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Filed pursuant to Rule 424(b)(2)
Registration No. 333-211489

PROSPECTUS SUPPLEMENT
(to Prospectus dated August 16, 2017)

9,000,000 Shares
TYME TECHNOLOGIES, INC.



Common Stock

We are offering 9 million shares of our common stock, par value \$0.0001 per share.

Our common stock is listed on The Nasdaq Capital Market under the symbol "TYME." On March 1, 2018, the last reported sales price for our common stock was \$2.77 per share.

Investing in our common stock involves risks. See "[Risk Factors](#)" beginning on page S-9 of this prospectus supplement and the discussion of risk factors contained in the reports we file with the Securities and Exchange Commission that are incorporated by reference into this prospectus supplement and the accompanying prospectus.

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 share	Total
Public Offering Price	\$ 2.25	\$20,250,000
Underwriting Discounts ⁽¹⁾	\$0.135	\$ 1,215,000
Proceeds to Tyme, Before Expenses	\$2.115	\$19,035,000

⁽¹⁾ We refer you to the section entitled "[Underwriting](#)" beginning on page S-21 of this prospectus supplement for additional information regarding total underwriter compensation.

The underwriters have the option to purchase up to 1,350,000 additional shares from us at the initial price to public less the underwriting discount.

Delivery of the shares of common stock is expected to be made on or about March 6, 2018.

Book-Running Managers

Evercore ISI

Stifel

Canaccord Genuity

Co-Manager

H.C. Wainwright & Co.

The date of this prospectus supplement is March 1, 2018.

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We are responsible for the information contained and incorporated by reference in this prospectus supplement, in any accompanying prospectus, and in any related free writing prospectus we prepare or authorize. We have not authorized anyone to provide you with information different from that contained in this prospectus supplement, the accompanying prospectus or any authorized free writing prospectus, and we take no responsibility for any other information that others may give you. We are offering to sell, and seeking offers to buy, common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus supplement, the accompanying prospectus and any authorized free writing prospectus is accurate only as of the date of this prospectus supplement, the accompanying prospectus and any such authorized free writing prospectus, regardless of the time of delivery of this prospectus supplement, the accompanying prospectus, any such authorized free writing prospectus or of any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and any free writing

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prospectus that we have authorized for use in connection with this offering, in their entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the sections of this prospectus supplement entitled “Where You Can Find More Information” and “Incorporation of Documents by Reference.”

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[Table of Contents](#)**ABOUT THIS PROSPECTUS SUPPLEMENT**

This prospectus supplement and the accompanying prospectus relate to the offering of shares of our common stock. Before buying any shares of our common stock offered hereby, we urge you to carefully read this prospectus supplement and the accompanying prospectus, together with the information incorporated herein and therein by reference as described under the headings “Where You Can Find More Information” and “Incorporation of Certain Documents by Reference.” These documents contain important information that you should consider when making your investment decision.

On May 19, 2016, we filed with the Securities and Exchange Commission, or SEC, a registration statement on Form S-3 (File No. 333-211489), as amended on August 8, 2017 utilizing a shelf registration process relating to the securities described in this prospectus supplement, which registration statement became effective on August 16, 2017. Under this shelf registration process, we may, from time to time, sell common stock and other securities, including those included in this offering.

This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of this offering of common stock and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into the prospectus and this prospectus supplement. The second part, the accompanying prospectus dated August 16, 2017, including the documents incorporated by reference therein, gives more general information, some of which does not apply to this offering. Generally, when we refer to this prospectus, we are referring to both parts of this document combined.

If the description of the offering varies between this prospectus supplement and the accompanying prospectus, you should rely on the information contained in this prospectus supplement. However, if any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference—the statement in the document having the later date modifies or supersedes the earlier statement. In particular, with respect to any information contained in this prospectus supplement, on the one hand, and information in the accompanying prospectus or documents incorporated by reference, on the other hand, the information in this prospectus supplement shall control.

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 prospectus supplement or 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.

The industry and market data and other statistical information contained herein or in the documents we incorporate by reference are based on management’s own estimates, independent publications, government publications, reports by market research firms or other published independent sources and, in each case, are believed by management to be reasonable estimates. Although we believe these sources are reliable, we have not independently verified the information.

Unless we have indicated otherwise, or the context otherwise requires, references in this prospectus supplement and the accompanying prospectus to “Tyme,” “the Company,” “we,” “us” and “our” or similar terms refer to Tyme Technologies, Inc. and its consolidated subsidiaries.

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[Table of Contents](#)**PROSPECTUS SUPPLEMENT SUMMARY**

This summary highlights information contained elsewhere or incorporated by reference in this prospectus supplement and the accompanying prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our common stock. You should read this entire prospectus supplement and the accompanying prospectus carefully, including the sections titled "Risk Factors" contained in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein, our financial statements and the related notes thereto and the other documents incorporated by reference in this prospectus supplement and the accompanying prospectus.

Our Company

We are a clinical-stage biotechnology company developing novel cancer therapeutics that are intended to be effective across many tumor types with low toxicity profiles. Our lead clinical program, SM-88, is a first-in-class combination therapy that has shown what we believe to be promising data in our First Human Study ("FHS"), an initial first-in-human monotherapy single arm study of 30 end-stage metastatic patients across a number of cancer types, as well as an ongoing Phase Ib/II trial in biomarker-recurrent prostate cancer. Our FHS involved 30 patients that had failed or refused available treatment options and had undergone what we believe was an appropriate washout period from prior therapy prior to enrolling in the study. We believe each FHS patient was estimated by his or her treating physicians to have three-to-six months to live.

In October 2017, we announced that we had completed a long-term follow-up analysis of patients from the FHS, who were originally enrolled during 2012. Patients achieved median overall survival ("OS") to 29.8 months and a 33% objective response rate ("ORR") while on monotherapy, consisting of four complete responses ("CR") and six partial responses ("PR"), based on Response Evaluation Criteria In Solid Tumors 1.1 ("RECIST"), which sets forth certain criteria for assessing treatment outcomes. Five FHS patients survived for over five years after commencing SM-88 treatment. All FHS patients improved or maintained Eastern Cooperative Oncology Group Performance Status ("ECOG PS"), a measure of quality of life, after initiating SM-88 therapy and overall survival was comparable for patients who entered the trial with ECOG PS ranging from 0 (asymptomatic) to 2 (unable to perform any work-related activities).

We have also reported multiple subgroup analyses of FHS patients. As of September 2017, 67% of FHS patients were reported to have had no additional systemic therapies since their initial enrollment in FHS in 2012, including all five of the surviving FHS patients. Patients without any further treatment beyond SM-88 showed greater mean and median OS (37 and 38 months, respectively) than patients who received subsequent treatments beyond SM-88 (30 and 28 months, respectively). Regarding therapies prior to SM-88, patients with two or more prior systemic therapies experienced a median OS of 23 months, including two CRs and three PRs after beginning SM-88 therapy. For the three most common cancer types in the FHS, we reported median and mean OS for the following patients by cancer type: breast cancer, 35 and 36 months (n=14); lung cancer, 25 and 30 months (n=5); and pancreatic cancer, 24 and 24 months (n=3). In the breast cancer subgroup, median OS of 35 months was achieved despite patients having an average of 2.5 prior lines of systemic drug therapy and 4.5 prior therapeutic lines, including systemic, surgical or radiation therapy. 43% of patients in the breast cancer subgroup achieved CR or PR while on SM-88 monotherapy and ECOG PS average baseline improved from 1.8 to 0.6 after six weeks of SM-88 therapy. Additionally, after having stopped SM-88 treatment in the FHS, three breast cancer patients received additional treatment with SM-88 at a later time and all three of such patients were alive as of the last reported data in October 2017. One of the re-treated patients experienced a second objective tumor response from SM-88 monotherapy as measured by RECIST criteria.

We believe that traditional RECIST response criteria, a commonly used clinical endpoint based primarily on static images, may not fully reflect the therapeutic benefit from SM-88 and that measuring metabolic function

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through positron emission tomography (“PET”) imaging may more accurately correlate the effect of SM-88. For example, one of the Surviving FHS Patients showed metabolically inactive target lesions using PET imaging after six weeks of monotherapy with SM-88 while still being designated RECIST stable disease (“SD”), indicating a mass was still present on imaging. This patient continued on SM-88 and, after 15 months, was determined to be a RECIST CR, indicating the mass was no longer present. This timeline may be associated with SM-88’s mechanism of action causing tumor cell death, as demonstrated by a lack of metabolic activity, prior to the clearance of those cells. In total, 17 of the 30 patients in the FHS achieved SD with median OS of 29.0 months. Because we believe many patients on SM-88 experience therapeutic benefit without necessarily achieving a CR or PR under RECIST criteria, we commonly refer to “Clinical Benefit,” which includes CR, PR and SD designations.

Additionally, as of March 31, 2017, 76 patients had been treated outside of the FHS with SM-88 (the “Compassionate Use Patients”) as part of a compassionate use program under Institutional Review Board (“IRB”) supervision. In early 2016, we performed a retrospective analysis on the first 53 (of 76) Compassionate Use Patients that had received treatment, which was later updated to 57 patients, including three additional pancreatic patients and one prostate patient. These patients had their scans reviewed by two independent radiologists to determine response under RECIST, and 79% of these patients (45 of 57) were deemed to have experienced Clinical Benefit, consisting of eight CRs, 19 PRs and 18 SD designations.

Through these two programs, patients being treated with SM-88 have achieved CRs or PRs across 13 different cancer types, including some of the most common and difficult to treat cancers, such as pancreatic, prostate, breast, lung, glioma, ovarian, sarcoma and colon cancer. For additional detail concerning these two studies, see “—SM-88: First Human Study” and “—SM-88: Compassionate Use Program Overview.” As of the release of the interim results in September 2017, SM-88 had not been associated with any drug-related moderate or severe adverse events (“AEs”). Based on preliminary data from the FHS and the Compassionate Use Patients suggesting SM-88 may have broad potential applicability and acceptable toxicity, we believe that SM-88 may ultimately be utilized as a treatment for a wide range of cancers prior to the end-stage setting.

SM-88 Mechanism of Action

SM-88 is an oral, combination therapy with our proprietary dysfunctional tyrosine derivative as the backbone. Tyrosine is a non-essential amino acid that has a high affinity for cancer cells, but has minimal uptake by healthy cells. The tyrosine derivative used in SM-88 is designed to interact with a cancer cell as if it were a functional tyrosine but cause, after uptake, any cellular process within the cancer cell using the tyrosine derivative, such as protein synthesis, to fail. The other active components of SM-88 are rapamycin, methoxsalen, and phenytoin, which are used to complement and augment the activity of the tyrosine derivative and ultimately cause apoptosis of the cancer cells as a result of oxidative stress. Each of these three non-tyrosine components have been FDA approved for other uses and are each administered at doses that are approximately 25% or less than their recommended therapeutic dosing levels for their approved indications. These four components are being individually orally administered to patients according to a dosage regimen in our Phase Ib/II trial described below. We believe the effectiveness of our tyrosine derivative in effecting cancer cell death is enhanced by combining it with small doses of the aforementioned three repurposed agents, which we believe may increase the uptake of the tyrosine derivative and enhance oxidative stress on the tumor cells.

SM-88 is intended to disrupt the cancer cell’s unique microenvironment following uptake of our tyrosine derivative. We believe that when the cancer cell attempts to use the dysfunctional tyrosine derivative for protein synthesis to create mucin, the process fails and the mucin layer begins to deteriorate. Mucin acts as a protective layer around the cancer cell that defends the tumor from the elements in the body outside the cancer cell. Without a stable protective coating from mucin, tumor cells become exposed to the host immune system. This can result in a heightened state of oxidative stress, when the number of free-radicals, or reactive oxygen species (“ROS”),

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increases to a level that is dangerous to the survival of the cancer cell. ROS can cause catastrophic cancer cell damage, leading to apoptosis, by pulling electrons from otherwise stable molecules, such as DNA or proteins.

Currently Enrolling Phase Ib/II Prostate Cancer Trial

We are currently enrolling an open-label single arm monotherapy Phase Ib/II trial in localized non-metastatic prostate cancer for biomarker-recurrent maintenance therapy. This six-month multi-center, open label study is expected to enroll approximately 34 subjects with biomarker-recurrent prostate cancer who have rising Prostate Specific Antigen (“PSA”) levels and no radiographically detectable lesions. Subjects receive daily oral doses of SM-88. Efficacy endpoints include radiographic progression free survival, reductions in circulating tumor cells (“CTCs”) or the need for subsequent chemotherapy or androgen deprivation therapy (“ADT”), and PSA doubling time. We completed our Phase Ib trial in January 2017, and we expect to complete our Phase II trial in prostate cancer in the second half of 2018.

As presented at the American Society of Clinical Oncology (“ASCO”) Genitourinary meeting in February 2018, of the 19 prostate cancer subjects consented in our Phase II trial, 13 subjects have received study medication with evaluable results and 12 have completed at least one 28-day cycle (median 6, range 1-16) of therapy. While on therapy, eight subjects had a greater than 50% reduction in CTCs, five subjects had less than 5 cells per 7.5ml of blood and five subjects had at least one measure reported as undetectable. The median time to achieving an undetectable level of CTCs was 20 weeks (with a range of three to 28 weeks). PSA levels similarly demonstrated positive trends, with 92% (12/13) of subjects having at least one cycle in which PSA velocity improved (i.e. at least one decrease in PSA). The median time since biologic recurrence of the trial subjects, as of December 2017, was 12 months. Radiographic recurrence was observed in only 8% (1/13) of trial subjects. All reported drug-related and possibly drug-related adverse events have been mild in nature (grade one), and none of the subjects required ADT or chemotherapies during treatment.

SM-88: First Human Study

Our 30-subject FHS study was initially designed for a three-month period to determine safety of SM-88 in the end-stage treatment setting. When multiple patients showed Clinical Benefit under RECIST criteria, treatment was continued for some patients for multiple years. This study was conducted under IRB supervision without FDA approval of an investigational new drug application (“IND”). We believe our FHS indicated that SM-88 was well-tolerated and showed preliminary activity across a number of different cancer types in terms of tumor regression, biomarker improvement, and overall survival. Summary results of the FHS as assessed through October 2017 are shown below:

Summary of Completed First in Human Monotherapy Study

Summary of Completed First Human Study

Population	30 progressive metastatic cancer subjects who had failed or refused available treatments. Physician estimated survival of 3-6 months
Treatment	Monotherapy with SM-88 after wash-out of prior therapy
Results	Overall Survival: Median of 29.8 months <ul style="list-style-type: none"> • Median overall survival of 29.0 months in patients achieving stable disease (n=17) 33% Objective Response Rate: Including four complete responses and six partial responses <ul style="list-style-type: none"> • 90% Clinical Benefit based on RECIST criteria
Safety	No drug-related serious AEs and few grade 1 or 2 AEs

[Table of Contents](#)**SM-88: Compassionate Use Program Overview**

As of March 31, 2017, SM-88 has been used with 76 Compassionate Use Patients under IRB oversight. This treatment regimen was initiated in 2012 using a protocol similar to the FHS protocol initiated in January 2012, with the most significant difference being the initiation of SM-88 to advanced-stage Compassionate Use Patients without a washout period from prior therapy. Nearly all the Compassionate Use Patients enrolled had metastatic disease, had failed or refused other possible available therapies and were treated with SM-88 in monotherapy. We were generally able to regularly receive detailed information on the treatment of Compassionate Use Patients; however, there may have been, and may continue to be, variations in the treatment administration as the treating physicians deem appropriate.

Retrospective Review of Pancreatic Patients Treated with SM-88

At the January 2018 ASCO Gastrointestinal annual meeting, we presented a retrospective review of the pancreatic cancer subjects treated through our FHS or as Compassionate Use Patients. Overall, of the 107 subjects treated in these programs, 12 patients with metastatic pancreatic cancer have received SM-88 therapy. Two of these 12 patients received less than one cycle (six weeks) of SM-88 and were excluded from this analysis. Of the remaining ten patients, three were from the FHS and seven were Compassionate Use Patients. We believe all subjects were considered incurable, with 70% (7/10) of these patients having progressive disease and 30% (3/10) having recurrent disease. These patients had also failed or refused other available therapies. The median baseline ECOG PS of patients was two at baseline and had improved by 20% to one within six weeks of SM-88 therapy initiation. In contrast to current standard of care therapies for pancreatic cancer, which produce serious adverse events in more than half of patients, ultimately, 80% (8/10) of SM-88 treated patients showed improvements in ECOG PS and 30% (3/10) had a greater than one point improvement. Median pain (as per NRS-11) reported by these patients improved from 3 at baseline to 0 at the end of the first SM-88 cycle. The range of pain scores also decreased from 0 – 7.5 points at baseline to 0 – 2.5 points at six weeks. While on therapy, 60% (6/10) of patients gained weight and 40% (4/10) maintained their weight. Additionally, all patients maintained or improved EORTC subject reported outcomes for health (QLQ-C30 #29) and quality of life (QLQ-C30 #30) after initiating SM-88 therapy. Despite treating patients with a range of 0 to 6 lines of prior therapy, patients experienced a median progression free survival of 4.6 months. 40% (4/10) of these patients experienced an overall survival greater than 12 months and 30% (3/10) achieved a complete or partial response under RECIST criteria. One patient whose cancer was progressing while receiving traditional chemotherapy treatment experienced a partial response when SM-88 was added. We are preparing a Phase II clinical trial for the treatment of pancreatic cancer that we expect will initiate in the first half of calendar year 2018.

Planned Phase II Trial for Pancreatic Cancer

Pancreatic cancer is one of the deadliest major cancers, with a one-year survival rate of 20% at diagnosis according to the American Cancer Society. The poor prognosis is partially due to more than 80% of cases being metastatic at the time of diagnosis. When patients with pancreatic cancer are refractory to first line therapy – as were all 12 patients with pancreatic cancer that were treated in our FHS and compassionate use program – survival is often only a few months and clinical response rates are very low. Because of our encouraging initial results described above and the dire state of the disease, we are preparing to initiate a Phase II trial in refractory pancreatic cancer patients during the first half of 2018. On September 29, 2017, we submitted an SM-88 IND to the FDA for pancreatic cancer patients. We are in discussions with the FDA to study eligibility criteria, patient disclosures and monitoring for potential known toxicities from the three approved drugs in SM-88 and their combined usage with tyrosine, based on specific requests from the FDA. While we currently expect to commence this trial in the first half of calendar year 2018, there is no assurance that this IND will become effective or that we will be able to commence the proposed study on time or at all.

[Table of Contents](#)**Other Clinical and Development Plans**

We intend to focus on expanding our clinical activities to certain late-stage cancer patient populations that have generally failed or refused all possible therapies with curative intent. We believe this strategy combines our objectives to address substantial unmet need with a more clear and rapid regulatory pathway. We believe lung, breast, bone and brain cancers may be appropriate additional indications given the demonstrated effect of SM-88 on these cancer types in our FHS and Compassionate Use Patients.

We intend to initiate additional Phase II studies in these or other cancers as resources become available, with no company-sponsored Phase III studies currently being planned. We may also develop other products for oncology using alternate delivery platforms as well as alternate product compositions. SM-88 is generally intended as an oral therapy that is broadly applicable to cancers; however, alternate routes of delivery may be more appropriate for use by certain patients or as treatment for certain types of cancer. For example, we have developed an injectable formulation that may be beneficial for patients with a compromised digestive system and as a result are not able to absorb the oral formulation. Confronted with this situation, applicable end-stage First Human Study patients were administered with small SM-88 subcutaneous doses in combination with an oral SM-88 dose to ensure absorption and we believe treating physicians for SM-88 Compassionate Use Patients also treated these end-stage patients with SM-88 by subcutaneous and/or oral delivery. We also have other alternative formulations, at various stages of development, such as transdermal and nasal, that we believe could provide an effective alternative therapeutic effect for patients with certain forms of cancer, including breast cancer and glioblastoma.

Intellectual Property

Tyme has five issued U.S. patents and eight patents issued outside of the United States, with over 60 patent applications worldwide. The earliest U.S. patent expires in 2032. Four of the five U.S. issued patents relate to SM-88, including various methods and alternative formulations. Filed patent applications include additional metabolic approaches as well as hormonal and transdermal techniques. We have and will continue to seek U.S. and international patent protection for a variety of technologies, including: pharmaceutical compositions, methods for treating diseases of interest, methods for manufacturing the pharmaceutical compositions and research tools and methods. We also intend to seek patent protection or rely upon trade secret rights to protect other technologies that we may develop that may be used to discover and validate targets, and those that may be used to identify and develop novel products. We will also seek protection, in part, through confidentiality and proprietary information agreements.

Corporate Governance Developments

Our Board of Directors and holders of a majority of the Company's outstanding common stock have approved changes to our certificate of incorporation that (a) implement a classified Board of Directors, (b) authorize the Board of Directors to exclusively fill any and all vacancies occurring on our Board of Directors, (c) authorize our Board of Directors to exclusively have the power to change, and set, the size of our Board of Directors and (d) authorize our Board of Directors to have the exclusive power to call a special meetings of our stockholders. Additionally, our Board of Directors may pursue certain other structural defenses such as a stockholder rights plan. Our Board of Directors reserves the right to modify or abandon the changes to our certificate of incorporation at any time prior to their effective date. As of the date of this prospectus supplement, directors and executive officers of the Company beneficially owned approximately 59.6% of the Company's outstanding common stock. As a result, the changes to our certificate of incorporation have been approved by our Co-Founders, which is sufficient to implement approval of such proposals under applicable law. Additionally, the approval of potential governance proposals by our Board of Directors and our executive officers would be sufficient to implement these proposals under applicable law. See "Risk Factors—Additional Risks Related to

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This Offering—*The ownership interests in our Company held by two co-founders who serve as executive officers and directors before and immediately after the offering will allow them to significantly influence corporate decision-making in a manner that may not reflect the interests of all of our stockholders.*”

At-the-Market Sales of Common Stock

On November 2, 2017, we entered into an equity distribution agreement with Canaccord Genuity Inc. (“Canaccord”), pursuant to which we may, from time to time, sell shares of our common stock having an aggregate offering price of up to \$30,000,000 through Canaccord, as our sales agent, in an at-the-market offering (the “ATM Financing Facility”). Since initiation, we have sold 1,543,364 shares of our common stock under this equity distribution agreement for net proceeds of \$5,967,415 and paid Canaccord aggregate commissions of \$184,559.

Corporate Information

We are incorporated under the laws of the State of Delaware. Our principal executive office is located at 44 Wall Street, 12th Floor, New York, New York 10005. Our telephone number is (646) 205-1603. Our website address is www.tymeinc.com. The information contained on our website is not a part of or incorporated by reference into this prospectus supplement or the accompanying prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our securities offered in this prospectus.

“Tyme,” the Tyme logo and other trademarks or service marks of the Company appearing in this prospectus are the property of Tyme Technologies, Inc. This prospectus supplement or the accompanying prospectus contain additional trade names, trademarks and service marks of others, which are the property of their respective owners.

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THE OFFERING	
Common stock offered by us	9,000,000 shares (or 10,350,000 shares if the underwriters' option to purchase additional shares is exercised in full).
Shares of common stock to be outstanding immediately after this offering⁽¹⁾	99,800,723 shares (or 101,150,723 shares if the underwriters' option to purchase additional shares is exercised in full).
Use of proceeds	We will retain broad discretion over the use of the net proceeds from the sale of the securities offered hereby. We currently intend to use the net proceeds from the sale of the securities offered hereby for research and further development of SM-88 and for general corporate purposes, including capital expenditures working capital and general and administrative expenses. We may also use a portion of the net proceeds to acquire or invest in businesses, products and technologies that are complementary to our own, although we have no current plans, commitments or agreements with respect to any acquisitions as of the date of this prospectus supplement. Please see the section entitled " Use of Proceeds " on page S-14 of this prospectus supplement.
Risk factors	Investing in our common stock involves a high degree of risk. You should carefully read and consider the information set forth under " Risk Factors " on page S-9 of this prospectus supplement and page 11 of the accompanying prospectus and in the documents incorporated by reference herein and therein to read about factors you should consider before buying shares of our common stock.
Common stock symbol	Our common stock is listed on the Nasdaq Capital Market under the symbol "TYME."
Lock-Up agreements	Our directors and executive officers have agreed with the underwriters that, without the prior written consent of Evercore and Stifel, Nicolaus & Company, Incorporated subject to certain exceptions, they will not, for a period of 90 days following the date of this prospectus supplement, offer or contract to sell any of our common stock. See " Underwriting " on page S-21 of this prospectus supplement.
<p>(1) The number of shares of common stock to be outstanding immediately after this offering is based on 90,800,723 shares outstanding on December 31, 2017 and excludes the following as of that date:</p> <ul style="list-style-type: none"> • outstanding options representing the right to purchase a total of 5,240,120 shares of common stock at a weighted average exercise price of \$5.22 per share, which were issued under our 2015 Equity Incentive Plan and 2016 Stock Option Plan for Non-Employee Directors; • outstanding warrants representing the right to purchase a total of 5,625,641 shares of common stock at a weighted-average exercise price of \$3.34 per share; 	

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- 5,382,042 shares of common stock reserved for future issuance pursuant to awards that have not been made under our 2015 Equity Incentive Plan and 2016 Stock Option Plan for Non-Employee Directors; and
- shares of common stock that may be issued pursuant to our \$30 million ATM Financing Facility, under which \$24,069,120 of availability remained at December 31, 2017.

Except as otherwise noted, all information in this prospectus supplement assumes no exercise of the underwriters' option to purchase additional shares.

[Table of Contents](#)**RISK FACTORS**

An investment in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should consider carefully the risks described below and discussed under the section captioned "Risk Factors" contained in this prospectus supplement and the accompanying prospectus, together with other information in this prospectus supplement, the accompanying prospectus, the information and documents incorporated by reference herein and therein, and in any free writing prospectus that we have authorized for use in connection with this offering. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

Additional Risks Related to This Offering

Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.

The public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock as of December 31, 2017, before giving effect to this offering. Accordingly, if you purchase our common stock in this offering, you will incur immediate and substantial dilution of approximately \$1.97 per share, representing the difference between the public offering price of \$2.25 per share and our pro forma as adjusted net tangible book value as of December 31, 2017. Furthermore, if outstanding options or warrants are exercised, you could experience further dilution. For a further description of the dilution that you will experience immediately after this offering, see the section in this prospectus supplement entitled "[Dilution](#)" beginning on page S-15.

Additionally, In order to raise additional capital, we may in the future offer additional shares of our common stock, including pursuant to the ATM Financing Facility, at prices that may not be the same as the price per share in this offering. If we issue additional shares of our common stock, including pursuant to the ATM Financing Facility, you could experience further dilution.

Our management will have broad discretion over the use of the net proceeds from this offering, and you may not agree with how we use the proceeds and the proceeds may not be invested successfully.

Our management will have broad discretion as to the use of the net proceeds from this offering and could use them for purposes other than those contemplated at the time of this offering. We will retain broad discretion over the use of the net proceeds from the sale of the securities offered hereby. We currently intend to use the net proceeds from the sale of the securities offered hereby for research and further development of SM-88 and for general corporate purposes, including capital expenditures working capital, and general and administrative expenses. We may also use a portion of the net proceeds to acquire or invest in businesses, products and technologies that are complementary to our own, although we have no current plans, commitments or agreements with respect to any acquisitions as of the date of this prospectus supplement. Accordingly, you will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds will be used appropriately. It is possible that the proceeds will be invested in a way that does not yield a favorable, or any, return for Tyme and cause the price of our common stock to decline.

The ownership interests in our Company held by our two co-founders who serve as executive officers and directors will allow them to significantly influence corporate decision-making in a manner that may not reflect the interests of all of our stockholders and one of such executive officers has license rights to certain of our patents and patent applications outside of cancer which may allow him to use our IP in ways that could be inconsistent with ours.

Steve Hoffman, our Chief Executive Officer, Chief Science Officer and a director, and Michael Demurjian, our Chief Operating Officer, Executive Vice President and a director (collectively, our "[Co-Founders](#)"), each

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owned more than 29% of our outstanding common stock as of the date of this prospectus supplement. It is expected that Messrs. Hoffman and Demurjian will also continue to own more than a majority of Tyme's common stock in the aggregate immediately following completion of this offering after giving effect to the terms herein. As a result, these individuals are positioned to exercise significant influence over our Company's management and affairs, including, but not limited to, electing members of our board of directors and exercising managerial influence and voting rights in connection with structural defenses and anti-takeover measures, and fundamental corporate transactions, and they may take action that may not reflect the best interests of all of the stockholders of our Company. See "Prospectus Supplement Summary—Corporate Governance Developments."

