

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended March 31, 2017

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

For the transition period from _____ to _____

Commission file number 333-179311

TYME TECHNOLOGIES, INC.
(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

45-3864597

(I.R.S. Employer Identification No.)

**44 Wall Street – 12th Floor
New York, New York**

(Address of principal executive offices)

10005

(Zip Code)

Registrant's telephone number, including area code: **(646) 205-1603**

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

(Note: The registrant was a voluntary filer of reports during the most recent fiscal year covered by this report and filed during the 12 months preceding March 31, 2017, and in the twelve preceding months, all reports it would have been required to file by Section 13 or 15(d) of the Securities Exchange Act if the registrant had been subject to one of such sections.)

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Rule 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant’s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

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

Large accelerated filer ☐

Accelerated filer [X]

Non-accelerated filer ☐

Smaller Reporting Company ☐

Emerging Growth Company [X]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No [X]

The aggregate market value of the common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant’s most recently completed second fiscal quarter, was approximately \$127.1 million.

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

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

Indicate the number of shares outstanding of each of the registrant’s classes of common stock, as of the latest practicable date.

Class	Outstanding at May 26, 2017
Common stock, \$0.0001 par value per share	89,341,067 shares

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the documents listed below have been incorporated by reference into the indicated parts of this report, as specified in the responses to the item numbers involved.

Designated portions of the Proxy Statement relating to the 2017 Annual Meeting of the Stockholders (the “Proxy Statement”): Part III (Items 9, 10, 11, 12, and 13), to be filed within 120 days of the Registrant’s fiscal year ended March 31, 2017. Except with respect to information specifically incorporated by reference in the Form 10-K, the Proxy Statement is not deemed to be filed as part hereof.

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PART I

Except for historical financial information contained herein, Tyme Technologies, Inc., including all subsidiaries (collectively referred to as “we,” “us,” “our,” or “Company” in this report) notes that certain of the matters discussed in this Form 10-K may be considered forward-looking statements. Such statements include declarations regarding our intent, belief, or current expectations and those of our management. Prospective investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve a number of risks, uncertainties and other factors, some of which are beyond our control; actual results could differ materially from those indicated by such forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, but are not limited to: (i) that the information is of a preliminary nature and may be subject to change; (ii) those risks and uncertainties identified under “Risk Factors;” and (iii) the other risks detailed from time-to-time in our reports and registration statements filed with the Securities and Exchange Commission, or SEC. Except as required by law, we undertake no obligation to revise or update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

ITEM 1. BUSINESS

Executive Summary of Our Business

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.

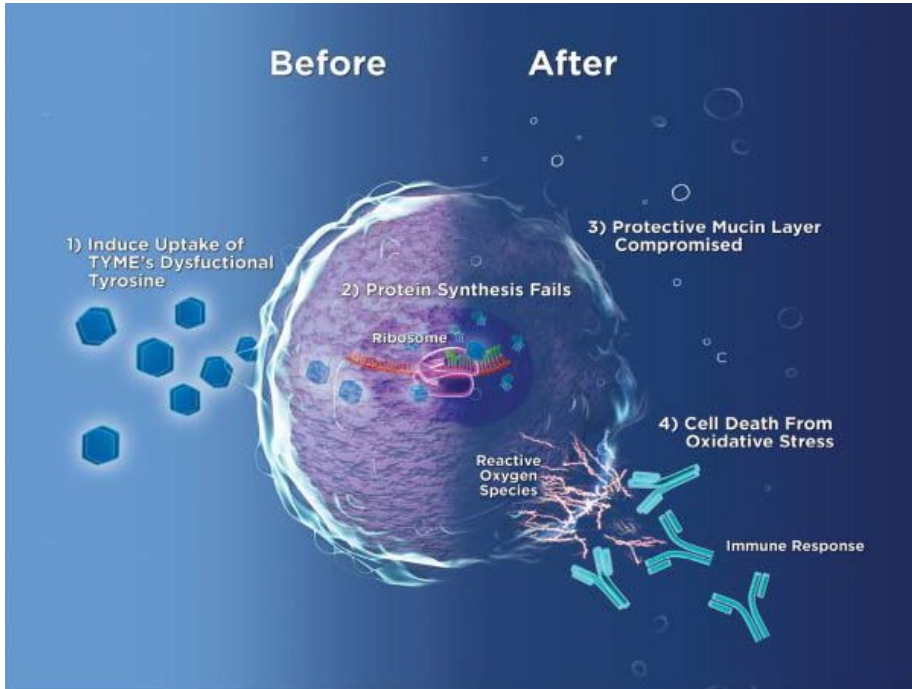
We believe, based on SM-88’s mechanism of action (described below) and proof-of-concept study data, that our lead candidate may ultimately improve overall response rates, clinical outcomes and survival rates in cancer patients. Based on its proposed mechanism of action and the factors described below, 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 following diagram describes our proposed MOA for SM-88 – a biological circuit that uses metabolism to break down a tumor's defense to apoptosis-causing oxidative stress.



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 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.

The SM-88 First Human Study and Compassionate Use Patients Background; Our Phase II Clinical Trial Program Objectives

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 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 are currently enrolling an open-label Phase II trial in localized prostate cancer for biomarker-recurrent maintenance therapy. We expect to complete enrollment by year-end 2017 with a seven-month treatment and follow-up period. Preliminary data from this trial was presented at ASCO 2017 and additional data may be presented prior to final completion.
- 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.

Our First Human Study

Our First Human Study, we believe, demonstrated 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. The 30-subject 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” (consisting of complete response, partial response or stable disease), treatment was continued for some patients for multiple years. This study was conducted under IRB supervision without FDA approval of an IND. Summary results of the study are shown below:

Summary of Completed First Human Study	
Population	30 progressive metastatic cancer subjects that had failed or refused available treatments. Physician estimated survival of 3-6 months
Treatment	Monotherapy with SM-88 after 60-day wash-out of prior therapy
Results	Overall Survival: Median of 25.7 months Progression Free Survival: Median of 14.7 months - 2.1x longer PFS than penultimate PFS where data was available 90% clinical benefit based on RECIST criteria - Complete response (n=2), partial response (n=6), stable disease (n=19)
Safety	No drug-related serious AEs and few grade 1 or 2 AEs

The study commenced in January 2012 as a single-center, monotherapy, open-label, proof-of-concept study conducted under an IRB reviewed protocol. Enrollment was restricted to 30 metastatic cancer patients who had failed or refused possible available treatments with physician-estimation of three-to-six months survival. In addition, patients had to have at least a 60-day washout period from any prior therapy before initiating monotherapy with SM-88. Subjects received one to ten six-week cycles of treatment, each consisting of small-dose subcutaneous plus oral daily administration, five days per week. Metastatic breast cancer was the most common site of origin (n=14), with lung (n=5), pancreatic (n=3) and seven other cancer types also enrolling.

Based on Response Evaluation Criteria In Solid Tumors 1.1 (“RECIST”) radiographic criteria assessed by two independent reviewers, median progression free survival was 15 months with 90% of subjects (27/30) showing Clinical Benefit, including complete response (n=2), partial response (n=6) or stable disease (n=19). We believe that stable disease is an important clinical outcome in this patient population setting since all subjects were enrolled with progressive disease and had a short period of estimated survival. Median overall survival was 25.7 months in comparison to physician expectation of three-to-six month survival at the initiation of therapy.

In evaluating SM-88’s safety, improvements were noted at the end of cycle one for patients: in Eastern Cooperative Oncology Group Performance Status (“ECOG PS”) (83.3% of patients) and statistically significant changes in European Organization for Research and Treatment of Cancer Quality of Life (“EORTC QoL”) scores, including global health status/QoL, physical functioning, role functioning, emotional functioning, cognitive functioning, social functioning, fatigue, pain and insomnia. SM-88 was well tolerated, and drug-related AEs in cycle one were mild to moderate and self-limiting, with no therapy required. Most AEs occurred within the first cycle of treatment, with the exception of hyperpigmentation, which eventually occurred in all subjects.

More complete First Human Study data is included in the “Prior Studies” section below.

Compassionate Use Patients

As of March 31, 2017, SM-88 has been used with 76 patients as part of a compassionate use program under IRB oversight. This treatment regimen was initiated in 2012 using a protocol similar to the First Human Study protocol initiated in January 2012, with the largest difference relating to the initiation of SM-88 to the advanced-stage Compassionate Use Patients without any 60-day

washout period from prior therapy. Nearly all the Compassionate Use Patients enrolled had metastatic disease, had failed or refused possible available therapies and were treated with SM-88 in monotherapy. We were generally able to receive regularly detailed information on the treatment of Compassionate Use Patients; however, their treatment is not part of a clinical trial under our control and there can be variations in the treatment administration, as the treating physicians deem appropriate.

We have presented limited initial data at ASCO 2017 or previously, and we intend to continue releasing Compassionate Use Patients data in peer-reviewed publications and conferences over the next 18 months.

In early 2016, we performed a retrospective analysis on the first 53 (of the 76) Compassionate Use Patients that had received treatment, which was later updated to 57 patients, including three additional pancreatic patients. These patients had their scans reviewed by two independent radiologists to determine Clinical Benefit, and 79% of these patients were deemed to have experienced Clinical Benefit, including eight complete responses, 19 partial responses and 18 stable disease designations. The safety profile of these subjects was evaluated with no drug-related SAEs reported and few grade one or two AEs attributed to SM-88 treatment.

