Mast Therapeutics, Inc.
Form 424B5
November 05, 2014
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Subject to completion, dated November 5, 2014

The information in this preliminary prospectus supplement is not complete and may be changed. This preliminary prospectus supplement and the accompanying prospectus are part of an effective registration statement filed with the Securities and Exchange Commission. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities and are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Filed Pursuant to Rule 424(b)(5)
Registration No. 333-179989

PROSPECTUS SUPPLEMENT

(To Prospectus dated May 1, 2012)

Series A Units consisting of Common Stock and Warrants

Series B Units consisting of Pre-Funded Warrants and Warrants

(Shares of Common Stock Underlying the Pre-Funded Warrants)

(Shares of Common Stock Underlying the Warrants)

Pursuant to this prospectus supplement and the accompanying prospectus, we are offering for sale Series A units, with each Series A unit consisting of one share of our common stock and of a warrant. Each whole warrant will be exercisable for one share of our common stock. The purchase price for each Series A unit is $. The Series A units will not be issued or certificated. The shares of common stock and the warrants included in the Series A units will be issued separately but can only be purchased together in the Series A units in this offering.

We are also offering to those purchasers whose purchase of Series A units in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock following the consummation of this offering, the opportunity to purchase, in lieu of Series A units that would otherwise result in ownership in excess of 4.99% of our outstanding common stock, Series B units. Each Series B unit will consist of one pre-funded warrant and of a warrant. Each pre-funded warrant will be exercisable for one share of our common stock. Each whole warrant will be exercisable for one share of our common stock. The purchase price for each Series B unit is $. The Series B units will not be issued or certificated. The pre-funded warrants and the warrants included in the Series B units will be issued separately but can only be purchased together in the Series B units in this offering.

We refer to the shares of our common stock, the warrants, and the pre-funded warrants issued in this offering, collectively, as the securities. We refer to the warrants included in the Series A units and the Series B units (but not the pre-funded warrants), collectively, as the warrants. We refer to the pre-funded warrants included in the Series B units, collectively, as the pre-funded warrants. The shares of our common stock issuable from time to time upon exercise of the pre-funded warrants and the warrants are also being offered pursuant to this prospectus supplement and the accompanying prospectus.

Each pre-funded warrant will have an initial exercise price of $0.01 per share, will be exercisable upon issuance, and will expire five years from the date of issuance. Each warrant will have an initial exercise price of $ per share, will be exercisable upon issuance, and will expire five years from the date of issuance.

Our common stock is listed on NYSE MKT under the symbol MSTX. The last reported sale price of our common stock on November 4, 2014 was $0.49 per share.

We do not intend to list the pre-funded warrants or the warrants on the NYSE MKT, any other national securities exchange or any other nationally recognized trading system.

Investing in our securities involves a high degree of risk. See Risk Factors, beginning on page S-6 of this prospectus supplement, as well as the documents incorporated by reference in this prospectus supplement, for a discussion of the factors you should carefully consider before deciding to purchase our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Series A Unit	Per Series B Unit	Total
Public offering price	$	$	$
Underwriting discounts and commissions[(1)]	$	$	$
Proceeds, before expenses, to us	$	$	$

(1) We have also agreed to reimburse the underwriters for fees and expenses incurred by them in connection with this offering, up to a maximum of $100,000. See Underwriting beginning on page S-41 of this prospectus supplement for more information regarding underwriting discounts and commissions and expense reimbursement.

The underwriters expect to deliver the securities offered hereby against payment on or about November , 2014.

Sole Book-Running Manager

Cowen and Company

The date of this prospectus supplement is November , 2014

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Prospectus Supplement

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ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is the prospectus supplement, including the documents incorporated by reference, which describes the specific terms of this offering. The second part, the accompanying prospectus, including the documents incorporated by reference, provides more general information. Before you invest, you should carefully read this prospectus supplement, the accompanying prospectus, all information incorporated by reference herein and therein, as well as the additional information described under Where You Can Find Additional Information on page S-45 of this prospectus supplement. These documents contain information you should consider when making your investment decision. This prospectus supplement may add, update or change information contained in the accompanying prospectus. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or any document incorporated by reference therein filed prior to the date of this prospectus supplement, on the other hand, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document filed after the date of this prospectus supplement and incorporated by reference in this prospectus supplement and the accompanying prospectus the statement in the document having the later date modifies or supersedes the earlier statement.

You should rely only on the information contained or incorporated by reference in this prospectus supplement, the accompanying prospectus and in any free writing prospectuses we may provide to you in connection with this offering. We have not, and Cowen has not, authorized any other person to provide you with any information that is different. If anyone provides you with different or inconsistent information, you should not rely on it. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the offering of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement outside the United States. This prospectus supplement does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference in the accompanying prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

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PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights selected information about us, this offering and information appearing elsewhere in this prospectus supplement, in the accompanying prospectus and in the documents we incorporate by reference. This summary is not complete and does not contain all the information you should consider before investing in our securities pursuant to this prospectus supplement and the accompanying prospectus. Before making an investment decision, to fully understand this offering and its consequences to you, you should carefully read this entire prospectus supplement and the accompanying prospectus, including Risk Factors beginning on page S-6 of this prospectus supplement and the financial statements and related notes and the other information that we incorporated by reference herein, including our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q that we file from time to time.

Unless the context otherwise requires, all references in this prospectus to Mast, we, us, our, the Company or similar words refer to Mast Therapeutics, Inc., together with our consolidated subsidiaries.

Overview

We are a clinical-stage, biopharmaceutical company developing novel therapies for serious or life-threatening diseases with significant unmet needs. We are leveraging our Molecular Adhesion & Sealant Technology, or MAST, platform, derived from over two decades of clinical, nonclinical, and manufacturing experience with purified and non-purified poloxamers, to develop MST-188, our lead product candidate, for serious or life-threatening diseases and conditions typically characterized by impaired microvascular blood flow and damaged cell membranes.

