or, to MIST's knowledge, threatened (in writing), adverse actions, claims, suits or proceedings against MIST or any of its Affiliate involving the Licensed IP or the Compound, Device, or Product. No claim or litigation has been brought or, to MIST's knowledge, threatened by any Person (i) alleging that the Licensed Patents are invalid or unenforceable, (ii) asserting the misuse, or non-infringement of any of the Licensed Patents, (iii) challenging MIST's Control of the Licensed Patents or (iv) alleging misappropriation of the Know-How used in the Development or Manufacture of the Compound, Device, or Product by or on behalf of MIST prior to the Effective Date;

(f) to its knowledge, it (and any Third Party acting under its authority) (i) has complied in all material respects with all Applicable Laws and applicable governmental regulations and industrial standards (including GLP, GCP, and GMP) in connection with the Development, Manufacture, storage and disposition of the Compound, Device and Product (including information and data provided to Regulatory Authorities), and (ii) has not used any employee, consultant or contractor who has been debarred by any Regulatory Authority, or is the subject of a debarment proceeding by any Regulatory Authority in connection therewith;

(g) no Upstream License exists as of the Effective Date.

11.3 Representations and Warranties of Ji Xing. Ji Xing represents, warrants, and covenants (as applicable) to MIST that:

(a) there is no pending or, to Ji Xing's knowledge, threatened (in writing), adverse actions, claims, suits or proceedings against Ji Xing or any of its Affiliate that involve any antitrust, anti-competition, anti-bribery or corruption violations or that may reasonably be expected to adversely affect Ji Xing's ability to perform its obligations under this Agreement;

(b) neither Ji Xing nor any of its Affiliates is, or has been, debarred or disqualified by any Regulatory Authority nor will any of them be debarred or disqualified by any Regulatory Authority at any time throughout the Term;

(c) it has sufficient financial wherewithal to (i) perform all of its obligations pursuant to this Agreement, and (ii) meet all of its obligations that come due in the ordinary course of business;

(d) it has, and will at all times throughout the Term have, the requisite approvals, permits, licenses, expertise, resources, experience and skill reasonably required to perform its obligations under this Agreement.

11.4 NO OTHER WARRANTIES. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY. ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED. Ji Xing acknowledges and agrees that the Product is the subject of ongoing clinical research and development and that MIST cannot assure the safety, usefulness or successful Development or Commercialization of the Product.

ARTICLE 12
INDEMNIFICATION

12.1 Indemnification by Ji Xing. Ji Xing shall indemnify, defend and hold harmless MIST, its Affiliates, and their directors, officers, employees and agents (individually and collectively, the "**MIST Indemnitee(s)**") from and against all losses, liabilities, damages and expenses (including reasonable attorneys' fees and costs) incurred in connection with any claims, demands, actions or other proceedings by any Third Party (individually and collectively, "**Losses**") to the extent arising from:

(a) the Development, Manufacture, and Commercialization of the Product in the Territory by Ji Xing or any of its Affiliates or sublicensees (including product liability claims resulting therefrom); or

(b) the negligence, willful misconduct or breach of this Agreement (including any representations, warranty or covenant of Ji Xing) by any Ji Xing Indemnitee;

except in each case to the extent such Losses arise out of the negligence, willful misconduct or breach of this Agreement by any MIST Indemnitee or arise from, are based on, or result from any activity or occurrence for which MIST is obligated to indemnify Ji Xing under Section 12.2.

12.2 Indemnification by MIST. MIST shall indemnify, defend and hold harmless Ji Xing, its Affiliates, and their directors, officers, employees and agents (individually and collectively, the "**Ji Xing Indemnitee(s)**") from and against all Losses to the extent arising from:

(a) activities conducted by or on behalf of MIST, its Affiliates or MIST Licensees, or contractors related to the Development or Manufacture of Licensed Products anywhere in the world prior to the Effective Date (including product liability claims resulting therefrom);

(b) the Development, Manufacture, and Commercialization of the Product outside the Territory by MIST or any of its Affiliates or MIST Licensees (including product liability claims resulting therefrom);

(c) the Development of the Product in the Territory by MIST or any of its Affiliates or MIST Licensees (including product liability claims resulting therefrom); or

(d) the negligence, willful misconduct or breach of this Agreement (including any representations, warranty or covenant of MIST) by any MIST Indemnitee;

except in each case to the extent such Losses arise out of the negligence, willful misconduct or breach of this Agreement by any Ji Xing Indemnitee or arise from, are based on, or result from any activity or occurrence for which Ji Xing is obligated to indemnify MIST under Section 12.1.