Further, the Company has granted Mr. Hoffman perpetual, exclusive non-royalty bearing license rights with respect to certain patents and patent applications that the Company uses for SM-88 in all fields other than in connection with the treatment of cancer. This license to Mr. Hoffman may limit the Company's ability to profit from alternative uses of SM-88, were such uses to be discovered. Further, the use of the patents or patent applications that are used for SM-88 could be associated with a negative event outside of the control of the Company and outside the treatment of cancer, which in either case may have an adverse effect on our business.

Sales of a significant number of shares of our common stock in the public markets, or the perception that such sales could occur, could depress the market price of our common stock.

Sales of a substantial number of shares of our common stock in the public markets could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities. A significant portion of our outstanding common stock is eligible for immediate resale in the public market. Our directors and our executive officers have agreed not to sell, dispose of or hedge any common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus supplement continuing through and including the date 90 days after the date of this prospectus supplement, subject to certain exceptions. We may also choose, following the completion of the 90-day lock-up period, to sell additional shares of our common stock pursuant to our ATM Financing Facility. Evercore Group L.L.C. and Stifel, Nicolaus & Company, Incorporated may, in their sole discretion, release the restrictions on any such shares at any time without notice.

Additionally, each of our Co-Founders has entered into an individual written trading plan (a "10b5-1 Plan") allowing for scheduled sales between February 2018 and January 2019 by each co-founder of a maximum of one million shares of our common stock (subject to weekly volume limitations), which represents, in the aggregate, approximately 2.2% of our outstanding common stock as of the date of this prospectus supplement. Under the 10b5-1 Plans, each of our Co-Founders will sell shares in one or more transactions, if the market price for our common stock reaches or exceeds certain minimum price thresholds specified in their respective 10b5-1 Plan.

We cannot predict the effect that future sales (or the perception of possible future sales) of our common stock would have on the market price of our common stock.

Additional Risks Related to Our Business and the Development, Regulatory Approval, and Commercialization of Our Drug Candidates.

In late September 2017, we submitted an SM-88 IND to the FDA for pancreatic cancer patients. We are engaged in a dialogue with the FDA on this submission that is ongoing and has included certain requests by the FDA regarding the proposed study, including with respect to study eligibility criteria, patient disclosures, and monitoring for potential known toxicities from the three approved drugs included in SM-88 and their combined usage with tyrosine. We are in the process of responding to these requests and, while we currently expect to commence this trial in the first half of calendar year 2018, the IND will not become effective until these requests are resolved and there is no assurance that FDA will permit the IND to become effective or that we will be able to commence the proposed study on time or at all. Even if the FDA allows the IND to become effective, our protocol is subject to review by an IRB at each trial site before we can commence our planned trial, which could

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result in delays. If we experience any delay from the FDA in commencing (or cannot commence) our planned pancreatic clinical trial, or are unable to establish clinical trial sites, we may incur significant expense and losses related to such developments, which could have an adverse effect on our prospects, our ability to advance other clinical trials, our ability to deploy a portion of the planned proceeds from this offering to advance our business plan, and the value of our common stock.

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[Table of Contents](#)**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus supplement and the information set forth in the accompanying prospectus and incorporated by reference in this prospectus supplement contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act that involve substantial risks and uncertainties. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, these forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements.

Forward-looking statements can be identified by the use of forward-looking words such as “believes,” “expects,” “hopes,” “may,” “will,” “plan,” “intends,” “estimates,” “could,” “should,” “would,” “continue,” “seeks,” “pro forma,” or “anticipates,” or other similar words (including their use in the negative), or by discussions of future matters such as the development of new products, technology enhancements, possible collaborations, the timing, scope and objectives of our planned clinical trials and other statements that are not historical. These statements include, but are not limited to, statements under this caption and under “Risk Factors” in this prospectus supplement and in the accompanying prospectus and under the captions “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” incorporated by reference from our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as applicable, as well as our other filings with the SEC. You should be aware that the occurrence of any of the events discussed herein under the heading “Risk Factors” or in the accompanying prospectus and any documents incorporated by reference herein or therein could substantially harm our business, operating results and financial condition and that if any of these events occurs, it could adversely affect the value of an investment in our securities.

Forward-looking statements include statements about:

- the success, cost, and timing of our ability to obtain and maintain regulatory approval of SM-88;
- our drug development plans and strategies;
- our completed studies;
- proposed timing of ongoing and planned clinical trials;
- preliminary data results and the therapeutic design and mechanisms of our drug candidates;
- our planned use of proceeds from this offering;
- our ability to successfully commercialize SM-88, if approved;
- the rate and degree of market acceptance of SM-88, if approved;
- our estimates of our expenses, losses, future revenue and capital requirements and our needs for or ability to obtain additional financing, including funding needed to advance or complete our clinical trials, commercialization and marketing;
- our ability to obtain and maintain intellectual property protection for SM-88 and our ability to operate our business without infringing on the intellectual property rights of others;
- our ability to identify and develop new product candidates;
- our ability to identify, recruit and retain key personnel and collaborators;
- our ability to raise capital on terms acceptable to us, or otherwise;
- our financial performance; and
- developments relating to our competitors and our industry.

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The forward-looking statements referred to above are subject to uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any historical results and future results, performances or achievements expressed or implied by such forward-looking statements. These risks, uncertainties and other factors include, but are not limited to:

- that the information is of a preliminary nature and may be subject to change;
- uncertainties inherent in research and development, including the ability to achieve clinical study start and completion dates;
- the possibility of unfavorable study results, including unfavorable new clinical data and additional analyses of existing data;
- risks associated with early, initial data, including the risk that the final Phase II data may differ from prior study data or preliminary Phase II data;
- risks identified under “Risk Factors” herein or in any filing we make under the Exchange Act or the Securities Act;
- final results of additional clinical trials that may be different from the preliminary data analysis and may not support further clinical development;
- that the data set forth in this prospectus supplement are not necessarily predictive of future patient or clinical data outcomes;
- whether and when any applications or other submissions for SM-88 may be filed with regulatory authorities;
- whether and when regulatory authorities may approve any applications or submissions;
- decisions by regulatory authorities regarding labeling and other matters that could affect commercial availability of SM-88; and
- competitive developments.

You should refer to the sections titled “Risk Factors” in this prospectus supplement and the accompanying prospectus 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. As a result of these factors, we cannot assure you that forward-looking statements in this prospectus supplement, the accompanying prospectus or documents incorporated by reference herein or therein will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us to any other person that we will achieve our objectives and plans in any specified time frame, or at all.

The cautionary statements referred to above, the accompanying prospectus and the incorporated documents are intended to be applicable to all related forward-looking statements wherever they may appear in this prospectus supplement or the accompanying prospectus or any documents incorporated by reference herein or therein. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date they are made. Except as required by law, we assume no obligation to update our forward-looking statements, even if new information becomes available in the future.

[Table of Contents](#)**USE OF PROCEEDS**

We estimate that the net proceeds we will receive from the sales of 9,000,000 shares of common stock in this offering, based on the public offering price of \$2.25, will be approximately \$18,835,000, or \$21,690,250 if the underwriters exercise their option to purchase additional shares in full, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

We will retain broad discretion over the use of the net proceeds from the sale of the securities offered hereby. We currently intend to use the net proceeds from the sale of the securities offered hereby for research and further development of SM-88 and for general corporate purposes, capital expenditures, working capital and general and administrative expenses. We may also use a portion of the net proceeds to acquire or invest in businesses, products and technologies that are complementary to our own, although we have no current plans, commitments or agreements with respect to any acquisitions as of the date of this prospectus supplement.

We have not determined the amounts we plan to spend on any of the areas listed above or the timing of these expenditures. As a result, our management will have broad discretion to allocate the net proceeds from this offering. Pending application of the net proceeds as described above, we intend to invest the net proceeds of the offering in short-term, investment-grade, interest-bearing securities.

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DILUTION

If you invest in our common stock, your ownership interest will be diluted immediately to the extent of the difference between the offering price per share of our common stock and the as adjusted net tangible book value per share of our common stock after this offering.

As of December 31, 2017, our net tangible book value was approximately \$8.9 million, or \$0.10 per share of common stock. Such net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the number of shares of common stock outstanding on December 31, 2017.

After giving effect to the sale of 9 million shares of common stock in this offering at the public offering price of \$2.25 per share, and after deducting estimated offering expenses payable by us and underwriting discounts, our pro forma net tangible book value as of December 31, 2017 would have been approximately \$27.7 million, or \$0.28 per share of common stock. This would represent an immediate increase in pro forma net tangible book value of \$0.18 per share to existing stockholders and an immediate dilution of \$1.97 per share to new investors purchasing shares of common stock in this offering after giving effect to the sale of 9 million shares of common stock in this offering at the public offering price of \$2.25 per share.

The following table illustrates this dilution on a per share basis:

Public offering price per share		\$2.25
Net tangible book value per share as of December 31, 2017	\$0.10	
Increase in net tangible book value (deficit) per share attributable to new investors	\$0.18	
Net tangible book value per share after the offering		\$0.28
Dilution per share to new investors		\$1.97

The table above does not include, as of December 31, 2017:

- outstanding options representing the right to purchase a total of 5,240,120 shares of common stock at a weighted average exercise price of \$5.22 per share, which were issued under our 2015 Equity Incentive Plan and 2016 Stock Option Plan for Non-Employee Directors;
- outstanding warrants representing the right to purchase a total of 5,625,641 shares of common stock at a weighted-average exercise price of \$3.34 per share;
- 5,382,042 shares of common stock reserved for future issuance pursuant to awards that have not been made under our 2015 Equity Incentive Plan and 2016 Stock Option Plan for Non-Employee Directors; and
- shares of common stock that may be issued pursuant to our \$30 million ATM Financing Facility, under which \$24,069,120 of availability remained at December 31, 2017.

To the extent that options or warrants are exercised, you will experience further dilution. In addition, we may choose to raise additional capital, including through our ATM Financing Facility, due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our stockholders.

[Table of Contents](#)**DIVIDEND POLICY**

We have not paid cash dividends on our common stock and do not anticipate paying dividends in the foreseeable future. Our board of directors currently intends to retain any future earnings for reinvestment in our growing business. Any future determination to pay dividends will also be at the discretion of our board of directors and will be dependent upon our results of operations and cash flows, our financial position and capital requirements, general business conditions, legal, tax, regulatory and any contractual restrictions on the payment of dividends, and any other factors our board of directors deems relevant. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future.

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[Table of Contents](#)**MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES
TO NON-U.S. HOLDERS**

The following discussion describes the material U.S. federal income tax consequences of the acquisition, ownership and disposition of our common stock acquired in this offering by Non-U.S. Holders (as defined below). This discussion does not address all aspects of U.S. federal income taxes, does not discuss the potential application of the alternative minimum or Medicare Contribution tax, and does not deal with state, local or non-U.S. tax consequences that may be relevant to Non-U.S. Holders in light of their particular circumstances, nor does it address U.S. federal tax consequences other than income taxes (except to the limited extent set forth below). Rules different from those described below may apply to certain Non-U.S. Holders that are subject to special treatment under the Internal Revenue Code of 1986, as amended, or the Code, such as financial institutions, insurance companies, tax-exempt organizations, "foreign governments," international organizations, broker-dealers and traders in securities, U.S. expatriates, "controlled foreign corporations," "passive foreign investment companies," corporations that accumulate earnings to avoid U.S. federal income tax, persons that hold our common stock as part of a "straddle," "conversion transaction," or other risk reduction strategy, partnerships and other pass-through entities, and investors in such pass-through entities or entities that are treated as disregarded entities for U.S. federal income tax purposes (regardless of their places of organization or formation). Such Non-U.S. Holders are urged to consult their tax advisors to determine the U.S. federal, state, local and other tax consequences that may be relevant to them. Furthermore, the discussion below is based upon the provisions of the Code, and U.S. Treasury Regulations, rulings and judicial decisions thereunder as of the date hereof, and such authorities may be repealed, revoked or modified, perhaps retroactively, so as to result in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the Internal Revenue Service, or IRS, with respect to the statements made and the conclusions reached in the following summary. This discussion assumes that the Non-U.S. Holder holds our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment).

The following discussion is for general information only and is not tax advice for Non-U.S. Holders under their particular circumstances. Persons considering the purchase of our common stock pursuant to this offering should consult their tax advisors concerning the U.S. federal income tax consequences of acquiring, owning and disposing of our common stock in light of their particular situations as well as any consequences arising under the laws of any other taxing jurisdiction, including any state, local and non-U.S. tax consequences and any U.S. federal non-income tax consequences.

For the purposes of this discussion, a "Non-U.S. Holder" is, for U.S. federal income tax purposes, a beneficial owner of common stock that is not a U.S. Holder. A "U.S. Holder" means a beneficial owner of our common stock that is for U.S. federal income tax purposes (a) an individual who is a citizen or resident of the United States, (b) a corporation or other entity treated as a corporation created or organized in or under the laws of the United States, any state thereof or the District of Columbia, (c) an estate the income of which is subject to U.S. federal income taxation regardless of its source or (d) a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person. Also, partnerships, or other entities that are treated as partnerships for U.S. federal income tax purposes (regardless of their place of organization or formation) and entities that are treated as disregarded entities for U.S. federal income tax purposes (regardless of their place of organization or formation) are not addressed by this discussion and are, therefore, not considered to be Non-U.S. Holders for the purposes of this discussion.

Distributions

Distributions, if any, made on our common stock to a Non-U.S. Holder of our common stock generally will constitute dividends for U.S. tax purposes to the extent made out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles) and will be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. To obtain a reduced rate of

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withholding under a treaty, a Non-U.S. Holder generally will be required to provide us with a properly executed IRS Form W-8BEN, W-8BEN-E or other appropriate form, certifying the Non-U.S. Holder's entitlement to benefits under that treaty. In the case of a Non-U.S. Holder that is an entity, U.S. Treasury Regulations and the relevant tax treaty provide rules to determine whether, for purposes of determining the applicability of a tax treaty, dividends will be treated as paid to the entity or to those holding an interest in that entity. If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to such agent. The holder's agent may then be required to provide certification to us or our paying agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty, you should consult with your tax advisor to determine if you are able to obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

Withholding tax is generally not imposed on dividends paid to a Non-U.S. Holder that are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment that such holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to us (or, if stock is held through a financial institution or other agent, to such agent). In general, such effectively connected dividends will be subject to U.S. federal income tax, on a net income basis at the regular federal income tax rates imposed on U.S. persons, unless a specific treaty exemption applies. A Non-U.S. Holder that is a corporation for U.S. federal income tax purposes that receives effectively connected dividends may also be subject to an additional "branch profits tax," which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments.

To the extent distributions on our common stock, if any, exceed our current and accumulated earnings and profits, they will first reduce your adjusted basis in our common stock as a non-taxable return of capital, but not below zero, and then any excess will be treated as gain and taxed in the same manner as gain realized from a sale or other disposition of common stock as described in the next section.

Distributions on our common stock will also be subject to the rules discussed below relating to backup withholding and foreign accounts.

Gain on Disposition of Our Common Stock

Subject to the discussion below regarding backup withholding and foreign accounts, a Non-U.S. Holder generally will not be subject to U.S. federal income tax with respect to gain realized on a sale or other disposition of our common stock unless (a) the gain is effectively connected with a trade or business of such holder in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment that such holder maintains in the United States), (b) the Non-U.S. Holder is a nonresident alien individual and is present in the United States for 183 or more days in the taxable year of the disposition and certain other conditions are met, or (c) we are or have been a "United States real property holding corporation" within the meaning of Code Section 897(c)(2) at any time within the shorter of the five-year period preceding such disposition or such holder's holding period.

If you are a Non-U.S. Holder described in (a) above, you will be required to pay tax on the net gain derived from the sale at the regular U.S. federal income tax rates, unless a specific treaty exemption applies, and corporate Non-U.S. Holders described in (a) above may be subject to the additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. If you are an individual Non-U.S. Holder described in (b) above, you will be required to pay a flat 30% tax on the gain derived from the sale, which gain may be offset by U.S. source capital losses (even though you are not considered a resident of the United States). With respect to (c) above, in general, we would be a United States real property holding corporation if interests in U.S. real estate constituted (by fair market value) at least half of our total worldwide real property interests

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plus business assets. We believe that we are not, and do not anticipate becoming, a United States real property holding corporation; however, there can be no assurance that we will not become a U.S. real property holding corporation in the future. Even if we are treated as a U.S. real property holding corporation, such treatment will not cause gain realized by a Non-U.S. Holder on a disposition of our common stock to be subject to U.S. federal income tax so long as (1) the Non-U.S. Holder owned, directly, indirectly and constructively, no more than five percent of our common stock at all times within the shorter of (i) the five-year period preceding the disposition or (ii) the holder's holding period and (2) our common stock is regularly traded on an established securities market. There can be no assurance that our common stock will continue to qualify as regularly traded on an established securities market.

Information Reporting Requirements and Backup Withholding

Generally, we or certain financial middlemen must report information to the IRS with respect to any dividends we pay on our common stock including the amount of any such dividends, the name and address of the recipient, and the amount, if any, of tax withheld. A similar report is sent to the holder to whom any such dividends are paid. Pursuant to tax treaties or certain other agreements, the IRS may make its reports available to tax authorities in the recipient's country of residence.

Dividends paid by us (or certain financial middlemen) to a Non-U.S. Holder may also be subject to U.S. backup withholding. U.S. backup withholding generally will not apply to a Non-U.S. Holder who provides a properly executed appropriate IRS Form W-8 or otherwise establishes an exemption.

Under current U.S. federal income tax law, U.S. information reporting and backup withholding requirements generally will apply to the proceeds of a disposition of our common stock effected by or through a U.S. office of any broker, U.S. or non-U.S., unless the holder provides a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E, as applicable, or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is considered effected outside the United States through a non-U.S. office of a non-U.S. broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the broker has actual knowledge, or reason to know, that the holder is, in fact, a U.S. person. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. brokers.

If backup withholding is applied to you, you should consult with your tax advisor to determine if you are able to obtain a tax refund or credit with respect to the amount withheld.

Foreign Accounts

A U.S. federal withholding tax of 30% may apply to dividends and the gross proceeds of a disposition of our common stock paid to a foreign financial institution (as specifically defined by applicable rules), including when the foreign financial institution holds our common stock on behalf of a Non-U.S. Holder, unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). This U.S. federal withholding tax of 30% will also apply to dividends and the gross proceeds of a disposition of our common stock paid to a non-financial foreign entity unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding direct and indirect U.S. owners of the entity. The withholding tax described above will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from the rules. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements.

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Under certain circumstances, a Non-U.S. Holder might be eligible for refunds or credits of such taxes. Holders are encouraged to consult with their tax advisors regarding the possible implications of this withholding tax on their investment in our common stock.

In general, the withholding provisions described above currently apply to payments of dividends and will apply to payments of gross proceeds from a sale or other disposition of common stock on or after January 1, 2019.

Federal Estate Tax

An individual who at the time of death is not a citizen or resident of the United States and who is treated as the owner of, or has made certain lifetime transfers of, an interest in our common stock will be required to include the value thereof in his or her taxable estate for U.S. federal estate tax purposes, and may be subject to U.S. federal estate tax. An applicable estate or gift tax treaty may alter the tax treatment described in the preceding sentence. The definition of when an individual is a resident of the United States for U.S. federal estate tax purposes differs from the definition used for U.S. federal income tax purposes. Some individuals, therefore, may be “Non-U.S. Holders” for U.S. federal income tax purposes, but not for U.S. federal estate tax purposes, and vice versa.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT HIS, HER OR ITS TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAW, AS WELL AS TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, NON-U.S. OR U.S. FEDERAL NON-INCOME TAX LAWS.

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UNDERWRITING

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus supplement, the underwriters named below, for whom Evercore Group L.L.C., Stifel, Nicolaus & Company, Incorporated and Canaccord Genuity Inc. are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them the number of shares indicated below:

<u>Name</u>	<u>Number of Shares</u>
Evercore Group L.L.C.	3,600,000
Stifel, Nicolaus & Company, Incorporated	3,600,000
Canaccord Genuity Inc.	1,350,000
H.C. Wainwright & Co., LLC	450,000
Total:	<u>9,000,000</u>

The underwriters and the representative are collectively referred to as the “underwriters” and the “representative,” respectively. The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus supplement are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus supplement if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters’ option to purchase additional shares described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus supplement and part to certain dealers. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representative.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus supplement, to purchase up to additional shares of common stock at the public offering price listed on the cover page of this prospectus supplement, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering sales of shares by the underwriters in connection with the offering of the shares of common stock offered by this prospectus supplement which exceed the number of shares specified in the table above. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter’s name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters’ option to purchase up to an additional 1,350,000 shares of common stock.

	<u>Per Share</u>	<u>Total</u>	
		<u>No Exercise</u>	<u>Full Exercise</u>
Public offering price	\$ 2.25	\$ 20,250,000	\$ 23,287,500
Underwriting discounts and commissions to be paid by us	\$ 0.135	\$ 1,215,000	\$ 1,397,250
Proceeds, before expenses, to us	\$ 2.115	\$ 19,035,000	\$ 21,890,250

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately \$200,000. We have agreed to reimburse the underwriters for expense relating to clearance of this offering with the Financial Industry Regulatory Authority up to \$10,000.

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The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of shares of common stock offered by them.

Our common stock is listed on The Nasdaq Capital Market under the symbol "TYME."

We and each of our executive officers and directors have agreed that, except as set forth below, without the prior written consent of the representative on behalf of the underwriters, we and they will not, subject to limited exceptions, during the period ending 90 days after the date of this prospectus supplement (the "restricted period"):

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of common stock of the Company beneficially owned (as such term is used in Rule 13d-3 of the Exchange Act), by the undersigned or any other securities so owned convertible into or exercisable or exchangeable for shares of common stock of the Company;
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of common stock of the Company; or
- publicly disclose the intention to do any of the foregoing,

whether any such transaction is to be settled by delivery of common stock of the Company or such other securities, in cash or otherwise.

In addition, we and each such person agrees that, without the prior written consent of the representative, on behalf of the underwriters, we will not file any registration statement with the SEC relating to the offering of, or such other person will not, during the restricted period, make any demand for or exercise any right with respect to the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock.

The restrictions described in the two immediately preceding paragraphs do not apply to certain transactions, including, but not limited to:

- subject to certain limitations, bona fide gifts or charitable contributions made by the holder;
- subject to certain limitations, transfers to an immediate family member or a trust for the direct or indirect benefit of the holder;
- subject to certain limitations, transactions involving common stock acquired in the open market after completion of the offering;
- transfers of securities by will or intestacy upon the death of the holder;
- subject to certain limitations, pursuant to a domestic order, divorce settlement agreement or decree or court order;
- the issuance of shares of Common Stock upon the exercise of outstanding stock options or restricted stock awarded under existing equity award plans described in (or incorporated by reference in) this prospectus supplement, or the issuance of shares of Common Stock upon the exercise of outstanding warrants described in (or incorporated by reference in) this prospectus supplement;
- subject to certain limitations, dispositions to the Company, or withholding by the Company, solely in connection with the "cashless" exercise of stock options;
- the issuance by the Company of certain stock options to certain of our directors and officers in lieu of unpaid director fees or unpaid potential salary; and
- sales made pursuant to our Co-Founders' 10b5-1 Plans that occur more than 45 days after the delivery of the shares of common stock pursuant to this prospectus supplement.

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Evercore Group L.L.C. and Stifel, Nicolaus & Company, Incorporated, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain, or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the option to purchase additional shares. The underwriters can close out a covered short sale by exercising the option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the option to purchase additional shares. The underwriters may also sell shares in excess of the option to purchase additional shares, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representative has repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

A prospectus or prospectus supplement in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representative may agree to allocate a number of shares of common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representative to underwriters that may make Internet distributions on the same basis as other allocations.

Other Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing, and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

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Selling Restrictions

Canada

The common stock may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of shares of the common stock must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State") an offer to the public of any shares of our common stock may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any shares of our common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- (a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- (b) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representative for any such offer; or
- (c) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of shares of our common stock shall result in a requirement for the publication by us or any underwriter of a prospectus supplement pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares of our common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of our common stock to be offered so as to enable an investor to decide to purchase any shares of our common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State, and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

United Kingdom

Each underwriter has represented and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of

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the Financial Services and Markets Act 2000 (“FSMA”) received by it in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and

(b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

Hong Kong

The shares may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), or (ii) to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a “prospectus” within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

Singapore

This prospectus supplement and accompanying prospectus have not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the “SFA”), (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 by a relevant person which is: (a) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries’ rights and interest in that trust shall not be transferable for 6 months after that corporation or that trust has acquired the shares under Section 275 except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (2) where no consideration is given for the transfer; or (3) by operation of law.

Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (the Financial Instruments and Exchange Law) and each underwriter has agreed that it will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

[Table of Contents](#)**LEGAL MATTERS**

The validity of the shares of common stock offered hereby will be passed upon for us by Drinker Biddle & Reath LLP (“DBR”), Philadelphia, Pennsylvania. Certain legal matters will be passed upon for the underwriters by Ropes & Gray LLP, Massachusetts. As of the date of this prospectus supplement, James Biehl, a partner of DBR who is a director of the Company, beneficially owned (in the form of shares and options exercisable within 60 days) 1.2% of the outstanding shares of Company common stock and is eligible to receive future grants of awards pursuant to the 2016 Stock Option Plan for Non-Employee Directors.

EXPERTS

The consolidated financial statements as of March 31, 2017 and 2016 and for the year ended March 31, 2017, three months ended March 31, 2016 and year ended December 31, 2015 incorporated by reference in this prospectus supplement and the accompanying prospectus have been so incorporated by reference in reliance upon the report of Grant Thornton LLP, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing.

The consolidated financial statements as of and for the year ended December 31, 2014, before the effects of the adjustments to retrospectively apply the change in accounting as described in Note 1 to the consolidated financial statements incorporated by reference in this prospectus supplement and the accompanying prospectus, have been audited by WithumSmith+Brown, PC, an independent registered public accounting firm. The adjustments to those financial statements to retrospectively apply the impact of the reverse merger described in Note 1 have been audited by Grant Thornton LLP, an independent registered public accounting firm.

The consolidated financial statements as of and for the year ended December 31, 2014 incorporated by reference in this prospectus supplement and the accompanying prospectus have been so incorporated by reference in reliance upon the reports of (i) WithumSmith+Brown, PC, solely with respect to those financial statements before the effects of the adjustments to retrospectively apply the impact of the reverse merger in Note 1 and (ii) Grant Thornton LLP solely with respect to the adjustments to those financial statements to retrospectively apply the impact of the reverse merger in Note 1, given on the authority of such firms as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the reporting requirements of the Exchange Act and file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy these reports, proxy statements and other information at the SEC’s public reference facilities at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference facilities. SEC filings are also available at the SEC’s website at <http://www.sec.gov>.

This prospectus supplement and the accompanying prospectus are only part of a registration statement on Form S-3 that we have filed with the SEC under the Securities Act of 1933 and therefore omits certain information contained in the registration statement. We have also filed exhibits and schedules with the registration statement that are excluded from this prospectus supplement, and you should refer to the applicable exhibit or schedule for a complete description of any statement referring to any contract or other document. You may inspect a copy of the registration statement, including the exhibits and schedules, without charge, at the public reference room or obtain a copy from the SEC upon payment of the fees prescribed by the SEC.

We also maintain a website at www.tymeinc.com, through which you can access our SEC filings. The information set forth on our website is not part of this prospectus supplement or the accompanying prospectus.

[Table of Contents](#)**INCORPORATION OF DOCUMENTS BY REFERENCE**

The SEC allows us to “incorporate by reference” information into this prospectus supplement, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The SEC file number for the documents incorporated by reference in this prospectus is 001-38169. The documents incorporated by reference into this prospectus supplement contain important information that you should read about us.