We have devoted substantially all of our resources to research and development, or R&D, and to acquisition of our product candidates. We have not yet marketed or sold any products or generated any significant revenue and we have incurred significant annual operating losses since inception. We incurred a loss from operations of $21.9 million for the nine months ended September 30, 2014. Our cash, cash equivalents, and investment securities were $43.1 million as of September 30, 2014.

We continue to focus our resources primarily on the development of MST-188. We believe that its pharmacologic effects support its development in a wide range of serious or life-threatening diseases and conditions, and we intend to develop MST-188 in multiple clinical indications, both independently and through collaborations. Enrolling patients in EPIC, our ongoing pivotal phase 3 study of MST-188 in sickle cell disease, is one of our top priorities. We expect to enroll 388 subjects in the study from approximately 70 medical centers within and outside the United States. We have opened 50 U.S. study sites and more than ten study sites outside of the U.S. More than half of the EPIC study sites have enrolled at least one patient. Although predicting the rate of enrollment for EPIC is subject to a number of significant assumptions and the actual rate may differ materially, we expect to complete enrollment by the end of 2015. If EPIC is successful, we plan to submit a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, based in large part on data from that study.

We also are enrolling patients with acute limb ischemia in a phase 2 clinical study of MST-188 in combination with recombinant tissue plasminogen activator (rt-PA) to evaluate whether MST-188 improves effectiveness of thrombolytic therapy. In addition, we are planning to initiate a phase 2 study of MST-188 in patients with acute decompensated heart failure in the first half of 2015. Our MST-188 pipeline also includes preclinical development programs in stroke and resuscitation following major trauma (*i.e.*, restoration of circulating blood volume and pressure).

In addition to our lead product candidate, we are developing AIR001, sodium nitrite inhalation solution for intermittent inhalation via nebulizer, in pulmonary hypertension (PH) associated with left heart disease. We

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acquired AIR001 in February 2014 through our acquisition of Aires Pharmaceuticals, Inc. In September 2014, we reported positive preliminary data from a phase 2 study of AIR001. Consistent with findings from earlier studies of AIR001, the data support AIR001 s potential as an agent that can have a positive effect on hemodynamic parameters in patients with PH. We believe AIR001 may be uniquely suited to address the serious unmet need of patients with PH associated with left heart disease, or World Health Organization, or WHO, Group 2 PH, and we are supporting three institution-sponsored phase 2a studies of AIR001 in that patient population.

Corporate Information

In March 2013, we changed our name from ADVENTRX Pharmaceuticals, Inc. to Mast Therapeutics, Inc.

Our principal executive offices are located at 12390 El Camino Real, Suite 150, San Diego, CA 92130 and our telephone number is (858) 552-0866.

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THE OFFERING

Series A units we are offering	Series A units, with each unit consisting of one share of our common stock and of a warrant. Each whole warrant is exercisable for one share of our common stock.
Series B units we are offering	Series B units, with each Series B unit consisting of one pre-funded warrant to purchase one share of our common stock and of a warrant. Each whole warrant is exercisable for one share of our common stock. We will offer the opportunity to purchase Series B units to those purchasers whose purchase of Series A units in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock following the consummation of this offering, in lieu of Series A units that otherwise would result in ownership in excess of 4.99% of our outstanding common stock.
Public offering price	$ per Series A unit and $ per Series B unit
Pre-funded warrants we are offering	Each pre-funded warrant included in a Series B unit will have an initial exercise price of $0.01 per share of common stock, will be exercisable upon issuance and will expire five years from the date of issuance. This prospectus supplement also relates to the offering of shares of our common stock issuable upon exercise of the pre-funded warrants.
Warrants we are offering	Each whole warrant included in Series A units and Series B units (other than the pre-funded warrant) will be exercisable for one share of our common stock, will have an initial exercise price of $ per share of common stock, will be exercisable upon issuance and will expire five years from the date of issuance. This prospectus supplement also relates to the offering of shares of our common stock issuable upon exercise of the warrants.
Common stock to be outstanding immediately after this offering	shares (assuming none of the pre-funded warrants or warrants issued in the offering is exercised).
Use of proceeds	We currently intend to use the net proceeds from this offering primarily to fund our clinical development programs, including EPIC, our ongoing phase 3 clinical study of MST-188 in sickle cell disease, and for working capital and general corporate purposes. Please see Use of Proceeds on page S-35.
Risk factors	See Risk Factors beginning on page S-6 of this prospectus supplement, as well as the other information included in or incorporated by reference in this prospectus supplement and the accompanying prospectus, for a discussion of risks you should carefully consider before investing in our securities.
NYSE MKT symbol	MSTX
Transfer agent, warrant agent and registrar	American Stock Transfer & Trust Company, LLC

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The number of shares of our common stock to be outstanding immediately after this offering as shown above assumes that all of the Series A units being offered are sold, and is based on 127,508,434 shares of our common stock outstanding as of September 30, 2014 and excludes:

- 44,416,875 shares of our common stock issuable upon exercise of warrants outstanding as of September 30, 2014, with a weighted-average exercise price of $1.05 per share;
- 13,062,271 shares of our common stock issuable upon exercise of options outstanding as of September 30, 2014, with a weighted-average exercise price of $1.02 per share;
- 10,942,557 shares and 276,945 shares of our common stock available for future grants under our 2013 Omnibus Incentive Plan and 2005 Employee Stock Purchase Plan as of September 30, 2014, respectively;
- 12,478,050 shares of common stock that may be issued to the former stockholders of SynthRx, Inc., subject to the achievement of performance milestones, pursuant to the terms of the merger agreement with SynthRx;
- 1,008,840 shares of our common stock sold after September 30, 2014 pursuant to our at the market equity offering program;
- shares of our common stock issuable upon exercise of the pre-funded warrants offered by this prospectus supplement and the accompanying prospectus; and
- shares of our common stock issuable upon exercise of the warrants included in the Series A units and Series B units offered by this prospectus supplement and the accompanying prospectus.