12.3 Indemnification Procedure. If either Party is seeking indemnification under Sections 12.1 or 12.2 (the "**Indemnified Party**"), it shall inform the other Party (the "**Indemnifying Party**") of the claim giving rise to the obligation to indemnify pursuant to such Section within [*] after receiving notice of the claim (it being understood and agreed, however, that the failure or delay by an Indemnified Party to give such notice of a claim shall not affect the indemnification provided hereunder except to the extent the Indemnifying Party shall have been prejudiced as a result of such failure or delay to give notice). The Indemnifying Party shall have the right to assume the defense of any such claim for which it is obligated to indemnify the Indemnified Party. The Indemnified Party shall cooperate with the Indemnifying Party and the Indemnifying Party's insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party's cost and expense. The Indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim that has been assumed by the Indemnifying Party. Neither Party shall have the obligation to indemnify the other Party in connection with any settlement made without the Indemnifying Party's written consent, which consent shall not be unreasonably withheld or delayed.

12.4 Mitigation of Loss. Each Indemnified Party shall take and shall procure that its Affiliates take all such reasonable steps and action as are reasonably necessary or as the Indemnifying Party may reasonably require in order to mitigate any claims (or potential losses or damages) under this Article 12. Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

12.5 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL (WHICH SHALL BE DEEMED TO INCLUDE, WITHOUT LIMITATION, ALL DAMAGES CONSTITUTING LOSS OF PROFIT, LOSS OF REVENUE AND LOSS OF GOODWILL), INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS

AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 12.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 12.1 OR 12.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF SECTION 2.7 OR ARTICLE 10.

12.6 Insurance. Each Party shall procure and maintain insurance, including product liability insurance, with respect to its activities hereunder and which is consistent with normal business practices of prudent companies similarly situated at all times during which any Product is being clinically tested in human subjects or commercially distributed or sold. Each Party shall provide the other Party with evidence of such insurance upon request and shall provide the other Party with written notice at least [*] prior to the cancellation, non-renewal or material changes in such insurance. Such insurance shall not be construed to create a limit of either Party's liability under this Agreement.

ARTICLE 13
TERM AND TERMINATION

13.1 Term.

(a) The term of this Agreement shall commence upon the Effective Date and continue in full force and effect, on a Product-by-Product and Region-by-Region basis, until the expiration of the Royalty Term for such Product in such Region, unless earlier terminated as set forth in Section 13.2 below (the "**Term**").

(b) Upon expiration (but not early termination) of the Royalty Term with respect to a particular Product in a particular Region, the licenses granted by MIST to Ji Xing under Section 2.1 with respect to such Product in such Region shall continue and shall become fully paid-up, royalty-free, perpetual and irrevocable, and [*] shall also continue except that [*].

13.2 Termination.

(a) Termination by Ji Xing for Convenience. At any time, Ji Xing may terminate this Agreement in its entirety by providing written notice of termination to MIST, which notice includes an effective date of termination at least one hundred eighty (180) days after the date of the notice.

(b) Termination for Material Breach. If either Party materially breaches this Agreement, then the non-breaching Party may deliver notice of such breach to the other Party, which notice will (i) expressly reference this Section 13.2(b), (ii) reasonably describe the alleged material breach which is the basis of such termination, and (iii) clearly state the non-breaching Party's intent to terminate this Agreement if the alleged breach is not cured within the [*]. Notwithstanding the foregoing, (A) if such material breach, by its nature, is curable, but is not reasonably curable within the applicable cure period, then such cure period will be extended if the alleged breaching Party provides a written plan for curing such breach to the non-breaching Party and uses Diligent Efforts to cure such breach in accordance with such written plan; provided, however, that no such extension will exceed [*] without the written consent of the non-breaching

Party; and (B) if the breaching Party disputes (1) whether it has materially breached this Agreement, (2) whether such material breach is reasonably curable within the applicable cure period, or (3) whether it has cured such material breach within the applicable cure period, to the extent the breaching Party notifies the non-breaching Party in writing of any such dispute within [*] after the non-breaching Party's receipt of the termination notice, such dispute will be resolved pursuant to Article 14, and this Agreement may not be terminated during the pendency of such dispute resolution procedure. During the pendency of such dispute, the applicable cure period shall be tolled, all the terms of this Agreement shall remain in effect, and the Parties shall continue to perform all of their respective obligations hereunder.