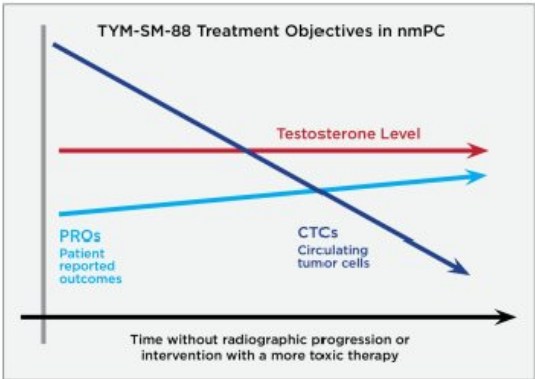
More complete data is included in the “Prior Studies” section below.

Our Currently Enrolling Phase Ib/II Prostate Clinical Trial Design and Objectives

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”).

Our Phase Ib/II prostate cancer trial is treating an earlier stage patient population than failed-or-refused patient population targeted in SM-88’s First Human Study and Compassionate Use Patients. 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. Subjects enrolling in our trial would be generally otherwise put on ADT therapy, inducing a chemical castration, or other more toxic therapies. By treating this patient population with SM-88 monotherapy, we hope to show:

- 1. Ability to prevent disease progression without chemically reducing testosterone
- 2. Ability to maintain quality-of-life
- 3. Reduction or elimination of CTCs, which we believe are a component in developing metastatic cancer
- 4. SM-88’s minimal side effect profile in a relatively healthy patient population.



Initial Phase Ib data showed non-detectable or declining circulating tumor cells (or CTCs) in all evaluable subjects, with no drug-related SAEs. This trial progressed from Phase Ib to Phase II following the initial dose escalation phase. The first subject enrolled received the lowest dose (230mg of tyrosine derivative) and experienced therapeutic benefit with no significant side effects. As a result, the dose was doubled to twice daily dosing with 230 mg of tyrosine derivative in the next three subjects. All three of these subjects also experienced therapeutic benefit with no significant side effects. The twice daily 230 mg dose was then taken into the Phase II trial, where we have initiated enrollment and intend to complete enrollment at 30 subjects.

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 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

While this represents encouraging initial data, there can be no guarantee that future results in the trial will be similar or that the overall trial will be successful in achieving its stated goals.

Planned Phase II Trial for Pancreatic Cancer

At ASCO 2017, we 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).

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. In the refractory setting, such as the setting where all 11 of the noted SM-88 patients were treated, 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 by first quarter 2018.

Other Clinical Plans

We intend to focus expanding clinical activities as a next priority to certain failed-and-refused end-stage cancer patient populations. 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 First Human Study and Compassionate Use Patients. We intend to initiate additional Phase II studies in these or other cancers as resources become available.

Our Strengths

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 Strategy

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.

Clinical Trials

Clinical trials to support New Drug Applications ("NDA") for marketing approval are typically conducted in three sequential phases, but the phases may overlap or be combined. In Phase I, the drug is initially introduced into healthy human subjects and is tested to assess pharmacokinetics, pharmacological actions, AEs associated with increasing doses and, if possible, early evidence of effectiveness. In the case of some products targeted for severe or life-threatening diseases, such as cancer treatments, initial human testing may be conducted in the intended patient population. Phase II usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, as well as identification of common adverse effects and safety risks.

If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase II, Phase III trials are initiated to obtain additional information about clinical efficacy and safety in a larger number of subjects, typically at geographically dispersed clinical trial sites. Phase III clinical trials are intended to establish data sufficient to demonstrate substantial evidence of the efficacy and safety of the product to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. Trials conducted outside of the U.S. under similar, GCP-compliant conditions in accordance with local applicable laws may also be acceptable to the FDA in support of product approval.

Prior Studies

Our First Human Study

We completed in 2014 a 30-patient, single-center, open-label, First Human Study using SM-88 for the treatment of advanced metastatic cancer. The purpose of our proof-of-concept study was to determine the safety, tolerability and efficacy of SM-88 in subjects with advanced metastatic cancer. The goals of the study were to:

- Assess Progression-Free Survival (or PFS) in patients treated with SM-88;
- Assess secondary measures of efficacy including Objective Response Rate (“ORR”), Duration of Response (“DR”) and overall survival (or OS);
- Evaluate safety and tolerability of SM-88; and
- Explore Patient Reported Outcomes, including health-related Quality-of-Life (“QoL”) and disease/treatment-related symptoms.

Between January and December 2012, 30 subjects with stage IV cancer and distant metastasis, including bone and central nervous system involvement, enrolled and were included in the trial. The patient population was comprised of patients who refused or failed other available anticancer treatments. Of the 30 patients, 16 patients had had prior surgery, 10 had had prior radiation therapy and 20 had had prior chemotherapy, including six patients with three or more prior regimens, four patients with two prior regimens and 10 patients with one prior regimen. Cancer types, subjects and RECIST results are presented below.

Best Overall Response Data from First Human Study

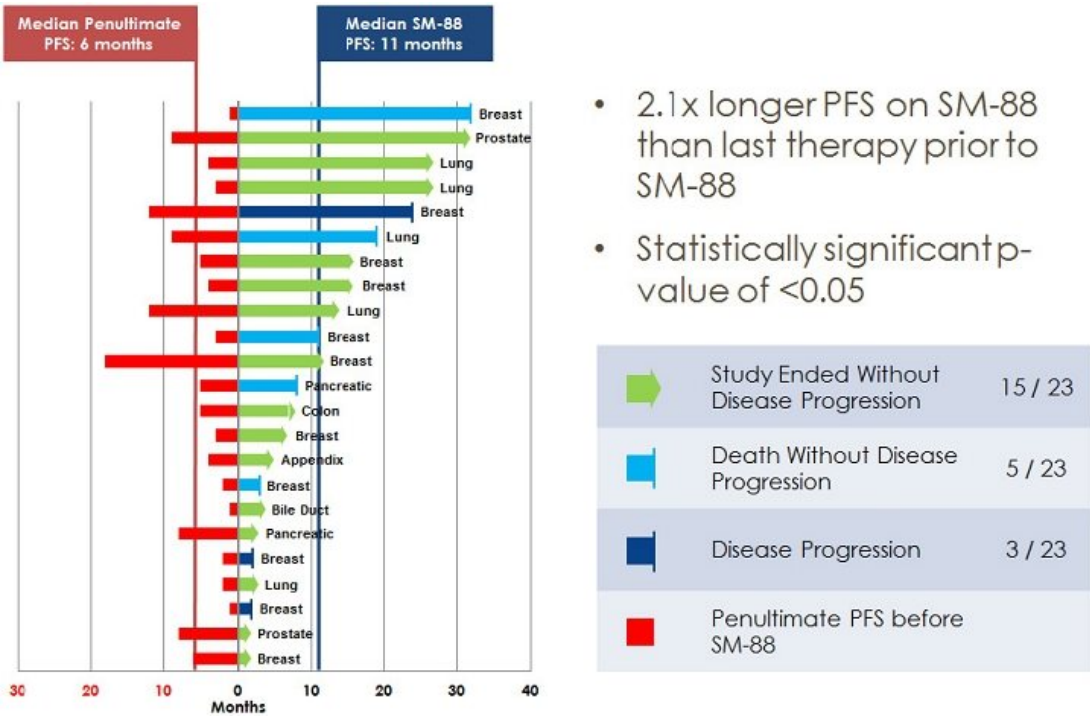
Using best overall response criteria, the following data was derived from the patients who participated in our First Human Study.

Primary Disease	Number of Patients	Best Overall Response			Clinical Benefit	PD
		CR	PR	SD	CR+PR+SD	
Breast Cancer	14	2	4	5	78.6% (11)	3
Lung Cancer	5	0	1	4	100.0% (5)	0
Pancreatic Cancer	3	0	0	3	100.0% (3)	0
Prostate Cancer	2	0	0	2	100.0% (2)	0
Liver Cancer	1	0	0	1	100.0% (1)	0
Thyroid Cancer	1	0	1	0	100.0% (1)	0
Biliary Cancer	1	0	0	1	100.0% (1)	0
Colon Cancer	1	0	0	1	100.0% (1)	0
Tongue Cancer	1	0	0	1	100.0% (1)	0
Appendix Cancer	1	0	0	1	100.0% (1)	0
OVERALL	30	2	6	19	90.0% (27)	10.0% (3)

Abbreviations: CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease. Clinical Benefit = CR & PR & SD.

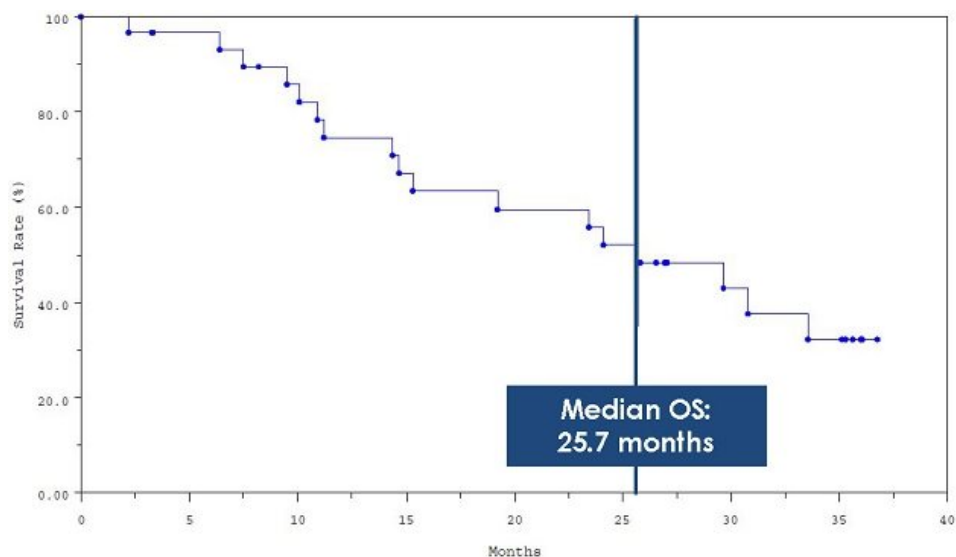
Many patients experienced an extended duration of response (or DOR) with median progression free survival (“PFS”) of 14.7 months. In order to provide a comparison to evaluate subject PFS, the following chart shows the subjects’ PFS on the therapy where available (n=23) just prior to initiation of SM-88, which is known as penultimate PFS. Certain subjects in the First Human Study (24/30) were censored in the PFS analysis, meaning that their data collection was stopped due to the conclusion of the study or loss of contact. Penultimate PFS for certain of these censored subjects is based on the date of the last radiological analysis for the subject and they are shown in green below. Subjects that had progression events (3/23) are shown in dark blue and subjects that died without cancer progression (5/23) are shown in light blue. Including all three subject groups, the PFS on SM-88 monotherapy was more than twice as long as the penultimate PFS.