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RISK FACTORS

Investing in our securities involves a high degree of risk and uncertainty. You should carefully consider these risk factors, together with all of the other information included or incorporated by reference in this prospectus supplement and the accompanying prospectus, as modified and superseded, before you decide to invest in our securities. The occurrence of any of the following risks could harm our business. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our operations. You should also refer to the other information contained in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus, including our financial statements and the notes to those statements and the information set forth in the section entitled Special Note Regarding Forward-Looking Statements.

RISKS RELATED TO OUR BUSINESS

Risks Related to Our Capital Requirements, Finances and Operations

We have incurred losses since our inception, we expect our operating expenses to continue to exceed our revenue for the foreseeable future, and we may never generate revenue sufficient to achieve profitability.

We are a clinical-stage company and have not generated sustainable revenue from operations or been profitable since inception, and we may never achieve profitability. We have devoted our resources to acquiring and developing proprietary product candidates, but such product candidates cannot be marketed until the regulatory process is completed and governmental approvals have been obtained. For the nine months ended September 30, 2014, we incurred a loss from operations of $21.9 million. We expect to continue to incur substantial operating losses for the next several years as we advance our product candidates through clinical studies and other development activities and seek approval from the FDA to commercialize them. Accordingly, there is no current source of revenue from operations, much less profits, to sustain our present activities. Further, no revenue from operations will likely be available until, and unless, we enter into an arrangement that provides for licensing revenue or other partnering-related funding or one of our product candidates is approved by the FDA or another regulatory agency and successfully marketed, outcomes which we may not achieve.

The success of our business currently is dependent largely on the success of MST-188 and this product candidate may not receive regulatory approval or be successfully commercialized.

None of our product candidates has been approved for sale by any regulatory agency. We are focusing our resources primarily on the development of MST-188. Accordingly, the success of our business currently depends on our ability, or that of a future partner, to successfully develop, obtain regulatory approval for and then successfully commercialize this product candidate and our efforts, or those of a future partner, in this regard may prove unsuccessful. MST-188 requires considerable additional clinical development and significant manufacturing and related activities prior to commencing any commercial manufacturing, all of which require us to expend significant resources and with which we have limited experience. MST-188 may not be successful in the EPIC study or in other clinical studies we initiate, and, even if successful in clinical studies, may not receive regulatory approval in a timely manner, or at all. If MST-188 is approved by the FDA or any foreign regulatory agency, our ability to generate revenue from it will depend in substantial part on the extent to which it is accepted by the medical community and reimbursed by third-party payors, as well as our ability to market and sell the product and ensure that our third-party manufacturers produce it in quantities sufficient to meet commercial demand, if any.

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The process of developing and seeking regulatory approval of investigational new drug products requires expenditure of substantial resources, and we cannot estimate with reasonable certainty the duration of or costs to complete our development programs.

Our capital requirements for the foreseeable future will depend in large part on, and could increase significantly as a result of, our expenditures on our development programs. Future expenditures on our development programs are subject to many uncertainties, and will depend on, and could increase significantly as a result of, many factors, including:

- the number and scope of development programs we pursue;
- the number of clinical and nonclinical studies necessary to demonstrate the safety and efficacy of a product candidate in a particular indication;
- the number of patients who participate in each clinical study;
- the number and location of sites and the rate of site initiation in each study;
- the rate of patient enrollment and ratio of randomized to evaluable patients in each clinical study;
- the duration of patient treatment and follow-up;
- the potential for additional safety monitoring or other studies requested by regulatory agencies;
- the time and cost to manufacture clinical trial material and commercial product, including process development and scale-up activities, and to conduct stability studies, which can last several years;
- the costs, requirements, timing of, and the ability to, secure regulatory approvals;
- the timing and terms of any collaborative or other strategic arrangement that we may establish;
- the extent to which we increase our workforce and the costs involved in recruiting, training and incentivizing new employees;

the costs related to developing, acquiring and/or contracting for sales, marketing and distribution capabilities, supply chain management capabilities, and regulatory compliance capabilities, if we obtain regulatory approval for a product candidate and commercialize it without a partner; and

the costs involved in establishing, enforcing or defending patent claims and other proprietary rights.

We may not be able to raise capital when needed or reduce other expenditures to offset expenditures on our development programs, which could have a material adverse effect on our financial condition and ability to pursue our business strategy.

We will need to obtain additional funding to pursue our current business strategy and we may not be able to obtain such funding on a timely basis, or on commercially reasonable terms, or at all. Any capital-raising transaction we are able to complete may result in dilution to our existing stockholders, require us to relinquish significant rights or restrict our operations.

We anticipate that our cash, cash equivalents and investment securities, which were approximately $43.1 million as of September 30, 2014, together with the net proceeds from this offering, will be sufficient to fund our currently planned level of operations for at least the next 12 months. However, we may determine to grow our organization and/or pursue development activities for MST-188, AIR001 or other product candidates at levels or on timelines, or we may incur unexpected expenses, that shorten the period through which our current operating funds will sustain us. Through our acquisition of Aires Pharmaceuticals in February 2014, we expanded our product pipeline to include AIR001. In the future, we may seek to further expand our product pipeline through acquisition of additional product candidates and/or technologies and the cost to acquire and develop such new product candidates and/or technologies may shorten the period through which our current operating funds will sustain us. We do not expect to generate any substantial revenue from operations in the next several years, and we will need to obtain additional capital to support our planned operating activities.