(c) Termination for Insolvency. Each Party shall have the right to terminate this Agreement in its entirety immediately upon written notice to the other Party in the event that (i) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (ii) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within [*] of its filing, or (iii) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors.

(d) Termination for [*]. Except to the extent the following is unenforceable under the laws of a particular jurisdiction, MIST may terminate this Agreement in its entirety with [*] prior written notice to Ji Xing if Ji Xing or its Affiliates or sublicensees, individually or in association with any other person or entity, commences a legal action challenging [*]. Notwithstanding the foregoing, MIST will not have the right to terminate this Agreement under this Section 13.2(d) if (i) such legal action was brought by a Third Party sublicensee and Ji Xing has terminated such sublicense within such [*] period, (ii) such legal action is based solely on the scope of a Licensed Patent or whether a claim therein qualifies as a Valid Claim and was made in defense of a breach claim first brought by MIST against Ji Xing, or (iii) such legal action is dismissed within [*] of MIST's notice to Ji Xing under this Section 13.2(d) and not thereafter continued.

(e) Termination for [*]. If, at any time during the Term, Ji Xing does not [*], then MIST may treat such lack of activity as Ji Xing's material breach of this Agreement and exercise the right to terminate this Agreement pursuant to Section 13.2(b), provided, that,[*].

13.3 Effect of Termination. Upon any termination of this Agreement:

(a) License to Ji Xing. All licenses and other rights granted by MIST to Ji Xing under the Licensed IP shall terminate, and all sublicenses granted by Ji Xing shall also terminate.

(b) Regulatory Materials. Ji Xing shall (and shall cause its Affiliates and sublicensees to), as instructed by MIST, either (i) if permitted by Applicable Laws, promptly transfer and assign to MIST or its designee all Regulatory Materials and Regulatory Approvals for the Product in the Territory, (ii) continue to hold any such Regulatory Materials and Regulatory

Approvals for the sole benefit of MIST or its designee (in which case, Ji Xing shall appoint MIST or its designee as the exclusive distributor (with the right to subcontract and appoint sub-distributors) under such Regulatory Materials and Regulatory Approvals for the Product in the Territory, and also as its agent to interact with the applicable Regulatory Authority in the Territory with respect to such Regulatory Materials and Regulatory Approvals), until such time MIST or its designee files its own Regulatory Materials and obtains its own Regulatory Approvals for the Product in the Territory; and/or (iii) terminate or withdraw any such Regulatory Materials and Regulatory Approvals. Upon MIST's request, Ji Xing shall also provide MIST with reasonable assistance and cooperation regarding any inquiries and correspondence with Regulatory Authorities relating to the Product.

(c) Data. Ji Xing shall (and shall cause its Affiliates and sublicensees to) promptly transfer and assign to MIST, at no cost to MIST (except where the Agreement is terminated by Ji Xing for MIST's uncured material breach pursuant to Section 13.2(b)), all data generated from the Development of the Product, including all Clinical Trials conducted by or on behalf of Ji Xing, its Affiliates and sublicensees, and all pharmacovigilance data (including all adverse event databases) relating to the Product in the Territory.

(d) Inventory. Ji Xing will have the right, for a period of [*] following termination of this Agreement, to sell or otherwise dispose of any Product in the Territory, on hand at the time of such termination or in the process of Manufacturing. Upon expiration of the [*], MIST shall have the right (but not the obligation) to purchase from Ji Xing any or all of the inventory of the Product then held by Ji Xing or its Affiliates or sublicensees at a price equal to [*], provided that [*].