Subgroup Analysis Where Penultimate PFS Available (n = 23)



First Human Study Overall Survival Data

Median overall survival for subjects in the First Human Study was 25.7 months, as shown in the chart below



Selected Efficacy Examples from First Human Study

Example #	Metastatic Cancer Type	Prior Therapy ⁽¹⁾	Penultimate PFS	PFS ⁽²⁾	OS ⁽²⁾
1	Breast: (TNB)	S,C,R	3	11	11
2	Breast: (TNB)	S,C	5	15	15
3	Breast	S,R,H	1	32	38
4	Lung	S,C,R	4	26	26
5	Lung	C	9	19	19
6	Lung	S,C	3	26	27
7	Pancreatic	S	n/a	24	24

SM-88 has achieved relatively long durations of survival for the following difficult cancers:

- (1) Prior therapy abbreviations: S – Surgery, C – Chemo, R – Radiation, H – Hormone therapy, N – No previous therapy.
- (2) As of most recent available data.

Subjects received between one to ten cycles of treatment with SM-88, each cycle consisting of daily administration, five days per week for six weeks. The therapy was well-tolerated with all drug-related AEs occurring within the first cycle of treatment, with the exception of hyperpigmentation, which eventually occurred in all subjects. Drug-related AEs in Cycle 1 were mild to moderate, self-limiting and did not require therapy. They are presented in the following table:

Drug-related Adverse Events Reported in SM-88, Cycle 1	
Adverse Events	Number of Treated Subjects (N = 30)
Hyperpigmentation	8
Fatigue	15
Lethargy	1
Pain	4
Paresthesia	1
Pigmentation change	2
Pruritus	1

Subjects experienced improvements in ECOG PS, EORTC QoL questionnaire and self-reported pain scores during Cycle 1. A measurable improvement in self-reported pain was seen in all subjects and most subjects reported an improved ECOG PS, as described below. As shown in the pain score table below for all treated subjects, at the end of Cycle 1, an additional eight subjects no longer experienced pain after treatment with SM-88.

Pain Scores* Following 1 Cycle of TYME-88 (n = 30)		
Number of Subjects		
Score	Start	End
0	4	12
1	6	7
2	3	7
3	5	2
4	3	1
5	2	0
6	3	1
7	3	0
8	0	0
9	0	0
10	1	0

* National Institutes of Health, Warren Grant Magnuson Clinical Center pain score: 0 (none), 1-3 (mild), 4-6 (moderate), 7-10 (severe).

ECOG PS Status* Following 1 Cycle of TYME-88 (n = 30)		
Number of Subjects		
Score	Start	End
0	1	14
1	15	14
2	10	2
3	3	0
4	1	0
5	0	0

* Eastern Cooperative Oncology Group Performance Score score: 0 (asymptomatic), 1-3 (symptomatic), 4 (bedbound), 5 (death).

We believe that SM-88 is a promising treatment for advanced metastatic cancer. It was well-tolerated among 30 subjects with a variety of cancers in our proof-of-concept clinical trial. We believe that SM-88 is not only unique, but thus far has shown no significant adverse side effects except for cutaneous hyperpigmentation.

We believe that the results of this study indicate that SM-88 holds promise as a successful monotherapy and likely has utility in combinations with both cytotoxic and current immunotherapies. We further believe that the magnitude of the positive clinical response in this end-stage cancer population, as well as the amelioration of disease-related symptoms, an increase in performance status and QoL, provides a solid rationale for further development of SM-88 as a potential cancer treatment.

Compassionate Use Patients

In addition to the 30-subject First Human Study, 76 individuals have been treated as Compassionate Use Patients. The first 53 of which were analyzed in a retrospective study in early 2016, with an additional four patients analyzed as a part of a 2017 retrospective pancreatic cancer analysis. RECIST response data from these 57 Patients included eight CRs and 19 PRs, as summarized below:

Summary of RECIST Complete and Partial Responses from 57 Compassionate Use Patients		
Primary Disease Origin	Complete Response	Partial Response
Prostate Cancer	2	1
Lymphoma	2	0
Breast Cancer	1	4
Pancreatic Cancer	1	2
Sarcoma	1	2
Tonsil Squamous Cell Carcinoma	1	0
Glioma	0	5
Ovarian Cancer	0	3
Bile Duct Cancer	0	1
Colon Cancer	0	1
Total	8/57 (14%)	19/57 (33%)

Our Ongoing and Planned Phase II Clinical Trials

On September 21, 2015, we submitted a SM-88 IND to the FDA for advanced metastatic breast cancer patients. On October 23, 2015, the FDA accepted the IND and authorized the breast trial to proceed (the “Anticipated Breast Trial”), including a pharmacokinetic (“PK”) study of the four components of SM-88. We subsequently determined to advance, instead of the Anticipated Breast Trial, a Phase Ib/II trial for prostate cancer patients and submitted this prostate protocol to the FDA on April 15, 2016 using the IND number assigned to the Anticipated Breast Trial. Subsequent to this, we received comments from the FDA on May 12, 2016, responded on May 17, 2016, received additional comments from the FDA on May 31, 2016, and responded on June 3, 2016. We submitted the final protocol to the FDA on June 10, 2016 and received no further comments. Pursuant to 21 CFR 312.40, the IND for prostate went into effect 30 days after submission of the final protocol.

Tyme subsequently initiated a Phase Ib/II trial in patients with recurrent, non-metastatic prostate cancer and reported initial data at ASCO 2017. Phase Ib was the dose ranging portion of the trial. After the first subject experienced therapeutic benefit, as measured by a decline of circulating tumor cells to an undetectable level within the first two months, and did not exhibit material side effects, a second cohort was launched that doubled the dose of Tyme’s proprietary tyrosine derivative (the other repurposed agents maintained the same dosage). The next three subjects also demonstrated therapeutic benefit, as measured by CTCs, without material side effects. At this point, the Phase II portion of the trial was initiated and the first patient was enrolled in February 2017. Targeted enrollment for the Phase II portion is 30 subjects.

In addition, we are planning to launch a Phase II trial in refractory pancreatic cancer by first calendar quarter 2018. As described above and presented at ASCO 2017, we believe there is compelling evidence of efficacy for SM-88 monotherapy in pancreatic cancer as well as a substantial market need for any improved therapy. We have partnered with a large, international contract research organization (“CRO”) to oversee the trial’s launch and management. We have also recently hired a Clinical Operations Officer with over 15 years’ experience in managing oncology trials while at Quintiles and Eli Lilly. We are currently evaluating clinical trial sites and intend to open more than 30 sites across North America as a part of the trial.

Further, we are in various levels of discussion with cancer treatment centers and physicians for potential clinical trials in lung, breast, bone and brain cancers, although there can be no guarantee that we will pursue trials in these areas.

The FDA's Fast Track program, a provision of the FDA Modernization Act of 1997, is designed to facilitate interactions between a sponsoring company and the FDA before and during submission of a NDA for an investigational agent that, alone or in combination with one or more other drugs, is intended to treat a serious or life-threatening disease or condition and which 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 product may be effective. A Fast Track designation provides the opportunity for more frequent interactions with the FDA and a fast track product could be eligible for priority review if supported by clinical data at the time of submission of the NDA. We intend to engage the FDA in future discussions concerning SM-88 qualification for FDA Fast Track designation, particularly in pancreatic cancer. However, there can be no assurance that such designation will be granted.

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act ("FDASIA") was signed into law. FDASIA provides a new designation for an expedited FDA review process called Breakthrough Therapy Designation. A breakthrough therapy is a drug that is intended alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and where 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. If a drug is designated as a breakthrough therapy, the FDA will expedite the development and review of such drug for trial and market approval. All requests for Breakthrough Therapy Designation will be reviewed within 60 days of receipt and FDA will either grant or deny the request. When appropriate, we intend to hold discussions with the FDA regarding SM-88's qualification for Breakthrough Therapy designation. However, there can be no assurance that such designation will be granted.

Target Markets

Cancer

Cancer is a group of diseases characterized by uncontrolled growth and spread of abnormal cells. In January 2017, the American Cancer Society projected that there will be an estimated 1,688,780 new cancer cases diagnosed and 600,920 cancer deaths in the United States in 2017. Current treatments for cancer include surgery, radiation therapy, chemotherapy, hormone therapy, targeted therapy and immunotherapy. The IMS Institute for Healthcare Informatics reported in 2016 that total global spending on oncology medicines, including therapeutic treatments and supportive care, reached the \$107 billion threshold in 2015.

Cancer is often referred to by Stage, ranging from I to IV, which indicates the size and location of tumors. Stages I, II and III are various sizes of localized tumors, meaning that they have not spread beyond the organ or area of origin, with Stage III indicating the largest tumors. Stage IV is metastatic cancer, meaning that tumors have been identified beyond the original location of the cancer. Stage IV typically has the poorest treatment outcomes since the cancer has aggressively spread within the patient. For example, the American Cancer Society estimates that patients diagnosed with Stage Ia pancreatic cancer has a five-year survival rate of approximately 14% in comparison to approximately 1% for patients diagnosed with Stage IV pancreatic cancer.