The following documents are incorporated by reference into this document:

- our Annual Report on Form 10-K and on Form 10-K/A for the year ended March 31, 2017 filed with the SEC on June 12, 2017 and amended on July 28, 2017;
- our Quarterly Reports on Form 10-Q for the quarter ended June 30, 2017 filed with the SEC on August 10, 2017, for the quarter ended September 30, 2017 filed with the SEC on November 3, 2017 and for the quarter ended December 31, 2017 filed with the SEC on February 7, 2018;
- our Current Reports on Form 8-K and on Form 8-K/A (other than information furnished under Item 2.02 or 7.01 rather than filed) filed with the SEC on April 4, 2017, April 17, 2017, June 15, 2017, August 2, 2017, August 10, 2017, September 7, 2017, November 6, 2017, November 13, 2017, November 29, 2017, December 5, 2017, February 9, 2018 and February 26, 2018;
- Our Preliminary Information Statement on Schedule 14C, filed with the SEC on February 21, 2018; and
- the description of our common stock, which is registered under Section 12 of the Exchange Act, in our registration statement on Form 8-A, filed with the SEC on July 27, 2017, including any amendments or reports filed for the purpose of updating such description.

We also incorporate by reference into this prospectus supplement all documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items) that are filed by us with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus supplement but prior to the termination of the offering.

We will provide to each person, including any beneficial owner, to whom a prospectus supplement is delivered, without charge upon written or oral request, a copy of any or all of the documents that are incorporated by reference into this prospectus supplement but not delivered with the prospectus supplement, including exhibits which are specifically incorporated by reference into such documents. You should direct any requests for documents by writing us at 44 Wall Street – 12th Floor, New York, NY 10005 Attn: Corporate Secretary or telephoning us at (646) 205-1603.

Any statement contained herein or in a document incorporated or deemed to be incorporated by reference into this document will be deemed to be modified or superseded for purposes of the document to the extent that a statement contained in this document or any other subsequently filed document that is deemed to be incorporated by reference into this document modifies or supersedes the statement.

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Prospectus

TYME TECHNOLOGIES, INC.

\$250,000,000
Common Stock
Preferred Stock
Debt Securities
Warrants

From time to time, we may offer up to \$250,000,000 of any combination of the securities described in this prospectus in one or more offerings. We may also offer securities as may be issuable upon conversion, redemption, repurchase, exchange or exercise of any securities registered hereunder, including any applicable anti-dilution provisions.

This prospectus provides a general description of the securities we may offer. Each time we offer securities, we will provide specific terms of the securities offered in a supplement to this prospectus. We may also authorize one or more free writing prospectuses to be provided to you in connection with these offerings. The prospectus supplement and any related authorized free writing prospectus may also add, update or change information contained in this prospectus. You should carefully read this prospectus, the applicable prospectus supplement and any related authorized free writing prospectus, as well as any documents incorporated by reference, before you invest in any of the securities being offered.

This prospectus may not be used to consummate a sale of any securities unless accompanied by a prospectus supplement.

Our common stock is currently traded on the Nasdaq Capital Market under the symbol "TYME." On August 16, 2017, the last reported sale price of our common stock was \$6.11 per share. The applicable prospectus supplement will contain information, where applicable, as to any other listing on any other securities market or other exchange of the securities, if any, covered by securities issued under the prospectus supplement.

We will sell these securities directly to investors, through agents designated from time to time or to or through underwriters or dealers, on a continuous or delayed basis. For additional information on the methods of sale, you should refer to the section entitled "Plan of Distribution" in this prospectus. If any agents or underwriters are involved in the sale of any securities with respect to which this prospectus is being delivered, the names of such agents or underwriters and any applicable fees, commissions, discounts or over-allotment options will be set forth in a prospectus supplement. The price to the public of such securities and the net proceeds we expect to receive from such sale will also be set forth in a prospectus supplement.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described and cross-referenced under the heading "Risk Factors" contained herein and in the applicable prospectus supplement and any related authorized free writing prospectus, and under similar headings in the other documents that are incorporated by reference into this prospectus.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ACCURACY OR ADEQUACY OF THE DISCLOSURES IN THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is August 16, 2017.

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[Table of Contents](#)**ABOUT THIS PROSPECTUS**

This prospectus is a part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or SEC, utilizing a “shelf” registration process. Under this shelf registration process, we may sell any combination of the securities described in this prospectus in one or more offerings up to a total aggregate offering price of \$250,000,000. This prospectus provides you with a general description of the securities we may offer.

Each time we sell securities under this prospectus, we will provide a prospectus supplement that will contain specific information about the terms of that offering. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to these offerings. The prospectus supplement and any related authorized free writing prospectus that we may authorize to be provided to you may also add, update or change information contained in this prospectus or in any documents that we have incorporated by reference into this prospectus. You should read this prospectus, any applicable prospectus supplement and any related authorized free writing prospectus, together with the information incorporated herein by reference as described under the heading “Incorporation of Certain Information by Reference,” before investing in any of the securities offered.

**THIS PROSPECTUS MAY NOT BE USED TO CONSUMMATE A SALE OF SECURITIES
UNLESS IT IS ACCOMPANIED BY A PROSPECTUS SUPPLEMENT.**

Neither we, nor any agent, underwriter or dealer has authorized any person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus, any applicable prospectus supplement or any related authorized free writing prospectus prepared by or on behalf of us or to which we have referred you. This prospectus, any applicable supplement to this prospectus or any related authorized free writing prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus, any applicable supplement to this prospectus or any related authorized free writing prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction.

You should not assume that the information contained in this prospectus, any applicable prospectus supplement or any related authorized free writing prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus, any applicable prospectus supplement or any related authorized free writing prospectus is delivered, or securities are sold, on a later date.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the heading “Where You Can Find More Information.”

[Table of Contents](#)**PROSPECTUS SUMMARY**

This summary highlights selected information from this prospectus and does not contain all of the information that you need to consider in making your investment decision. You should carefully read the entire prospectus, the applicable prospectus supplement and any related authorized free writing prospectus, including the risks of investing in our securities discussed under the heading “Risk Factors” contained herein as well as in the applicable prospectus supplement and any related authorized free writing prospectus and under similar headings in the other documents that are incorporated by reference into this prospectus. You should also carefully read the information incorporated by reference into this prospectus, including our financial statements, and the exhibits to the registration statement of which this prospectus is a part.

As used in this prospectus, unless the context indicates otherwise, the terms “we,” “our,” “us,” the “Company,” or “registrant” refer to Tyme Technologies, Inc. and includes its subsidiaries and predecessors.

Tyme Technologies, Inc. is a clinical-stage biotechnology company developing cancer therapeutics that are intended to be broadly effective across tumor types and have low toxicity profiles. Unlike targeted therapies that attempt to regulate specific mutations within cancer, our therapeutic approach is designed to take advantage of a cancer cell’s innate metabolic weaknesses to compromise its defenses, leading to cell death through oxidative stress and exposure to the body’s natural immune system. Our lead clinical program, SM-88, is a first-in-class combination therapy in Phase II development for prostate cancer, and we are preparing to initiate an additional Phase II clinical trial for pancreatic cancer.

We believe SM-88 can be broadly effective across multiple cancer types based on results from 106 advanced-stage patients treated with SM-88 through first-in human and compassionate use programs. Our first-in-human study began as a three-month safety study of SM-88, which was approved by an Institutional Review Board (“IRB”) and enrolled 30 end-stage metastatic cancer patients; based on patient response during this three-month period, SM-88 treatment was continued for multiple years under IRB oversight (collectively, “our First Human Study”). Additionally, as of March 31, 2017, SM-88 had been used with 76 patients as part of a separate compassionate use program under IRB oversight where most of these 76 patients had failed or refused possible available therapies and were treated with SM-88 as a monotherapy (collectively, the “Compassionate Use Patients”).

Through these two programs, SM-88 has shown complete and partial responses for over 13 different cancer types, including some of the most common and difficult-to-treat cancers, such as pancreatic, prostate, breast, lung, glioma, ovarian, Ewing’s sarcoma, sarcoma and colon cancer. Based on our First Human Study, where 30 subjects had failed or refused possible available therapies and were estimated by treating physicians to have three to six months to live, median overall survival (“OS”) with SM-88 monotherapy was 25.7 months and median progression-free survival (“PFS”) was 14.7 months.

To date, SM-88 has not been associated with any drug-related serious adverse events (“SAEs”), and SM-88 patients have experienced relatively few grade 1 or 2 adverse events (“AEs”). We believe that SM-88 may be appropriate for a wide range of cancers prior to the end-stage setting, based on preliminary data from our First Human Study and Compassionate Use Patients that indicate SM-88’s broad applicability and relatively low toxicity. The Company has an ongoing Phase II trial in biochemically-recurrent localized prostate cancer to evaluate earlier-stage effectiveness. Preliminary in-progress data from this Phase II trial presented at the June 2017 American Society of Clinical Oncology annual meeting (“ASCO 2017”) indicated SM-88’s potential effectiveness as prostate cancer maintenance therapy without significant toxicity and without quality-of-life altering characteristics.

We believe, based on SM-88’s mechanism of action (described below) and proof-of-concept study data, that our lead candidate may ultimately improve overall response rates, clinical outcomes and survival rates in cancer

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patients. Based on its proposed mechanism of action and the factors described below, SM-88 may prove particularly beneficial to cancer patients who have relapsed following traditional cancer therapies or cancer patients and clinicians who seek an effective, low toxicity treatment option between an observation strategy and toxic treatment options.

Tyme's Mechanism of Action and Platform Overview

We believe SM-88's mechanism of action ("MOA") can be broadly effective across different cancer types because it has a unique composition that is designed to selectively invade a cancer cell, weaken a cancer cell's defenses, and expose a cancer cell's microenvironment to oxidative stress and host immune system defenses, regardless of a tumor's origin. SM-88, including our proprietary tyrosine derivative compound, is designed to be selective to tumors with minimal impact on normal healthy cells. We believe our research, as well as independent studies, suggest that cancer cells have a high affinity for tyrosine, especially in a glucose-deprived or cellular ketosis state, while normal cells have less affinity to tyrosine and do not significantly use tyrosine as a metabolite.

Our product development strategy is based on using "biological circuits" to selectively destroy tumor cells with minimal toxicity. In this regard, the term biological circuit is meant to describe a cascading process of cellular function when a cancer cell is in its natural state. SM-88 is designed to increase the "current" of this circuit and then cause a break at a critical juncture to induce a catastrophic collapse of the cancer cell. We believe this can be a highly effective strategy against cancer since all cancers have an altered glycolytic metabolism, known as the Warburg Effect, involving glucose breakdown. SM-88 is designed as a therapeutic treatment to utilize a cancer cell's glycolytic process and create a potential universal entry point for producing cancer cell death through oxidative stress and the body's immune system defenses.

The backbone component of SM-88 is a proprietary dysfunctional tyrosine derivative. Tyrosine is a non-essential amino acid that has a high affinity with cancer cells, but has minimal uptake by healthy cells. The tyrosine derivative used in SM-88 is designed to interact with the cancer cell as if it were a functional tyrosine but, after uptake, cause any cellular process using the tyrosine derivative, such as protein synthesis, to fail.

One of the critical proteins in cancer that uses tyrosine as an important building block is mucin. Mucin acts as a protective layer around the cancer cell that defends the tumor from external elements, such as the host immune system, and also helps maintain a stable balance inside of the cancer cells. Cancers have an internal microenvironment that would be toxic to healthy cells and we believe that mucins help keep the microenvironment in a state of balance. SM-88 is intended to disrupt the cancer cell's unique microenvironment following uptake of our tyrosine derivative.

We believe that when the cancer cell attempts to use the dysfunctional tyrosine derivative for protein synthesis to create mucin, the process fails and the mucin layer begins to deteriorate. Without a stable protective coating from mucin, tumor cells become exposed to the host immune system as well as internal toxicity. This can result in a heightened state of oxidative stress, when the number of free-radicals, or reactive oxygen species ("ROS"), increases to a dangerous level. ROS can cause catastrophic cancer cell damage, leading to apoptosis, by pulling electrons from otherwise stable molecules, such as DNA or proteins.

We believe the effectiveness of our tyrosine derivative in effecting cancer cell death is substantially enhanced by combining it with small doses of three repurposed agents that may increase the uptake of the tyrosine derivative and enhance oxidative stress against the tumor cells.

One repurposed agent, sirolimus, is administered with the intent to increase the rate at which a cell exhausts its supply of glucose and, as a result, must use amino acids and lipids for metabolism. We believe that by

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decreasing glucose supply with sirolimus, cancer cells will more quickly exhaust their glucose supply and begin pulling in preferred amino acids, such as tyrosine. Because it is estimated that cancer cells utilize glucose at less than 1/15th the efficiency of normal cells, cancer cells are expected to deplete their glucose far more rapidly than normal cells, causing a dramatic increase in tyrosine uptake, including SM-88's tyrosine derivative.

The other two repurposed agents, methoxsalen and phenytoin, are administered to increase the oxidative stress on cancer cells. We believe that phenytoin can stimulate the production of reactive lipid species and increase the overall level of oxidation surrounding a cancer cell. We believe that methoxsalen can promote an electron transfer process and enhance the effect of ROS and the ability to catalyze oxygen into the cancer cell, which produces cell death within the cancer cell microenvironment.

All three of these repurposed agents are administered at doses that are approximately 25% or less than their recommended therapeutic dosing levels. We believe that small doses of these repurposed agents should have too little of an effect to cause disruption of normal cellular function, but in combination should meaningfully increase the effectiveness of SM-88 therapy against cancer.

By using SM-88 to disrupt cancer's metabolic circuit, our intention is to create a therapy that is:

- **Broadly effective across different cancer types** – Since all cancers use the same metabolic process, they also have the same potential entry point for therapy, regardless of origin;
- **Highly specific to cancer** – As supported by recent advances in radiographic imaging that use tyrosine to selectively image cancer cells, cancer has a high affinity for tyrosine while normal cells have minimal uptake;
- **Relatively non-toxic** – Studies in relatively healthy individuals have not shown significant side effects;
- **An effective treatment for patients who have failed other therapeutic options** – Due to its a novel MOA and low toxicity profile, we believe SM-88 can be an effective alternative to existing standard of care treatments that have failed and many previous therapies should not produce enhanced resistance to SM-88;
- **Suitable for monotherapy or combination therapy** – Although most of Tyme's clinical and compassionate use experience has been in monotherapy, SM-88's differentiated MOA and safety profile could allow it to be effective in combination with other cancer therapeutics; and
- **Less likely to create cancer resistance** – By taking advantage of cancer's natural state rather than trying to target specific mutations, cancer may have less ability to find alternate pathways to function.

We intend to develop other products for oncology using our biological circuit approach, both by means of alternate delivery platforms as well as alternate product compositions. SM-88 is intended in general, as an oral therapy that is broadly applicable to cancers; however, alternate routes of delivery may be more appropriate for certain patients or cancers. For example, our First Human Study patients were administered with small SM-88 subcutaneous doses in combination with an oral SM-88 dose. In addition, treating physicians for SM-88 Compassionate Use Patients had discretion over bedside administration of SM-88, and we believe that a significant number of these patients received SM-88 by subcutaneous and/or oral delivery. Given the potential need for alternative administration of patient doses, we have developed an injectable formulation that, for example, may be beneficial for patients with a compromised digestive system and who are not able to absorb the oral formulation. We also have other alternative formulations, such as topical, transdermal and nasal, at various stages of development that we believe could provide an effective alternative therapeutic effect for certain forms of cancer, including, for example, breast cancer and glioblastoma. In addition, we plan to advance novel products under development that are intended to either improve on the effectiveness seen in SM-88 or be used in combination with other cancer therapies.

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We believe we can become a leader in developing cancer therapies with our platform technology for the following reasons:

- We are using low-toxicity combination therapies to disrupt cancer's normal metabolic reaction in order to cause tumor cell death;
- Our lead drug candidate, SM-88, is believed to be a first-in-class metabolic-oxidative cancer therapy;
- SM-88 has demonstrated its potential as an effective and selective combination drug product treatment, with encouraging antitumor activity that has not, to date, shown significant toxic side effects at current therapeutic dose levels;
- We have a technology base and patent portfolio supporting SM-88 and have filed patents for additional drug candidates to provide a pipeline of oncology drug development programs based on our technology platform; and
- We currently retain all commercial rights for SM-88 and have undertaken an extensive multinational patent effort to protect those rights.

Our goal is to develop and commercialize metabolically-targeted cancer therapies aimed at improving and extending lives. Key elements of our strategy to achieve this goal are:

- **Successfully advance SM-88 through clinical development, including registration trials and commercial launch.** We intend to pursue a worldwide development and commercialization plan for SM-88.
- **Continue to invest in our technology platform and IP portfolio to further build our pipeline.** We plan to expand our R&D efforts to encompass multiple indications and products within the oncology field. We have undertaken additional early development programs for improved formulations of SM-88 as well as wholly new compounds.
- **Build a balanced portfolio of proprietary and partnered programs.** We plan to independently develop and commercialize multiple drug candidates for human indications within the oncology field. For targets outside our core areas of interest or where a partner can contribute specific expertise, we intend to evaluate potential collaborations with strategic partners and/or potential acquisitions of other companies who can augment our expertise and technology, as well as a means to acquire rights or ownership of additional IP. We also contemplate exploring global development partners and arrangements, where appropriate.

Past Human Studies and Ongoing and Planned Clinical Trials

We have focused our research and development efforts on a proprietary platform technology, for which we retain global IP and commercial rights, for use in creating drugs to treat the unmet medical needs of human oncology patients. This population includes patients with limited life expectancy and scarce therapeutic options, such as those with refractory cancer (i.e., cancer that is unresponsive to treatment with standard therapies), those who are undergoing salvage therapy for metastatic disease or patients who have refused additional toxic therapies. We believe this development strategy directed at this patient population could allow for faster regulatory approval and could require smaller clinical trials, as compared to those indications with more therapeutic options and/or larger patient populations.

Our completed past programs and our on-going clinical initiatives have been focused on use of SM-88 in variable treatment settings, as summarized below and in the following sections:

- Our First Human Study began as an IRB-approved protocol initially designed as a three-month safety study of SM-88 in 30 end-stage metastatic cancer patients. This study, which commenced without our submission

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concerning, or receipt of, United States Food and Drug Administration (the “FDA”) approval of an investigational new drug application (“IND”), was continued under IRB supervision over multiple years given the clinical benefit experienced by a large portion of these patients who were treated with SM-88.

- In addition to the First Human Study, 76 Compassionate Use Patients who had failed-or-refused possible available treatments were treated with SM-88 through IRB-reviewed compassionate use. Some of these patients had been treated for over four years, demonstrating complete and partial responses across a multitude of cancer types. We intend to publish additional data on Compassionate Use Patients through peer-reviewed publications and medical conferences during the course of 2017 and 2018.
- We intend to initiate a Phase II pancreatic cancer trial by the first quarter of calendar year 2018. The trial is expected to be focused on refractory subjects who have failed or refused possible available treatment options. Data on 11 refractory pancreatic cancer subjects treated in either our First Human Study or as Compassionate Use Patients were reported at ASCO 2017, showing clinical benefit as follows: complete response (n=1/11), partial response (n=2/11) or stable disease (n=8/11). Some of these patients demonstrated duration of response for over a year. We believe SM-88 could be a viable treatment for this usually terminal disease and it is also our intention to seek breakthrough therapy designation in this treatment population, as appropriate.
- We intend to initiate additional trials in other treatment populations as resources are available. SM-88 has shown efficacy in 13 different cancer types, and our current priorities for additional trials include lung, breast, bone and brain cancers.

On June 13, 2016, we announced that we began recruiting for a Phase Ib/II clinical trial, using our proprietary compound, SM-88, to treat prostate cancer. Unlike traditional chemotherapy, SM-88 is designed to target only active cancer cells. The trial is designed, among other things, to confirm SM-88’s earlier reported activity in reducing the prostate-specific antigen (“PSA”) without causing the medical castration-like effects often experienced with a current standard of care treatment, androgen deprivation therapy (“ADT”). All subjects in our Phase Ib/II trial (1) had prostate cancer and achieved remission with previous therapy, (2) had subsequently experienced recurrence at enrollment biochemically with circulating tumor cells (“CTCs”) or PSA, and (3) have not yet progressed to radiographically visible lesions

Endpoints of our Phase II prostate study include:

- Prevention of radiographically-detectable lesions (i.e. maintained rPFS)
- Reduction in circulating tumor cells
- Safety and patient reported outcomes
- PSA-doubling time (PCWG3 definition)
- Relevant biomarkers.

We presented initial data from the Phase Ib/II trial at ASCO 2017. The following table summarizes our preliminary data in prostate patients (n=8) that had been on treatment long enough for evaluation.

Summary of Ongoing Phase Ib/II Trial in Biomarker Recurrent Prostate Cancer

Endpoint	Evaluable subject response
CTC count undetectable or significantly improved	87.5%
Radiographic progression free survival (rPFS)	100%
Need for subsequent toxic therapy	None
PSA doubling stable or improved	All subjects
Patient reported outcomes (PROs) improved or stable	All subjects

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At ASCO 2017 we also presented a retrospective review of 11 late-stage pancreatic cancer patients who were treated in our First Human Study or as Compassionate Use Patients, each of whom had failed or refused other available therapies. Clinical Benefit was documented for all subjects. Overall reduction in tumor size was seen in 27.3% (3/11) of patients, including one complete response (“CR”) with progression free survival (or PFS) of at least six months duration, and two partial responses with one known PFS of 15 weeks. 72.7% (8/11) of patients had stable disease ranging from six-61 weeks. Two subjects who were listed as stable disease had an overall survival of 43.2 and 23.3 months, with no further treatment. All 11 subjects had quality-of-life benefits, including 1-3 points improvement in Eastern Cooperative Oncology Group Performance Status (“ECOG PS”); 1-5 point mean improvement on EORTC questionnaire (scale 1-7); weight gain (1-5 lbs.); and reduction in pain levels (1-9 points/10 scale) with cessation of all analgesics by the end of cycle 1 (six weeks) in 36% of subjects (4/11).

We intend to initiate a Phase II pancreatic cancer trial by the first quarter of calendar 2018. The trial is expected to be focused on refractory subjects who have failed or refused possible available treatment options. Data on 11 refractory pancreatic cancer subjects treated in either our First Human Study or as Compassionate Use Patients were reported at ASCO 2017, showing clinical benefit as follows: complete response (n=1/11), partial response (n=2/11) or stable disease (n=8/11). Some of these patients demonstrated duration of response for over a year. We believe SM-88 could be a viable treatment for this usually terminal disease and it is also our intention to seek breakthrough therapy designation in this treatment population, as appropriate.

We intend to initiate additional trials in other treatment populations as resources are available. SM-88 has shown efficacy in 13 different cancer types, and our current priorities for additional trials include lung, breast, bone and brain cancers.

The Securities We May Offer

We may offer shares of our common stock and preferred stock, one or more series of debt securities and warrants to purchase any of our securities, up to a total aggregate offering price of \$250,000,000 from time to time in one or more offerings under this prospectus, together with any applicable prospectus supplement and any related authorized free writing prospectus, at prices and on terms to be determined by market conditions at the time of the relevant offering. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities under this prospectus, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities, including, to the extent applicable:

- aggregate offering price;
- aggregate principal amount;
- maturity, if applicable;
- original issue discount, if any;
- rates and times of payment of interest or dividends, if any;
- redemption, conversion, exchange or sinking fund terms, if any;
- conversion or exchange prices or rates, if any, and, if applicable, any provisions for changes to or adjustments in the conversion or exchange prices or rates and in the securities or other property receivable upon conversion or exchange;
- ranking, if applicable;
- restrictive covenants, if any;

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- designation or classification;
- voting or other rights, if any; and
- material U.S. federal income tax considerations.

The prospectus supplement and any related authorized free writing prospectus that we may authorize to be provided to you may also add, update or change information contained in this prospectus or in documents we have incorporated by reference. However, no prospectus supplement or free writing prospectus will offer a security that is not registered and described in this prospectus at the time of the effectiveness of the registration statement of which this prospectus is a part.

This prospectus may not be used to consummate a sale of securities unless it is accompanied by a prospectus supplement.

We may sell the securities directly to investors or through underwriters, dealers or agents. We, and our underwriters or agents, reserve the right to accept or reject all or part of any proposed purchase of securities. If we do offer securities through underwriters or agents, we will include in the applicable prospectus supplement:

- the names of underwriters;
- the name of agents;
- applicable underwriting discounts, fees and commissions to be paid to them;
- details regarding over-allotment terms, if any; and
- the estimated net proceeds to us.

Common Stock. We may issue shares of our common stock from time to time. Holders of our common stock are entitled to one vote per share for the election of directors and on all other matters that require stockholder approval. Subject to any preferential rights of any then outstanding preferred stock, in the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in the assets remaining after payment of liabilities and the liquidation preferences of any then outstanding preferred stock. Our common stock does not carry any preemptive rights enabling a holder to subscribe for, or receive shares of, any class of our common stock or any other securities convertible into shares of any class of our common stock, or any redemption rights.

Preferred Stock. We may issue shares of our preferred stock from time to time, in one or more series. Under our Amended and Restated Certificate of Incorporation (our "Certificate of Incorporation"), our board of directors has the authority, without further action by stockholders, to designate up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges, qualifications and restrictions granted to or imposed upon the preferred stock, including dividend rights, conversion rights, voting rights, rights and terms of redemption, liquidation preference and sinking fund terms, any or all of which may be greater than the rights of the common stock. To date, none of the 10,000,000 authorized shares of preferred stock have been designated by our board of directors. Convertible preferred stock will be convertible into our common stock or exchangeable for our other securities. Conversion may be mandatory or at the option of the holders of our preferred stock and would be at prescribed conversion rates.

We will fix the rights, preferences, privileges, qualifications and restrictions of the preferred stock of each series that we sell under this prospectus and applicable prospectus supplements in the certificate of designation relating to that series. We will incorporate by reference into the registration statement of which this prospectus is a part the form of any certificate of designation that describes the terms of the series of preferred stock we are

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offering before the issuance of the related series of preferred stock. We urge you to read the prospectus supplements (and any related authorized free writing prospectus that we may authorize to be provided to you) related to the series of preferred stock being offered, as well as the complete certificate of designation that contains the terms of the applicable series of preferred stock.

Debt Securities. We may issue debt securities from time to time, in one or more series, as either senior or subordinated debt or as senior or subordinated convertible debt. The senior debt securities will rank equally with any other unsecured and unsubordinated debt. The subordinated debt securities will be subordinate and junior in right of payment, to the extent and in the manner described in the instrument governing the debt, to all of our senior indebtedness. Convertible debt securities will be convertible into our common stock or preferred stock. Conversion may be mandatory or at the holder's option and would be at prescribed conversion rates as set forth in any applicable prospectus statement.

The debt securities will be issued under one or more documents called indentures, which are contracts between us and a national banking association or other eligible party, as trustee. In this prospectus, we have summarized certain general features of the debt securities. We urge you, however, to read the applicable prospectus supplement (and any free writing prospectus that we may authorize to be provided to you) related to the series of debt securities being offered, as well as the complete indentures that contain the terms of the debt securities. A form of indenture has been filed as an exhibit to the registration statement of which this prospectus is a part, and supplemental indentures and forms of debt securities containing the terms of the debt securities being offered will be filed as exhibits to the registration statement of which this prospectus is a part or will be incorporated by reference from reports that we file with the SEC.

Warrants. We may issue warrants for the purchase of common stock, preferred stock and/or debt securities in one or more series. We may issue warrants independently or together with common stock, preferred stock and/or debt securities, and the warrants may be attached to or separate from these securities. In this prospectus, we have summarized certain general features of the warrants. We urge you, however, to read the applicable prospectus supplement (and any free writing prospectus that we may authorize to be provided to you) related to the particular series of warrants being offered, as well as the complete warrant agreements and warrant certificates that contain the terms of the warrants. Forms of the warrant agreements and forms of warrant certificates containing the terms of the warrants being offered have been filed as exhibits to the registration statement of which this prospectus is a part, and supplemental warrant agreements and forms of warrant certificates will be filed as exhibits to the registration statement of which this prospectus is a part or will be incorporated by reference from reports that we file with the SEC.