(e) Transition Assistance. Ji Xing shall (and shall cause its Affiliates and sublicensees to) reasonably cooperate with MIST to facilitate orderly transition of the Development, Manufacture and Commercialization of the Product to MIST, including (i) assigning or amending as appropriate, upon request of MIST, any agreements or arrangements with Third Party vendors (including distributors) to Develop, Manufacture, supply, promote, distribute, sell or otherwise Commercialize the Product or, to the extent any such Third Party agreement or arrangement is not assignable to MIST, reasonably cooperating with MIST to arrange to continue to provide such services for a reasonable time after termination; (ii) to the extent that Ji Xing or its Affiliate or sublicensee is performing any activities described above in (i), reasonably cooperating with MIST to transfer such activities to MIST or its designee, and continuing to perform such activities on MIST's behalf for a reasonable time after termination until such transfer is completed (not to exceed [*]); and (iii) providing MIST with reasonable quantities of materials used or generated by Ji Xing, its Affiliates and sublicensees in the Development and Commercialization of the Product in the Territory, such as clinical brochures and promotional materials, or any chemical or biological materials, that were not received from MIST.

(f) Ongoing Clinical Trials. If at the time of such termination, any Clinical Trials for the Product are being conducted by or on behalf of Ji Xing, its Affiliates or sublicensees, then, at MIST's election on a trial-by-trial basis and to the extent permissible under Applicable Laws: (i) Ji Xing shall (and shall cause its Affiliates and sublicensees to) fully cooperate with MIST to transfer the conduct of all such Clinical Trials to MIST, and MIST shall assume any and

all liability and costs for such Clinical Trials after the effective date of such termination; or (ii) Ji Xing shall (and shall cause its Affiliates and sublicensees to), orderly wind down, in compliance with Applicable Laws, the conduct of any such Clinical Trial which is not assumed by MIST under clause (i).

(g) Return of Confidential Information. Ji Xing shall (and shall cause its Affiliates and sublicensees to) promptly return or destroy (at MIST's election) all tangible materials comprising, bearing or containing any Confidential Information of MIST that are in Ji Xing's or its Affiliates' or sublicensees' possession or control.

(h) Termination Press Releases. Subject to the provisions of Section 10.5, the Parties shall cooperate in good faith to coordinate public disclosure of the termination of this Agreement and the reasons therefor, and neither Party shall, except to the extent required by Applicable Laws, disclose any such information without the prior approval of the other Party. The principles to be observed in such disclosures shall be accuracy, compliance with Applicable Laws and regulatory guidance documents, and reasonable sensitivity to potential negative investor reaction to such news.

(i) Trademarks. Ji Xing shall (and shall cause its Affiliates and sublicensees to) promptly transfer and assign to MIST all Product Marks (excluding any such mark that includes, in whole or in part, any corporate name or logos of Ji Xing or its Affiliates or sublicensees).

(j) Transition Costs. MIST will reimburse Ji Xing for the internal and external costs incurred in performing such transition activities or providing such assistance under Sections 13.3(b), 13.3(e), 13.3(f) and 13.3(i), unless this Agreement is terminated by MIST in accordance with Section 13.2(b) or Section 13.2(d) or by Ji Xing in accordance with Section 13.2(a).

(k) Termination by Ji Xing for MIST's Material Breach. If this Agreement is terminated by Ji Xing for MIST's uncured material breach pursuant to Section 13.2(b), without limiting the foregoing, in consideration of Ji Xing's assignment to MIST all Arising Product IP under this Agreement and Ji Xing's performance of the assignment, transition, and assistance activities post such termination, on a Product-by-Product and Region-by-Region basis, MIST shall pay to Ji Xing royalties for exploiting the Product in the Territory for [*] starting from the First Commercial Sale of such Product in such Region by or on behalf of MIST, at the applicable royalty rate set forth below:

(i) [*] in a Region in the Territory, if [*];

(ii) [*] in a Region in the Territory, if [*]; and

(iii) [*] in a Region in the Territory, if [*].

The definition of Net Sales and Sections 8.5 through 8.8 (excluding 8.5(a) and 8.5(b)) shall apply *mutatis mutandis* with respect to the sale of the Product by or on behalf of MIST in the Territory.

13.4 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the following provisions shall survive the termination or expiration of this Agreement for any reason: Article 1 (DEFINITIONS), Article 10 (CONFIDENTIALITY)(for the duration stipulated therein), Article 12 (INDEMNIFICATION) (excluding Section 12.6(Insurance)), Article 14 (DISPUTE RESOLUTION), Article 15 (MISCELLANEOUS) (as applicable, and excluding Section 15.7 (Foreign Corrupt Practices Act Compliance) and Section 15.16 (Further Actions)), Section 6.4 (Audit by Ji Xing)(for the duration stipulated therein), Sections 8.5 (Royalty Payments) through 8.9 (Taxes) (solely with respect to payment obligations accrued prior to such expiration or termination), Section 9.1 (Arising Product IP), Section 11.4 (No Other Warranties), Section 13.1(b) (Term) (solely in the event of expiration), Section 13.3 (Effects of Termination), Section 13.4(Survival), Section 13.5 (Termination Not Sole Remedy).