Many marketed products and product candidates for treating cancer patients are cytotoxic chemotherapies that exert their anti-tumor effect on cancer generally through nonspecific damage to cellular components with the goal of causing cancer cell malfunction and cell death. Other products and product candidates alter cell metabolism or internal repair mechanisms leading to the demise of the cancer cell. More recently, targeted anti-cancer agents have been designed by scientists to inhibit the action of specific molecules within cancer cells that are driving the aberrant growth responsible for tumor development.

All of these approaches may be associated with various side effects experienced by cancer patients that result from the treatments having an adverse impact on normal functioning cells and organ systems. Some of the more common side effects of cancer therapy include nausea, vomiting or emesis, infections, fatigue and diarrhea. Of common therapies, cytotoxic chemotherapies often have the most extensive side effect profiles given their effect on both healthy and cancer cells. Targeted therapies are usually designed to have fewer toxicities than cytotoxic chemotherapies, although drug-related cancer therapies commonly have some level of side effects.

Treatment centers (such as hospitals and community cancer centers) and the healthcare professionals who treat cancer patients (physicians, nurse practitioners, physician assistants, nurses and pharmacists) utilize various combinations of medical procedures, cancer therapeutics and supportive care products to extend and improve the quality of life of these patients. The most common methods of treating patients with cancer, including surgery, radiation and drug therapy, can be used as a standalone treatment or in combination at the discretion of the physician depending on type and stage of disease. In more advanced cancers, especially when initial therapies have failed and more toxic therapies would be required, treatment may be modified or reduced to balance aggressiveness of drug therapy with quality-of-life for the cancer patient.

Revenue/Payment Structure within the Healthcare Industry

Pharmaceutical Coverage, Pricing and Reimbursement

In the U.S. and other countries, the level of sales of any product for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payers, including government health administrative authorities, managed care providers, private health insurers and other organizations. Increasingly, third-party payers examine the medical necessity and cost effectiveness of medical products and services, in addition to their safety and efficacy and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Third-party reimbursement is necessary to adequately realize an appropriate return on our investment in research and product development, but may not be available for our products.

Significant uncertainty exists as to the coverage and reimbursement status for SM-88 in the U.S. and international markets once the drug candidate has been approved by the applicable regulatory authorities. Commercial sale of SM-88 will depend, in part, on the availability of reimbursement from third-party payers. The process for determining whether a third-party payer will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate. Third-party payers may limit coverage to the specific drug products on an approved list or formulary, which might not include all of the FDA-approved drugs for a particular indication. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approval. It is possible that SM-88 may not be considered as medically necessary or cost-effective by one or more third party payers. A decision by a third-party payer to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved.

In 2003, the U.S. government enacted legislation providing a partial prescription drug benefit for Medicare beneficiaries, which became effective at the beginning of 2006. Government payment for some of the costs of prescription drugs may increase demand for any products for which we receive marketing approval. However, to obtain payments under this program, drug manufacturers are required to sell products to Medicare recipients through prescription drug plans operating pursuant to this legislation, which likely carry discounted prices.

The Healthcare Reform Law of 2010 substantially changed the way healthcare is financed in the U.S. by both government and private insurers. Among other cost containment measures, the Healthcare Reform Law established:

- An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;
- A new Medicare Part D coverage gap discount program, in which pharmaceutical manufacturers who wish to have their drugs covered under Part D must offer discounts to eligible beneficiaries during their coverage gap period (the “donut hole”); and
- A new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program.

We expect that federal, state and local governments in the U.S. will continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs. Future legislation could limit payments for pharmaceuticals such as SM-88.

The marketability of SM-88, if and when approved, may suffer if government and third-party payers fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on managed care in the U.S. has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for SM-88, less favorable coverage policies and reimbursement rates could be implemented in the future.

Competition

Our business strategy is intended to effectively position SM-88 for competition with products manufactured by other companies in the highly fragmented and competitive cancer treatment market. Our competition comes from other commercial and research enterprises working in the field of cancer research. This includes pharmaceutical and biotechnology companies, academic institutions and government research institutes around the globe.

Important competitive factors include patient safety, effectiveness, quality-of-life and ease of use of products; price and demonstrated cost-effectiveness; marketing effectiveness; and research and development of new products and processes. Most new products we intend to market, assuming regulatory approval, will and must compete with other products already on the market as well as products that are later developed by existing or new competitors. If competitors introduce new products or delivery systems with therapeutic or cost advantages, our products would be subject to progressive price reductions, decreased volume of sales or both. Increasingly, to obtain favorable reimbursement and formulary positioning with government payers, managed care organizations and pharmacy benefits managers, we would be required to demonstrate that our products offer not only medical benefits but also more value as compared with other treatment regimens.

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, development and regulatory plans in addition to proprietary scientific knowledge provide us with certain competitive advantages, we currently have limited financial resources and face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions, each of whom has significantly greater financial resources than us. Any drugs that we successfully develop and commercialize will compete with existing therapies and new potential therapies that may become available in the future.

Our products, if approved for sale, would eventually be subject to competition from generic drug manufacturers. Manufacturers of generic pharmaceuticals generally invest far less than R&D companies such as us. We anticipate that any manufacturer of a generic version of our drugs will invest far less than we have in the past and intend to do in the future in R&D and marketing our products, including SM-88. They therefore, have the advantage in that they can price their drugs much lower than the brand-name drugs for which we obtain approval. Additionally, in many countries outside the U.S., IP protection is weak or nonexistent and we would be forced to compete with generic or counterfeit versions of our products in such countries whether or not we hold legal exclusivity.

The most common methods of treating patients with cancer are surgery, radiation and drug therapy, including chemotherapy, hormone therapy and targeted drug therapy. Our products once approved, would compete not only with other drugs, but also with such other types of therapies and treatments.

There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. Some of the currently approved drug therapies are branded and subject to patent protection and others are available on a generic basis. Many of these approved drugs are well-established therapies and widely accepted by physicians, patients and third-party payers. In general, although there has been considerable progress over the past few decades in the treatment of cancer with currently marketed therapies providing benefits to many patients, these therapies often are limited to some extent by a lack of efficacy and/or the significance or frequency of AEs.

In addition to currently marketed therapies, there are also a number of medicines in late-stage clinical development to treat cancer. These medicines in development may provide efficacy, safety, convenience and other benefits that are not provided by currently marketed therapies. As a result, they may provide significant, additional competition for SM-88.

Intellectual Property

We will strive to protect and enhance our proprietary technology, inventions and improvements that are commercially important to the development of our business, including through seeking, maintaining and defending patent rights (when required), whether developed internally or licensed from third parties. We also intend to rely on trade secrets related to our proprietary technology platform and our know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of cancer treatment, which may be important for the development of our business. We additionally may rely on regulatory protection afforded through data exclusivity, market exclusivity and patent term extensions, where available.

Our commercial success may depend, in part, on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing the valid enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing our products may depend on the extent to which we have rights under valid and enforceable licenses, patents or trade secrets that cover these activities. With respect to both our owned and licensed IP, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial products and methods of manufacturing such products, as well as being held valid if challenged.

Tyme has filed 67 patent applications in the US and abroad, with six U.S. patents issued thus far. The patents encompass SM-88 as well as citing inventions that fight cancer and aid in the creation of novel mechanisms to further that effort. Filed patents include additional metabolic approaches as well as hormonal and fluid transfer techniques. Our policy is to file patent applications to protect technology, inventions and improvements to inventions that are commercially important to the development of our business. 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 may be used to discover and validate targets and that may be used to identify and develop novel products. We will also seek protection, in part, through confidentiality and proprietary information agreements.

We believe we have no need to license any technologies for SM-88 to be commercially viable. We believe our Company owns all the IP necessary for our SM-88 to perform as intended and to be commercially marketed, once all applicable regulatory requirements have been obtained. Additionally, we believe the drug substances utilized in SM-88 are not covered by any patents that would impede our use of such drug substances.

Regulatory Process

Government Regulation and Product Approval

Government authorities in all major pharmaceutical markets extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing and import and export of pharmaceutical products, such as those we are developing. Although our initial focus will be in the U.S. and Europe, we intend to develop and seek marketing approval for our products in other countries and territories, such as Canada and Japan and for markets that follow the leading authorities, such as Brazil and South Korea. The processes for obtaining regulatory approvals in the U.S., Europe and in other countries, along with subsequent compliance with applicable statutes and regulations, will require the expenditure of substantial time and financial resources.

FDA Approval Process

SM-88 is subject to regulation in the U.S. by the FDA as a drug product. The FDA subjects drug products to extensive pre- and post-market regulation. The Public Health Service Act (“PHSA”), the Federal Food, Drug and Cosmetic Act and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and the import and export of drugs. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications (“NDAs”), withdrawal of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or fines or civil or criminal penalties.

The PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the U.S. and between states.