We will evidence each series of warrants by warrant certificates that we will issue. Warrants may be issued under an applicable warrant agreement that we enter into with a warrant agent. We will indicate the name and address of the warrant agent, if applicable, in the prospectus supplement relating to the particular series of warrants being offered.

Corporate Information

We are incorporated under the laws of the State of Delaware. Our principal executive office is located at 44 Wall Street, 12th Floor, New York, New York 10005. Our telephone number is (646) 205-1603. Our website address is www.tymeinc.com. The information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our securities offered in this prospectus.

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“Tyme,” SM-88, the Tyme logo and other trademarks or service marks of the Company appearing in this prospectus are the property of Tyme Technologies, Inc. This prospectus contains additional trade names, trademarks and service marks of others, which are the property of their respective owners.

On July 31, 2017, the Company, listed its shares of common stock (the “Common Stock”), which were previously quoted on the OTCQB® Venture Market (“OTC”) under the ticker symbol “TYMI,” on the Nasdaq Capital Market (“Nasdaq”) under the ticker symbol “TYME.” In connection with such action, the listing and trading of the Common Stock on OTC ceased at market close on July 28, 2017, and trading of the Common Stock commenced on Nasdaq upon the opening of business on July 31, 2017.

[Table of Contents](#)**INDUSTRY AND MARKET DATA**

Certain industry data and market data included in this prospectus were obtained from independent third-party surveys, market research, publicly available information, reports of governmental agencies and industry publications and surveys. All of such data presented herein is based upon management's review of independent third-party surveys and industry publications prepared by a number of sources and other publicly available information. All of the market data used in this prospectus involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We believe that the information from these industry publications and surveys included in this prospectus is reliable. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled "Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully review the risks and uncertainties described below as well as information contained in any applicable prospectus supplement and any related authorized free writing prospectus, under similar headings. Please consult all of these risk factors before deciding whether to purchase any of the securities being registered pursuant to the registration statement of which this prospectus is a part. Each of the risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities, and the occurrence of any of these risks might cause you to lose all or part of your investment. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations.

Risks Related to Owning Our Stock

The ownership interests in our Company held by two of our executive officers and directors could allow them to significantly influence corporate decision-making in a manner that may not reflect the interests of all of our stockholders.

Steve Hoffman, our Chief Executive Officer, Chief Science Officer and a director, and Michael Demurjian, our Chief Operating Officer, Executive Vice President and a director, each beneficially owned 30.10% of our outstanding common stock as of July 24, 2017. As a result, these individuals are positioned to exercise significant influence over our Company's management and affairs, including, but not limited to, electing our board of directors and exercising managerial influence and voting rights in connection with fundamental corporate transactions, and take action that may not reflect the best interests of all of the stockholders of our Company.

Substantial blocks of our total outstanding common stock, compared to historical average daily trading volume, may be sold into the market through this registration statement. If there are substantial sales of shares of our common stock, the price of our common stock could decline.

The price of our common stock could decline if there are substantial sales of our common stock through this registration statement. For the three months preceding the date of this prospectus, our average daily trading volume equaled 4,111 shares, which is substantially less than the number of shares registered through this registration statement. The market price of our common stock could decline as a result of the sale of, or our issuance of, a substantial number of shares of our common stock, compared to historical average trading volume, or due to the perception in the market that the holders listed herein and/or we intend to sell common stock.

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Our share price is likely to be volatile due to factors beyond our control and may drop below prices paid by investors, including selling stockholders listed in this prospectus.

All readers of this prospectus should consider an investment in our common stock as risky and purchase our common stock only if the purchaser can withstand a significant loss and wide fluctuations in the market value of an investment. Purchasers who acquire shares pursuant to this prospectus may be unable to sell their shares of our common stock at or above the price they paid for their shares due to fluctuations in the market price of our common stock arising from factors affecting our drug discovery and development objectives as well as changes in our operating performance or prospects. In addition, the stock market has recently experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. Some of the factors that may cause the market price of our common stock to fluctuate include, but are not limited to:

- results and timing of our clinical trials and clinical trials of our competitors' products;
- the failure or discontinuation of any of our development programs;
- issues in manufacturing SM-88 or any future drugs we may develop and receive governmental approval to market;
- regulatory developments or enforcement in the United States and non-U.S. countries with respect to our or our competitors' products;
- failure to achieve pricing and reimbursement levels expected by us or the market;
- competition from existing products or new products that may emerge;
- developments or disputes concerning patents or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- changes in estimates or recommendations by securities analysts, to the extent any cover our common stock;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- public concern over SM-88 or any future drugs we may develop and receive governmental approval to market;
- litigation or the threat of litigation;
- future issuances and sales of our common stock;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key personnel;
- changes in the structure of healthcare payment systems in the United States or overseas;
- the failure of SM-88, if approved, or any other approved drug product we may develop, to achieve commercial success;
- economic and other external factors or other disasters or crises;
- period-to-period fluctuations in our financial condition and results of operations, including the timing of receipt of any milestone or other payments under commercialization or licensing agreements, if any;
- general market conditions and market conditions for biopharmaceutical stocks; and
- overall fluctuations in U.S. equity markets.

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In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit and divert the time and attention of our management, which could seriously harm our business.

As of July 31, 2017, our common stock became listed on the Nasdaq Capital Market. Prior to such listing, our common stock was characterized by low and/or erratic trading volume, and the intraday per share price of our common stock has fluctuated from \$1.22 to \$11.25 between March 31, 2015 and March 31, 2017, the date of our last completed fiscal year.

As of July 31, 2017, our common stock became quoted on the Nasdaq Capital Market under the symbol "TYME." Even though recently listed on the Nasdaq Capital Market, the market for our stock may be impaired because of the limited number of investors, the significant ownership stakes of Messrs. Demurjian and Hoffman, and our small market public float and small capitalization, which is less than that authorized for investment by many institutional investors.

Historically, the public market for our common stock has been characterized by low and/or erratic trading volume, often resulting in price volatility. For the fiscal year ended March 31, 2017 ("Fiscal 2017") the average daily trading volume for our common stock was approximately 4,308 shares. In addition, the price of our common stock has been volatile. Our common stock had a closing price of \$6.00 on April 1, 2016 and ended fiscal year 2017 at a closing price of \$2.88. During the fiscal year 2017, our common stock had a low trading price of \$1.22, which occurred on December 27, 2016, and had a high closing price of \$11.00 which occurred on April 29, 2016.

The market price of our common stock is subject to wide fluctuations due to factors that we cannot control, including the results of preclinical and clinical testing of our products under development, decisions by collaborators regarding product development, regulatory developments, market conditions in the pharmaceutical and biotechnology industries, future announcements concerning our competitors, adverse developments concerning proprietary rights, public concern as to the safety or commercial value of any products and general economic conditions.

Furthermore, the stock market has experienced significant price and volume fluctuation unrelated to the operating performance of particular companies. These market fluctuations can adversely affect the market price and volatility of our common stock.

Risks Related to Our Business and the Development, Regulatory Approval, and Commercialization of Our Drug Candidates.

Our proprietary lead combination drug product, SM-88, is in the early stages of clinical development in two principal areas. We are currently advancing our first Phase II clinical trial for prostate cancer and are finalizing a Phase II clinical trial protocol for pancreatic cancer. Clinical drug development is expensive, time-consuming and uncertain and we may ultimately not be able to obtain regulatory approval for the commercialization of our lead candidate.

The risk of failure for drugs in clinical development is high and it is impossible to predict when our lead drug candidate for the treatment of cancer, SM-88, will prove effective or safe in humans or will receive regulatory approval.

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the U.S. Food and Drug Administration (the "FDA"), the European Medicines Agency (the "EMA"), national competent authorities in Europe and other non-U.S. regulatory authorities, which establish regulations that differ from country to country. We are not permitted to market SM-88 and any other

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drug product we may develop in the United States or in other countries until we receive approval of a New Drug Application (an “NDA”) from the FDA or marketing approval from applicable regulatory authorities outside the United States. Since SM-88 is in the early stages of development, it is subject to the risk of failure inherent in the drug development process. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA or EMA. Obtaining approval of an NDA or a Marketing Authorization Application (“MAA”) can be a lengthy, expensive and uncertain process. In addition, failure to comply with the FDA, EMA and/or other non-U.S. regulatory requirements prior to regulatory approval, could subject our Company to administrative or judicially imposed sanctions, which include, but are not limited to:

- restrictions on our ability to conduct clinical trials, including issuing full or partial clinical holds or other regulatory objections to ongoing or planned trials;
- recalls;
- restrictions on the use of drugs, manufacturers or our planned manufacturing process;
- warning letters;
- clinical investigator disqualification;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- drug seizures, detentions or import/export bans or restrictions;
- voluntary or mandatory drug recalls and publicity requirements;
- total or partial suspension of drug;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending NDAs or supplements to approved NDAs in the United States and refusal to grant marketing approvals in other jurisdictions, such as a MAA in the EU.

The FDA, EMA and other non-U.S. regulatory authorities also have substantial discretion in the drug approval process. Generally, the number of nonclinical and clinical trials that will be required for regulatory approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to address and the regulations applicable to any particular drug candidate. Regulatory agencies can delay, limit or deny approval of a drug for many reasons, which include, but are not limited to:

- the drug candidate may be deemed unsafe or ineffective;
- evolving results may not continue to confirm any or all of the positive results from earlier nonclinical or clinical trials;
- failure to select optimal drug doses and suitable trial endpoints;
- populations studied did not reflect populations likely to use the drug;
- mortality rates in clinical trials for drug candidates such as SM-88 are shown to be numerically higher given the fact that subjects are being treated for late stage cancer than participants in other clinical trial programs;
- regulatory agencies may not find the data from nonclinical and clinical trials sufficient or well-controlled;
- regulatory agencies might not approve or might require changes to manufacturing processes or facilities; and
- regulatory agencies may change their approval policies or adopt new regulations.

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Any delay in obtaining or failure to obtain, required approvals could materially adversely affect our ability to generate revenue from SM-88, which would likely result in significant harm to our financial position and adversely impact our share price. Furthermore, any regulatory approval to market SM-88 may be subject to limitations on the indicated uses for which we may market the drug. These limitations may limit the size of the market for SM-88 and any other drug product we may develop.

We have no history of conducting large-scale, pivotal Phase II or III clinical trials or commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

Our operations to date have been limited to financing and staffing our Company, developing our technology platform, SM-88 and other potential drug candidates, and conducting small-scale ongoing Phase Ib/II clinical trial for SM-88. We have not yet developed our commercialization strategy and marketing plan. In addition, our executive team has no prior experience in obtaining regulatory approval for a drug or commercializing an approved drug. Accordingly, we have not had experience completing a large-scale or pivotal clinical trial (whether Phase II, III, or otherwise), obtaining marketing approval, manufacturing product on a commercial scale or conducting sales and marketing activities. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

If we are unable to identify and qualify enough patients for our clinical trials, it could delay or prevent development of SM-88 and adversely affect our future business prospects.

The timing and length of our clinical trials depends in part on the speed at which we can identify and recruit patients to participate in clinical trials of our product candidates. Difficulties with enrollment or finding qualifying patients may cause delays in current and future clinical trials. If patients are unwilling to participate in our clinical trials due to any negative publicity in the industry, the trials for other third-party product candidates, or for other reasons, our clinical trials could be delayed or terminated.

We or our clinical trial sites may not be able to identify, recruit and enroll a sufficient number of patients, or those with the required or desired characteristics in a clinical trial, to complete our clinical trials in a timely manner. Patient enrollment is affected by factors including the design of clinical trial protocols, size of patient populations, eligibility criteria, proximity and availability of clinical trial sites, and other factors. If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business.

If clinical trials for SM-88 are prolonged, delayed or stopped, we may be unable to obtain regulatory approval and commercialize our drug on a timely basis, which would require us to incur additional costs and delay revenue.

SM-88 is in the early stages of development. We are working towards conducting our first Phase II clinical trials and their initiation is subject to numerous factors that can cause interruptions or delays, many of which may be beyond our control. Should we experience any interruption or delay, our future plans and expected future revenue could be adversely affected and could result in our inability to continue our operations.

The commencement of these planned trials could be substantially delayed or prevented due to several factors, which include, but are not limited to:

further discussions with the FDA, the EMA or other regulatory agencies regarding the scope or design of our clinical trials;

the limited number of and competition for, suitable sites to conduct our clinical trials, many of which may already be engaged in other clinical trial programs, including trials for the same potential indications as SM-88;

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inability to recruit, identify, and enroll qualifying patients to participate in our clinical trials;

delay or failure to obtain regulatory approval or agreement to commence a clinical trial in any of the countries where enrollment is planned;

inability to obtain sufficient funds required to execute our clinical and regulatory development plans;

clinical holds on or other regulatory objections to, a new or ongoing clinical trial;

delay or failure to supply regulatory-required data and other information to regulators, including the FDA and EMA;

delay or failure in the testing, validation, manufacture and delivery of sufficient supplies of SM-88 for our clinical trials;

delay or failure to reach agreement on acceptable clinical trial terms or clinical trial protocols with prospective investigational sites or clinical research organizations (“CRO”), the terms of which can be subject to extensive negotiation and may vary significantly among different sites or CROs;

delays or failures of third parties, including other agents, consultants and advisors, to provide required resources and services and submit data and information to us and the applicable regulators; and

delay or failure to obtain institutional review board or independent ethics committee (“IEC”) approval to conduct a clinical trial at a prospective investigational site.

Additionally, many factors could substantially delay or prevent the timely completion of our planned clinical trials due to several factors, which include, but are not limited to:

slower than expected rate of subject recruitment and enrollment;

slower than projected IRB/IEC review and approval;

the Data Monitoring Committee (“DMC”) for a clinical trial requires the clinical trial be delayed or stopped or requests major or minor modifications to the clinical trial;

failure of subjects to complete their full participation in clinical trial or return for post-treatment follow-up;

unforeseen safety issues, including severe or unexpected drug-related adverse effects experienced by subjects, including the possibility of death;

lack of SM-88 efficacy during the clinical trials;

poor trial design for one or more of our clinical trials;

withdrawal of participation by a Principal Investigator (“PI”) in one or more of our clinical trials;

withdrawal of participation by one of our CROs;

inability or unwillingness of subjects or clinical investigators to comply with clinical trial procedures;

resolution of data discrepancies;

inadequate CRO management and/or monitoring in one or more of our clinical trials;

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the need to repeat, reconstruct or terminate a clinical trial due to inconclusive or negative results or unforeseen complications in testing; and
a request by the FDA to abandon our current drug development programs.

Changes in regulatory requirements and guidance may also occur and we may need to significantly amend ongoing clinical trial protocols or revise planned prospective clinical trial protocols to reflect such changes mandated by regulatory authorities. Amendments may require us to renegotiate terms with CROs or resubmit clinical trial protocols to IRBs or IEUs for re-review, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by the FDA, the EMA, other regulatory authorities or the IRB/IEC overseeing the clinical trial, due to a number of factors, which include, but are not limited to:

failure to conduct the clinical trial in accordance with regulatory requirements or compliance with the clinical protocol;

unforeseen safety issues or any determination that a clinical trial presents unacceptable health risks to subjects;

lack of adequate funding to continue the clinical trial due to higher or additional unforeseen costs or other business decisions; and

upon a breach or pursuant to the terms of any agreement with or for any other reason by, current or future collaborators that have responsibility for the clinical development of SM-88.

Any failure or significant delay in clinical and regulatory development plans for SM-88 or any other drug candidate we may pursue would likely adversely affect our ability to obtain regulatory approval for the drug and would diminish our ability to generate revenue.

The results of previous studies may not be predictive of future results, our progress in future trials for one drug candidate may not be indicative of progress in trials for other drug candidates and the results of our current and planned clinical trials may not satisfy the requirements of the FDA, the EMA or other non-U.S. regulatory authorities.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. Before obtaining marketing approval from regulatory authorities any sale of SM-88, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and has a risk of uncertainty as to its outcome.

Clinical failure can occur at any stage of clinical development and the outcome of early clinical trials may not be predictive of the success of later clinical trials. Additionally, interim results of a clinical trial do not necessarily predict final trial results. In addition, nonclinical and clinical data are often susceptible to varying interpretations and analyses. In this regard, many companies that have believed their drug performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products from regulatory organizations.

Drug candidates that have shown promising results in early clinical trials, studies (such as our First Human Study) and compassionate use (such as our Compassionate Use Patients) may still suffer significant setbacks in subsequent registration clinical trials. Many companies in the pharmaceutical industry, including those with greater resources and experience than us, as well as those that have conducted highly powered clinical trials under an IND (in contrast to our limited number of First Human Study patients and Compassionate Use Patients, all of whom were treated outside of an IND approved clinical trial) have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials. In light of these factors, and the fact that our dosage and method of delivery from our First Human Study and Compassionate Use Patients

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differ from our current Phase II trial, and may differ from future Phase II trials, no assurance can be given that our ongoing or future Phase II (or subsequent) trials may produce results similar to our First Human Study or those experienced by Compassionate Use Patients.

We may, from time to time, publish interim or preliminary data from our clinical trials, First Human Study or Compassionate Use Patients. Adverse changes between this interim data and final data obtained from our future clinical trials could harm our business prospects. In the 30 patients who received SM-88 in our First Human Study, treatment-related AEs were reported in all of patients, of which hyperpigmentation was the only consistent, lasting AE. The most common treatment-related AEs were hyperpigmentation (100%), mild transient fatigue (57%), and mild transient pain (13%). Many of these patients who were treated with SM-88 were late-stage cancer patients with one or more previous treatments or existing medical conditions, which can cause AEs unrelated to SM-88. Patients may also report additional AEs that have not yet been predicted. Patients who will be administered SM-88 in our clinical trials are, or may be, seriously ill and as more patient data becomes available, there is a risk that future clinical outcomes may materially differ from First Human Study or Compassionate Use Patient data. Any negative material changes could have an adverse effect on our business and product development efforts.

Clinical trials may also produce negative or inconclusive results and we may decide to, or regulators may require us to, conduct additional clinical or nonclinical testing. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that SM-88 is safe and effective for use in diverse populations before we can seek regulatory approvals for its commercial sale.

In addition, the design of a clinical trial can determine whether its results will support approval of a drug. Flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval in general, or in an efficient manner given our limited resources.

In some instances, there may be significant variability in safety and/or efficacy results between different trials of the same drug due to numerous factors, including amendment to trial protocols, variability in size and type of the patient populations, adherence to the dosing regimen and other trial procedures and the rate of dropout among clinical trial subjects. We do not know whether any of the clinical trials in our current development plans will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market SM-88, and we may need to further refine or redesign our combination drug candidate formula or modify production methodology based on such clinical trials, each of which could result in delays in the regulatory approval process.

There is always the possibility that SM-88 may not gain regulatory approval even if it achieves its primary endpoints in its Phase III clinical trials, which may only be initiated if we are successful in complying with all regulatory requirements necessary to commence Phase III clinical trials. The FDA, the EMA or other non-U.S. regulatory authorities may disagree with our trial design and/or our interpretation of data from nonclinical and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a drug even after reviewing and providing comments or advice on a protocol for a clinical trial. In addition, any of these regulatory authorities may also approve a drug for fewer or more limited indications than requested or may grant approval that is contingent on the performance of costly post-marketing clinical trials. Further, the FDA, the EMA or other non-U.S. regulatory authorities may not accept the labeling claims that we believe would be necessary or desirable for the successful commercialization of SM-88.

Even if SM-88 obtains regulatory approval, it could be subject to continual regulatory review.

If marketing authorization is obtained for our lead drug candidate, SM-88, the drug could continue to be under review by regulatory authorities. As a result, authorization could be subsequently withdrawn or restricted at any time for a number of reasons, including safety issues. We will be subject to ongoing obligations and oversight by regulatory authorities, including AE reporting requirements, marketing restrictions and, potentially, other post-

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marketing obligations, all of which may result in significant expense and limit our ability to successfully commercialize our drug product.

If there are changes in the application of legislation or regulatory policies or if problems are discovered with SM-88 or our manufacturer(s) or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include imposing fines on us, imposing restrictions on the drug or its manufacture and requiring us to recall or remove the drug from the market. The regulators could also suspend or withdraw our marketing authorizations, requiring us to conduct additional clinical trials, change our drug labeling or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell SM-88 may be impaired and we may incur substantial additional expense to comply with regulatory requirements, which could adversely affect our business, financial condition and the results of operations and the value of our share price.

We may not be successful in our efforts to use and expand our technology platform to build a pipeline of drug candidates.

A key element of our business strategy is to further develop and expand our technology platform so that we can build a steady pipeline that we ultimately hope will be successful in the treatment of a variety of cancers, as well as other diseases that affect health and quality-of-life. However, we may not be able to develop and obtain approval to market our drugs if regulators do not conclude that they are safe and effective. Furthermore, the potential drug candidates that we discover may not be suitable for further clinical development, whether due to the potential that they produce harmful adverse effects or possess other characteristics that indicate that they are unlikely to receive marketing approval and/or market acceptance. In addition, unexpected technical issues involving such product candidates could be encountered that could cause the products to be prohibitively too expensive to manufacture and market. If we do not continue the steady development and commercialization of products utilizing our technology platform, we will face difficulty in achieving increased revenues in future periods, which could result in significant harm to our financial position and adversely affect our share price.

We have filed patents relating to additional drug candidates based on our technology platform. However, to date, the FDA and other regulatory authorities have not approved products that utilize this technology platform.

In the future, we plan to develop additional drug candidates based on our technology platform. This platform incorporates novel technologies and methods and actions. Since regulators have not yet approved such a platform, the approval of the drug candidates in our pipeline is less certain than approval of drugs that do not employ such novel technologies or methods of action. We intend to work closely with the FDA, the EMA and other non-U.S. regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for these future drug candidates. It is possible that the validation process may take time and significant expenditures of resources, require independent third-party analyses or not be accepted by the FDA, the EMA and other non-U.S. regulatory authorities. Delays or failure to obtain regulatory approval of any of our future drug candidates could adversely affect our business prospects and the value of our share price.

Even if we obtain marketing approval for SM-88 in a major pharmaceutical market such as the United States or Europe, we may never obtain approval or commercialize in other major markets, which would limit our ability to realize the drug's full market potential.

In order to market any products in a country or territory, we must establish and comply with numerous and varying regulatory requirements of such countries or territories regarding safety and efficacy. Clinical trials conducted in one country may not be acceptable for review by regulatory authorities in other countries and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures differ among countries and can involve additional testing and validation as well as varying administrative review periods. Seeking regulatory approvals in multiple countries could result in significant

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delays, difficulties and costs and may require additional nonclinical or clinical trials, which would be costly and time-consuming or even delay or prevent the introduction of SM-88 in those countries. In addition, our failure to obtain regulatory approval in one country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any drug candidates approved for sale in any jurisdiction, including international markets and we therefore do not have experience in obtaining regulatory approval. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to create stockholder value for SM-88 will be harmed.

In the United States, we may seek fast track or breakthrough designation for SM-88. There is no assurance that the FDA will grant either designation and even if it does, such designation may not actually lead to a faster development process, regulatory review or ultimate approval compared to conventional FDA procedure. Any achievement of fast track or breakthrough designation for SM-88 would not increase the likelihood that SM-88 will receive marketing approval in the United States.

The fast track program, a provision of the Food and Drug Administration Modernization Act of 1997 (“FDAMA”), is designed to facilitate interactions between a sponsor and the FDA before and during submission of an NDA for an investigational agent that, alone or in combination with one or more drugs, that is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need for that disease or condition. Under the fast track program, the FDA may consider reviewing portions of a marketing application before the sponsor submits the complete application, if the FDA determines, after a preliminary evaluation of the clinical data, that a fast track drug may be effective. A fast track designation provides the opportunity for more frequent interactions with the FDA and could make the drug eligible for priority review if supported by clinical data at the time of submission of the NDA.

The FDA is authorized to designate a new drug as a breakthrough therapy if it finds that the drug is intended, alone or in combination with one or more drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Products designated as breakthrough therapies by the FDA are also eligible for accelerated approval.

The FDA has broad discretion whether or not to grant fast track or breakthrough designation. Accordingly, even if we believe SM-88 meets the criteria for fast track or breakthrough designation, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of fast track or breakthrough designation for a drug candidate may not result in a faster development process, review or approval compared to drug candidates considered for approval under conventional FDA procedures and, in any event, does not assure ultimate approval by the FDA. The FDA may even withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Further, in connection with fast track designation, we may be required to provide government regulators with additional manufacturing and production information, some of which we may not be able to provide in a timely manner and to the extent required by such regulators.

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Should we choose to pursue orphan drug designation, we may be unable to obtain orphan drug designation or exclusivity for SM-88 or any other drug candidate we may develop. If our competitors instead are able to obtain orphan drug exclusivity for their products in the same indications for which we are developing SM-88 or any other drug candidate we may develop, we may be at a competitive disadvantage and may not be able to have our products approved by the applicable regulatory authority for a significant period of time, if at all. Conversely, if we obtain orphan drug exclusivity for SM-88 or any other drug we may develop, we may not be able to fully benefit from the associated marketing exclusivity.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate SM-88 as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. In the European Union (the "EU"), the European Commission may designate a drug candidate as an orphan medicinal drug if it is a medicine for the diagnosis, prevention or treatment of life-threatening or very serious conditions that affects not more than five in 10,000 persons in the EU or it is unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development. If SM-88 or any other drug candidate we may develop were to receive orphan drug designation, we still may not have market exclusivity in particular markets. There is no assurance we will be able to receive orphan drug designation for SM-88 or any other drug candidate we may develop. Further, the granting of a request for orphan drug designation does not alter the standard regulatory requirements and process for obtaining marketing approval.

Generally, if a drug candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which, subject to certain exceptions, precludes the FDA from approving the marketing application of another drug for the same indication for that time period or precludes the EMA and other national drug regulators in the EU, from accepting the marketing application for another medicinal drug for the same indication. The applicable period is seven years in the United States and ten years in the EU. The EU period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. In the EU, orphan exclusivity may also be extended for an additional two years (*i.e.*, a maximum of 12 years' orphan exclusivity) if the drug is approved based on a dossier that includes pediatric clinical trial data generated in accordance with an approved pediatric investigation plan. Orphan drug exclusivity may be lost in the United States if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for SM-88 or any other drug candidate we may develop, that exclusivity may not effectively protect the drug from competition because exclusivity can be suspended under certain circumstances. In the United States, even after an orphan drug is approved, the FDA can subsequently approve another drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the EU, orphan exclusivity will not prevent a marketing authorization from being granted for a similar drug in the same indication if the new drug is safer, more effective or otherwise clinically superior to the first drug or if the marketing authorization holder of the first drug is unable to supply sufficient quantities of the drug.

SM-88 or any other drug product we may develop may have serious adverse, undesirable or unacceptable side effects, which may delay or prevent marketing approval. If such side effects are identified during the development of SM-88 or any other drug candidate we may develop or following such drug product's approval, if any, we may need to abandon our development of SM-88 or such other drug product, the commercial profile of any approved label may be limited and/or we may be subject to other significant negative consequences following marketing approval, if any.

Although SM-88 and any other drug products we may develop will undergo safety testing to the extent possible and agreed to with regulatory authorities, not all adverse effects of drugs can be predicted or anticipated. SM-88,

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our proprietary combination drug product is based on a mechanism designed to utilize oxidative stress, among other techniques, to selectively kill cancer cells, yet is powerful and could lead to serious side effects that we only discover in clinical trials. Unforeseen side effects from SM-88 or any other drug product we may develop could arise either during clinical development or, if such side effects are sporadic, after it has been approved by regulatory authorities and the approved drug has been marketed, resulting in the exposure of additional patients. While our proof-of-concept clinical trial for SM-88 demonstrated a favorable safety profile, the results from future trials of SM-88 may not confirm these results. Any new therapy to kill cancer tumors is risky and may have unintended consequences. We have not fully demonstrated that SM-88 is safe in humans and we may not be able to do so.

Furthermore, we are initially developing SM-88 for patients with cancer for whom no other therapies have succeeded and survival times are frequently short. Therefore, we expect that certain subjects may die during the clinical trials and it may be difficult to ascertain whether such deaths are attributable to the underlying disease, complications from the disease, SM-88 or a combination of such factors.