13.5 Termination Not Sole Remedy. Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies shall remain available except as agreed to otherwise herein.

ARTICLE 14
DISPUTE RESOLUTION

14.1 Disputes. The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 14 to resolve any controversy or claim arising out of, relating to, or in connection with any provision of this Agreement, if and when a dispute arises under this Agreement.

14.2 Internal Resolution. With respect to all disputes arising between the Parties under this Agreement, including, without limitation, any alleged breach under this Agreement or any issue relating to the interpretation or application of this Agreement, if the Parties are unable to resolve such dispute within [*] after such dispute is first identified by either Party in writing to the other, the Parties shall refer such dispute to the Executive Officers of the Parties for attempted resolution by good faith negotiations within [*] after such notice is received.

14.3 Binding Arbitration.

(a) If the Parties fail to resolve the dispute through escalation to the Executive Officers under Section 14.2, and a Party desires to pursue resolution of the dispute, the dispute shall be submitted by either Party for resolution in arbitration administered by the International Chamber of Commerce ("**ICC**") pursuant to its arbitration rules and procedures then in effect.

(b) The arbitration shall be conducted by a panel of three arbitrators experienced in the pharmaceutical business. Within [*] after initiation of arbitration, each Party shall select one person to act as arbitrator and the two Party-selected arbitrators shall select a third arbitrator (who shall be the chairperson of the arbitration panel) within [*] of their appointment.

If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by ICC. If, however, the aggregate award sought by the Parties is less than [*] and equitable relief is not sought, the arbitration shall be conducted by a single arbitrator agreed by the Parties (or appointed by ICC if the Parties cannot agree).

(c) The seat and location of the arbitration shall be [*], and the language of the proceedings shall be English. The arbitral tribunal shall determine the dispute by applying the provisions of this Agreement and the governing law set forth in Section 15.6. The Parties agree that any award or decision made by the arbitral tribunal shall be final and binding upon them and may be enforced in the same manner as a judgment or order of a court of competent jurisdiction.

(d) By agreeing to arbitration, the Parties do not intend to deprive any court of its jurisdiction to issue, at the request of a Party, a pre-arbitral injunction, pre-arbitral attachment or other order to avoid irreparable harm, maintain the status quo, preserve the subject matter of the dispute, or aid the arbitration proceedings and the enforcement of any award. Without prejudice to such provisional or interim remedies in aid of arbitration as may be available under the jurisdiction of a competent court, the arbitral tribunal shall have full authority to grant provisional or interim remedies and to award damages for the failure of any Party to the dispute to respect the arbitral tribunal's order to that effect.

(e) Each Party shall bear its own attorney's fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the administrator and the arbitrator; provided, however, the arbitrator shall be authorized to determine whether a Party is the prevailing party, and if so, to award to that prevailing party reimbursement for any or all of its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, travel expenses, etc.), and/or the fees and costs of the administrator and the arbitrator.

(f) Notwithstanding anything in this Section 14.3, in the event of a dispute with respect to the validity, scope, enforceability or ownership of any Patent or other intellectual property rights, and such dispute is not resolved in accordance with Section 14.2, such dispute shall not be submitted to an arbitration proceeding in accordance with this Section 14.3, unless otherwise agreed by the Parties in writing, and instead either Party may initiate litigation in a court of competent jurisdiction in any country in which such rights apply.

ARTICLE 15
MISCELLANEOUS

15.1 Force Majeure. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, epidemic or pandemic, fire, floods, or other acts of God or any other deity, or acts, omissions or delays in acting by any Governmental Authority. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to mitigate such force majeure circumstances.

15.2 Assignment.

(a) Except as provided in Section 15.2(b) below, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the prior written consent of the other Party. Any attempted assignment not in accordance with the foregoing shall be null and void and of no legal effect. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement. The terms and conditions of this Agreement shall be binding upon, and shall inure to the benefit of, the Parties and their respected successors and permitted assigns.