The drug development process required by the FDA before a new drug may be marketed in the U.S. is long, expensive and inherently uncertain. Drug development in the U.S. typically involves preclinical laboratory and animal testing, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Developing the data to satisfy FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conducting of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices (“GLP”). The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls (“CMC”) and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

An IND must become effective before U.S. clinical trials may begin. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND submission within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or subjects with the condition under investigation, all under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practices (“GCP”), an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; and (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the ongoing IND file.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to clinical trial subjects. The study protocol and informed consent information for subjects in clinical trials must be submitted to an IRB for review and approval. An IRB may also require the clinical trial at a clinical site to be halted, either temporarily or permanently, for failure to comply with the IRB’s requirements or may impose other conditions to assure subject safety. The study sponsor may also suspend a clinical trial at any time on various grounds, including a determination that the subjects are being exposed to an unacceptable health risk.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap or be combined. In Phase I, the drug is initially introduced into healthy human subjects and is tested to assess pharmacokinetics, pharmacological actions, AEs associated with increasing doses and, if possible, early evidence of effectiveness. In the case of some products targeted for severe or life-threatening diseases, such as cancer treatments, initial human testing may be conducted in the intended patient population. Phase II usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, as well as identification of common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase II, Phase III trials are initiated to obtain additional information about clinical efficacy and safety in a larger number of subjects, typically at geographically dispersed clinical trial sites. Phase III clinical trials are intended to establish data sufficient to demonstrate substantial evidence of the efficacy and safety of the product to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. Trials conducted outside of the U.S. under similar, GCP-compliant conditions in accordance with local applicable laws may also be acceptable to the FDA in support of product licensing.

Sponsors of clinical trials for investigational drugs must publicly disclose certain clinical trial information, including detailed trial design and trial results, in FDA public databases. These requirements are subject to specific timelines and apply to most controlled clinical trials of FDA-regulated products.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. The FDA review and approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product’s pharmacology and CMC and must demonstrate the safety and efficacy of the product based on these results. The NDA must also contain extensive manufacturing information. The cost of preparing and submitting an NDA is substantial and is in addition to the costs of conducting clinical trials. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, as well as annual product and establishment user fees, which may total several million dollars and are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency’s threshold determination that the NDA is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most such applications for standard review drugs are reviewed within 10 months from the date the application is accepted for filing. Although the FDA often meets its user fee performance goals, it can extend these timelines if necessary and its review may not occur on a timely basis at all. The FDA usually refers applications for novel drugs, which present complex questions of safety or efficacy, to an advisory committee - typically a panel that includes clinicians and other experts - for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it

generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the drug product unless it verifies that compliance with current good manufacturing practice (“cGMP”) standards is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication(s) being studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional nonclinical or clinical testing or supplemental information in order for the FDA to reconsider the application. If or when those deficiencies have been addressed to the FDA’s satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two to six months depending on the type of information that was included. The FDA approval is never guaranteed and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied.

Under the PHSA, the FDA may approve a NDA if it determines that the product is safe, pure and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure and potent. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. The approval for a drug may be significantly more limited than requested in the application, including limitations on the specific diseases and dosages or the indications for use, which could restrict the commercial value of the product. The FDA may also require that certain contraindications, warnings or precautions be included in the product labeling. In addition, as a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy (“REMS”) to further ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals and elements to assure safe use (“ETASU”). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS or use of a companion diagnostic with a drug can materially affect the potential market and profitability of the drug. Moreover, product approval may require, as a condition of approval, substantial post-approval testing and surveillance to monitor the drug’s safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

In September of 2015, we submitted an IND to the FDA for our SM-88 drug candidate for use in treatment of breast cancer, which we referred to earlier as the Anticipated Breast Trial. In October of 2015, the FDA advised us that it had completed its 30-day safety review of the IND and concluded that we may proceed with our proposed clinical investigation of SM-88 for breast cancer. The FDA further noted that it had certain comments for our consideration, including matters regarding CMC compliance and clinical pharmacology. Among such comments, the FDA requested clarification regarding a clinical batch’s identifiable impurity; notification for monitoring release and stability testing levels; specifications for impurities meeting regulatory guidelines; revisions to a proposed protocol for monitoring plasma concentrations or justification for not making revisions to applicable proposed protocols; and, in the development of SM-88, characterizing single and proportional dosage PK levels, develop valid age analytical methods used to determine concentrations of study drugs and their active metabolite(s), if any, conduct population PK analyses to evaluate intrinsic and extrinsic factors, and explore the exposure/response relationships for measures of effectiveness, toxicity and PD biomarkers. We have taken such comments under advisement. The FDA also requested stability data for the drug substance as soon as it becomes available.

We subsequently determined to advance, instead of the Anticipated Breast Trial, a Phase Ib/II trial for prostate cancer patients and submitted this prostate protocol to the FDA on April 15, 2016 using the IND number assigned to the Anticipated Breast Trial. Subsequent to this, we received comments from the FDA on May 12, 2016, responded on May 17, 2016, received additional comments from the FDA on May 31, 2016, and responded on June 3, 2016. We submitted the final protocol to the FDA on June 10, 2016 and received no further comments. Pursuant to 21 CFR 312.40, the IND for prostate went into effect 30 days after submission of the final protocol. As previously disclosed, Tyme completed the Ib dose ranging portion of the trial and the Phase II portion of the trial was initiated with the first patient enrolled in February 2017. Targeted enrollment for the Phase II portion is 30 subjects.

Priority Review/Standard Review (U.S.) and Accelerated Review (EU)

The FDA may grant a New Drug Application a priority review designation based both upon the request of an applicant and the results of the Phase III clinical trial(s) submitted in the NDA. This designation sets the target date at six months for FDA action on the application. Priority review is granted where preliminary trial results indicate that a product, if approved, has the potential to provide a safe and effective therapy for a situation where no satisfactory alternative therapy exists or where the product is possibly a significant improvement over existing marketed products. If these criteria are not met for priority review, the NDA is subject to the standard FDA review period of ten months. However, priority review designation does not change the scientific/medical standard for regulatory approval or the quality of evidence necessary to support approval.

Under the Centralized Procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application is 210 days, which excludes clock stops when additional written or oral information needs to be provided by the applicant in response to questions asked by The Committee for Medicinal Products for Human Use (“CHMP”). Accelerated evaluation might be granted by the CHMP in exceptional cases, such as when a medicinal product is expected to be a major public health interest, as defined by three cumulative criteria: the seriousness of the disease to be treated (e.g. , heavily disabling or life-threatening); the absence or insufficiency of an appropriate alternative therapeutic approach; and an anticipation of high therapeutic benefit. Under these circumstances, the European Medicines Agency ensures that the opinion of the CHMP is delivered within 150 days, excluding clock stops.

There can be no assurance that we would be able to satisfy any of these requirements to conduct preclinical or clinical trials or receive any regulatory approvals including priority or accelerated evaluation.

Breakthrough Therapy Approvals

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (“FDASIA”) was signed into law. FDASIA provides a new designation for an expedited FDA review process called Breakthrough Therapy Designation. A breakthrough therapy is a drug that is intended alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and where 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. If a drug is designated as a breakthrough therapy, the FDA will expedite the development and review of such drug for trial and market approval. All requests for Breakthrough Therapy Designation will be reviewed within 60 days of receipt and FDA will either grant or deny the request.

As with the Fast Track program, promising results from early phase clinical studies indicate that SM-88 may qualify as an FDA Breakthrough Therapy Designation while the clinical testing program continues. When appropriate, we intend to hold discussions with the FDA regarding SM-88’s qualification for Breakthrough Therapy Designation. There can be no assurance that such designation will be granted.

The Hatch-Waxman Act

Under the Hatch-Waxman Act, newly approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active moiety. The Hatch-Waxman Act prohibits having an effective approval date for an Abbreviated New Drug Application or a Section 505(b)(2) NDA for another version of such drug during the five-year exclusive period; however, submission of an ANDA or Section 505(b)(2) NDA containing a paragraph IV certification is permitted after four years, which may trigger a 30-month stay of approval of the ANDA or Section 505(b)(2) NDA. Protection under the Hatch-Waxman Act will not prevent the submission or approval of another “full” NDA; however, the applicant for the “full” NDA would be required to conduct its own preclinical and adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosages or strengths of an existing drug, if new clinical investigations that were conducted or sponsored by the applicant are determined by the FDA to be essential to the approval of the application.

In addition to non-patent marketing exclusivity, the Hatch-Waxman Act amended the Food, Drug and Cosmetic Act to require each NDA sponsor to submit with its application information on any patent that claims the active pharmaceutical ingredient, drug product (formulation and composition) and method-of-use for which the applicant submitted the NDA and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug. Generic applicants that wish to rely on the approval of a drug listed in the Orange Book must certify to each listed patent. The Orange Book is a listing of all drug products that have been approved by the FDA and their generic equivalences. We intend to submit for Orange Book listing all relevant patents for SM-88 and to vigorously defend any Orange Book-listed patents for our approved products.

The Hatch-Waxman Act also permits a patent term extension of up to five years as compensation for the patent term lost during product development and the FDA regulatory review process. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years after the FDA approves a marketing application. The patent term extension period is generally equal to the sum of one-half the time between the effective date of an IND and the submission date of an NDA and all of the time between the submission date of an NDA and the approval of that application, up to a total of five years. Only one patent applicable to a regulatory review period that represents the first commercial marketing of that drug is eligible for the extension and it

must be applied for prior to expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for patent term extension. We will consider applying for a patent term extension for some of our patents, to add patent life beyond the expiration date, depending on our ability to meet certain legal requirements permitting such extension and the expected length of clinical trials and other factors involved in the submission of an NDA. There can be no assurance that such an extension, if applied for, will be granted.

Advertising and Promotion

Once an NDA is approved, a product will be subject to continuing post-approval regulatory requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Failure to comply with these regulations can result in significant penalties, including the issuance of warning letters directing a company to correct deviations from FDA standards, a requirement that future advertising and promotional materials are pre-cleared by the FDA and federal and state civil and criminal investigations and prosecutions.

Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes to indications, labeling or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing original and resubmitted NDAs.

AE Reporting and cGMP Compliance

AE reporting and submission of periodic reports are required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase IV testing, REMS and surveillance to monitor the effects of an approved product or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, manufacturing, packaging, labeling, storage and distribution procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain manufacturing subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals, request product recalls or impose marketing restrictions through labeling changes or product removals if a company fails to comply with regulatory standards, if the product encounters problems following initial marketing or if previously unrecognized problems are subsequently discovered.