The results of future clinical trials may show that SM-88 causes undesirable or unacceptable side effects, which could interrupt, delay or halt our clinical trials and result in delay of or failure to obtain, marketing approval from the FDA, the European Commission and other non-U.S. regulatory authorities or result in marketing approval from the FDA, the European Commission and other non-U.S. regulatory authorities with restrictive label warnings or potential drug liability claims.

If SM-88 or any other drug candidate we may develop receives marketing approval and it is later identified as undesirable or has unacceptable side effects, we are at risk for the following actions:

regulatory authorities may require us to take SM-88 or such other drug product off the market;

regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;

regulatory authorities may require post-market clinical trials to assess possible serious risks associated with SM-88 or such other drug product, which will require us to provide the FDA with additional data;

we may be required to change the way SM-88 or such other drug product is administered, conduct additional clinical trials or change the labeling of the drug;

we may be subject to limitations on how we may promote SM-88 or such other drug product;

sales of SM-88 or such other drug product may never gain traction or could decrease significantly;

we may be subject to litigation or drug liability claims; and

our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of SM-88 or such other drug product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of SM-88 or such other drug product.

We depend on continued patient enrollment into our clinical trials. If we are unable to enroll patients in our clinical trials, our research and development efforts could be materially adversely affected.

Successful and timely completion of clinical trials will require that we enroll and complete the trials with a sufficient number of evaluable subjects. Our clinical trials may be subject to delays resulting from the trials'

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slower enrollment or subject withdrawal. Subject enrollment depends on many factors, including the size and nature of the patient population, eligibility criteria for the clinical trial, the proximity of patients to clinical sites, the design of the clinical protocol, the availability of competing clinical trials for the same population of subjects, the availability of new drugs approved for the drug candidate that is the subject of the clinical trial, and clinicians' and patients' perceptions as to the potential advantages of SM-88 and any other drug product we may develop in relation to other available therapies.

These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial for SM-88 and any other drug product we may develop will increase our costs, slow down our drug development and delay or potentially jeopardize our ability to commence drug sales and generate revenue. In addition, some of the factors that cause or lead to, a delay in the completion of clinical trials may also ultimately lead to the denial of regulatory approval of SM-88 and any other drug product we may develop.

Even if approved, if SM-88 does not achieve broad market acceptance among physicians, patients, the medical community and third-party payors, our revenue generated from its sales will be limited.

The commercial success of our SM-88 and any other drug product we may develop will depend upon its acceptance among physicians, patients and the overall medical community. The degree of market acceptance of SM-88, which would be applicable to any other drug product we may develop, will depend on a number of factors, which include, but are not limited to:

limitations or warnings contained in the approved labeling for SM-88;

changes in the standard of care for the targeted therapy;

limitations in the approved clinical indications for SM-88;

demonstrated clinical safety and efficacy of SM-88 compared to other drugs;

lack of significant adverse effects;

limitations on how we promote SM-88;

sales, marketing and distribution support;

availability and extent of reimbursement from managed care plans and other third-party payors;

timing of market introduction and perceived effectiveness of competitive drugs;

the degree of cost-effectiveness of SM-88;

availability of alternative therapies, whether or not at a similar or lower cost, including generic and over-the-counter drugs;

the extent to which SM-88 is approved for inclusion on formularies of hospitals and managed care organizations;

whether SM-88 is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy;

adverse publicity about SM-88 or favorable publicity about competitive drugs;

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convenience and ease of administration; and

potential drug liability claims.

If SM-88 or any other drug candidate we may develop is approved but does not achieve an adequate level of acceptance by physicians, patients and the overall medical community, we may not generate sufficient revenue to become profitable or to sustain operations. In addition, efforts to educate the medical community and third-party payors on the benefits of SM-88 or any other drug candidate we may develop may require significant resources and may never be successful.

We are subject to manufacturing risks that could substantially increase our costs and limit the supply of SM-88 and any other drug product we may develop.

As is likely to be common with any other drug candidate we may develop, the process of manufacturing SM-88 is complex, highly regulated and subject to several risks, which include, but are not limited to the following risks:

We do not have experience in manufacturing SM-88 in bulk quantity or at commercial scale. We plan to contract with external manufacturers to develop a larger scale process for manufacturing SM-88 in parallel with our Phase II trial of SM-88. We may not succeed in the scaling up of our process or we may need a larger manufacturing process for SM-88 than what we have planned. Any changes to our manufacturing processes may result in the need to obtain additional regulatory approvals. Difficulties in achieving commercial-scale production or the need for additional regulatory approvals could delay the development and regulatory approval of SM-88 and ultimately affect our success.

The process of manufacturing drugs, such as SM-88, is extremely susceptible to loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in drug characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, drug defects and other supply disruptions. If microbial, viral or other contaminations are discovered in SM-88 or in the manufacturing facilities in which SM-88 is made, such manufacturing facilities may need to be closed for an extended time to investigate and remedy the contamination.

A shortage of one or more SM-88 drug substance(s) or ingredients.

The manufacturing facilities in which SM-88 is made could have delays in manufacturing due to delays created by other sponsor company drug manufacturing runs, which could affect our manufacturing runs.

An unforeseen increase in ingredients procurement or other manufacturing costs.

The manufacturing facilities in which SM-88 is made could be adversely affected by equipment failures, labor shortages, labor strikes, natural disasters, power failures, lack of phone or internet services, riots, crime, act of foreign enemies, war, nationalization, government sanction, blockage, embargo, any extraordinary event or circumstance beyond control and numerous other factors.

We and our manufacturing partners must comply with applicable current Good Manufacturing Practice (“cGMP”) and local and state regulations and guidelines. Compliance with cGMP can be time consuming and expensive. Further, cGMP may not be flexible in situations where business pressures would normally call for immediate ingenuity. We or our manufacturing partners may encounter difficulties in achieving quality controls and quality assurance and may experience shortages in qualified personnel. We and our manufacturing partners will be subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm compliance with applicable regulatory requirements. Any failure to follow cGMPs or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging or storage of SM-88 that result

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from a failure at the facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize SM-88. This could lead to significant delays in the availability of our drug for clinical trials or the termination or clinical hold on a trial or the delay or prevention of a filing or approval of marketing applications for SM-88. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for SM-88, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we and/or our manufacturing partners are not able to maintain regulatory compliance, we may not be permitted to market SM-88 and/or may be subject to drug recalls, seizures, injunctions or criminal prosecution.

Any adverse developments affecting manufacturing operations for SM-88, if approved for marketing by the FDA, may result in shipment delays, inventory shortages, lot inspection failures, drug withdrawals or recalls or other interruptions in the supply of SM-88. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet regulator-approved manufacturing specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives; and

Drug products that have been produced and stored for later use may degrade, become contaminated or suffer other quality defects, which could cause the affected products to no longer be suitable for its intended use in clinical trials or other development activities. If the defective drug cannot be replaced in a timely fashion, we may incur significant delays in our development programs that could adversely affect the value of SM-88.

One component of SM-88 is a derivation of an existing FDA-approved drug that has been modified to contribute to the functionality of SM-88. This drug substance is being manufactured by a FDA-approved, third party and to date that manufacturer is our sole supplier of this drug substance. Even though the drug substance is currently being manufactured, its modification and the modified drug's manufacturing and use in our combination drug product must still undergo regulatory review and approval. To our knowledge, the current manufacturer of this drug substance is the only FDA-approved supplier of the existing drug in the United States. We believe this cGMP manufacturer has sufficient capacity to meet our projected needs into the near future. In the event of a catastrophic event or this manufacturer is unable to meet our needs, we will, due to the nature of the drug substance and the modifications required for this drug substance, need to find an alternative source of supply, which will likely result in time delays in the clinical development process. We believe that replacement for this supplier, in the event it becomes necessary, is not impossible, but would cost us in development time. Currently, we do not have an arrangement in place for a secondary supplier for this drug substance.

We currently have no marketing, sales or distribution infrastructure. If we are unable to develop sales, marketing and distribution capabilities on our own or through collaborations or if we fail to achieve adequate pricing and/or reimbursement, we will not be successful in commercializing SM-88 and any other drug product we may develop.

We currently have no marketing, sales and distribution capabilities because our lead drug candidate, SM-88, is still in clinical development and initial trials and our other drug candidates are only in the initial stages of development. If SM-88 is approved, we intend either to have established a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our drug or to have outsourced this function or portions, to one or more experienced third parties. Either of these options is expensive and time-consuming. Some of these costs may be incurred well in advance of any regulatory approvals for SM-88. In addition, we may not be able to hire a sales force that is sufficient in size or has adequate expertise in the medical markets that we intend to target. Any failure or delay in the development of our internal sales, marketing and distribution capabilities or to outsource these functions, in whole or part, would adversely affect the commercialization of our products.

To the extent that we enter into collaborative agreements for marketing, sales and/or distribution, our revenue may be lower than if we directly marketed and sold SM-88. In addition, any revenue we receive will depend in

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whole or in part upon the efforts and success of these third-party collaborators, which are likely not to be entirely within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize SM-88. If we are not successful in commercializing SM-88, either on our own or through collaborations with one or more third parties, our future revenues will suffer, we may incur significant and additional losses and we may be forced to curtail operations. These factors would have an adverse effect on our share price.

SM-88 and any other drug product we may develop will face significant competition and, if competitors develop and market products that are more effective, safer or less expensive than our drug, our commercial opportunity will be negatively impacted.

The anticancer treatment industry is highly competitive and subject to rapid and significant technological changes. We are currently developing SM-88 to compete with other drugs that currently exist or are being developed. Drugs we may develop in the future are also likely to face competition from other drugs, some of which we may not be currently be aware of. In marketing our products, we will have domestic and international competitors, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, patient recruitment and manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in more advanced stages of development or collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies also may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make SM-88 and any other drug product we may develop obsolete. Some or all of these factors may contribute to our competitors succeeding in obtaining patent protection and/or marketing approval or developing and commercializing products in our field before we do.

There are a large number of companies working to develop and/or market various types of anticancer treatments. These treatments consist both of small molecule drugs, as well as biological drugs that work by using next-generation technology platforms to address specific cancer targets. These treatments are often combined with one another in an attempt to maximize a response rate. In addition, several companies are developing drugs that work by targeting additional specificities using a single recombinant molecule.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient or are less expensive than SM-88. Our competitors also may obtain FDA, EU or other non-U.S. regulatory approval for their products more rapidly than we may, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if SM-88 achieves marketing approval, it may be priced at a significant premium over competitive products, if any have been approved by then, resulting in our product's reduced competitiveness.

In addition, our future ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of similar or biosimilar products.

In addition, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Health Care Reform Law also created a new regulatory scheme authorizing the FDA to approve biosimilars. Under the Health Care Reform Law, a manufacturer may submit an application for licensure of a

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biologic product that is “biosimilar to” or “interchangeable with” a previously approved biological product or “reference product,” without the need to submit a full package of nonclinical and clinical data. Under this new statutory scheme, an application for a biosimilar product may not be submitted to the FDA until four years following approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full NDA for such product containing the sponsor’s own nonclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. Furthermore, recent legislation has proposed that the 12-year exclusivity period for each a reference product may be reduced to seven years.

Smaller and other early-stage companies also may prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, recruiting clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to or necessary for, SM-88. In addition, the biopharmaceutical industry is characterized by rapid technological changes. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval and commercialization of SM-88 or any other drug candidate we may develop and may affect the price we set. Our successful commercialization will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement and pricing policies.

In the United States, the EU, its member states and some other foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system. These changes could prevent or delay marketing approval of SM-88 or any other drug product we may develop, restrict or regulate post-approval activities and affect our ability to sell and recognize revenue from SM-88 or any other drug product we may develop. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing health care costs, improving quality and/or expanding access to health care.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the “Medicare Modernization Act”) changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sale prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost-reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

In addition, the Health Care Reform Law, among other things, increased rebates a manufacturer must pay to the Medicaid program, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, established a new Medicare Part D coverage gap discount program in which manufacturers must provide 50% point-of-sale discounts on products covered under Part D and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain health care services through bundled payment models. Further, the new law imposed a significant annual fee on companies that manufacture or import branded prescription drug

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products. Substantial new provisions affecting compliance were enacted, which may affect our business practices with health care practitioners. The goal of the Health Care Reform Law is to reduce the cost of health care and substantially change the way health care is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the Health Care Reform Law may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of and the price we may charge for, any products we develop that receive regulatory approval. We also cannot predict the impact of the Health Care Reform Law on our business or financial condition, as many of the Health Care Reform Law reforms require the promulgation of detailed regulations implementing the statutory provisions, which has not yet occurred.

Moreover, other legislative changes have also been proposed and adopted in the United States since the Health Care Reform Law was enacted. On September 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our future results from operations.

The delivery of health care in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the health care budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of SM-88 and any other drug product we may develop, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval.

If any drug liability lawsuits are successfully brought against us or any of our collaborators, we may incur substantial liabilities and may be required to limit commercialization of SM-88 and any other drug product we may develop.

We face an inherent risk of drug liability lawsuits related to the testing of SM-88 and any other drug candidate we may develop that is intended to treat seriously ill patients. In addition, we face risk of liability lawsuits if SM-88 or any of other drug product of ours is approved by regulatory authorities and introduced commercially. Drug liability claims may be brought against us or our collaborators, if any, by subjects enrolled in our clinical trials, patients, health care providers or others using, administering or selling SM-88 or such other drug product. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities. Regardless of their merit or eventual outcome, liability claims may result in, but are not limited to:

decreased demand for SM-88 or any other drug candidate we may develop;

injury to our reputation;

withdrawal of subjects in our clinical trials;

withdrawal of clinical trial sites or entire trial programs;

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increased regulatory scrutiny;

significant litigation costs;

substantial monetary awards to or costly settlements with patients or other claimants;

drug recalls or a change in the indications for which they may be used;

loss of revenue;

diversion of management and scientific resources from our business operations; and

the inability to commercialize SM-88 or such other drug product.

If SM-88 is approved for commercial sale, we will be highly dependent upon consumer perception and the safety and quality of SM-88. We could be adversely affected if we are subject to negative publicity or if SM-88 proves to be or is asserted to be, harmful to patients. Because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of SM-88 could have a material adverse impact on our financial condition or results of operations. This would also be true with respect to any other drug product we may develop, receive regulatory approval of and, thereafter, seek to market.

When necessary, we intend to obtain clinical trial insurance for the SM-88 Phase II clinical trial. We also intend to obtain drug liability insurance coverage at appropriate levels for our operations, which will vary as the level of our operations vary during our growth from a R&D company to a company manufacturing and/or marketing drugs to the public. Our planned insurance coverage may not be adequate to cover all liabilities that we may incur. We also may need to increase our insurance coverage when we begin the commercialization of SM-88. Insurance coverage can be expensive for pharmaceutical products and candidates. As a result, we may be unable to obtain or maintain sufficient liability insurance at a reasonable cost to protect us against losses, which could have a material adverse effect on our business. A successful drug liability claim or series of claims brought against us, particularly if judgments exceed any insurance coverage we may have, could decrease our cash resources and adversely affect our business, financial condition and results of operations and could possibly cause us to cease our operations in their entirety.

Our management lacks experience in obtaining FDA approval of products, which could result in delays or the failure to obtain required regulatory approval of our products.

Although they have experience in creating and marketing various products, our chief executive and chief operation officers have never previously organized, managed or completed FDA-required submissions and clinical trials concerning new drug products. While we intend to retain employees, advisors and consultants with experience in the FDA approval process and have retained and utilized a number of such advisors and consultants currently and in the past, the lack of experience by our chief executive and operating officers could result in: delays in obtaining necessary regulatory approvals, both in conducting clinical trials and final marketing approvals; additional costs; and the possibility that approvals will not be obtained due to the failure to comply with the regulatory approval process; such delays, costs and/or failure would likely adversely affect our business, financial condition and results of operations and could possibly cause us to cease our operations in their entirety

Risks Related to our Financial Condition and Need for Additional Capital

We have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We have no products approved for commercial sale and to date we have not generated any revenue or profit from drug sales. We may never realize revenue or profitability.

We are a clinical-stage pharmaceutical company with a limited operating history. We have incurred significant losses since our inception. As of March 31, 2017, our accumulated deficit was \$33,862,088. Our losses have

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resulted principally from expenses incurred in the discovery and development of SM-88 and from general and administrative expenses incurred while building our business infrastructure. We expect to continue to incur losses for the near future. Furthermore, we expect these losses to increase as we continue our research and development of and seek regulatory approval for our drug candidate SM-88, prepare for and begin to commercialize SM-88 or any other regulatory-approved products and add infrastructure and personnel to support our drug development efforts and operations as a public company. The net losses and negative cash flows incurred to date, together with expected future losses, have had and likely will continue to have, an adverse effect on our stockholders' equity and working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of increased expenses or when or if, we will be able to realize revenue or achieve profitability. For example, our expenses could increase if FDA or EMA require us to conduct supplemental clinical trials not included in our current development plan or if there are any delays in completing our planned clinical trials or in the development of SM-88 or any other drug product we may pursue.

To become and remain profitable, we must succeed in the development and commercialization of drug products with significant market potential. This will require us to be successful in a range of challenging activities for which we are only in the preliminary stages, including, with respect to the near term, developing SM-88, obtaining regulatory approval and manufacturing, marketing and selling SM-88. We may never succeed with these activities or generate revenue from drug sales that is significant enough to achieve profitability. Our ability to generate future revenue from drug sales depends heavily on our success in many areas, which include, but are not limited to:

completing research and clinical development of SM-88, including successful completion of required clinical trials;

obtaining marketing approval for SM-88;

developing a sustainable and scalable manufacturing process for SM-88 and maintaining supply and manufacturing relationships with third parties that can conduct the process and provide adequate (in amount and quality) drugs to support clinical development and the market demand for SM-88, if approved;

launching and commercializing SM-88, either directly or with a collaborator or distributor;

establishing sales, marketing and distribution capabilities in the United States and in other markets, such as the EU;

obtaining market acceptance of SM-88 as a viable treatment option;

addressing any competing technological and market developments;

identifying, assessing, acquiring and/or developing new drug candidates;

negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;

maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and

attracting, hiring and retaining qualified personnel.

These factors applicable to SM-88 would be applicable to any other drug candidate we may develop.

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Even if SM-88 or another drug candidate that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercialization. Because of the numerous risks and uncertainties with drug development, we are unable to accurately predict the timing or amount of increased expenses or when or if, we will be able to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to realize revenue or become or remain profitable could depress our market value and could impair our ability to raise capital, expand our business, develop other drug candidates or continue our operations. A decline in the value of our shares could also cause investors in our common stock (or other securities we may issue in the future) to lose all or part of their investment.

We will require substantial additional funding, which may not be available to us on acceptable terms or at all and, if not available, may require us to delay, scale back or cease our drug development programs or operations.

In addition to SM-88, we seek to advance multiple drug candidates through our research and clinical development process. The completion of the development and the potential commercialization of SM-88 or any other drug candidate will require substantial funds. Our future financing requirements will depend on many factors, some of which are beyond our control, which include, but are not limited to:

the number and characteristics of drug candidates that we pursue;

the scope, progress, timing, cost and results of nonclinical and clinical development and research;

the costs, timing and outcome of our seeking and obtaining FDA, EMA and other non-U.S. regulatory approvals;

the costs associated with manufacturing SM-88, as well as other potential drug candidates, and establishing sales, marketing and distribution capabilities;

our ability to maintain, expand and defend the scope of our IP portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other IP rights;

the extent to which we acquire or in-license other products or technologies;

our need and ability to hire additional administrative, managerial, scientific, operational and medical personnel;

the effect of competing products that may limit market penetration of SM-88 and any other drug candidates we may develop;

the amount and timing of revenues, if any, we receive from commercial sales of SM-88 or any other drug candidates for which we receive marketing approval in the future;

our need to implement additional internal systems and infrastructure, including financial and reporting systems; and

the economic and other terms, timing of and ultimate success of any future collaboration, licensing or other arrangements, including the timing of achievement of milestones and receipt of any milestone or royalty payments under such agreements.

Until we can generate sufficient drug and royalty revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. Any additional fundraising efforts may divert management's attention from day-to-day activities

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and product development, which may adversely affect our ability to develop and commercialize our product candidates. Additional financing may not be available to us when we need it or financings may not be available on favorable terms. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our drug candidates, technologies, future revenue streams or research programs and/or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interests of our then existing stockholders could be diluted and the terms of these securities may include liquidation or other preferences that adversely affect stockholders' rights. In addition, certain holders of our outstanding securities that acquired our securities in March and April 2017 private placement transactions (the "2017 Private Placement Investors") have limited anti-dilution protection that could result in additional dilution to our stockholders generally. These provisions provide that if we raise certain funds before the Anti-dilution Expiry Date (defined below) at an effective average consideration and/or exercise or conversion price per share price less than \$2.55 per share, subject to exceptions for issuances of certain "exempt securities," anti-dilution protections could apply which could obligate us to issue additional securities to the 2017 Private Placement Investors. "Anti-Dilution Expiry Date" means the earliest to occur of (i) the business day after we raise \$10 million or more in one or more public or private offerings within six months of the applicable purchase date for the 2017 Private Placement Investors or (ii) the six month anniversary of the applicable purchase date for the 2017 Private Placement Investors.

If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain adequate financing when needed and on favorable terms, we may have to delay, reduce the scope of or suspend one or more of our clinical trials or research and development programs or our commercialization efforts.

We may expend our limited resources to pursue SM-88 for certain indications that may not be the most profitable or do not have the greatest likelihood of success.

Because we have limited financial and managerial resources, we currently are focusing our research programs on SM-88 for the treatment of specified cancer therapies. As a result, we may forego or delay pursuit of opportunities with other drug candidates or other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and drug candidates for specific indications may not yield any commercially viable products.

If we do not accurately evaluate the commercial potential or target market for SM-88 or any other drug candidate, we may relinquish valuable rights through collaboration, licensing or other royalty arrangements in cases where it would have been advantageous for us to retain sole development and commercialization rights.

If we do not achieve our projected development goals in the periods we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.

Over the course of our development efforts, we will estimate the successful completion of various scientific, clinical, regulatory and other drug development goals, which we refer to as milestones. These milestones may include the commencement or completion of clinical trials and the submission of planned regulatory filings. Occasionally, we may publicly announce the expected timing of some of these milestones. For example, throughout this prospectus, we state that we plan to begin Phase II trials during 2016. All of these milestones will be based on a variety of assumptions. The actual timing of achieving these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, the commercialization of our products may be delayed and, as a result, our stock price may decline.

[Table of Contents](#)**Risks Related to our Reliance on Third Parties**

We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of these trials.

We will not independently conduct clinical trials for SM-88 and may not do so for any other drug product we may develop. We will and may rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators to perform these functions. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, the FDA requires us to comply with standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible, accurate and that the rights, integrity and confidentiality of subjects in clinical trials are protected, even though we are not in control of these processes. These third parties also may have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for SM-88 or other products we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize SM-88 and any other drug product we may develop.

We also will rely on other third parties to store and distribute supplies for our clinical trials. Any performance failure on the part of our existing or future distributors could delay clinical development or regulatory approval of SM-88, producing additional losses and depriving us of potential revenue.

We intend to rely on third-party contract manufacturing organizations to manufacture and supply SM-88 for us. If one of our suppliers or manufacturers fails to perform adequately or fulfill our needs, we may be required to incur significant costs and devote significant efforts to find new suppliers or manufacturers. We may also face delays in the development and commercialization of SM-88 and any other drug product we may develop.

We currently have limited experience in and we do not own facilities for, clinical-scale manufacturing of SM-88 and we will rely upon third-party contract manufacturing organizations to manufacture and supply drug for our clinical trials. The manufacture of pharmaceutical products in compliance with the FDA's cGMP requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, quality control, including drug stability, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced cGMP requirements and other federal and state regulatory requirements and foreign regulations. If our manufacturers were to encounter any of these difficulties or otherwise fail to comply with their obligations to us or under applicable regulations, it would jeopardize our ability to supply investigational drug for our clinical trials. Any delay or interruption in the supply of clinical trial materials could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical development programs and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the ongoing trials.

All manufacturers used to formulate the components of SM-88 must comply with cGMP requirements, which are enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance and the documentation and maintenance of records. Manufacturers of our drug candidates may be unable to comply with cGMP requirements and/or with other FDA, state and foreign regulatory requirements. The FDA or similar foreign regulatory agencies may also implement new standards at any time or change their interpretation and enforcement of existing standards for the manufacture, packaging or testing of drug products. We have little control over our manufacturers' compliance with these regulations and standards and a failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in drug approval, drug seizure or recall or withdrawal of a drug approval. If the safety of any drug supplied is compromised due to a manufacturers' failure to adhere to applicable laws or for

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other reasons, we may not be able to obtain regulatory approval for or successfully commercialize SM-88 and as a result, may be held liable for any injuries sustained. Any of these factors could cause a delay of clinical trial completion, regulatory submission, approval or commercialization of SM-88, increase our costs or impair our reputation.

We currently rely on single-source suppliers for each of the drug components in SM-88. Supplies are obtained under individual purchase orders and we do not have any long-term supply agreements in place at this time. Although we believe alternative sources of supplies exist, the number of third-party suppliers with the necessary manufacturing and regulatory expertise and facilities is limited, could be more expensive and it could take a significant amount of time to source, any of which would adversely affect our business. New suppliers of SM-88 would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable IP laws to the method of manufacturing the drug candidate. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party IP rights could result in a significant interruption of supplies and could require the new manufacturer(s) to bear significant additional costs which may be passed on to us.

Our reliance on third parties may require us to share our trade secrets, which increase the possibility that a competitor could discover them or that our trade secrets could be misappropriated or disclosed.

Because we rely on third parties to assist in the research, development and manufacture of SM-88 and may do so with any other drug candidate we may develop, we must, at times, share trade secrets with such third parties. We will seek to protect our proprietary technology in part by initially entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees and third-party contractors prior to disclosing any proprietary information. These agreements typically limit the rights of third parties to use or disclose our confidential information, which include our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets could become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's independent discovery of our trade secrets or other unauthorized use or disclosure could impair our competitive position and could have a material adverse effect on our business.

In addition, these agreements would typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data that could potentially relate to our trade secrets, even though our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with in the future can be, based on customary practice, expected to be granted rights to publish data arising out of such collaboration, provided that we are notified in advance and given the opportunity to delay publication for a limited time period in order for us to secure patent protection of IP rights arising from the collaboration, in addition to the opportunity to remove confidential or trade secret information from any such publication. In the future, we may also conduct joint research and develop programs that may require us to share trade secrets under the terms of such research. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development, publication of information by any of our third-party collaborators or otherwise. A competitor's discovery of our trade secrets could impair our competitive position and could have an adverse impact on our business.

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We may enter into license agreements with third parties with respect to SM-88 and any other drug candidates we may develop that may place the development of SM-88 and any other drug candidates partially or entirely outside of our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us. If our collaborations are not successful, SM-88 and any other drug candidates we may choose to develop may not reach their full market potential.

For financial and efficiency reasons, we may enter into licensing or collaboration agreements with third parties. Collaborations, if any are entered into, involving SM-88 and any other drug candidates we may develop, will be and are subject to numerous risks, which may include, but are not limited to:

collaborators may have significant discretion in determining the efforts and resources that they will apply to collaborations;

collaborators may not perform their obligations as expected;

collaborators may not pursue development and commercialization of SM-88 or any other drug candidate we may choose to develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;

collaborators may delay clinical trials, provide insufficient funding for a clinical program, stop a clinical trial, abandon SM-88 or other drug candidate, repeat or conduct new clinical trials or require a new formulation of SM-88 or other drug candidate;

collaborators could independently develop or develop with third parties, products that compete directly or indirectly with SM-88;

a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;

we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;

collaborators may not properly maintain or defend our IP rights or may use our IP or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our IP or proprietary information or expose us to potential liability;

collaborators may not aggressively or adequately pursue litigation against Abbreviated New Drug Application (“ANDA”) filers or may settle such litigation on unfavorable terms;

disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of SM-88 or any other drug candidate we may develop or results in costly litigation or arbitration that diverts management attention and resources;

collaborations may be terminated, sometimes at-will, without penalty;

collaborators may own or co-own IP covering our products that results from our collaborating with them and, in such cases, we would not have the exclusive right to commercialize such IP; and

a collaborator’s sales and marketing activities or other operations may not be in compliance with applicable laws and could result in civil or criminal proceedings.