(b) Notwithstanding the foregoing, either Party may, without consent of the other Party, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate of such Party, or in whole to its successor-in-interest in connection with the sale of all or substantially all of its stock or its assets to which this Agreement relates, or in connection with a merger, acquisition or similar transaction.

(c) [*].

15.3 Performance by Affiliates. Each Party may discharge any obligations (other than the payment obligations set forth under Article 8) and exercise any right hereunder through any of its Affiliates, without notice to and without consent from, the other Party, and each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance.

15.4 Severability. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

15.5 Notices. All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to MIST:

Milestone Pharmaceuticals, Inc.
7422 Carmel Executive Drive, Suite 300
Charlotte, NC 28226
Attn: [*]

with a copy to:

Cooley LLP
3175 Hanover Street
Palo Alto, CA 94304, USA
Attn: [*]
Fax: [*]

If to Ji Xing:

Ji Xing Pharmaceuticals Limited

c/o RTW Investments, LP
40 10th Avenue, 7th Floor
New York, NY 10014
Attn: [*]
Email:[*]

with a copy to:

Ropes & Gray LLP
36/F, Park Place
1601 Nanjing Road West
Shanghai, The People's Republic of China
Attn: [*]
Email: [Geoffrey.Lin@ropesgray.com]
Fax: [*]

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given (a) when delivered if personally delivered or sent by facsimile on a Business Day; (b) on the second Business Day after dispatch if sent by internationally-recognized overnight courier; or (c) on the fifth Business Day following the date of mailing if sent by mail.

15.6 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, U.S., without giving effect to any choice of law principles that would require the application of the laws of a different jurisdiction. The application of the U.N. Convention on Contracts for the International Sale of Goods is excluded.

15.7 Foreign Corrupt Practices Act Compliance.

(a) Compliance with FCPA. The U.S. government imposes and enforces prohibitions on the payment or transfer of anything of value to governments, government officials, political parties or political party officials (or relatives or associates of such officials) ("**FCPA Covered Person**") for the purpose of illegally influencing them, whether directly or indirectly, to obtain or retain business. This U.S. law is referred to as the Foreign Corrupt Practices Act

("**FCPA**"), and it can have application to conduct of a U.S. corporation's foreign subsidiaries, employees, agents and distributors. A summary of the law and related information can be found at http://www.justice.gov/criminal/fraud/fcpa. By signing this Agreement, Ji Xing represents, warrants and covenants (as applicable) to MIST that:

(i) it is familiar with the provisions and restrictions contained in the OECD Convention and FCPA;

(ii) it shall comply with the FCPA in the Development and Commercialization of the Product under this Agreement;

(iii) it shall not, in the course of its duties under the Agreement, offer, promise, give, demand, seek or accept, directly or indirectly, any gift or payment, consideration or benefit in kind to any FCPA Covered Person that would or could be construed as an illegal or corrupt practice;

(iv) it is not an FCPA Covered Person or affiliated with any FCPA Covered Person; and

(v) it shall immediately notify MIST of any attempt by any FCPA Covered Person to directly or indirectly solicit, ask for, or attempt to extort anything of value from Ji Xing, its Affiliates or sublicensees, and shall refuse any such solicitation, request or extortionate demand except a facilitating payment as expressly permitted under the FCPA.

(b) Compliance Certificate. From time to time upon request from MIST, Ji Xing shall submit a compliance certificate in the form reasonably requested by MIST that (i) it fully understands its obligations under this Section 15.7 and any other Applicable Laws mentioned herein or as may come into existence from time to time after the Effective Date; (ii) it has been complying with this Section 15.7 and any other Applicable Laws mentioned herein or as may come into existence from time to time after the Effective Date; and (iii) it shall continue to comply with this Section 15.7 and any other Applicable Laws mentioned herein or as may come into existence from time to time after the Effective Date.

(c) No Action. In no event shall any Party be obligated under the Agreement to take any action or omit to take any action that such Party believes, in good faith, would cause it to be in violation of any Applicable Laws, including the anti-bribery laws referenced in this Section 15.7.

(d) Due Diligence. MIST shall have the right to visit the offices of Ji Xing from time to time during the term of the Agreement on an "as needed" basis and conduct due diligence in relation to Ji Xing's business related to performance of its obligations under this Section 15.7 and may do so in the way it deems necessary, appropriate or desirable so as to ensure that Ji Xing complies with this Section 15.7 and any other Applicable Laws in its business operations. Ji Xing shall make every effort to cooperate fully with MIST in any such due diligence.