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For the foreseeable future, we likely will seek to fund our operations through public or private equity and debt financings and/or through collaborations, such as licensing arrangements or partnering transactions, and may execute any such transaction at any time, subject to applicable laws and regulations. Although we were able to raise significant funds in the past through equity financings, the conditions of and our access to capital markets are highly variable and adequate additional financing may not be available to us in the future on acceptable terms, or on a timely basis, or at all. Further, each of these financing alternatives carries risks. Raising capital through the issuance of our common stock, or securities convertible into or exercisable for our common stock, may depress the market price of our stock and may substantially dilute our existing stockholders. If instead we seek to raise capital through strategic transactions, such as licensing arrangements or sales of one or more of our technologies or product candidates, we may be required to relinquish valuable rights and dilute the current and future value of our assets. For example, any licensing arrangement likely would require us to share with our licensee a significant portion of any revenues generated by our licensed technologies. Additionally, our control over the development and/or marketing of any products or product candidates licensed or sold to third parties may be reduced and thus we may not realize the full value of any such products or product candidates. Debt financings would likely involve covenants that would restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens or make investments and may, among other things, preclude us from making distributions to stockholders (either by paying dividends or redeeming stock) and taking other actions beneficial to our stockholders. In addition, investors could impose more one-sided investment terms and conditions on companies that have or are perceived to have limited remaining funds or limited ability to raise additional funds. The lower our cash balance, the more difficult it is likely to be for us to raise additional capital on commercially reasonable terms, or at all.

For particular development programs, such as development of MST-188 for resuscitation following major trauma, we plan to seek funding from the U.S. government. The process of obtaining government contracts is lengthy and uncertain and highly competitive. In addition, changes in government budgets and agendas may result in decreased availability of funding for drug research and development. If we do secure government funding, the contracts for such funding may contain termination and audit provisions that are unfavorable to us and cause us to incur significant additional administrative expense. In addition, the U.S. government may require march-in rights that allow it to grant licenses to inventions that arise from development programs it funds if, for example, we do not commercialize the technology within a certain timeframe or the government deems such action necessary to alleviate health or safety needs that are not being reasonably satisfied by us. If the government exercises its march-in rights, we could be obligated to license intellectual property developed by us on terms unfavorable to us and we may not receive compensation from the government for its exercise of such rights.

Notwithstanding any effort on our part to raise additional capital, adequate additional funding may not be available on acceptable terms, or on a timely basis, or at all. Even if we incur costs in pursuing, evaluating and negotiating particular capital-raising and/or strategic or partnering transactions, our efforts may not prove successful. We believe global economic conditions, such as volatility in the U.S. and international equity markets, may adversely impact our ability to raise additional capital. Our failure to raise capital as needed would have a material adverse effect on our financial condition and ability to pursue our business strategy.

Our ability to raise capital may be limited by applicable laws and regulations.

Historically, we have raised capital through the sale of our equity securities. Between June 2009 and November 2011, we completed seven equity financings and, in February 2014, we commenced an at the market equity offering program under shelf registration statements on Form S-3. Using a shelf registration statement on Form S-3 to raise additional capital generally takes less time and is less expensive than other means, such as conducting an offering under a Form S-1 registration statement. However, our ability to raise capital using a shelf registration statement may

be limited by, among other things, SEC rules and regulations. Under current SEC rules and regulations, we must meet certain requirements to use a Form S-3 registration statement to

raise capital without restriction as to the amount of the market value of securities sold thereunder. One such requirement is that the market value of our outstanding common stock held by non-affiliates, or public float, be at least $75.0 million as of a date within 60 days prior to the date of filing the Form S-3. If we do not meet that requirement, then the aggregate market value of securities sold by us or on our behalf under the Form S-3 in any 12-month period is limited to an aggregate of one-third of our public float. Moreover, even if we meet the public float requirement at the time we file a Form S-3, SEC rules and regulations require that we periodically re-evaluate the value of our public float, and if, at a re-evaluation date, our public float is less than $75.0 million, we would become subject to the one-third of public float limitation described above. If our ability to utilize a Form S-3 registration statement for a primary offering of our securities is limited to one-third of our public float, we may conduct such an offering pursuant to an exemption from registration under the Securities Act or under a Form S-1 registration statement, which we have done in the past, including in June 2013, and we would expect either of those alternatives to increase the cost of raising additional capital relative to utilizing a Form S-3 registration statement.

In addition, under current SEC rules and regulations, our common stock must be listed and registered on a national securities exchange in order to utilize a Form S-3 registration statement (i) for a primary offering, if our public float is not at least $75.0 million as of a date within 60 days prior to the date of filing the Form S-3, or a re-evaluation date, whichever is later, and (ii) to register the resale of our securities by persons other than us (i.e., a resale offering). While currently our common stock is listed on the NYSE MKT equities market, there can be no assurance that we will be able to maintain such listing. The NYSE MKT reviews the appropriateness of continued listing of any issuer that falls below the exchange s continued listing standards. Previously, including during part of 2010, we were not in compliance with certain NYSE MKT continued listing standards and were at risk of having our common stock delisted from the NYSE MKT equities market. For additional information regarding this risk, see the risk factor below titled If we are unable to maintain compliance with NYSE MKT continued listing standards, our common stock may be delisted from the NYSE MKT equities market, which would likely cause the liquidity and market price of our common stock to decline.

Our ability to timely raise sufficient additional capital also may be limited by the NYSE MKT s stockholder approval requirements for transactions involving the issuance of our common stock or securities convertible into our common stock. For instance, the NYSE MKT requires that we obtain stockholder approval of any transaction involving the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value, which (together with sales by our officers, directors and principal stockholders) equals 20% or more of our then outstanding common stock, unless the transaction is considered a public offering by the NYSE MKT staff. Based on 128,517,274 shares of our common stock outstanding as of October 31, 2014 and the closing price per share of our common stock on such date, which was $0.51, we could not raise more than approximately $13.1 million without obtaining stockholder approval, unless the transaction is deemed a public offering or does not involve the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value. In addition, certain prior sales by us may be aggregated with any offering we may propose in the future, further limiting the amount we could raise in any future offering that is not considered a public offering by the NYSE MKT staff and involves the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value. The NYSE MKT also requires that we obtain stockholder approval if the issuance or potential issuance of additional shares will be considered by the NYSE MKT staff to result in a change of control of our company.