[Table of Contents](#)**Risks Related to the Operation of our Company*****Our future operational success depends on our ability to retain our key executives and to attract, retain and motivate qualified personnel.***

We are highly dependent on our chief executive officer, chief operating officer, chief financial officer and the other members of our executive and scientific teams. Our executives may terminate their employment with us at any time. The loss of the services of any of these people could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, administrative, operations, manufacturing and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development, preparing filings and communicating with the FDA and other regulatory authorities, preparing for and the conducting of clinical trials and formulating commercialization strategies. Our consultants and advisors may be employed or contracted by other businesses in addition to ours and may have commitments with other entities that may limit their availability to us.

To date, our drug discovery process and development program has been led by Steve Hoffman, our chief executive and science officer. He has been instrumental in providing scientific, technical and business expertise. We do not currently maintain “key person” insurance on Mr. Hoffman or any of our other executives or employees. While we may, in the future, seek to obtain key man insurance on Mr. Hoffman and/or such other executives and employees, we may not be able to obtain the insurance at favorable rates or at all. Any insurance proceeds we may receive under such “key person” insurance may not adequately compensate us for the loss of Mr. Hoffman’s or other insured’s services. Development of SM-88 could ultimately continue without Mr. Hoffman’s or others’ contributions, but future development of SM-88 and all other drug products in our pipeline would be adversely affected without his continued involvement.

We expect to expand our development, regulatory and marketing capabilities and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of March 31, 2017, we had nine full-time employees. Over the next several years, we expect to experience significant growth in the number of our employees and the scope of our operations. To manage our anticipated future growth, we must continue to: implement and improve our managerial, operational and financial systems, expand our facilities and recruit and train additional qualified personnel. Future growth would impose significant added responsibilities on management. Due to our limited financial resources and the limited experience of our management team in managing a life sciences company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Our current management has limited experience in managing a company that had the life sciences research and development and operational growth we anticipate for our Company. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Business disruptions (domestic and/or international) could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to equipment failures, labor shortages, labor strikes, earthquakes, power shortages, telecommunications failures, floods, hurricanes, typhoons, fires, extreme weather conditions, terrorist activities, medical epidemics, riots, crime, act of foreign enemies, war, nationalization, government sanction, blockage, embargo and other natural or manmade disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and could increase our costs and expenses.

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Our corporate headquarters is located in New York, New York. Our current and future, third-party collaborators, future partners, supplies, CROs and investigational sites are or will be, located throughout the United States or internationally and may be located near major high-risk terrorist targets, earthquake faults, flood and fire zones. The ultimate impact on us, our significant partners and suppliers as well as our and their general infrastructures being located near major high-risk terrorist targets, earthquake faults, flood and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major terrorist attack, earthquake, fire, flood or other natural or manmade disaster.

Our business is also subject to risks associated with conducting international business. If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business. Some of our third-party collaborators, future partners, supplies, CROs and investigational sites could be located outside the United States. Accordingly, our future success could be harmed by a variety of factors, which include, but are not limited to:

economic weakness, including inflation or political instability in particular non-U.S. economies and markets;

differing regulatory requirements for drug approvals in non-U.S. countries;

potentially reduced protection for IP rights;

difficulties in compliance with non-U.S. laws and regulations;

changes in non-U.S. regulations and customs, tariffs and trade barriers;

changes in non-U.S. currency exchange rates and currency controls;

changes in a specific country's or region's political or economic environment;

trade protection measures, import/export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;

negative consequences from changes in tax laws;

compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

workforce uncertainty in countries where labor unrest is more common than in the United States;

difficulties associated with staffing and managing international operations, including differing labor relations;

production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

business interruptions resulting from geo-political actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires.

Our internal computer systems or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drug development program.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we believe we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause

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interruptions in our operations, it could result in a material disruption of our drug development program. For example, the loss of clinical data from completed or ongoing clinical trials for SM-88 could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of SM-88 could be delayed.

Substantial amounts of information concerning our products, employees, consultants, vendors, service providers and ongoing business are stored digitally and are subject to threats of theft, tampering, or other intrusion.

We collect and maintain information in digital form that is necessary to conduct our business. This digital information includes, but is not limited to, confidential and proprietary information as well as personal information regarding our employees, consultants, CROs, CMOs, patients participating in our clinical trials and others. Data maintained in digital form is subject to the risk of intrusion, tampering, and theft. We have established physical, electronic, and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools and monitoring to provide security for the processing, transmission and storage of digital information. We are monitoring the abilities of such measures and will seek additional enhancements of the measures as necessary. However, the development and maintenance of these systems is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly more sophisticated. Despite our efforts, the possibility of a future data compromise cannot be eliminated entirely, and risks associated with intrusion, tampering and theft remain. In addition, we provide confidential, proprietary and personal information to third parties when it is necessary to pursue our business objectives. While we obtain assurances that these third parties will protect this information and, where appropriate, monitor the protections employed by these third parties, there is a risk the confidentiality of data held by third parties may be compromised. If our data systems are compromised, our business operations may be impaired, we may lose profitable opportunities or the value of those opportunities may be diminished, and we may lose revenue as a result of unlicensed use of our intellectual property. If personal information of our employees, consultants, CROs, CMOs, patients participating in our clinical trials and such others is misappropriated, our reputation with our employees, consultants, CROs, CMOs, patients participating in our clinical trials and others may be injured resulting in loss of business and/or morale, and we may incur costs to remediate possible injury to such parties or be required to pay fines or take other action with respect to judicial or regulatory actions arising out of such incidents.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Cybersecurity attacks are evolving and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems,

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misappropriation of our confidential or otherwise protected information and corruption of data. Cybersecurity incidents resulting in the failure of our systems to operate effectively or to integrate with other systems, including those of third-parties with whom we rely on for research, clinical trial services or other business and administrative services, or a breach in security or other unauthorized access of these systems, may affect our ability to manage and maintain our operations. A breach in security, unauthorized access resulting in misappropriation, theft, or sabotage with respect to our proprietary and confidential information, including research or clinical data, could require significant investments of capital and time to remediate and could adversely affect our business, financial condition and results of operations.

Risks Related to Intellectual Property

Our ability to successfully commercialize our technology and drug candidate may be materially adversely affected if we are unable to obtain and maintain effective IP.

Our success is largely dependent on our ability to obtain and maintain patent and other IP protection in the United States and in other countries with respect to our proprietary technology and drug candidates. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications or to maintain or enforce the patents, covering technology or products that we license to third parties or, conversely, that we may license from third parties. Therefore, if we are subject to patent infringement, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. In addition, if third parties who license patents to us or from us fail to maintain such patents or lose rights to those patents, licensing rights may be reduced or eliminated.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. This process is expensive and time-consuming and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is also possible that we fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Our pending and future patent applications may be insufficient to protect our technology or products, completely or in part. In addition, existing and any future patents we obtain may not be extensive enough to prevent others from using our technologies or from developing competing drugs and technologies.

The patent position of specialty pharmaceutical and biotechnology companies generally is highly uncertain and involves complex legal and factual questions for which many legal principles remain unresolved. In recent years, patent rights have been the subject of significant litigation and, as a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may result in patents not being issued to us in the United States or in other countries. Changes in either the patent laws or interpretation of patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in scientific literature often lag behind the actual discoveries and patent applications in the United States and other countries are typically not published until 18 months after filing or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications or that we were the first to file for patent protection of such inventions. In addition, the United States Patent and Trademark Office (the "USPTO"), might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights is highly uncertain.

Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In March of 2013, under the recently enacted Leahy-Smith America Invents Act (the "America Invents Act"), the United States moved from a

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“first to invent” to a “first-to-file” system. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are currently unclear as the USPTO only recently developed new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the first-to-file provisions, only became effective in 2013. In addition, the courts have yet to address any of these provisions and the applicability of the Act and new regulations on specific patents discussed in this prospectus have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. We may become involved in opposition, interference, derivation, inter parties review or other proceedings that challenge our patent rights or the patent rights of others and the outcome of any proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of or invalidate, our patent rights, allowing third parties to commercialize our technology or drug products and compete directly with us, without payment to us or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or drugs in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the patent claims of our owned or licensed patents being narrowed, invalidated or held unenforceable. This could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and drugs or limit the duration of the patent protection of our technology and drugs. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting our drug might expire before or shortly after SM-88 or any other drug product we develop is commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to our drug products or otherwise provide us with a competitive advantage.

We may not be able to protect our IP rights throughout the world.

Filing, prosecuting and defending patents for SM-88 or any other drug product we may develop throughout the world would be prohibitively expensive. Competitors may use our technologies in countries where we have not obtained patent protection to develop their own drugs and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as in the United States. These products may compete with our drug products in countries where we do not have any issued patents and our patent claims or other IP rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending IP rights in foreign countries. The legal systems of a number of countries, particularly a number of developing countries, do not favor the enforcement of patents and other IP protection, including those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights. Further, the initiation of proceedings to enforce or protect our patent rights in foreign countries could result in substantial cost and divert our efforts and attention from other aspects of our business.

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Obtaining and maintaining our patent protection depends upon compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies. Our patent protection could be reduced or eliminated for noncompliance with these requirements.

The USPTO and various non-U.S. patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during and following the patent prosecution process. Our failure to comply with such requirements could result in abandonment or lapse of a patent or patent application, which would result in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would have been the case if our patents were in force.

We may become involved in lawsuits or other proceedings to protect or enforce our patents or other IP, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other IP. To counter infringement or unauthorized use, we or our licensees may be required to file infringement claims, which can be expensive and time-consuming. For example, if we need to file patent infringement lawsuits in the future against manufacturers of generic pharmaceuticals that have filed ANDAs with the FDA seeking approval to manufacture and sell generic versions of SM-88 or any other drug product we may develop, we anticipate that the prosecution of such lawsuits will require a significant amount of time and attention from our chief executive officer, chief financial officer and other senior executives. In addition, in a patent infringement proceeding, a court may decide that our patent is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in the litigation or proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Such a result could limit our ability to prevent others from using or commercializing similar or identical technology and drugs, limit our ability to prevent others from launching generic versions of our drug products and could limit the duration of patent protection for our products, all of which could have a material adverse effect on our business. A successful challenge to our patents could reduce or eliminate our right to receive royalties. Furthermore, because of the substantial amount of discovery required in connection with IP litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import/export SM-88, or any other approved drug, or impair our competitive position.

Patents could be issued to third parties that we may ultimately be found to infringe. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing drug candidates using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition and results of operations. Moreover, our failure to maintain a license to any technology that we require for our drug products may also materially harm our business, financial condition and results of operations. Furthermore, we would be exposed to a threat of litigation.

In the pharmaceutical industry, significant litigation and other proceedings regarding patents, patent applications, trademarks and other IP rights have become commonplace. The types of situations in which we may become a party to such litigation or proceedings include:

we or our collaborators, may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our drugs or processes do not infringe those third parties' patents;

if our competitors file patent applications that claim technology also claimed by us or our licensors or collaborators, we or our licensors or collaborators may be required to participate in interference or opposition

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proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third-party with a dominant patent position;

if third parties initiate litigation claiming that our processes or products infringe their patent or other IP rights, we and our licensors or collaborators will need to defend against such proceedings; and

if a license to necessary drug technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other IP rights and/or that we breached our obligations under the license agreement and we and our collaborators would need to defend against such proceedings.

These lawsuits would likely be costly and could affect our results of operations and divert the attention of our management and scientific personnel. There is a risk that a court would decide that we or our collaborators are infringing the third party's patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our collaborators may not have a viable alternative to the technology protected by the patent and may need to halt work on the affected drug candidate or cease commercialization of an approved product. In addition, there is a risk that a court will order us or our collaborators to pay the other party damages. An adverse outcome in any litigation or other proceeding could subject us to significant liabilities to third parties and require us to cease using the technology that is at issue or to license the technology from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all. Any of these outcomes could have a material adverse effect on our business.

The pharmaceutical and biotechnology industries have produced a significant number of patents and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts and the interpretation is not always uniform or predictable. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent or that the patent claims are invalid. We may not be able to do this because proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing SM-88 or any other drug candidate to market and be precluded from manufacturing or selling one or more of our drug products.

As noted previously, the cost of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

We may not be successful in obtaining or maintaining necessary rights to IP through acquisitions and in-licenses.

Because our drugs may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license, maintain or use these proprietary rights. In addition, our drug products may require specific formulations to work effectively and efficiently and the rights to these formulations may be held by others. We may be unable to acquire or in-license any compositions, methods of

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use, processes or other third-party IP rights from third parties that we identify as necessary for one or more of our drug candidates. The licensing and acquisition of third-party IP rights is a competitive area and a number of more established companies are also pursuing strategies to license or acquire third-party IP rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we may sometimes need to collaborate with U.S. and non-U.S. academic institutions to accelerate our nonclinical research or development under written agreements with these institutions. Typically, these institutions could provide us with an option to negotiate a license to any of the institution's rights in technology resulting from our collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the IP rights to other parties, potentially blocking our ability to pursue the applicable drug candidate or program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party IP rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain a license to third-party IP rights necessary for the development of our drug products, we may have to abandon its development and therefore, our business and financial condition could suffer.

We may be unable to protect the confidentiality of our trade secrets, thus harming our business and competitive position.

In addition to our patented technology and drug, we rely upon trade secrets, including unpatented know-how, technology and other proprietary information to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our current and future employees, as well as our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. However, while it is our policy to require our employees and contractors who may be involved in the conception or development of IP to execute such agreements, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops IP that we regard as our own. In addition, it is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. While to our knowledge the confidentiality of our trade secrets has not been compromised, if the employees, consultants or collaborators that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could be disclosed, misappropriated or otherwise become known or be independently discovered by our competitors. In addition, IP laws in foreign countries may not protect our IP to the same extent as the laws of the United States. If our trade secrets are disclosed or misappropriated, it would harm our ability to protect our rights and adversely affect our business.

We may be subject to claims that our employees and outside contractors have wrongfully used or disclosed IP from their former employers and clients. IP litigation or proceedings could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Although we will try to ensure that our employees and outside contractors do not use the proprietary information or the know-how of others in their work for us and we have no knowledge of any instances of wrongful use or disclosure by our employees and outside contractors to date, we may be subject to claims that we or these employees and outside contractors have used or disclosed IP, including trade secrets or other proprietary information from their former employers or clients. Litigation may be necessary to defend our Company against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable IP rights, personnel or consulting services. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to IP claims may cause us to incur significant expenses and could distract our scientific and management personnel from their normal responsibilities. In addition, there could be

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public announcements of the results of hearings, motions or other interim proceedings or developments. Should this occur and securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce resources available to us for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other IP-related proceedings could adversely affect our ability to compete in the marketplace.

If we do not obtain protection under the Hatch-Waxman Amendments and similar non-U.S. legislation for extending the term of patents covering SM-88 and any other drug product we may develop, our business may be materially harmed.

Depending upon the timing, duration and conditions of FDA marketing approval of SM-88 and any other drug product we may develop in the future, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments") and similar legislation in the EU. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved drug as compensation for effective patent term lost during drug development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that drug will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue could be materially reduced.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names, to the extent we obtain and use them, may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other IP may be ineffective and could result in substantial costs and a diversion of resources and could adversely affect our financial condition or results of operations.

Risks Related to Government Regulations

Health care reform measures could hinder or prevent the commercial success of SM-88 any other drug product we may develop.

In the United States, there have been and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future revenue and profitability and the future revenue and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to

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contain or reduce the costs of medical products and services. For example, the Health Care Reform Law contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will affect existing government healthcare programs and will result in the development of new programs. The Health Care Reform Law, among other things:

imposes a non-deductible annual fee on entities that manufacture or import certain branded prescription drugs;

increases the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;

requires collection of rebates for drugs paid by Medicaid managed care organizations; and

provides for a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may, among other things, adversely affect:

our ability to set a price we believe is fair for our drug products;

our ability to generate revenue and achieve or maintain profitability; and

the availability of capital.

Judicial challenges, executive orders and legislative repeal measures relating to the Health Care Reform Law may create regulatory uncertainty with respect to the pharmaceutical, biotechnology and other life sciences industries and may materially harm our business, financial condition and results of operations.

While the U.S. Supreme Court upheld most of the constitutional elements of the Health Care Reform Law in June 2012, other legal challenges are still pending final adjudication in several jurisdictions.

On January 20, 2017, President Trump signed an executive order directing federal agencies with authorities and responsibilities under the Health Care Reform Law to exercise all available authority and discretion to waive, defer, grant exemptions from or delay the implementation of any provision of the Health Care Reform Law that would impose a fiscal burden on any U.S. state or a cost, fee, tax, penalty or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance or makers of medical devices, products or medications (the "Executive Order"). The Executive Order does not describe specific federal rules that it applies to but seems to contemplate discretion for federal agencies to delay or stop the implementation of certain Health Care Reform Law taxes and requirements. As a result, the practical effect of the Executive Order is unclear.

On May 4, 2017, the U.S. House of Representatives passed the American Health Care Act of 2017 (the "AHCA"). As drafted, the AHCA would amend or repeal significant portions of the Health Care Reform Law. On July 28, 2017, the U.S. Senate voted on, and failed to pass, the AHCA's proposed analogue in the U.S. Senate, the Health Care Freedom Act. It is uncertain what legislation amending or repealing the Health Care Reform Law will ultimately be enacted by the U.S. Congress and signed into law by President Trump, if any.

On July 29, 2017, President Trump stated that he is considering cessation of cost-sharing reduction payments from the U.S. government for low-income health insurance enrollees' copayments and deductibles (the "CSR Payments"). Cessation of the CSR Payments could have significant adverse impacts, including, but not limited to, insurance premium increases and increased uncertainty in the health insurance markets.

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Such judicial challenges, if any succeed, the Executive Order, other legislation, if it becomes law, or cessation of the CSR Payments could result in increased uncertainty with respect to the pharmaceutical, biotechnology and other life science industries and may materially harm our business, financial condition and results of operations. Further, we can provide no assurance that the Health Care Reform Law, as currently enacted or as amended in the future, will not adversely affect our business, financial condition or results of operations. Nor can we predict how future federal or state legislative or administrative changes relating to health care reform will affect our business, financial condition or results of operations.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are, and will be, applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include, but are not limited to:

the federal healthcare program Anti-Kickback Statute, which prohibits knowingly and willfully offering, soliciting, receiving or providing any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce either the referral of an individual for or the purchase order, lease or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs, such as the Medicare and Medicaid programs;

the federal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented, false or fraudulent claims for payment or approval or knowingly using false statements, to obtain payment from the federal government and which may apply to entities like us which provide coding and billing advice to customers;

the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") which created new federal criminal statutes that prohibit knowingly and willfully executing or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of or payment for, healthcare benefits, items or services relating to healthcare matters;

the federal physician self-referral law, commonly known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services reimbursed by Medicare or Medicaid if the physician or a member of the physician's family has a financial relationship with the entity and which also prohibits the submission of any claims for reimbursement for designated health services furnished pursuant to a prohibited referral;

the federal transparency requirements under the Health Care Reform Law require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the U.S. Department of Health and Human Services ("HHS") information related to physician payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family members;

HIPAA, the Health Information Technology for Economic and Clinical Health Act and their respective implementing regulations, which govern the conduct of certain electronic healthcare transactions and protect the security and privacy of protected health information; and

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state-law equivalents of each of the above federal laws, such as anti-kickback, false claims and transparency laws which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers.

The Health Care Reform Law, among other things, amended the intent standard of the federal Anti-Kickback Statute and criminal healthcare fraud statutes to a stricter standard such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Health Care Reform Law codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil, criminal and/or administrative penalties, damages, fines, disgorgement and possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these or other laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Because we and our suppliers are subject to environmental, health and safety laws and regulations, we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities, which may adversely affect our business and financial condition.

Our operations, including our discovery, development, testing, research and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to release of or exposure to, hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, our production and development efforts may be interrupted or delayed and our financial condition and results of operations may be materially adversely affected.

The third parties with whom we contract to manufacture SM-88 or any other drug products we may develop are also subject to these and other environmental, health and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or, in certain circumstances, an interruption in operations, any of which could adversely affect our business and financial condition if we are unable to find an alternate supplier in a timely manner.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA or EMA regulations, to provide accurate information to the FDA or EMA or intentional failures to report financial information or data accurately or to disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course

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of clinical trials, which could result in regulatory sanctions and serious harm to our reputation and subjects. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

If generic manufacturers use litigation and regulatory means to obtain approval for generic versions of products on which our future revenue depends, our business will suffer.

Under the Federal Food, Drug, and Cosmetic Act (the “FDCA”), the FDA can approve an ANDA for a generic version of a branded drug without the ANDA applicant undertaking the clinical testing necessary to obtain approval to market a new drug. In place of such clinical trials, an ANDA applicant usually needs only to submit data demonstrating that its drug has the same active ingredient(s) and is bioequivalent to the branded product, in addition to any data necessary to establish that any difference in strength, dosage form, inactive ingredients or delivery mechanism does not result in different safety or efficacy profiles, as compared to the reference drug.

The FDCA requires that an applicant for approval of a generic form of a branded drug certify either that its generic drug does not infringe any of the patents listed by the owner of the branded drug in the Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book, or that those patents are not enforceable. This process is known as a Paragraph IV Challenge. Upon receipt of the Paragraph IV notice, the owner has 45 days to bring a patent infringement suit in federal district court against the company seeking ANDA approval of a drug covered by one of the owner’s patents. The discovery, trial and appeals process in such suits can take several years. If this type of suit is commenced, the FDCA provides a 30-month stay on the FDA’s approval of the competitor’s application. This type of litigation is often time-consuming, costly and may result in generic competition if the patents at issue are not upheld or if the generic competitor is found not to infringe upon the owner’s patents. If the litigation is resolved in favor of the ANDA applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA may thereafter approve the application based on the usual standards for approval of ANDAs.

For various strategic and commercial reasons, manufacturers of generic medications frequently file ANDAs shortly after FDA approval of a branded drug regardless of the perceived strength and validity of the patents associated with such products. Based on these past practices, we believe it is likely that one or more such generic manufacturers will file ANDAs with respect to SM-88, if approved by the FDA, prior to the expiration of the patents related to those compounds.

The filing of an ANDA as described above with respect to any of our products could have an adverse impact on our stock price. Moreover, if any such ANDAs were to be approved and the patents covering the relevant products were not upheld in litigation or if a generic competitor were found not to infringe these patents, the resulting generic competition would negatively affect our business, financial condition and results of operations.

The marketing of SM-88, if approved, will be limited to use for the treatment of specific cancer indications and, if we want to expand the indications for which these drug candidates may be marketed, additional regulatory approvals will need to be obtained, which may not be granted.

If SM-88 is approved for the first indication that we decide to pursue to an NDA, the FDA will restrict our ability to market or advertise SM-88 for other indications, which could limit physician and patient adoption. We may attempt to develop, promote and commercialize new treatment indications and protocols for additional indications for SM-88, but we cannot predict when or if the approval required to do so will be received. In addition, we would be required to conduct additional clinical trials to support approvals for additional indications for SM-88, which would be time-consuming and expensive and may produce results that do not support regulatory approvals. If we do not obtain additional regulatory approvals, our ability to expand our business will be limited.

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If SM-88 is approved for marketing and we are found to have improperly promoted off-label uses or if physicians misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, significant fines, penalties, sanctions and drug liability claims. Additionally, our image and reputation within the industry and marketplace could be harmed.

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about approved drugs. In particular, a drug may not be promoted for use or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. For example, if we receive marketing approval for SM-88 for the first indication we are pursuing, we cannot prevent physicians from using SM-88 for their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses prior to FDA approval for the applicable indication(s), we may receive warning letters and become subject to significant liability, which would materially harm our business. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred and our reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA prohibitions on the sale or marketing of our products or significant fines and penalties and the imposition of these sanctions could also affect our reputation and position within the industry.

Physicians may also misuse our products, potentially leading to adverse results, side effects or injury, which may lead to drug liability claims. If our products are misused, we may become subject to costly litigation by our customers or their patients. Drug liability claims could divert management's attention from our core business, be expensive to defend and result in sizable damage awards against us that may not be covered by liability insurance. Furthermore, the use of our products for indications other than those approved by the FDA may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. Any of these events could harm our business and results of operations and cause our stock price to decline.

Additionally, as with an existing number of previously approved therapeutics to treat cancer, the FDA may require us to educate health care providers and patients about the proper use and administration of SM-88 or any other drug products we develop in the future and obtain FDA approval to market.

Being a public company is expensive and administratively burdensome.

As a public reporting company, we are subject to the information and reporting requirements of the Securities Act, the Exchange Act and other federal securities laws, rules and regulations related thereto, including compliance with the Sarbanes-Oxley Act of 2002 ("SOX"). Complying with these laws and regulations requires the time and attention of our board of directors and management and increases our expenses. Among other things, we are required to:

maintain and evaluate a system of internal controls over financial reporting in compliance with the requirements of Section 404 of SOX and the related rules and regulations of the SEC and the Public Company Accounting Oversight Board;

maintain policies relating to disclosure controls and procedures;

prepare and distribute periodic reports, proxy statements, Forms 8-K and other reports and filings in compliance with our obligations under applicable federal securities laws;

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institute a more comprehensive compliance function, including with respect to corporate governance; and

involve, to a greater degree, our outside legal counsel and accountants in the above activities and incur additional expenses relating to such involvement.

The costs of preparing and filing annual and quarterly reports and Forms 8-K, proxy statements and other information with the SEC and furnishing annual reports containing audited financial statements to stockholders is expensive and much greater than that of a privately-held company and compliance with these rules and regulations may require us to hire additional financial reporting, internal controls and other finance personnel and will involve a material increase in regulatory, legal and accounting expenses and the attention of management. There can be no assurance that we will be able to comply with the applicable regulations in a timely manner, if at all. In addition, being a public company makes it more expensive for us to obtain director and officer liability insurance. In the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain this coverage. These factors could also make it more difficult for us to attract and retain qualified executives and members of our board of directors, particularly directors willing to serve on our audit committee.

We will continue to incur relatively outsized costs as a result of recently becoming a public company and in the administration of our organizational structure.

As a public company, we will incur significant legal, accounting, insurance and other expenses that we have not incurred as a private company, including costs associated with public company reporting requirements. We also have incurred and will incur costs associated with SOX and related rules implemented by the SEC. We will continue to incur ongoing periodic expenses in connection with the administration of our organizational structure. The expenses incurred by public companies generally for reporting and corporate governance purposes have been increasing. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. In estimating these costs, we took into account expenses related to insurance, legal, accounting, and compliance activities, as well as other expenses not currently incurred. These laws and regulations could also make it more difficult or 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 same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation.

Any failure to maintain effective internal control over our financial reporting could materially adversely affect us.

Section 404 of SOX requires us to include in our Annual Reports on Form 10-K an assessment by management of the effectiveness of our internal control over financial reporting. Based upon an evaluation conducted in connection with the preparation of Tyme's audited consolidated financial statements as of March 31, 2017, our current management concluded that our disclosure controls and procedures were not effective as of such date. Specifically, our management determined that there were control deficiencies constituting material weaknesses, including those relating to inadequate segregation of duties consistent with control objectives and ineffective controls over period end financial disclosure and reporting processes, including inadequate management oversight of our outside accounting firm.

We intend to implement a number of changes in our internal control over financial reporting. With the additional recent funding provided and the recent retention of a full-time chief financial officer, we intend to conduct a full analysis of our controls and procedures, segregate duties regarding processing disbursements, enact procedures aimed at timely and effectively maintaining our books and records and financial statement preparations, establish

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further procedures for analyzing both financial and transactional activities including verifying that all amounts are properly recorded, and take other appropriate steps aimed at giving us reasonable assurance that required disclosures are properly included and amounts properly presented in our financial statements.