Orphan Drug

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition; generally, a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting a NDA. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not necessarily convey any advantage in or shorten the duration of the regulatory review and approval process. The first NDA applicant to receive FDA approval for a product to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the U.S. for the product for treatment of the specified indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee. When appropriate, we intend to hold discussions with the FDA regarding pursuing orphan drug designation for SM-88. There can be no assurance given that such discussions, if commenced, would result in our pursuing orphan drug designation for SM-88 or that, if pursued, the FDA would grant SM-88 an orphan drug designation.

Other Healthcare Laws and Compliance Requirements

In the U.S., our activities are potentially subject to regulation by federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services (for example, the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice and state and local governments.

The EMA is a decentralized scientific agency of the EU. It coordinates the evaluation and monitoring of centrally authorized medicinal products. It is responsible for the scientific evaluation of applications for EU marketing authorizations, as well as the development of technical guidance and the provision of scientific advice to sponsors. The EMA decentralizes its scientific assessment of medicines by working through a network of about 4,500 experts throughout the EU, nominated by the Member States. The EMA draws on resources of over 40 National Competent Authorities of European Member States.

The process regarding regulatory approval of medicinal products in the EU follows roughly the same lines as in the U.S. and likewise generally involves satisfactorily completing each of the following:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the applicable European GLP regulations;
- submission to the relevant national authorities of a clinical trial application (“CTA”) for each trial in humans, which must be approved before the trial may begin;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;
- submission to the relevant competent authorities of a Marketing Authorization Application (“MAA”), which includes the data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labeling;
- satisfactory completion of an inspection by the relevant national authorities of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with strictly enforced cGMPs;
- potential audits of the nonclinical and clinical trial sites that generated the data in support of the MAA; and
- review and approval by the relevant competent authority of the MAA before any commercial marketing, sale or shipment of the product.

Preclinical Studies

The conduct of the preclinical tests and formulation of the compounds for testing must comply with the relevant European regulations and requirements. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animal studies in order to assess the potential safety and efficacy of the product. The results of the preclinical tests, together with relevant manufacturing information and analytical data, are submitted as part of the CTA.

Clinical Trial Approval

Pursuant to the Clinical Trials Directive 2001/20/EC, as amended, a system for the approval of clinical trials in the EU has been implemented through national legislation of the Member States. Under this system, approval must be obtained from the competent national authority of each European Member State in which a study is planned to be conducted. To this end, a CTA is submitted, which must be supported by an investigational medicinal product dossier (IMPD) and further supporting information prescribed by the Clinical Trials Directive and other applicable guidance documents. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application in that country.

Manufacturing and import into the EU of investigational medicinal products is subject to the holding of appropriate authorizations and must be carried out in accordance with cGMPs.

Health Authority Interactions

During the development of a medicinal product, frequent interactions with the EU regulators are vital to make sure all relevant input and guidelines/regulations are taken into account in the overall program.

Regulation (EC) 1901/2006, which came into force in the EU on January 26, 2007, aims to facilitate the development and accessibility of medical products for use in children without subjecting children to unnecessary trials or delaying the authorization of medicinal products for use in adults. The regulation established the Pediatric Committee (“PDCO”), which is responsible for coordinating the EMA’s activities regarding medicines for children. The PDCO’s main role is to determine which studies that marketing authorization applicants need to complete in the pediatric population as part of the so-called Pediatric Investigation Plans (“PIP”). All applications for marketing authorization for new medicines that were not authorized in the EU before January 26, 2007 have to include either the results of studies carried out in children of different ages (as agreed with the PDCO) or proof that a waiver or a deferral of these studies has been obtained from the PDCO. As indicated, the PDCO determines what pediatric studies are necessary and describes them in a PIP. This requirement for pediatric studies also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The PDCO can grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults and can also grant waivers when development of a medicine in children is not needed or is not appropriate, such as for diseases that only affect the elderly population.

Before an MAA can be filed or an existing marketing authorization can be varied, the EMA checks that companies are in compliance with the agreed studies and measures listed in each relevant PIP.

Regulation (EC) 1901/2006 also introduced several incentives for the development of medicines for children in the EU:

- medicines that have been authorized across the EU in compliance with an agreed PIP are eligible for an extension of their patent protection by six months (this is the case even when the pediatric studies’ results are negative);
- for orphan medicines, the incentive is an additional two years of market exclusivity, extending the typical 10-year period to 12 years;
- scientific advice and protocol assistance at the EMA are free of charge for questions relating to the development of medicines for children; and
- medicines developed specifically for children that are already authorized but are not protected by a patent or supplementary protection certificate, may be eligible for a pediatric use marketing authorization (PUMA); and
- if a PUMA is granted, the product will benefit from 10 years of market protection as an incentive for the development of the product for use in children.

MAA

Authorization to market a product in the EU member states proceeds under one of four procedures: a centralized authorization procedure, a mutual recognition procedure, a decentralized procedure or a national procedure.

Centralized Authorization Procedure

Certain drugs, including medicinal products developed by means of biotechnological processes, must be approved via the centralized authorization procedure for marketing authorization. A successful application under the centralized authorization procedure results in a marketing authorization from the European Commission, which is automatically valid in all EU member states. The other European Economic Area member states (namely Norway, Iceland and Liechtenstein) are also obligated to recognize the Commission decision. The EMA and the European Commission administer the centralized authorization procedure.

Under the centralized authorization procedure, the Committee for Medicinal Products for Human Use (“CHMP”) serves as the scientific committee that renders opinions about the safety, efficacy and quality of human products on behalf of the EMA. The CHMP is composed of experts nominated by each member state’s national drug authority, with one of them appointed to act as Rapporteur for the co-ordination of the evaluation with the possible assistance of a further member of the Committee acting as a Co-Rapporteur. After approval, the Rapporteur(s) continue to monitor the product throughout its life cycle. The CHMP is required to issue an opinion within 210 days of receipt of a valid application, though the clock is stopped if it is necessary to ask the applicant for clarification or further supporting data. The process is complex and involves extensive consultation with the regulatory authorities of member states and a number of experts. Once the procedure is completed, a European Public Assessment Report is produced. If the CHMP concludes that the quality, safety and efficacy of the medicinal product are sufficiently proven, it adopts a positive opinion. The CHMP’s opinion is sent to the European Commission, which uses the opinion as the basis for its decision whether or not to grant a marketing authorization. If the opinion is negative, information is given as to the grounds on which this conclusion was reached.

After a drug has been authorized and launched, it is a condition of maintaining the marketing authorization that all aspects relating to its quality, safety and efficacy must be kept under review. Sanctions may be imposed for failure to adhere to the conditions of the marketing authorization. In extreme cases, the authorization may be revoked, resulting in withdrawal of the product from sale.

Mutual Recognition Procedure and Decentralized National Procedure

Under a Mutual Recognition Procedure (“MRP”) or a Decentralized Procedure (“DCP”), the applicant must select which and how many EU member states in which to seek approval. In the case of an MRP, the applicant must initially receive national approval in one EU member state. This will be the so-called reference member state (“RMS”) for the MRP. Then, the applicant seeks approval for the product in other EU member states, the so-called concerned member states (“CMS”) in a second step.

For the DCP, the applicant will approach all chosen Member States at the same time. To do so, the applicant will identify the RMS that will assess the submitted MAA and provide the other selected Member States with the conclusions and results of the assessment. In principle, the applicant can choose any EU Member State as the RMS; however, in almost all Member States, the applicant needs to send a request for a time slot when the applicant will be allowed to submit the application. Depending on the Member State selected as RMS, the interval between submission of the request to the actual submission date can be two years or longer.

Accelerated Assessment Procedure

When an application is submitted for a marketing authorization in respect of a drug for human use, which is of major interest from the point of view of public health and in particular, from the viewpoint of therapeutic innovation, the applicant may request an accelerated assessment. Under the accelerated assessment procedure, the CHMP is required to issue an opinion within 150 days of receipt of a valid application, subject to clock stops. We believe that SM-88 may qualify for this provision and we will take advantage of this provision, if appropriate.

Conditional Approval

Under EU regulations, a medicine that would fulfill an unmet medical need may, if its immediate availability is in the interest of public health, be granted a conditional marketing authorization on the basis of less complete clinical data than are normally required, subject to specific obligations being imposed on the authorization holder. These specific obligations are to be reviewed annually by the EMA. The list of these obligations is to be made publicly accessible. Such an authorization shall be valid for one year, on a renewable basis.

Period of Authorization and Renewals

A marketing authorization is initially valid for five years and may then be renewed on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder is to provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variants introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization shall be valid for an unlimited period, unless the Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the European market (in case of centralized procedure) or on the market of the authorizing Member State within three years after authorization shall cease to be valid (the so-called sunset clause).

Orphan Drug Designation

EU regulations also provide for an orphan drug designation. This designation is granted if its sponsor can establish:

- (a) (i) that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU when the application is made; or
(ii) that the product is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the EU and that without incentives it is unlikely that the marketing of the drug in the EU would generate sufficient return to justify the necessary investment; and
- (b) that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, the drug will be of significant benefit to those affected by that condition.

An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. However, this period may be reduced to six years if at the end of the fifth year it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify continued market exclusivity. Market exclusivity can be revoked only in very selected cases, such as consent from the marketing authorization holder, inability to supply sufficient quantities of the product, demonstration of “clinically relevant superiority” by a similar medicinal product or, after a review by the Committee for Orphan Medicinal Products, requested by a Member State in the fifth year of the marketing exclusivity period (if the designation criteria are believed to no longer apply). Medicinal products designated as orphan drugs are eligible for incentives made available by the EU and by its Member States to support research into and the development and availability of orphan drugs. It is not our current intention to pursue orphan drug designation for SM-88.