Obtaining stockholder approval is a costly and time-consuming process. If we are required to obtain stockholder approval for a potential transaction, we would expect to spend substantial additional money and resources. In addition, seeking stockholder approval would delay our receipt of otherwise available capital, which may materially and adversely affect our ability to execute our current business strategy, and there is no guarantee our stockholders

ultimately would approve a proposed transaction. A public offering under the NYSE MKT rules typically involves broadly announcing the proposed transaction, which often times has the effect of depressing

the issuer s stock price. Accordingly, the price at which we could sell our securities in a public offering may be less, and the dilution existing stockholders experience may in turn be greater, than if we were able to raise capital through other means.

If we are unable to raise sufficient additional capital as needed, we may be forced to delay, scale back or discontinue our development of our product candidates, partner them at inopportune times or pursue less expensive but higher-risk and/or lower-return development paths.

If we are not able to raise sufficient additional capital as needed, we may be required to delay, scale back or discontinue one or more of our development programs, or to seek collaborators at an earlier stage than otherwise would be desirable or on terms less favorable than might otherwise be available. For example, if we do not have sufficient capital, we may determine not to investigate certain additional indications for MST-188 or to conduct other studies or activities intended to enhance our intellectual property position, improve the probability of regulatory approval, or expand the scope of MST-188 s clinical benefit and market potential. Delays in and/or reduction of development activities could impair our ability to realize the full clinical and market potential of a product candidate and have a material adverse effect on our business and financial condition. In addition, discontinuation of a development program may be viewed negatively, which could adversely affect our stock price.

To the extent we discontinue independent development of a product candidate, we may not realize any value from our investment in the discontinued program. Even if we pursue a strategic option, such as partnering, selling or exclusively licensing the program to a third party, such an option may be not be available on acceptable terms or at all. For example, in prior years, we were focused on developing Exelbine and ANX-514 and expended significant resources on their development; however, in 2011 and 2012, respectively, we elected to discontinue independent development of those programs. Although we are evaluating other opportunities for further development of those agents, such as partnering and licensing arrangements, none may be available and we may not realize any return on our investment in those programs.

Our business may suffer if we are unable to retain and attract highly qualified personnel and manage internal growth.

Currently, we have a small number of employees and we rely on third parties to perform many essential services for us. Our ability to execute on our business strategy and compete in the highly competitive biopharmaceutical, specialty pharmaceutical, pharmaceutical and biotechnology industries depends, in part, on our ability to attract and retain highly qualified personnel. We are highly dependent on certain personnel, including our chief executive officer, our president and chief operating officer, our chief medical officer, and our senior vice president, development. Our industries in general and our company in particular historically have experienced a high rate of turnover of management personnel. If we lose any of our key employees, our ability to successfully implement our current business strategy could be seriously harmed. Replacing key employees may be a difficult, costly and protracted process, particularly due to the fact that we currently do not have other executive officers or personnel to assume all of the responsibilities of these key employees. In addition, we may seek to increase the size of our organization as development of our product candidates progresses. Competition for qualified personnel, particularly for key positions, is intense among companies in our field, universities and other research organizations, particularly in the San Diego, California area, and many of the organizations against which we compete for qualified personnel have greater financial and other resources and different risk profiles than our company, which may make them more attractive employers. Our ability to compete for qualified personnel may be adversely affected by our highly volatile stock price. The value of stock options we offer to candidates to induce their employment and to our employees to retain and incentivize them is significantly affected by movements in our stock price that we cannot control and may at any time be insufficient to counteract more lucrative offers from other companies. All of our employees, including our

executive officers, may terminate their employment with us at any time without notice. If we cannot attract and retain skilled personnel, as needed, we may not achieve our development and other goals.

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Future internal growth could impose significant added responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees. We may need to devote a significant amount of time to managing these activities and may not be able to do so effectively. If we are unable to effectively manage future internal growth, our expenses may increase more than expected, we may not be able to achieve our development goals, and our ability to generate and/or grow revenue could be diminished. In the meantime, the success of our business also depends, in part, on our ability to develop and maintain relationships with respected service providers and industry-leading consultants and advisers. If we cannot develop and maintain such relationships, as needed, the rate and success at which we can develop and commercialize product candidates may be limited. In addition, our outsourcing strategy, which has included engaging consultants that spend considerable time in our office to manage key functional areas, may subject us to scrutiny under labor laws and regulations, which may divert management time and attention and have an adverse effect on our business and financial condition.

If we determine to grow our business through the acquisition of new technologies and/or product candidates, our existing stockholders may experience substantial dilution, we may fail to realize the benefits of any future strategic acquisition or investment and we may incur unexpected costs and disruptions to our business.

From time to time, we may evaluate pipeline expansion opportunities and execute the acquisition of new technologies and/or product candidates that we believe will increase the long-term value of our company. The process of identifying, evaluating, negotiating and implementing the purchase or license of new assets is lengthy and complex and may disrupt other development programs and distract our personnel. We have limited resources with respect to identifying, evaluating, negotiating and implementing the acquisition of new assets or rights thereto and integrating them into our current infrastructure. Supplementing our current resources to complete one or more of these transactions may be costly.