We must perform system and process evaluation and testing of our internal control over financial reporting to allow management and (when required in future) our independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of SOX. Our compliance with Section 404 of SOX may require that we incur substantial accounting expenses and expend significant management efforts. We currently do not have an internal audit group and we will need to retain the services of additional accounting and financial staff or consultants with appropriate public company experience and technical accounting knowledge to satisfy the ongoing requirements of Section 404 of SOX. We intend to review the effectiveness of our internal controls and procedures and make any changes management determines appropriate, including those intended to assure that we achieve full compliance with Section 404 by the date on which we are required to so comply.

While we intend to diligently and thoroughly document, review, test and improve our internal control over financial reporting in order to ensure compliance with Section 404 in the future, management may not be able to conclude that our internal control over financial reporting is effective. Furthermore, even if management were to reach such a conclusion, if our independent registered public accounting firm is not satisfied with the adequacy of our internal control over financial reporting or if the independent auditors interpret the requirements, rules or regulations differently than we do, then they may decline to attest to management's assessment or may issue an auditor's report that is qualified. Any of these events could result in a loss of investor confidence in the reliability of our financial statements, which in turn could negatively affect the price of our common stock.

We are an "emerging growth company," and we cannot be certain whether the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"), which was enacted on April 5, 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of SOX or SOX's reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of our initial public offering of securities, which occurred in April 2012, (b) in which we have total annual gross revenue of at least \$1,000,000,000 or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700,000,000 as of a preceding measurement date, and (2) the date on which we have issued more than \$1,000,000,000 in non-convertible debt securities during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may suffer or be more volatile.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, each prospectus supplement and the information incorporated by reference in this prospectus and each prospectus supplement contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act that involve substantial risks and uncertainties. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be

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based on facts and factors currently known by us. Consequently, these forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements.

Forward-looking statements can be identified by the use of forward-looking words such as “believes,” “expects,” “hopes,” “may,” “will,” “plan,” “intends,” “estimates,” “could,” “should,” “would,” “continue,” “seeks,” “pro forma,” or “anticipates,” or other similar words (including their use in the negative), or by discussions of future matters such as the development of new products, technology enhancements, possible collaborations, the timing, scope and objectives of our planned clinical trials and other statements that are not historical. These statements include, but are not limited to, statements under this caption and under “Risk Factors” in this prospectus and under the captions “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” incorporated by reference from our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as applicable, as well as our other filings with the SEC. You should be aware that the occurrence of any of the events discussed herein under the heading “Risk Factors” or in any applicable prospectus supplement and any documents incorporated by reference herein or therein could substantially harm our business, operating results and financial condition and that if any of these events occurs, it could adversely affect the value of an investment in our securities.

Forward-looking statements include statements about:

- the success, cost, and timing of our ability to obtain and maintain regulatory approval of SM-88;
- our ability to successfully commercialize SM-88, if approved;
- the rate and degree of market acceptance of SM-88, if approved;
- our estimates of our expenses, losses, future revenue and capital requirements and our needs for or ability to obtain additional financing, including funding needed to advance or complete our clinical trials;
- our ability to maintain intellectual property protection for SM-88 and our ability to operate our business without infringing on the intellectual property rights of others;
- our ability to maintain intellectual property protection for SM-88;
- our ability to identify and develop new product candidates;
- our ability to identify, recruit and retain key personnel and collaborators;
- our ability to raise capital on terms acceptable to us, or otherwise;
- our financial performance; and
- developments relating to our competitors and our industry.

You should refer to the section titled “Risk Factors” 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. As a result of these factors, we cannot assure you that forward-looking statements in this prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us to any other person that we will achieve our objectives and plans in any specified time frame, or at all.

The cautionary statements made in this prospectus are intended to be applicable to all related forward-looking statements wherever they may appear in this prospectus or in any prospectus supplement or any documents incorporated by reference herein or therein. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date they are made. Except as required by law, we assume no obligation to update our forward-looking statements, even if new information becomes available in the future.

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RATIO OF EARNINGS TO FIXED CHARGES

The following table sets forth our ratio of earnings to fixed charges and the ratio of our combined fixed charges and preference dividends to earnings for each of the periods indicated. The following table is qualified by the more detailed information appearing in the computation table set forth in Exhibit 12.1 to the registration statement of which this prospectus is part and the historical financial statements, including the notes to those financial statements, incorporated by reference in this prospectus. We have paid no dividends on preferred shares during the periods indicated. Therefore, the ratios of earnings to combined fixed charges and preferred dividends are the same as the ratios of earnings to fixed charges.

	Year Ended December 31,			Year Ended March 31,	
	2012	2013	2014	2015	2017
Ratio of earnings to fixed charges	N/A	N/A	N/A	N/A	N/A
Ratio of combined fixed charges and preference dividends to earnings	N/A	N/A	N/A	N/A	N/A

For purposes of computing the ratio of earnings to fixed charges and the ratio of our combined fixed charges and preference dividends to earnings, earnings consist of income (loss) from continuing operations before income taxes plus fixed charges. Fixed charges consist of interest expense on indebtedness and an estimate of the interest within rental expense.

Our earnings were insufficient to cover fixed charges for the year ended March 31, 2017 and for each of the years ended December 31, 2015, 2014, 2013 and 2012. Accordingly, we are unable to disclose a ratio of earnings to fixed charges for such periods. The dollar amount of the deficiency in earnings available for fixed charges for the year ended March 31, 2017 was \$15.2 million and for the years ended December 31, 2015, 2014, 2013 and 2012 was approximately \$11.7 million, \$2.7 million, \$1.1 million and \$0.9 million, respectively.

USE OF PROCEEDS

We will retain broad discretion over the use of the net proceeds from the sale of the securities offered hereby. Except as described in any prospectus supplement or any related authorized free writing prospectus that we may authorize to be provided to you, we currently intend to use the net proceeds from the sale of the securities offered hereby for general corporate purposes, which may include research and development, capital expenditures, working capital and general and administrative expenses. We may also use a portion of the net proceeds to acquire or invest in businesses, products and technologies that are complementary to our own, although we have no current plans, commitments or agreements with respect to any acquisitions as of the date of this prospectus. We will set forth in the applicable prospectus supplement or free writing prospectus our intended use for the net proceeds received from the sale of any securities sold pursuant to the prospectus supplement or free writing prospectus. Pending these uses, we intend to invest the net proceeds primarily in a money market mutual fund with a large financial institution.

DESCRIPTION OF CAPITAL STOCK

Common Stock

As of the date of this prospectus, we are authorized to issue up to 300,000,000 shares of common stock, \$0.0001 par value per share. As of July 24, 2017, 89,321,067 shares of common stock were outstanding.

Voting

Each holder of common stock is entitled to one vote per share on all matters requiring a vote of the stockholders, including the election of directors. We do not have cumulative voting rights. Accordingly, the holders of a majority of the shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election.

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Dividends

Holders of common stock are entitled to receive dividends, in cash, securities, or property, as may from time to time be declared by our board of directors, subject to the rights of the holders of the preferred stock.

Rights Upon Liquidation

In the event of our voluntary or involuntary liquidation, dissolution, or winding up, the holders of common stock will be entitled to share equally in our assets available for distribution after payment in full of all debts and after the holders of preferred stock have received their liquidation preferences in full.

Rights and Preferences.

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock in general are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Fully Paid and Nonassessable.

All of our outstanding shares of common stock are fully paid and nonassessable.

Circumstances that Could Affect Our Presently Outstanding Number of Shares of Common Stock

As of July 24, 2017, we had 89,321,067 shares of common stock outstanding. This number could be affected in the future by the following circumstances: Certain holders of our outstanding securities that acquired our securities in March and April 2017 private placement transactions (the "2017 Private Placement Investors") have limited anti-dilution protection concerning the common stock (but not warrants) purchased at such closings that could result in additional dilution to our stockholders generally. These provisions provide that if we raise certain funds before the Anti-dilution Expiry Date (defined below) at an effective average consideration and/or exercise or conversion price per share price less than \$2.55 per share, subject to exceptions for issuances of certain "exempt securities," anti-dilution protections could apply which could obligate us to issue additional common stock in respect of such common stock purchased by the 2017 Private Placement Investors. "Anti-dilution Expiry Date" means the earliest to occur of (i) the business day after we raise \$10 million or more in one or more public or private offerings within six months of the applicable purchase date for the 2017 Private Placement Investors, or (ii) the six month anniversary of the applicable purchase date for the 2017 Private Placement Investors.

At June 30, 2017, 5,625,641 common stock purchase warrants relating to securities purchase agreements (including certain warrants issued to the 2017 Private Placement Investors) were outstanding and exercisable. The following summarizes the common stock warrant activity for the years ended March 31, 2017 and March 31, 2016:

	<u>Warrant Shares of Common Stock</u>	<u>Weighted Average Exercise Price</u>
Outstanding at January 1, 2016	476,267	\$ 5.00
Granted	461,384	5.00
Exercised	—	—
Cancelled	—	—
Outstanding at March 31, 2016	<u>937,651</u>	<u>5.00</u>
Granted	3,618,387	3.02
Exercised	—	—
Cancelled	—	—
Outstanding at March 31, 2017	<u><u>4,556,038</u></u>	<u><u>\$ 3.42</u></u>

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We also have two equity compensation plans that authorize the issuance of up to 10,750,000 shares of our common stock, and there were stock option awards outstanding under such plans concerning 4,039,444 shares of common stock as of March 31, 2017 and 6,710,556 shares available for the future issuance as of such date.

Statutory Provisions

Section 203 of the Delaware General Corporation Law (the “DGCL”) prohibits a defined set of transactions between a Delaware corporation, such as us, and an interested stockholder. An interested stockholder is generally defined as a person who, together with any affiliates or associates of such person, beneficially owns, directly or indirectly, 15% or more of the outstanding voting shares of a Delaware corporation. This provision may prohibit business combinations between an interested stockholder and a corporation for a period of three years after the date the interested stockholder becomes an interested stockholder. The term business combination is broadly defined to include mergers, consolidations, sales or other dispositions of assets having a total value in excess of 10% of the consolidated assets of the corporation, and some other transactions that would increase the interested stockholder’s proportionate share ownership in the corporation.

This prohibition is effective unless:

- the business combination is approved by the corporation’s board of directors prior to the time the interested stockholder becomes an interested stockholder;
- the interested stockholder acquired at least 85% of the voting stock of the corporation, other than stock held by directors who are also officers or by qualified employee stock plans, in the transaction in which it becomes an interested stockholder; or
- the business combination is approved by a majority of the board of directors and by the affirmative vote of two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

In general, the prohibitions do not apply to business combinations with persons who were stockholders before we became subject to Section 203.

By-Law Provisions

Vacancies, and newly-created directorships resulting from any increase in the size of our board, may be filled by a majority vote of all remaining directors.

These provisions, together with the provisions of Section 203 of the DGCL, could have the effect of delaying, deferring or preventing a change in control or the removal of existing management, of deterring potential acquirors from making an offer to our stockholders and of limiting any opportunity to realize premiums over prevailing market prices for our common stock in connection therewith. This could be the case notwithstanding that certain of our stockholders might benefit from such a change in control or offer.

Miscellaneous

Shares of common stock are not redeemable and have no subscription, conversion or preemptive rights.

Preferred Stock

The following is a description of general terms and provisions of the preferred stock. The particular terms of any series of preferred stock will be described in the applicable prospectus supplement.

All of the terms of the preferred stock are, or will be, contained in our Certificate of Incorporation and the certificate of amendment relating to each series of the preferred stock, which will be filed with the SEC at or prior to the time of issuance of the series of the preferred stock.

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We are authorized to issue up to 10,000,000 shares of preferred stock, par value \$0.0001 per share. As of the date of this prospectus, no shares of preferred stock were outstanding. Subject to limitations prescribed by law, the board of directors is authorized at any time to issue one or more series of preferred stock.

The board of directors is authorized to determine, for each series of preferred stock, and the prospectus supplement will set forth with respect to each series such preferences and relative participations, optional or special rights and such qualifications, limitations or restrictions thereof, which may include the following information:

- the designation for any series by number, letter or title that shall distinguish the series from any other series of preferred stock;
- the number of shares in any series;
- whether dividends on that series of preferred stock will be cumulative;
- the dividend rate (or method for determining the rate);
- any liquidation preference per share of that series of preferred stock;
- any conversion provisions applicable to that series of preferred stock;
- any redemption or sinking fund provisions applicable to that series of preferred stock;
- any voting rights of that series of preferred stock; and
- the terms of any other preferences or rights applicable to that series of preferred stock.

The preferred stock, when issued, will be fully paid and non-assessable.

Dividends

Holders of preferred stock will be entitled to receive, when, as and if declared by the board of directors, cash dividends at the rates and on the dates as set forth in the applicable prospectus supplement. Generally, no dividends will be declared or paid on any series of preferred stock unless full dividends for all series of preferred stock, including any cumulative dividends still owing, have been or contemporaneously are declared and paid. When those dividends are not paid in full, dividends will be declared pro-rata so that the amount of dividends declared per share on each series of preferred stock will bear to each other series the same ratio that accrued dividends per share for each respective series of preferred stock bear to aggregate accrued dividends for all outstanding shares of preferred stock. In addition, generally, unless all dividends on the preferred stock have been paid, no dividends will be declared or paid on the common stock and we may not redeem or purchase any common stock.

Payment of dividends on any series of preferred stock may be restricted by loan agreements, indentures and other transactions we may enter into.

Liquidation

If we voluntarily or involuntarily liquidate, dissolve or wind up our affairs, the holders of each series of preferred stock will be entitled to receive the liquidation preference per share specified in the applicable prospectus supplement plus any accrued and unpaid dividends. Holders of preferred stock will be entitled to receive these amounts before any distribution is made to the holders of common stock. If the amounts payable with respect to preferred stock are not paid in full, the holders of preferred stock will share ratably in any distribution of assets based upon the aggregate liquidation preference for all outstanding shares for each series. After the holders of shares of preferred stock are paid in full, they will have no right or claim to any of our remaining assets.

Neither the par value nor the liquidation preference will be indicative of the price at which the preferred stock will actually trade on or after the date of issuance.

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Voting

Generally, the holders of preferred stock will not be entitled to vote except as set forth in the prospectus supplement, our Amended and Restated Certificate of Incorporation or any certificate of amendment or as otherwise required by law.

No Other Rights

The shares of a series of preferred stock will not have any preemptive rights, preferences, voting powers or relative, participating, optional or other special rights except as set forth in the prospectus supplement, the Certificate of Incorporation or any certificate of amendment or as otherwise required by law.

Transfer Agent

The transfer agent for our common stock is Continental Stock Transfer & Trust Company. The transfer agent's address is One State Street, 30th Floor, New York, NY 10004, and its telephone number is (212) 509-4000. The transfer agent for each series of preferred stock will be designated in the prospectus supplement.

Depository Shares Associated with Preferred Stock

We may, at our option, elect to offer fractional shares of preferred stock, rather than full shares of preferred stock. If we do, we will issue to the public receipts for depository shares and each of these depository shares will represent a fraction of a share of a particular series of preferred stock. Each owner of a depository share will be entitled, in proportion to the applicable fractional interest in shares of preferred stock underlying that depository share, to all rights and preferences of the preferred stock underlying that depository share. Those rights include dividend, voting, redemption and liquidation rights.

The shares of preferred stock underlying the depository shares will be deposited with a depository under a deposit agreement between us, the depository and the holders of the depository receipts evidencing the depository shares. The depository will be a bank or trust company selected by us. The depository will also act as the transfer agent, registrar and dividend disbursing agent for the depository shares.

Holders of depository receipts agree to be bound by the deposit agreement, which requires holders to take certain actions such as filing proof of residence and paying certain charges.

The following is a summary of the most important terms of the depository shares. The deposit agreement, our Certificate of Incorporation and the certificate of amendment for the applicable series of preferred stock that are, or will be, filed with the SEC will set forth all of the terms relating to the depository shares.

Dividends on Depository Shares Associated with Preferred Stock

The depository will distribute all cash dividends or other cash distributions received in respect of the series of preferred stock underlying the depository shares to the record holders of depository receipts in proportion to the number of depository shares owned by those holders on the relevant record date. The record date for the depository shares will be the same date as the record date for the preferred stock.

In the event of a distribution other than in cash, the depository will distribute property received by it to the record holders of depository receipts that are entitled to receive the distribution. However, if the depository determines that it is not feasible to make the distribution, the depository may, with our approval, adopt another method for the distribution.

The method may include selling the property and distributing the net proceeds to the holders.

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Liquidation Preference for Depositary Shares Associated with Preferred Stock

In the event of our voluntary or involuntary liquidation, dissolution or winding up, the holders of each depositary share will be entitled to receive the fraction of the liquidation preference accorded each share of the applicable series of preferred stock, as set forth in the applicable prospectus supplement.

Redemption of Depositary Shares Associated with Preferred Stock

If a series of preferred stock underlying the depositary shares is subject to redemption, the depositary shares will be redeemed from the proceeds received by the depositary resulting from the redemption, in whole or in part, of preferred stock held by the depositary. Whenever we redeem any preferred stock held by the depositary, the depositary will redeem, as of the same redemption date, the number of depositary shares representing the preferred stock so redeemed. The depositary will mail the notice of redemption to the record holders of the depositary receipts promptly upon receiving the notice from us and not less than 35 nor more than 60 days prior to the date fixed for redemption of the preferred stock and the depositary shares.

Voting Rights of Holders of Depositary Shares Associated with Preferred Stock

Upon receipt of notice of any meeting at which the holders of preferred stock are entitled to vote, the depositary will mail the information contained in the notice of meeting to the record holders of the depositary receipts underlying the preferred stock. Each record holder of those depositary receipts on the record date will be entitled to instruct the depositary as to the exercise of the voting rights pertaining to the amount of preferred stock underlying that holder's depositary shares. The record date for the depositary shares will be the same date as the record date for the preferred stock. The depositary will try, as far as practicable, to vote the preferred stock underlying the depositary shares in accordance with the instructions of the holders of the depositary receipts. We will agree to take all action which may be deemed necessary by the depositary in order to enable the depositary to do so. The depositary will not vote the preferred stock to the extent that it does not receive specific instructions from the holders of depositary receipts.

Withdrawal by Holders of Depositary Shares of Preferred Stock Underlying Depositary Shares

Owners of depositary shares are entitled, upon surrender of depositary receipts at the principal office of the depositary and payment of any unpaid amount due the depositary, to receive the number of whole shares of preferred stock underlying the depositary shares. Partial shares of preferred stock will not be issued. These holders of preferred stock will not be entitled to deposit the shares under the deposit agreement or to receive depositary receipts evidencing depositary shares for the preferred stock.

United States Federal Income Tax Consequences Associated with the Depositary Shares

Owners of the depositary shares associated with our preferred stock will be treated for United States Federal income tax purposes as if they were owners of the preferred stock underlying the depositary shares. Accordingly, the owners will be entitled to take into account for United States Federal income tax purposes income and deductions to which they would be entitled if they were holders of the preferred stock. In addition:

- no gain or loss will be recognized for United States Federal income tax purposes upon the withdrawal of preferred stock in exchange for depositary shares;
- the tax basis of each share of preferred stock to an exchanging owner of depositary shares will, upon the exchange, be the same as the aggregate tax basis of the depositary shares exchanged; and
- the holding period for preferred stock in the hands of an exchanging owner of depositary shares will include the period during which the person owned the depositary shares.

The prospectus supplement for each series of preferred stock may include a description of additional applicable United States Federal income tax or other considerations with respect to the preferred stock.

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Amendment and Termination of Deposit Agreement

The form of depositary receipt evidencing the depositary shares and any provision of the deposit agreement may be amended at any time and from time to time by agreement between us and the depositary. However, any amendment which materially and adversely alters the rights of the holders of depositary shares, other than any change in fees, will not be effective unless the amendment has been approved by at least a majority of the depositary shares then outstanding. The deposit agreement may be terminated by us or the depositary only if:

- all outstanding depositary shares have been redeemed or
- there has been a final distribution in respect of the preferred stock in connection with our dissolution and such distribution has been made to all the holders of depositary shares.

Charges of Depositary

We will pay all transfer and other taxes and governmental charges arising solely from the existence of the depositary arrangements. We will also pay charges of the depositary in connection with the initial deposit of the preferred stock and the initial issuance of the depositary shares, any redemption of the preferred stock and all withdrawals of preferred stock by owners of depositary shares. Holders of depositary receipts will pay transfer, income and other taxes and governmental charges and certain other charges as provided in the deposit agreement to be for their accounts. In certain circumstances, the depositary may refuse to transfer depositary shares, may withhold dividends and distributions and sell the depositary shares evidenced by the depositary receipt if the charges are not paid.

Reports to Holders of Depositary Shares

The depositary will forward to the holders of depositary receipts all reports and communications we deliver to the depositary that we are required to furnish to the holders of the preferred stock. In addition, the depositary will make available for inspection by holders of depositary receipts at the principal office of the depositary, and at other places as it may from time to time deem advisable, any reports and communications we deliver to the depositary as the holder of preferred stock.

Liability and Legal Proceedings

Neither we nor the depositary will be liable if either of us are prevented or delayed by law or any circumstance beyond our control in performing our respective obligations under the deposit agreement. Our obligations and those of the depositary will be limited to performance in good faith of our respective duties under the deposit agreement. Neither we nor the depositary will be obligated to prosecute or defend any legal proceeding in respect of any depositary shares or preferred stock unless satisfactory indemnity is furnished. We and the depositary may rely on written advice of counsel or accountants, on information provided by holders of depositary receipts or other persons believed in good faith to be competent to give such information and on documents believed to be genuine and to have been signed or presented by the proper party or parties.

Resignation and Removal of Depositary

The depositary may resign at any time by delivering a notice to us of its election to do so. We may remove the depositary at any time. Any such resignation or removal will take effect upon the appointment of a successor depositary and its acceptance of such appointment. The successor depositary must be appointed within 60 days after delivery of the notice for resignation or removal. In addition, the successor depositary must be a bank or trust company having its principal office in the United States of America and having a combined capital and surplus of at least \$150,000,000.

[Table of Contents](#)**DESCRIPTION OF DEBT SECURITIES**

The following description of the terms of the debt securities sets forth general terms that may apply to the debt securities. The particular terms of any debt securities will be described in the prospectus supplement relating to those debt securities.

The debt securities will be issued under an indenture between us and one or more trustees (the "Indenture"). The Indenture is subject to and governed by the Trust Indenture Act of 1939, as amended.

The following is a summary of the most important provisions of the Indenture. A copy of the Indenture is an exhibit to the registration statement of which this prospectus is a part. Section references below are to the section in the Indenture. The referenced sections of the Indenture are incorporated by reference.

General

The Indenture does not limit the amount of debt securities that we may issue. The Indenture provides that debt securities may be issued up to the principal amount authorized by us from time to time. The debt securities will be unsecured and will have the same rank as all of our other unsecured and unsubordinated debt.

The debt securities may be issued in one or more separate series. The prospectus supplement relating to the particular series of debt securities being offered will specify the particular amounts, prices and terms of those debt securities. These terms may include:

- the title of the debt securities;
- any limit upon the aggregate principal amount issued;
- the maturity date or dates;
- the interest rate or rates, or the method of determining those rates;
- the date or dates from which interest shall accrue, the interest payment dates and the record dates for determining the holders to whom interest is payable;
- the places where payments may be made;
- any mandatory or optional redemption provisions;
- any sinking fund or analogous provisions;
- if other than denominations of \$1,000 and any multiple thereof (for debt securities denominated in dollars, the denominations in which the debt securities will be issued);
- the portion of principal amount of the debt security payable upon acceleration of maturity if other than the full principal amount;
- any deletions of, or changes or additions to, the events of default or covenants;
- the form of the debt securities;
- if other than U.S. dollars, the currency or currencies, including composite currencies, in which payments on the debt securities will be payable and whether we or a holder may elect payment to be made in a different currency;
- the method of determining the amount of any payments on the debt securities which are linked to an index;
- whether the debt securities will be issued in the form of one or more global securities in temporary or definitive form;

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- any trustees, authenticating or paying agents, warrant agents, transfer agents or registrars with respect to the debt securities; and
- any other specific terms of the debt securities.

(Section 2.3)

Unless otherwise specified in the prospectus supplement, debt securities denominated in U.S. dollars will be issued in denominations of \$1,000 or an integral multiple of \$1,000. (Section 2.7)

We may issue some of the debt securities as original issue discount debt securities. Original issue discount securities bear no interest or bear interest at below-market rates and will be sold at a discount below their stated principal amount.

Certain Covenants of the Company

Limitation on Liens — Subject to the exceptions set forth below under “Exempted Indebtedness,” we covenant that we will not create or assume, nor will we permit any Restricted Subsidiary (as hereinafter defined) to create or assume, any,

- mortgage
- security interest,
- pledge, or
- lien

(together, we refer to these transactions as “liens”) of or upon any Principal Property (as hereinafter defined) or shares of capital stock or indebtedness of any Restricted Subsidiary, whether owned at the date of the Indenture or thereafter acquired, without equally and ratably securing the outstanding debt securities. This restriction will not apply to certain permitted liens, including the following:

- (i) liens on any Principal Property (including any underlying real estate) acquired, constructed or improved by us or any Restricted Subsidiary after the date of the Indenture which are created or assumed contemporaneously with, or within 120 days after (or in the case of any such Principal Property which is being financed on the basis of long-term contracts or similar financing arrangements for which a firm commitment is made by one or more banks, insurance companies or other lenders or investors (not including us or any Restricted Subsidiary), then within 360 days after), the completion of the acquisition, construction or improvement of such Principal Property to secure or provide for the payment of any part of the purchase price of such property or the cost of such construction or improvement, or liens on any Principal Property at the time of acquisition thereof;
- (ii) liens on property or shares of capital stock or indebtedness of a corporation existing at the time such corporation is merged into or consolidated with us or a Restricted Subsidiary or at the time of a sale, lease or other disposition of the properties of a corporation as an entirety or substantially as an entirety to us or a Restricted Subsidiary;
- (iii) liens on property or shares of capital stock or indebtedness of a corporation existing at the time such corporation becomes a Restricted Subsidiary;
- (iv) liens to secure indebtedness of a Restricted Subsidiary to us or to another Restricted Subsidiary, but only so long as such indebtedness is held by us or a Restricted Subsidiary;
- (v) liens in favor of the United States of America or any State thereof, or any department, agency or political subdivision of the United States of America or any State thereof, to secure certain payments pursuant to any contract or statute, including liens to secure indebtedness of the pollution control or industrial revenue bond type, or to secure indebtedness incurred for the purpose of financing all or any part of the purchase price or cost of constructing or improving property subject to such liens;

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- (vi) liens in favor of any customer arising in respect of certain payments made by or on behalf of such customer for goods produced for or services rendered to such customer in the ordinary course of business not exceeding the amount of such payments;
- (vii) liens to extend, renew or replace in whole or in part any lien referred to in the foregoing clauses (i) to (vi), or in this clause (vii), or any lien created prior to and existing on the date of the Indenture, provided that the principal amount of indebtedness secured thereby shall not exceed the principal amount of indebtedness so secured at the time of such extension, renewal or replacement, and that such extension, renewal or replacement shall be limited to all or a part of the property subject to the lien so extended, renewed or replaced (plus improvements on such property); and
- (viii) certain statutory liens, liens for taxes and certain other liens.

(Section 3.6)

Limitations on Sale and Lease-Back Transactions — Subject to the exceptions set forth below under “Exempted Indebtedness,” sale and lease-back transactions by us or any Restricted Subsidiary of any Principal Property which has been owned and operated by us or a Restricted Subsidiary for more than 120 days are prohibited unless

- (i) the property involved is property which could be the subject of a lien without equally and ratably securing the debt securities; or
- (ii) an amount equal to the Attributable Debt (as hereinafter defined) of any such sale and lease-back transaction is applied to the acquisition of another Principal Property of equal or greater fair market value or to retirement of indebtedness for borrowed money (including the debt securities) which by its terms matures on or is renewable at the option of the obligor to a date more than twelve months after the creation of such indebtedness.

This restriction will not apply to temporary leases for a term of not more than three years (including any renewal thereof) and leases between us and our Restricted Subsidiaries or between Restricted Subsidiaries.

(Section 3.7)

Exempted Indebtedness — We and our Restricted Subsidiaries may create or assume liens and enter into sale and lease-back transactions, notwithstanding the limitations outlined above, provided that at the time thereof and after giving effect thereto the aggregate amount of indebtedness secured by all such liens and Attributable Debt of all such sale and lease-back transactions outstanding shall not exceed 5% of Consolidated Net Tangible Assets (as hereinafter defined).