Regulatory Data Protection

Without prejudice to the law on the protection of industrial and commercial property, marketing authorizations for new medicinal products in the EU benefit from an 8+2+1 year period of regulatory protection.

This regime consists of a regulatory data protection period of eight years plus a concurrent market exclusivity of ten years plus an additional market exclusivity of one further year if, during the first eight years of those ten years, the marketing approval holder obtains an approval for one or more new therapeutic indications which, during the scientific evaluation prior to their approval, are determined to bring a significant Clinical Benefit in comparison with existing therapies. Under the current rules, a third party may reference the preclinical and clinical data of the reference product beginning eight years after first approval, but the third party may market a generic version only after ten (or eleven) years have lapsed. Additional regulatory data protection can be applied for when an applicant has complied with all requirements as set forth in an approved PIP.

International Conference on Harmonization (ICH)

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (“ICH”) is a project that brings together the regulatory authorities of Europe, Japan and the U.S. and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of pharmaceutical product registration. The purpose of ICH is to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines by recommending ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration. Harmonization would lead to a more economical use of human, animal and material resources, the elimination of unnecessary delay in the global development and availability of new medicines, while maintaining safeguards on quality, safety, efficacy and regulatory obligations to protect public health.

ICH guidelines have been adopted as law in many countries, but are only used as guidance in the U.S. by the FDA. In many areas of drug regulation, ICH has resulted in comparable requirements, for instance with respect to the Common Technical Document, which has become the core document for filings for market authorization in several jurisdictions. In this manner, ICH has facilitated a more efficient path to markets.

Pharmaceutical Coverage, Pricing and Reimbursement

As previously noted, in the U.S. and other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payers, including government health administrative authorities, managed care providers, private health insurers and other organizations. The division of competences within the EU leaves to its Member States the power to organize their own social security systems, including health care policies to promote the financial stability of their health care insurance systems.

In this context, each of the Member States’ national authorities is free to set the prices of medicinal products and to designate the treatments that they wish to reimburse under their social security system. However, the EU has defined a common procedural framework through the adoption what is generally known as the “Transparency Directive.” This directive aims to ensure that national pricing and reimbursement decisions are made in a transparent manner and do not disrupt the operation of the internal market.

The pharmaceutical pricing and reimbursement systems established by Member States are usually quite complex. Each country uses different schemes and policies, adapted to its own economic and health needs. We would have to develop or access special expertise in this field to prepare health economic dossiers on our medicinal products if we would market our products, if and when approved, in the EU.

Manufacturing

We do not own or operate, and currently have no near-term plans to establish, any manufacturing facilities. We currently rely on and expect to continue to rely on, third party contract manufacturers for supplies of SM-88 for preclinical and clinical testing, as well as for the initial commercial manufacture of any products that we may market following regulatory approval.

We currently purchase all our drug substance and drug products from contract manufacturers and intend to continue to do so on an as-needed purchase order basis. We do not have long-term supply arrangements in place at this time. We intend to identify and qualify any further necessary contract manufacturers to provide all active pharmaceutical ingredients (“API”) and finished drug product services during the IND stages and prior to submission of an NDA to the FDA.

Our current intention is that, during the course of the IND program through the End-of-Phase II (“EOP2”), we will conduct the manufacturing, CMC and GMP programs towards commercial manufacturing. The overall manufacturing program includes, but is not limited to, the development of product and process specifications, producing and validating standards and the development of suitable analytical methods for test and release, as well as stability testing. Before and during the use of contract manufacturers, we (or qualified designee) will conduct audits to ensure compliance with the mutually agreed process descriptions and cGMP regulations. Our manufacturers themselves must comply with their in-house quality assurance programs and be available for inspections by regulatory agencies, including the FDA and European drug regulatory agencies. During the development of our drug candidates, we will scale the manufacturing process to a suitable size. Such scaling up involves several steps and may involve modification of the process, in which case modifications to our CMC sections will occur, with continuous submissions to the FDA and EU regulatory authorities.

As we progress through the regulatory approval process, there is a possibility that our intended manufacturing process will undergo modifications, primarily based on initial manufacturing results and data generated during the manufacture of drug substance and product to be used in our clinical trials. Such modifications could cause delays to our obtaining regulatory approval of SM-88, if at all, as well as an increase our research and development and manufacturing costs and could make such product cost prohibitive to our intended end users and their medical insurance providers.

SM-88 is a combination drug that is comprised of four active ingredients. Three of the components of SM-88 previously received regulatory approval in areas other than cancer treatment. The four active ingredients that comprise SM-88 are organic compounds of low molecular weight, generally called small molecules. They can be manufactured in reliable and reproducible synthetic processes from readily available starting materials. The chemistry is amenable to scale-up and we believe does not require unusual equipment in the manufacturing process.

Our tyrosine-based component is a derivative product that has been modified by a proprietary process to modify its functionality. This drug substance is being manufactured on an exclusive-basis by a leading, FDA-audited contract manufacturer that has previously manufactured tyrosine-based products on a commercial scale. This manufacturer currently is our sole supplier of this drug substance. To our knowledge, the current manufacturer of this drug substance is the only FDA-approved supplier of this drug. We believe this cGMP contract manufacturer has sufficient capacity to meet our projected needs into the near future and we maintain inventory on hand to meet our immediate clinical needs. In the event of a catastrophic event or if this contract manufacturer is unable to meet our needs, we will need to find an alternative source. This will likely result in delays for the clinical development program. It is not impossible to find a substitute for this supplier in the event that it becomes necessary, but it may be costly in terms of development time. We do not currently have arrangements in place for a redundant supply of the drug substance.

To date, we have, through an FDA-audited contract manufacturer, produced cGMP drug substance for use in our planned clinical trials. In addition, we have produced cGMP clinical trial materials utilizing such drug substance, through a FDA-audited contract manufacturer. Such newly produced drug substance and clinical trial materials are currently undergoing long term regulatory testing. We believe we have produced enough drug substance to create an inventory to meet our immediate needs regarding our planned clinical trials.

For future work involving the drug product, it is anticipated that manufacture process development work will continue, with focus of manufacturing improvements, and scale up. It is anticipated that future manufacturing of clinical trial materials may be required to fill clinical trial needs. Additional tyrosine derivative drug product variations have also been developed for research purposes and some are being validated and tested for clinical purposes.

The remaining three active pharmaceutical ingredients (“APIs”) in SM-88 are available from several contract manufacturers, each holding Drug Master Files at the FDA for their respective API’s. We believe that the loss of or the inability of, any of single source to provide our required ingredients would not have any substantive delaying effect on our research program, clinical trials or future commercial sale of SM-88, as we believe other sources are readily available.

Employees

As of March 31, 2017, we had a total of 9 full-time employees, all located in the United States. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We have not experienced any work stoppages, and we consider our relations with our employees to be good. Of the 9 employees, 5 perform research and development activities and 4 serve in general and administrative functions. Our Chief Executive Officer, Steve Hoffman, is also our Chief Science Officer and, as such, may be considered engaged in R&D activities, for purposes of the immediately preceding sentence, as well as his being categorized as serving in an administrative capacity. Where necessary, we have entered into consulting contracts to provide us with subject matter expertise. We believe there is available a sufficient number of contractors with appropriate subject matter expertise for our current and near-term needs.

Corporate Information

We were reincorporated on September 18, 2014 under the laws of the State of Delaware, after being incorporated in Florida as Global Group Enterprises Corp. on November 22, 2011, as discussed further below under Corporate History; Significant Organizational Events. Our principal executive offices are located at 44 Wall Street – 12th Floor, New York, New York 10005. Our telephone number is 646-205-1603. Our website address is www.tymetechnologiesinc.com.

Corporate History; Significant Organizational Events

Overview

We were originally incorporated in Florida as Global Group Enterprises Corp. on November 22, 2011. Effective as of September 18, 2014, we reincorporated in the State of Delaware and later engaged in a merger and certain other transactions (described under the sub-captions below). As a result of these events, among other things,

- we changed our jurisdiction of incorporation from Florida to Delaware;
- we changed our name from Global Group Enterprises Corp. to Tyme Technologies, Inc.;
- we increased our authorized capital stock from 250,000,000 shares of common stock, par value \$0.0001 per share, to 300,000,000 shares of common stock, par value \$0.0001 per share and 10,000,000 shares of “blank check” preferred stock, par value \$0.0001 per share.

Subsequent to this organizational merger, we entered into a merger in 2015, whereby we acquired our current clinical-stage pharmaceutical business. The effects of such 2015 merger and associated financing transactions are described below under “[Merger Agreement](#).”

Merger Agreement

On March 5, 2015, we, our wholly-owned subsidiary formed for the purposes of completing the merger (which we refer to as “Acquisition Sub”), Tyme, Inc. (“Tyme”) and certain other parties entered into an Agreement and Plan of Merger and Reorganization (the “Merger Agreement”). Simultaneous with the execution of the Merger Agreement, we and the other parties to the Merger Agreement consummated the transactions contemplated by the Merger Agreement (the “Merger”). We refer to the date that the transactions contemplated by the Merger Agreement, including the Merger, were consummated as the “Closing Date.” Pursuant to the terms of the Merger Agreement, Acquisition Sub merged with and into Tyme. Tyme was the surviving corporation in the Merger and thus became our wholly-owned subsidiary.

In accordance with the Merger Agreement, we also completed a split-off transaction whereby we transferred all of our pre-Merger assets and liabilities to a newly formed subsidiary, Global Group Enterprises Corp., a Florida corporation (“Split-Off Subsidiary”), and transferred our entire equity interest in Split-Off Sub to our pre-Merger principal stockholder, who was a founder and former executive officer (the “Split-Off”). The Split-Off was effected in consideration for the surrender to us for cancellation of all of this founder’s 13,000,200 shares of our Common Stock. For further details, see “Split-Off Transaction” below. As a result of the consummation of the Merger and Split-Off Transaction, our sole business became the business of Tyme, a research and development company focused on developing drug candidates for the treatment of cancer in humans.