We may use cash, shares of our common stock, securities convertible into our common stock or a combination of cash and our securities to pay the purchase price or license fee for any future strategic transaction. The use of cash could negatively impact our financial position and ability to advance our current development programs. The use of shares of our common stock or securities convertible into shares of our common stock would dilute the holdings of our existing stockholders and such dilution could be substantial. For example, to acquire SynthRx we agreed to issue up to such number of shares that represented a 41% ownership stake in our company at the time we completed the acquisition in April 2011, if development of MST-188 fully achieved the milestones under the merger agreement. The issuance of shares in connection with future strategic transactions, if any, may result in the stockholders who own the majority of our voting securities prior to one or more of such transactions owning less than a majority after such transactions.

Further, strategic transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management s time and attention to develop and/or commercialize acquired technologies and/or products candidates;
- incurrence of substantial debt to pay for acquisitions;

greater than anticipated difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;

impairment of relationships with key suppliers of any acquired business due to changes in management and ownership; and

inability to retain key employees of any acquired business.

Our stockholders will be required to rely on the judgment of our management and board of directors as to which new product candidates and/or technologies we pursue and may have limited or no opportunity to evaluate

potential new assets prior to completion of a transaction, including the terms of acquisition, the costs of their future development and their commercial potential. We may devote resources to potential acquisition or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. Any technology and/or product candidate that we acquire or to which we acquire rights likely will require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are subject to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities and other risks described under the section titled Risks Related to Drug Development and Commercialization.

We expend substantial resources to comply with laws and regulations relating to public companies, and any failure to maintain compliance could subject us to regulatory scrutiny and cause investors to lose confidence in our company, which could harm our business and have a material adverse effect on our stock price.

Laws and regulations affecting public companies, including provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and the Sarbanes-Oxley Act of 2002, or SOX, and the related rules and regulations adopted by the SEC and by the NYSE MKT have resulted in, and will continue to result in, significant costs to us as we evaluate the implications of these rules and respond to their requirements. For example, compliance with Section 404 of SOX, including performing the system and process documentation and evaluation necessary to issue our annual report on the effectiveness of our internal control over financial reporting and, if applicable, obtain the required attestation report from our independent registered public accounting firm, requires us to incur substantial expense and expend significant management time. Further, we have in the past discovered, and may in the future discover, areas of internal controls that need improvement. If we identify deficiencies in our internal controls that are deemed to be material weaknesses, we could become subject to scrutiny by regulatory authorities and lose investor confidence in the accuracy and completeness of our financial reports, which could have a material adverse effect on our stock price. Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations, including the possibility of human error and circumvention by collusion or overriding of controls. Accordingly, even an effective internal control system may not prevent or detect material misstatements on a timely basis, or at all. Also, previously effective controls may become inadequate over time as a result of changes in our business or operating structure, and we may fail to take measures to evaluate the adequacy of and update these controls, as necessary, which could lead to a material misstatement.

In addition, new laws and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees, and as our executive officers. We cannot predict or estimate with any reasonable accuracy the total amount or timing of the costs we may incur to comply with these laws and regulations.

Our ability to use net operating loss carry forwards and research and development tax credits to offset future taxable income or future tax will be limited and may be limited further in the future due to changes in ownership (within the meaning of IRC Section 382) that have occurred and may occur in the future.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or IRC, a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, and certain other tax assets to offset future taxable income, and an ownership change is generally defined as a cumulative change of 50% or more in the ownership positions of certain stockholders during a rolling three year period. In 2012, we identified several ownership changes within the meaning of IRC Section 382 that had occurred

during 2010 and 2011, with the most recent as a result of our November 2011 common stock and warrant financing. As a result of those ownership changes, we do not expect

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to be eligible to utilize the NOL carry forwards and research and development tax credits we had accumulated as of November 11, 2011. In addition, although we have not yet conducted a formal study to identify ownership changes within the meaning of IRC Section 382 for periods after December 31, 2011, we believe that the common stock and warrant financing we completed in June 2013 may be an ownership change for purposes of Sections 382 and 383 of the IRC, which would further limit the availability of our NOL carry forwards. Other ownership changes within the meaning of IRC Section 382 may occur in the future, including as a result of this offering, and such future ownership changes could eliminate or restrict our ability to use NOL carry forwards and research and development tax credits generated after June 19, 2013. Limitations on our ability to use NOL carry forwards and research and development tax credits to offset future taxable income could require us to pay U.S. federal income taxes earlier than would be required if such limitations were not in effect. Similar rules and limitations may apply for state income tax purposes.

Our operations might be interrupted by the occurrence of a natural disaster or other catastrophic event.

Our corporate headquarters are located in a single commercial facility in San Diego, California. Important documents and records, including copies of our regulatory documents and other records for our product candidates, are located at our facilities and we depend on our facilities for the continued operation of our business. Natural disasters and other catastrophic events, such as wildfires and other fires, earthquakes and extended power interruptions, which have impacted San Diego businesses in the past, and terrorist attacks or severe weather conditions, could significantly disrupt our operations and result in additional, unplanned expense. As a small company, we have limited capability to establish and maintain a comprehensive disaster recovery program and, accordingly, we do not have a formal business continuity or disaster recovery plan, and any natural disaster or catastrophic event could disrupt our business operations and result in setbacks to our development programs. Even though we believe we carry commercially reasonable insurance, we might suffer losses that are not covered by or exceed the coverage available under these insurance policies.

Risks Related to Drug Development and Commercialization

Further testing and validation of our product candidates and related manufacturing processes are required and regulatory approval may be delayed or denied, which would delay or prevent us from marketing our product candidates and substantially harm our business.