(e) Audit. In the event that MIST has reason to believe that a breach of any obligation of Ji Xing under this Section 15.7 has occurred or may occur, MIST shall have the right

to select an independent third party to conduct an audit of Ji Xing and review relevant books and records of Ji Xing, to satisfy itself that no breach has occurred. Unless otherwise required under Applicable Laws or by order of a competent court or regulatory authority, MIST shall ensure that the selected independent third party shall keep confidential all audited matters and the results of the audit. MIST shall not disclose to the U.S. or foreign government, its agencies and/or any other government or non-government party, information relating to a possible violation by Ji Xing of any Applicable Law, including a violation of the FCPA or any other applicable anti-bribery law, unless MIST is required to do so under Applicable Laws.

15.8 Entire Agreement; Amendments. The Agreement, together with the Exhibits attached hereto, contains the entire understanding of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, with regard to the subject matter hereof (including the licenses granted hereunder) are superseded by the terms of this Agreement. Neither Party is relying on any representation, promise, nor warranty not expressly set forth in this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties hereto.

15.9 Headings. The captions to the several Sections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the Sections of this Agreement.

15.10 Independent Contractors. It is expressly agreed that MIST and Ji Xing shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither MIST nor Ji Xing shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

15.11 Waiver. The waiver by either Party of any right hereunder, or the failure of the other Party to perform, or a breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise.

15.12 Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

15.13 Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

15.14 Business Day Requirements. In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day then such notice or other action or omission shall be deemed to be required to be taken on the next occurring Business Day.

15.15 Translations. This Agreement is in the English language only, which language shall be controlling in all respects, and all versions hereof in any other language shall be for accommodation only and shall not be binding upon the Parties. All communications and notices to be made or given pursuant to this Agreement, and any dispute proceeding related to or arising hereunder, shall be in the English language. If there is a discrepancy between any translation of this Agreement and this Agreement, this Agreement shall prevail.

15.16 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as necessary or appropriate in order to carry out the purposes and intent of this Agreement.

15.17 Construction. Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation", (c) the word "will" shall be construed to have the same meaning and effect as the word "shall", (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person shall be construed to include the person's successors and assigns, (f) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections, Schedules, or Exhibits shall be construed to refer to Sections, Schedules or Exhibits of this Agreement, and references to this Agreement include all Schedules and Exhibits hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree", "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or Section, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "and/or."

15.18 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each Party shall be entitled to rely on the delivery of executed facsimile copies of counterpart execution pages of this Agreement and such facsimile copies shall be legally effective to create a valid and binding agreement among the Parties.

{Signature Page Follows}

IN WITNESS WHEREOF, the Parties intending to be bound have caused this License and Collaboration Agreement to be executed by their duly authorized representatives as of the Effective Date.

MILESTONE PHARMACEUTICALS, INC.	**JI XING PHARMACEUTICALS LIMITED**
By:_____	By:_____
Name:_____	Name:_____
Title:_____	Title:_____
Date:_____	Date:_____

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

List of Exhibits

Exhibit A: Compound and Device
Exhibit B: Existing Licensed Patents
Exhibit C: Initial Development Plan
Exhibit D: Technology Transfer Plan
Exhibit E: Securities Purchase Agreement
Exhibit F: Joint Press Release
Schedule 2.8: Approved Subcontractors

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

Exhibit A
Compound and Device

Compound Description

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential

Exhibit B

Existing Licensed Patents

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential

Exhibit C
Initial Development Plan

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential

Exhibit D
Technology Transfer Plan

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential

Exhibit E

Securities Purchase Agreement

[*]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential

Exhibit F

Press Release

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

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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

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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 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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Schedule 2.8
Approved Subcontractors

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Exhibit 31.1

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

I, Joseph Oliveto, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Milestone Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2021

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

Exhibit 31.2

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

I, Amit Hasija, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Milestone Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2021

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

Exhibit 32.1

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

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

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2021, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 11, 2021

/s/ Joseph Oliveto	/s/ Amit Hasija
Joseph Oliveto Chief Executive Officer (Principal Executive Officer)	Amit Hasija Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)