(Section 3.8)

Limitations on Mergers, Consolidations and Sales of Assets — If, upon our consolidation or merger with or into any other corporation, or upon any sale, conveyance or lease of substantially all or substantially all of our properties, any Principal Property would become subject to any lien, we, prior to such event, will secure the debt securities equally and ratably with any of our other obligations then entitled thereto by a direct lien on all such Principal Property prior to all other liens other than any theretofore existing thereon.

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(Section 3.9)

Certain Definitions

The term “Restricted Subsidiary” means any Subsidiary

- (a) substantially all the property of which is located, or substantially all the business of which is carried on, within the United States of America and
- (b) which owns or leases a Principal Property.

The term “Principal Property” means any manufacturing plant, research facility or warehouse owned or leased by us or any of our subsidiaries which is located within the United States and has a net book value exceeding the greater of \$5,000,000 and 1% of the stockholders’ equity of our company and our consolidated subsidiaries, excluding any property which our board of directors by resolution declares is not of material importance to our total business as consolidated with the business of our subsidiaries.

The term “Attributable Debt” means, as to any particular lease under which any person is at the time liable, at any date as of which the amount thereof is to be determined, the total net amount of rent required to be paid by such person under such lease during the remaining term thereof, excluding renewals, discounted as provided in the Indenture, compounded semi-annually. The net amount of rent required to be paid under any such lease for any such period shall be the amount of the rent payable by the lessee with respect to such period, after excluding amounts required to be paid on account of maintenance and repairs, insurance, taxes, assessments, water rates and similar charges and contingent rents such as those based on sales. In the case of any lease which is terminable by the lessee upon the payment of a penalty, such net amount may, if we so elect, also include the amount of such penalty, in which case no rent shall be considered as required to be paid under such lease subsequent to the first date upon which it may be so terminated.

The term “Consolidated Net Tangible Assets” means the total of all assets appearing on a consolidated balance sheet of our company and our consolidated subsidiaries, prepared in accordance with generally accepted accounting principles, at our and their net book values (after deducting related depreciation, depletion, amortization and all other valuation reserves which, in accordance with such principles, are set aside in connection with the business conducted), but excluding goodwill, trademarks, patents, unamortized debt discount and all other like segregated intangible assets, and amounts on the asset side of such balance sheet for our capital stock, all as determined in accordance with such principles, less Consolidated Current Liabilities.

The term “Consolidated Current Liabilities” means the aggregate of the current liabilities of us and our consolidated subsidiaries appearing on a consolidated balance sheet of our company and our consolidated subsidiaries, all as determined in accordance with generally accepted accounting principles.

(Section 1.1)

Other than the restrictions on liens and sale and lease-back transactions described above, neither the Indenture nor the debt securities afford you protection in the event of a highly leveraged transaction involving us or any of our subsidiaries, including any takeover, recapitalization or other restructuring that may result in a sudden and significant decline in credit rating.

Events of Default, Waiver and Notice

As to any series of debt securities, an “event of default” is defined in the Indenture as being any of the following events:

- (i) default for 30 days in the payment of any interest on the debt securities of such series;
- (ii) default in the payment of principal or premium due on the debt securities of any series;

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- (iii) default in the payment of any sinking fund installment on the debt securities of such series, when due;
- (iv) our failure to observe or perform any other of the covenants or agreements in the Indenture (other than those set forth exclusively in the terms of any other series of debt securities) for a period of 90 days after notice of such failure has been given to us by the trustee;
- (v) certain events of bankruptcy, insolvency and reorganization of our company; or
- (vi) any other events as may be established in any applicable supplement.

(Section 5.1)

The trustee must give notice of a default to the holders of the series of debt securities on which the default exists within 90 days unless the default is cured or waived. However, the trustee may withhold this notice if the trustee considers it in the interest of the holders of debt securities of such series to do so. The trustee may not withhold notice in the event of a payment default with regard to principal, interest or a sinking fund. (Section 5.11)

If an event of default has occurred and is continuing:

- and the event of default is as described in clause (i), (ii) or (iii) above, either the trustee or the holders of 25% in principal amount of the debt securities of such series then outstanding may declare the principal (or, in the case of discounted debt securities, the amount specified in the terms thereof) of all such debt securities to be due and payable immediately.
- and the event of default is as described in clause (iv) or (v) above, either the trustee or the holders of not less than 25% in principal amount of all debt securities then outstanding, voting as a single class, may declare the principal (or, in the case of discounted securities, the amount specified in the terms thereof) of all debt securities to be due and payable immediately.

However, upon certain conditions, past defaults may be waived by the holders as provided in the Indenture, except for defaults in

- the payment of principal of, or any premium or interest on, such debt securities or
- with respect to any covenant or provision which may not be amended without the approval of each holder affected.

(Sections 5.1 and 5.10)

The holders of a majority in principal amount of the debt securities of each series affected, voting as a separate class, may direct the time, method and place of conducting any proceeding for any remedy available to the trustee under the Indenture, subject to certain limitations specified in the Indenture, provided that the holders of debt securities shall have offered to the trustee reasonable indemnity against costs, expenses and liabilities. (Sections 5.9 and 6.2(d)) We must certify to the trustee on a yearly basis as to the absence of certain defaults. (Section 3.5)

Modification of the Indenture

Together with the trustee, and subject to the consent of the holders of at least 66 2/3% of the outstanding principal amount of the outstanding debt securities of all affected series, we may modify the Indenture or any supplement to the Indenture. Without the consent of each affected holder, we may not:

- (i) extend the final maturity of any debt security;
- (ii) reduce the principal amount or rate of interest of any debt security;
- (iii) extend the time of payment of interest of any debt security;

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- (iv) reduce the amount payable upon the redemption of any debt security;
- (v) reduce the amount of the principal of a discounted debt security payable upon acceleration of the maturity of the debt security or in the event of bankruptcy;
- (vi) impair the right to institute suit to enforce payment or repayment; or
- (vii) change the provisions in the Indenture that relate to its modification or amendment.

(Section 8.2)

Concerning the Trustee

The trustee or trustees to be appointed under the Indenture may also perform other services for us, such as for example cash management services, and may provide in the future certain credit facilities to us in the normal course of business.

Defeasance of the Indenture and Securities

We may, at any time, satisfy our obligations with respect to any payments of principal, premium or interest of any debt security or debt securities of any series by depositing in trust with the trustee:

- (a) money (in the currency in which the debt securities are payable),
- (b) in the case of debt securities denominated in U.S. dollars, U.S. Government Obligations (as defined in the Indenture), or a combination of U.S. Government Obligations and money, or
- (c) in the case of debt securities denominated in a foreign currency, Foreign Government Securities (as defined in the Indenture) or a combination of Foreign Government Securities and money.

If the deposit is sufficient to make all payments of interest, principal and premium when due, our obligations with respect to such securities will be discharged and terminated (except as to certain of our obligations to the trustee), and you will be able to look only to the trust fund for any payment of principal, premium and interest on securities of such series until maturity or redemption. (Article Ten)

Under United States Federal income tax law, any deposit as described just above is viewed as a taxable exchange of the securities deposited in the trust for interests in, or for an instrument representing indebtedness of, the trust. Accordingly, at such time as we may elect to deposit securities in a trust as described above, you would be required to recognize taxable gain or loss as if the securities had been sold for an amount equal to the sum of the amount of money and the fair market value of the securities held in the trust (or, alternatively, the value of the instrument). You then may be required to include in taxable income your share of the income, gain and loss of the trust.

Alternatively, the trust might be considered a separate taxable entity, in which case you might also be taxable on original issue discount as well as interest on the instrument. You should consult your own advisors with respect to the more detailed tax consequences of such deposit and discharge, including possible liabilities with regard to tax laws other than United States Federal income tax law.

Global Securities Evidencing Debt Securities

We may issue the debt securities of a series in whole or in part in the form of one or more global certificates that will be deposited with a depository we will identify in a prospectus supplement. We will describe the specific terms of the depository arrangement with respect to a series of debt securities in the accompanying prospectus supplement.

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Upon the issuance of a global security, the depositary will credit, on its book-entry registration and transfer system, the respective principal amounts of that global security to the accounts of participants in the depositary. Ownership of beneficial interests in a global security will be limited to participants or persons that hold interests through participants.

So long as the depositary for a global security, or its nominee, is the registered owner of the global security, the depositary or its nominee, as the case may be, will be considered the sole owner or holder of the securities represented by that global security. Except as provided in the Indenture, owners of beneficial interests in securities represented by a global security will not

- (a) be entitled to have such securities registered in their names,
- (b) receive or be entitled to receive physical delivery of certificates representing such securities in definitive form,
- (c) be considered the owners or holders thereof under the Indenture or
- (d) have any rights under the Indenture.

We may, in our sole discretion, at any time determine that any series of securities issued or issuable in the form of a global security shall no longer be represented by such global security and such global security shall be exchanged for securities in definitive form pursuant to the Indenture.

(Section 2.14)

DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplements and free writing prospectuses, summarizes the material terms and provisions of the warrants that we may offer under this prospectus, which may consist of warrants to purchase common stock, preferred stock or debt securities and may be issued in one or more series. Warrants may be issued independently or together with common stock, preferred stock or debt securities offered by any prospectus supplement, and may be attached to or separate from those securities. While the terms we have summarized below will apply generally to any warrants that we may offer under this prospectus, we will describe the particular terms of any series of warrants that we may offer in more detail in the applicable prospectus supplement and any applicable free writing prospectus. The terms of any warrants offered under a prospectus supplement may differ from the terms described below. However, no prospectus supplement will fundamentally change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness.

We may issue warrants for the purchase of debt securities, preferred stock or common stock. Warrants may be issued independently or together with our debt securities, preferred stock or common stock and may be attached to or separate from any offered securities. Each series of warrants will be issued under a separate warrant agreement to be entered into between us and a bank or trust company, as warrant agent. The warrant agent will act solely as our agent in connection with the warrants and will not have any obligation or relationship of agency or trust for or with any holders or beneficial owners of warrants. A copy of the warrant agreement will be filed with the SEC in connection with the offering of warrants.

The following summaries of material provisions of the warrants and the warrant agreements are subject to, and qualified in their entirety by reference to, all the provisions of the warrant agreement and warrant certificate applicable to the particular series of warrants that we may offer under this prospectus. We urge you to read the applicable prospectus supplements related to the particular series of warrants that we may offer under this prospectus, as well as any related authorized free writing prospectuses, and the complete warrant agreements and

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warrant certificates that contain the terms of the warrants. The prospectus supplement relating to a particular issue of warrants will describe the terms of those warrants, including the following:

- the title of the warrants;
- any offering price for the warrants;
- the aggregate number of the warrants;
- the designation and terms of the securities that may be purchased upon exercise of the warrants;
- if applicable, the designation and terms of the securities together with which the warrants are issued and the number of warrants issued with each security;
- any date from and after which the warrants and any securities issued with them will be separately transferable;
- the principal amount of or number of shares of stock that may be purchased upon exercise of a warrant and the price at which the debt securities may be purchased upon exercise;
- the dates on which the right to exercise the warrants will commence and expire;
- any minimum or maximum amount of the warrants that may be exercised at any one time;
- the currency or currency units in which the offering price and the exercise price are payable;
- if applicable, a discussion of material United States Federal, or other income tax considerations;
- any anti-dilution provisions of the warrants;
- any redemption or call provisions applicable to the warrants;
- any additional terms of the warrants, including terms, procedures, and limitations relating to the exchange and exercise of the warrants;
- whether the warrants represented by the warrant certificates or debt securities that may be issued upon exercise of the warrants will be issued in registered or bearer form; and
- any information with respect to book-entry procedures.

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including:

- in the case of warrants to purchase debt securities, the right to receive payments of principal of, or premium, if any, or interest on, the debt securities purchasable upon exercise or to enforce covenants in the applicable indenture; or
- in the case of warrants to purchase common stock or preferred stock, the right to receive dividends, if any, or, payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

Exercise of Warrants

Each warrant will entitle the holder to purchase the securities that we specify in the applicable prospectus supplement at the exercise price that we describe in the applicable prospectus supplement. Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants at any time up to the specified time on the expiration date that we set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants by delivering the warrant certificate representing the warrants to be exercised together with specified information, and paying the required amount to the warrant agent in immediately available funds, as provided in

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the applicable prospectus supplement. We will set forth on the reverse side of the warrant certificate and in the applicable prospectus supplement the information that the holder of the warrant will be required to deliver to the warrant agent in connection with the exercise of the warrant.

Upon receipt of the required payment and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement, we will issue and deliver the securities purchasable upon such exercise. If fewer than all of the warrants represented by the warrant certificate are exercised, then we will issue a new warrant certificate for the remaining amount of warrants. If we so indicate in the applicable prospectus supplement, holders of the warrants may surrender securities as all or part of the exercise price for warrants.

Governing Law

Unless we provide otherwise in the applicable prospectus supplement, the warrants and warrant agreements, and any claim, controversy or dispute arising under or related to the warrants or warrant agreements, will be governed by and construed in accordance with the laws of the State of Delaware.

Enforceability of Rights by Holders of Warrants

Each warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants.

LEGAL OWNERSHIP OF SECURITIES

We can issue securities in registered form or in the form of one or more global securities. We describe global securities in greater detail below. We refer to those persons who have securities registered in their own names on the books that we or any applicable trustee or depository maintain for this purpose as the “holders” of those securities. These persons are the legal holders of the securities. We refer to those persons who, indirectly through others, own beneficial interests in securities that are not registered in their own names, as “indirect holders” of those securities. As we discuss below, indirect holders are not legal holders, and investors in securities issued in book-entry form or in street name will be indirect holders.

Book-Entry Holders

We may issue securities in book-entry form only, as we will specify in the applicable prospectus supplement. This means securities may be represented by one or more global securities registered in the name of a financial institution that holds them as depository on behalf of other financial institutions that participate in the depository’s book-entry system. These participating institutions, which are referred to as participants, in turn, hold beneficial interests in the securities on behalf of themselves or their customers.

Only the person in whose name a security is registered is recognized as the holder of that security. Global securities will be registered in the name of the depository or its participants. Consequently, for global securities, we will recognize only the depository as the holder of the securities, and we will make all payments on the securities to the depository. The depository passes along the payments it receives to its participants, which in turn pass the payments along to their customers who are the beneficial owners. The depository and its participants do so under agreements they have made with one another or with their customers; they are not obligated to do so under the terms of the securities.

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As a result, investors in a global security will not own securities directly. Instead, they will own beneficial interests in a global security, through a bank, broker or other financial institution that participates in the depository's book-entry system or holds an interest through a participant. As long as the securities are issued in global form, investors will be indirect holders, and not legal holders, of the securities.

Street Name Holders

A global security may be terminated in certain situations as described under “—Special Situations When a Global Security Will Be Terminated,” or issue securities that are not issued in global form. In these cases, investors may choose to hold their securities in their own names or in “street name.” Securities held by an investor in street name would be registered in the name of a bank, broker or other financial institution that the investor chooses, and the investor would hold only a beneficial interest in those securities through an account he or she maintains at that institution.

For securities held in street name, we or any applicable trustee or depository will recognize only the intermediary banks, brokers and other financial institutions in whose names the securities are registered as the holders of those securities, and we or any such trustee or depository will make all payments on those securities to them. These institutions pass along the payments they receive to their customers who are the beneficial owners, but only because they agree to do so in their customer agreements or because they are legally required to do so. Investors who hold securities in street name will be indirect holders, not holders, of those securities.

Legal Holders

Our obligations, as well as the obligations of any applicable trustee or third party employed by us or a trustee, run only to the legal holders of the securities. We do not have obligations to investors who hold beneficial interests in global securities, in street name or by any other indirect means. This will be the case whether an investor chooses to be an indirect holder of a security or has no choice because we are issuing the securities only in global form.

For example, once we make a payment or give a notice to the legal holder, we have no further responsibility for the payment or notice even if that legal holder is required, under agreements with its participants or customers or by law, to pass it along to the indirect holders but does not do so. Similarly, we may want to obtain the approval of the holders to amend an indenture, to relieve us of the consequences of a default or of our obligation to comply with a particular provision of an indenture, or for other purposes. In such an event, we would seek approval only from the legal holders, and not the indirect holders, of the securities. Whether and how the legal holders contact the indirect holders is up to the legal holders.

Special Considerations for Indirect Holders

If you hold securities through a bank, broker or other financial institution, either in book-entry form because the securities are represented by one or more global securities or in street name, you should check with your own institution to find out:

- how it handles securities payments and notices;
- whether it imposes fees or charges;
- how it would handle a request for the holders' consent, if ever required;
- whether and how you can instruct it to send you securities registered in your own name so you can be a holder, if that is permitted in the future;
- how it would exercise rights under the securities if there were a default or other event triggering the need for holders to act to protect their interests; and
- if the securities are in book-entry form, how the depository's rules and procedures will affect these matters.

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Global Securities

A global security is a security that represents one or any other number of individual securities held by a depository. Generally, all securities represented by the same global securities will have the same terms.

Each security issued in book-entry form will be represented by a global security that we issue to, deposit with and register in the name of a financial institution or its nominee that we select. The financial institution that we select for this purpose is called the depository. Unless we specify otherwise in the applicable prospectus supplement, The Depository Trust Company, New York, New York, known as DTC, will be the depository for all securities issued in book-entry form.

A global security may not be transferred to or registered in the name of anyone other than the depository, its nominee or a successor depository, unless special termination situations arise. We describe those situations below under “—Special Situations When a Global Security Will Be Terminated.” As a result of these arrangements, the depository, or its nominee, will be the sole registered owner and legal holder of all securities represented by a global security, and investors will be permitted to own only beneficial interests in a global security. Beneficial interests must be held by means of an account with a broker, bank or other financial institution that in turn has an account with the depository or with another institution that does. Thus, an investor whose security is represented by a global security will not be a legal holder of the security, but only an indirect holder of a beneficial interest in the global security.

If the prospectus supplement for a particular security indicates that the security will be issued as a global security, then the security will be represented by a global security at all times unless and until the global security is terminated. If termination occurs, we may issue the securities through another book-entry clearing system or decide that the securities may no longer be held through any book-entry clearing system.

Special Considerations for Global Securities

As an indirect holder, an investor’s rights relating to a global security will be governed by the account rules of the investor’s financial institution and of the depository, as well as general laws relating to securities transfers. We do not recognize an indirect holder as a holder of securities and instead deal only with the depository that holds the global security.

If securities are issued only as global securities, an investor should be aware of the following:

- an investor cannot cause the securities to be registered in his or her name, and cannot obtain non-global certificates for his or her interest in the securities, except in the special situations we describe below;
- an investor will be an indirect holder and must look to his or her own bank or broker for payments on the securities and protection of his or her legal rights relating to the securities, as we describe above;
- an investor may not be able to sell interests in the securities to some insurance companies and to other institutions that are required by law to own their securities in non-book-entry form;
- an investor may not be able to pledge his or her interest in the global security in circumstances where certificates representing the securities must be delivered to the lender or other beneficiary of the pledge in order for the pledge to be effective;
- the depository’s policies, which may change from time to time, will govern payments, transfers, exchanges and other matters relating to an investor’s interest in the global security;
- we and any applicable trustee have no responsibility for any aspect of the depository’s actions or for its records of ownership interests in the global security, nor will we or any applicable trustee supervise the depository in any way;

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- the depositary may, and we understand that DTC will, require that those who purchase and sell interests in the global security within its book-entry system use immediately available funds, and your broker or bank may require you to do so as well; and
- financial institutions that participate in the depositary's book-entry system, and through which an investor holds its interest in the global security, may also have their own policies affecting payments, notices and other matters relating to the securities.

There may be more than one financial intermediary in the chain of ownership for an investor. We do not monitor and are not responsible for the actions of any of those intermediaries.

Special Situations When a Global Security Will Be Terminated

In a few special situations described below, a global security will terminate and interests in it will be exchanged for physical certificates representing those interests. After that exchange, the choice of whether to hold securities directly or in street name will be up to the investor. Investors must consult their own banks or brokers to find out how to have their interests in securities transferred to their own names, so that they will be direct holders. We have described the rights of holders and street name investors above.

A global security will terminate when the following special situations occur:

- if the depositary notifies us that it is unwilling, unable or no longer qualified to continue as depositary for that global security and we do not appoint another institution to act as depositary within 90 days;
- if we notify any applicable trustee that we wish to terminate that global security; or
- if an event of default has occurred with regard to securities represented by that global security and has not been cured or waived

The applicable prospectus supplement may also list additional situations for terminating a global security that would apply only to the particular series of securities covered by the prospectus supplement. When a global security terminates, the depositary, and neither we nor any applicable trustee, is responsible for deciding the names of the institutions that will be the initial direct holders.

PLAN OF DISTRIBUTION

We may sell the securities from time to time pursuant to underwritten public offerings, negotiated transactions, block trades or a combination of these methods. We may sell the securities to or through underwriters or dealers, through agents, or directly to one or more purchasers. We may distribute securities from time to time in one or more transactions:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

We may also sell equity securities covered by this registration statement in an "at the market offering" as defined in Rule 415 under the Securities Act. Such offering may be made into an existing trading market for such securities in transactions at other than a fixed price, either:

- on or through the facilities of the Nasdaq Capital Market or any other securities exchange or quotation or trading service on which such securities may be listed, quoted or traded at the time of sale; and/or
- to or through a market maker other than on the Nasdaq Capital Market or such other securities exchanges or quotation or trading services.

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Such at-the-market offerings, if any, may be conducted by underwriters acting as principal or agent.

A prospectus supplement or supplements (and any related authorized free writing prospectus that we may authorize to be provided to you) will describe the terms of the offering of the securities, including, to the extent applicable:

- the name or names of any underwriters, dealers or agents, if any;
- the purchase price of the securities and the proceeds we will receive from the sale;
- any over-allotment options under which underwriters may purchase additional securities from us;
- any agency fees or underwriting discounts and other items constituting agents' or underwriters' compensation;
- any public offering price;
- any discounts or concessions allowed or reallocated or paid to dealers; and
- any securities exchange or market on which the securities may be listed.

Only underwriters named in the prospectus supplement are underwriters of the securities offered by the prospectus supplement.

If underwriters are used in the sale, they will acquire the securities for their own account and may resell the securities from time to time in one or more transactions at a fixed public offering price or at varying prices determined at the time of sale. The obligations of the underwriters to purchase the securities will be subject to the conditions set forth in the applicable underwriting agreement. We may offer the securities to the public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate. Subject to certain conditions, the underwriters will be obligated to purchase all of the securities offered by the prospectus supplement. Any public offering price and any discounts or concessions allowed or reallocated or paid to dealers may change from time to time. We may use underwriters with whom we have a material relationship. We will describe in the prospectus supplement, naming the underwriter, the nature of any such relationship.

We may sell securities directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of securities, and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, our agent will act on a best-efforts basis for the period of its appointment.

We may authorize agents or underwriters to solicit offers by certain types of institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement.

We may provide agents and underwriters with indemnification against civil liabilities related to this offering, including liabilities under the Securities Act, or contribution with respect to payments that the agents or underwriters may make with respect to these liabilities. Agents and underwriters may engage in transactions with, or perform services for, us in the ordinary course of business.

All securities we offer, other than common stock, will be new issues of securities with no established trading market. Any underwriters may make a market in these securities, but will not be obligated to do so and may discontinue any market making at any time without notice. We cannot guarantee the liquidity of the trading markets for any securities.

Any underwriter may engage in over-allotment, stabilizing transactions, short covering transactions and penalty bids. Over-allotment involves sales in excess of the offering size, which create a short position. Stabilizing

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transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of the securities in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a stabilizing or covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time. These transactions may be effected on any exchange or over-the-counter market or otherwise.

Any underwriters who are qualified market makers on the Nasdaq Capital Market may engage in passive market making transactions in the securities on the Nasdaq Capital Market in accordance with Rule 103 of Regulation M, during the business day prior to the pricing of the offering, before the commencement of offers or sales of the securities. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security; if all independent bids are lowered below the passive market maker's bid, however, the passive market maker's bid must then be lowered when certain purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

LEGAL MATTERS

The legality of the securities in respect of which this prospectus is being delivered will be passed on for us by Drinker Biddle & Reath LLP ("DBR"), Philadelphia, Pennsylvania. The validity of any securities offered in the prospectus supplement relating to such securities will be passed upon for any underwriters or agents by counsel to be named in the prospectus supplement relating to such securities. As of the date of this prospectus, James Biehl, a partner of DBR and a director of the Company, beneficially owned 1,012,650 shares of Company common stock and is eligible to receive future grants of awards pursuant to the 2016 Non-Employee Director Stock Plan.

EXPERTS

The consolidated financial statements as of March 31, 2017 and 2016 and for the year ended March 31, 2017, three months ended March 31, 2016 and year ended December 31, 2015 incorporated by reference in this prospectus and elsewhere in the registration statement have been so incorporated by reference in reliance upon the report of Grant Thornton LLP, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing.

The consolidated financial statements as of and for the year ended December 31, 2014, before the effects of the adjustments to retrospectively apply the change in accounting as described in Note 1 to the consolidated financial statements incorporated by reference in this prospectus and elsewhere in the registration statement, have been audited by WithumSmith+Brown, PC, an independent registered public accounting firm. The adjustments to those financial statements to retrospectively apply the impact of the reverse merger described in Note 1 have been audited by Grant Thornton LLP, an independent registered public accounting firm.

The consolidated financial statements as of and for the year ended December 31, 2014 incorporated by reference in this prospectus and elsewhere in the registration statement have been so incorporated by reference in reliance upon the reports of (i) WithumSmith+Brown, PC, solely with respect to those financial statements before the effects of the adjustments to retrospectively apply the impact of the reverse merger in Note 1 and (ii) Grant Thornton LLP solely with respect to the adjustments to those financial statements to retrospectively apply the impact of the reverse merger in Note 1, given on the authority of such firms as experts in accounting and auditing.

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We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any document we file at the SEC's Public Reference Room, 450 Fifth Street, N.W., Washington, D.C. 20549. You may call the SEC at 1-800-SEC-0330 for further information on the SEC's Public Reference Room. You may also access our SEC filings at the SEC's web site at <http://www.sec.gov>.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" into this prospectus the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and later information that we file with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and their amendments, except information furnished under Item 2.02 or Item 7.01 of Form 8-K, which is neither deemed filed nor incorporated by reference herein and any future filings made with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act until this offering is completed:

- Our Annual Report on Form 10-K for the fiscal year ended March 31, 2017, filed with the SEC on June 12, 2017 as amended by Form 10-K/A filed with the SEC on July 28, 2017;
- Our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, filed with the SEC on August 10, 2017;
- Our Current Report on Form 8-K/A filed with the SEC on March 31, 2017, April 17, 2017, and July 13, 2017 and our Current Reports on Form 8-K filed with the SEC on April 4, 2017, June 15, 2017, August 2, 2017 and August 10, 2017; and
- The description of our capital stock in our Form 8-A filed with the SEC on July 27, 2017.

We also incorporate by reference into this prospectus all documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items) that are filed by us with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (i) after the date of the initial filing of the registration statement of which this prospectus forms a part and prior to effectiveness of the registration statement, or (ii) after the date of this prospectus but prior to the termination of the offering. These documents include periodic reports, such as Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as proxy statements.

You may request a copy of these filings at no cost, by writing to or telephoning us at:

Chief Financial Officer's Office
TYME TECHNOLOGIES, INC.
44 Wall Street – 12th Floor
New York, New York
Telephone: (646) 205-1603

You should rely only on the information incorporated by reference or provided in this prospectus or the accompanying prospectus supplement. We have not authorized anyone to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus, any prospectus supplement or any document which we incorporate by reference is accurate as of any date other than the date on its cover.

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**DISCLOSURE OF COMMISSION'S POSITION ON INDEMNIFICATION
FOR SECURITIES ACT LIABILITY**

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling the Company pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

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9,000,000 Shares

TYME TECHNOLOGIES, INC.



Common Stock

PROSPECTUS SUPPLEMENT

Book-Running Managers

Evercore ISI

Stifel

Canaccord Genuity

Co-Manager

H.C. Wainwright & Co.

March 1, 2018