Human pharmaceutical products generally are subject to rigorous nonclinical testing and clinical studies and other approval procedures mandated by the FDA and foreign regulatory authorities. Various federal and foreign statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of pharmaceutical products. The process of obtaining these approvals and the subsequent compliance with appropriate U.S. and foreign statutes and regulations is time-consuming and requires the expenditure of substantial resources. In addition, these requirements and processes vary widely from country to country. Government regulation and the need for FDA and other regulatory agency approval will delay commercialization of our product candidates, impose costly procedures upon our activities, and may put us at a disadvantage relative to other companies with which we compete. There can be no assurance that FDA or any other regulatory agency will grant marketing approval for any of our product candidates on a timely basis, or at all, including due to factors not within our control. For example, federal government shut-down or budget sequestration, such as occurred during 2013, may result in significant reductions to the FDA s budget and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of or obtain approval for our product candidates.

Clinical studies typically involve a lengthy and expensive process with an uncertain outcome.

Clinical testing typically is expensive and can take years to complete, and its outcome is inherently uncertain. Clinical studies may not commence on time or be completed on schedule, if at all. The commencement and completion of clinical studies can be delayed for a variety of reasons, including difficulties and delays related to:

- obtaining regulatory approval to commence a clinical study;

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obtaining institutional review board, or IRB, approval to conduct a clinical study at a prospective site;

identifying appropriate study sites and reaching agreement on acceptable terms with prospective study sites and investigators, the terms of which can be subject to extensive negotiation and may vary significantly among study sites;

reaching agreement on acceptable terms with prospective contract research organizations, or CROs, for the conduct of clinical studies and contract manufacturing organizations, or CMOs, for the production of clinical trial material, the terms of which agreements can be subject to extensive negotiation and may vary significantly among different CROs and CMOs;

failures on the part of our CROs and CMOs in developing procedures and protocols or otherwise conducting activities on timelines requested by us;

identifying and hiring or engaging, as applicable, additional employees or consultants to assist us in managing CRO and/or CMO activities, managing a clinical study and analyzing the data resulting from a study;

recruiting and enrolling patients to participate in a clinical study;

manufacturing sufficient quantities of clinical trial material due, among other things, to lack of availability of capacity at a CMO or of the component materials, including the active pharmaceutical ingredient, or API;

having patients complete a study and/or return for and complete post-treatment follow-up; and

unforeseen results from other clinical studies or nonclinical testing that require us to amend a study design or halt or terminate a clinical study.

Patient enrollment, a critical component to successful completion of a clinical study, is affected by many factors, including the size and nature of the study subject population, the proximity of patients to clinical sites, the eligibility criteria for the study, the design of the clinical study, competing clinical studies and clinicians and patients perceptions as to the potential advantages of the drug being studied in relation to available alternatives, including therapies being investigated by other companies. Further, completion of a clinical study and/or its results may be adversely affected by failure to retain subjects who enroll in a study but withdraw due to adverse side effects, lack of efficacy, improvement in condition before treatment has been completed or for personal issues or who fail to return for or complete post-treatment follow-up.

In addition, a clinical study may be suspended or terminated by us, an IRB, a data safety monitoring board, the FDA or other regulatory authorities due to a number of factors, including:

failure to conduct the study in accordance with regulatory requirements or the study s protocol;

inspection of clinical study operations or sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

unforeseen safety issues, including adverse side effects;

changes in governmental regulations or administrative actions; or

lack of adequate funding to continue the study.

Changes in governmental regulations and guidance relating to clinical studies may occur and we may need to amend study protocols to reflect these changes, or we may amend study protocols for other reasons. Amendments may require us to resubmit protocols to IRBs for reexamination or renegotiate terms with CROs, study sites and investigators, all of which may adversely impact the costs or timing of or our ability to successfully complete a trial.

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Clinical studies may not begin on time or be completed in the timeframes we anticipate and may be more costly than we anticipate for a variety of reasons, including one or more of those described above. For example, although we expect to move MST-188 directly into phase 2 studies for most new indications we plan to pursue, an IRB or the FDA or another regulatory agency may require additional clinical or nonclinical studies prior to initiation of any planned phase 2 study, which likely would increase the total time and cost of development in that indication. The length of time necessary to complete clinical studies varies significantly and is difficult to predict accurately. We may make statements regarding anticipated timing for completion of enrollment in and/or availability of results from our clinical studies, but such predictions are subject to a number of significant assumptions and actual timing may differ materially for a variety of reasons, including patient enrollment rates and other factors described above. If we experience delays in the completion of a clinical study or if a clinical study is terminated, the commercial prospects for our product candidate may be harmed and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical studies likely will increase our development costs. Further, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may ultimately lead to the denial of regulatory approval of a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same indications may be introduced to the market in the interim and establish a competitive advantage or diminish the need for our products.

Positive results in nonclinical testing and prior clinical studies do not ensure that ongoing or future clinical studies will be successful or that our product candidates will receive the regulatory approvals necessary for their commercialization.

Before obtaining regulatory approval for the commercial sale of any of our product candidates, we must demonstrate through nonclinical testing and clinical studies that each product is safe and effective for use in each target indication. Based on extensive nonclinical testing, we believe we understand our product candidates respective mechanisms of action; however, previously observed pharmacologic effects and clinical benefits may not be observed in ongoing or future nonclinical or clinical studies. Success in nonclinical testing and prior clinical studies does not ensure that subsequent or larger-scale studies will be successful. For example, non-purified poloxamer 188 was tested in more than 2,000 human subjects in various indications before the program was discontinued, principally due to concerns regarding acute renal dysfunction observed in patients who received the study drug. In contrast, MST-188 was generally well-tolerated in seven completed clinical studies and no clinically significant changes in renal function were observed. However, patient safety concerns may be observed in ongoing or future clinical studies, including EPIC. With respect to efficacy, although there is compelling data from nonclinical and clinical studies of poloxamer 188 in multiple indications, ongoing and future studies may fail to demonstrate clinical benefits to human subjects.

Further, clinical study results frequently are susceptible to varying interpretations. Medical professionals, investors and/or regulatory authorities may analyze or weigh study data differently than we do. In addition, determining the value of clinical data typically requires application of assumptions and extrapolations to raw data. Alternative methodologies may lead to differing conclusions, including with respect to the safety or efficacy of our product candidates. For example, alternative methods for applying missing or imputed data may have impacted the treatment effect observed in the prior-sponsor phase 3 study of MST-188 in sickle cell disease. If regulatory authorities disagree with us as to the appropriate methods for analyzing study data, regulatory approval for our product candidates may be delayed, limited or withheld. For instance, despite positive nonclinical testing that indicated bioequivalence between ANX-514 and the reference product, Taxotere, our bioequivalence study of ANX-514 did not demonstrate bioequivalence between ANX-514 and Taxotere based on the FDA s benchmark regulatory standards and the FDA determined ANX-514 could not be approved based on the findings from that study.

In addition, if we license to third parties rights to develop our product candidates in other geographic areas or in other indications, we may have limited control over nonclinical testing or clinical studies that may be

conducted by such third-party licensees in those territories or indications. If data from third-party testing identifies a safety or efficacy concern, such data could adversely affect our or another licensee s development of our product candidates.

There is significant risk that our product candidates, including MST-188, could fail to show anticipated results in ongoing and future nonclinical testing and/or clinical studies and, as a result, we may elect to discontinue one or more of our development programs. A failure to obtain requisite regulatory approvals or to obtain approvals of the scope requested will delay or preclude us from marketing our products or limit the commercial use of the products, and would have a material adverse effect on our business, financial condition and results of operations.

We do not have, and do not have plans to establish, any manufacturing facilities and are dependent on third parties for the manufacture and supply of MST-188, and the loss of any of these manufacturers, or their failure to provide to us with an adequate supply of drug product in a timely manner and on commercially acceptable terms, or at all, could harm our business.

We do not have, and do not have plans to establish, our own manufacturing facilities. For clinical trial material, we have entered into supply agreements with third parties for both API and finished drug product, but our current agreements may not cover all of our clinical trial material needs and we may need to negotiate new or amended agreements with these CMOs or rely on individual proposals or statements of work, which inherently involves uncertainty as to ongoing supply and may result in delays in the completion of ongoing clinical studies or initiation of new studies. In addition, as development of our product candidates progress, we will need to negotiate agreements for commercial supply.

If we fail to maintain relationships with our current CMOs, we may not be able to complete development of our product candidates, including MST-188, or market them, if approved, on a timely basis, or at all, which would have a material and adverse effect on our business. Third-party manufacturers and suppliers may not perform as agreed or may terminate their agreements with us. For example, because these third parties provide manufacturing services to a number of other pharmaceutical companies, they may experience capacity constraints or choose to prioritize one or more of their other customers over us. Any significant problem that our manufacturers or suppliers experience could delay or interrupt our supply of clinical trial material or commercial product until the manufacturer or supplier cures the problem or until we locate, negotiate for and validate an alternative source of supply, if one is available.

In addition to our reliance on third parties to manufacture clinical trial material, we rely on them to conduct or assist us in conducting key manufacturing development activities, including qualification of equipment, developing and validating methods, defining critical process parameters, releasing component materials and conducting stability testing, among other things. If these third parties are unable to perform successfully in a timely manner, whether for technical, financial or other reasons, we may be unable to secure clinical trial material, which likely would delay the initiation, conduct or completion of our clinical studies, which, in turn, likely would have a material and adverse effect on our business.

All manufacturers of our clinical trial material and, as applicable, commercial product, including API manufacturers, must comply with cGMP requirements enforced by the FDA through its facilities inspection program and applicable requirements of foreign regulatory authorities. These requirements include quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our clinical trial material may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. While we or our representatives generally monitor and audit our manufacturers systems, we have little control over their ongoing compliance with these regulations. Failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product

approval.

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Currently, we do not have alternative sources to backup our primary sources of clinical trial material. Therefore, if our primary sources become unable or unwilling to perform, we could experience protracted delays or interruptions in the supply of clinical trial material and, ultimately, product for commercial sale, which could materially and adversely affect our development programs, commercial activities, operating results and financial condition. For example, if we are unable to maintain our relationship with our current supplier of MST-188 API, we may be unable to identify or establish a relationship with an alternate CMO that has the technical capabilities and desire to perform the development and supply services that we require for MST-188 API on commercially reasonable terms, or at all. Production of the API in MST-188 requires application of our proprietary fluid extraction process. This extraction process is complex and requires highly specialized equipment and there are a limited number of CMOs capable of performing and willing to perform the process as we require, which makes identifying and establishing relationships with CMOs more difficult and may provide them with leverage over us in any negotiations. In addition, we use commercially-available poloxamer 188 as API starting material. There are a limited number of sources of poloxamer 188, and we are not aware of any that currently manufacture it to cGMP requirements applicable to API. The current supplier of our MST-188 API starting material manufactures it under excipient-grade cGMP conditions. Prior to approval of MST-188, the FDA or other regulatory agencies may require our API starting material to be manufactured consistent with cGMP requirements applicable to API, in which case regulatory approval and commercialization of MST-188 could be delayed significantly and require substantial additional financial resources as we seek to contract with a third party to manufacture poloxamer 188 consistent with cGMP requirements applicable to API or undertake to manufacture it ourselves, and conduct any additional clinical or nonclinical activities with such material as the FDA may require. Even if the FDA accepts our current approach with respect to API starting material, we do not have any control over its production and the third-party supplier may change its manufacturing process and/or limit the availability of its poloxamer 188 product in the future. If the supplier makes changes to its poloxamer 188 product, the FDA may determine that it is not acceptable API starting material and we may have difficulty obtaining an alternate supply of API starting material that the FDA finds acceptable without our conducting additional clinical or nonclinical activities or taking other remedial measures, which could require substantial time and financial resources. As a result, we