At the closing of the Merger, the shares of Tyme's common stock that were issued and outstanding immediately prior to the Merger were converted into shares of our Common Stock, resulting in an aggregate of 68 million shares of our Common Stock being issued in connection with the Merger to the holders of Tyme's common stock immediately preceding the effective time of the Merger (the "Pre-Merger Tyme Stockholders").

The Merger Agreement contained representations and warranties and pre- and post-closing covenants of each party and customary closing conditions. Breaches of the representations and warranties under the Merger Agreement are subject to indemnification provisions. Each of the Pre-Merger Tyme Stockholders initially received in the Merger 95% of the shares to which each such stockholder was entitled under the terms of the Merger Agreement, with the remaining 5% of such shares being held in escrow for two years to satisfy post-closing claims for indemnification by the Company ("Indemnity Shares"), pursuant to an Indemnification Shares Escrow Agreement. As the Company and the indemnification representative are aware of no post-closing claims during the two-year period, a joint instruction was sent on April 7, 2017 asking for the release of the Indemnity Shares. The Company expects all of the Indemnity Shares to be distributed to the Pre-Merger Tyme Stockholders on a *pro rata* basis in June of 2017. The Merger Agreement also contained a provision providing for a post-Merger share issuance, as a means for which claims for indemnity may be made by the Pre-Merger Tyme Stockholders. Pursuant to this provision, up to one million additional shares ("R&W Shares") of our Common Stock may be issued to the Pre-Merger Tyme Stockholders during the one-year period following the Merger for breaches of representations and warranties of the pre-Merger Company contained in the Merger Agreement. The foregoing mechanisms are the exclusive remedies of the Company on the one hand and the Pre-Merger Tyme Stockholders on the other hand for satisfying indemnification claims under the Merger Agreement, other than claims based on fraud or willful misconduct.

The Merger Agreement also called for the surrender for cancellation, effective as of the Merger Closing, of a number of shares of our Common Stock by the owners of such shares. In addition to the surrender and cancellation of 13,000,200 shares in connection with the Split-Off transaction, a further 26,276,600 shares (the "Merger Related Surrendered Shares") were surrendered by their owners and canceled.

The Merger was treated as a recapitalization or reverse acquisition for financial accounting purposes. Tyme is considered the acquirer for accounting purposes and our historical financial statements before the Merger will be replaced with the historical financial statements of Tyme before the Merger in all future filings with the SEC.

The Merger is intended to be treated as a tax-free reorganization under Section 368(a) of the Internal Revenue Code of 1986, as amended.

The issuance of shares of our Common Stock to holders of Tyme's common stock in connection with the Merger was not registered under the Securities Act, in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act, which exempts transactions by an issuer not involving any public offering. These securities may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirement and are subject to further contractual restrictions on transfer as described below.

We and the Pre-Merger Tyme Stockholders entered into additional agreements concerning the registration or sale of shares of our Common Stock, in certain circumstances, the terms of which have expired prior to March 31, 2017.

All descriptions of the Merger Agreement, Indemnification Shares Escrow Agreement and Lock-Up Agreements herein are qualified in their entirety by reference to the texts thereof incorporated by reference herein and listed as exhibits hereto.

Split-Off Transaction

Immediately prior to the closing of the Merger, under the terms of a Split-Off Agreement and a General Release Agreement, we effected the Split-Off, whereby we (x) transferred all of our pre-Merger operating assets and liabilities to Split-Off Subsidiary, our wholly-owned special-purpose subsidiary and (y) transferred all of the outstanding shares of capital stock of Split-Off Subsidiary to Andrew Keck, our founder and a principal stockholder of our Company prior to the consummation of the Merger, in consideration of and in exchange for (i) the surrender for cancellation of an aggregate of 13,000,200 shares of our Common Stock owned by him and (ii) certain representations, covenants and indemnities (the "Split-Off"). Mr. Keck served as our sole executive officer and director from our initial formation through April 26, 2013.

All descriptions of the Split-Off Agreement and the General Release Agreement herein are qualified in their entirety by reference to the texts thereof incorporated by reference herein and listed as exhibits hereto.

Bridge Financing by Tyme

In July 2014, Tyme offered and sold to an accredited investor a Tyme senior subordinated secured convertible note in the principal amount of \$1.1 million. The note bore interest at 10% per annum and was payable on October 11, 2015, subject to earlier conversion as described below. In November of 2014, the holder of such note loaned Tyme an additional \$250,000 and the note was amended and restated to reflect a principal amount of \$1.35 million. In January of 2015, the holder of such note loaned Tyme an additional \$960,000 and the note was further amended and restated to reflect a principal amount of \$2.31 million. In February of 2015, the note was further amended to reflect a change in its mandatory conversion feature to a fixed amount, as further discussed below. The note as amended and restated is referred to in this report as the “Bridge Note.”

Interest on the Bridge Note would have been payable at maturity; however, upon conversion of the Bridge Note as described below, accrued interest was, in accordance with the terms of the Bridge Note, forgiven. The Bridge Note was secured by a security interest on all of the assets of Tyme and its Luminant Biosciences, LLC wholly-owned subsidiary of Tyme (“Luminant”), subject to certain limited exceptions, as well as a pledge of certain shares of stock of Tyme then held by two principal stockholders of Tyme and Tyme’s membership interest in Luminant.

Upon the closing of the Merger and the private placement offering (the “PPO”) (described below), the outstanding principal amount of the Bridge Note was automatically converted into 2.31 million shares (the “Conversion Shares”) of our Common Stock, at a rate of one share for every \$1.00 of Bridge Note principal then outstanding. The security interest and pledges terminated upon conversion of the Bridge Note.

All descriptions of the Bridge Note original and as amended and restated, herein are qualified in their entireties by reference to the texts thereof incorporated by reference herein and listed as exhibits hereto.

The PPO

Concurrently with the closing of the Merger and in contemplation of the Merger, we held a closing of a PPO in which we sold 2.716 million shares of our Common Stock at a purchase price of \$2.50 per share for gross proceeds of \$6.79 million. Only \$4.29 million of such gross proceeds was paid in cash. The remaining \$2.5 million was paid by the delivery to us of a 90-day, limited recourse promissory note in the principal amount of \$2.5 million (the “PPO Note”). The PPO Note was secured by an escrow of five million shares of our Common Stock, pursuant to a Subscription Note Shares Escrow Agreement among us, the purchaser in the PPO and an escrow agent (the “PPO Note Escrow Agreement”).

The PPO Note had an original maturity date of June 5, 2015. Under an Omnibus Amendment, dated as of June 5, 2015, among Christopher Brown, GEM Global Yield Fund LLC SCS (“GEM”) and us, among other matters, GEM made a payment to us equal to one-half of the original principal amount of the PPO Note and we extended the maturity date with respect to the balance due under the PPO Note (\$1,250,000 in principal amount) to July 6, 2015. Following such receipt of one-half of the PPO Note, 2,500,000 of such shares were released from escrow and the remaining 2,500,000 shares remained in escrow. We entered into a Second Omnibus Amendment as of July 23, 2015 (the “Second Omnibus Amendment”), pursuant to which, among other matters, we agreed to the extension of the maturity date of the remaining \$1,250,000 outstanding amount due under the PPO Note to a date which is five business days following our providing the maker of the PPO Note of written evidence that the IND for our SM-88 drug candidate has been submitted by us to the FDA. The IND was received by the FDA on September 21, 2015 and notice of such was given to the maker of the PPO Note on September 25, 2015. Subsequently, the remaining \$1,250,000 PPO Note balance was paid and we authorized the release of the 2,500,000 shares then remaining in escrow.

The PPO investor and the Bridge Note purchaser who received the Conversion Shares upon the automatic conversion of the Bridge Note, which occurred simultaneous with the closing of the PPO, were granted, pursuant to the subscription agreement for the PPO and pursuant to the Bridge Note, anti-dilution protection on the shares purchased in the PPO and the Conversion Shares (as the case may be) such that, if within two years after the closing of the Merger, our Company issues additional shares of our Common Stock or Common Stock equivalents (subject to customary exceptions, including but not limited to Exempt Securities (defined below)) for a consideration per share less than \$0.50 (the “Lower Price”), the PPO investor and former Bridge Note holder would be entitled to receive from the Company additional shares of our Common Stock (the “Lower Price Shares”) in an amount such that, when added to the number of shares initially purchased by such investor or received upon conversion of the Bridge Note, will equal the number of shares that such investor’s PPO subscription amount would have purchased or the Bridge Note holder would have received upon conversion of the Bridge Note at the Lower Price, respectively. “Exempt Securities” include: (a) options and other equity awards issued under our 2015 Equity Incentive Plan (as discussed below); (b) shares of our Common Stock, options or convertible securities issued pursuant to or in conjunction with a joint venture, development, technology license or similar type of collaboration or strategic partnership agreement; (c) shares issued in the Merger and (d) securities issued to financial institutions, institutional investors or

lessors in connection with credit arrangements, equipment financings, lease arrangements or similarly transaction (in each case, subject to a maximum number equal to 10% of the number of shares of our Common Stock outstanding at the time of issuance); provided, however, no such issuance shall include any type of anti-dilutive “death spiral” provision. The anti-dilution rights described above have expired in March 2017.

The PPO was exempt from registration under Section 4(a)(2) of the Securities Act. The sole investor in the PPO was GEM Global Yield Fund LLC SCS, a “société en commandite simple” formed under the laws of Luxembourg (“GEM”). The Bridge Note investor designated GEM as the party to receive the Conversion Shares. GEM was a principal stockholder of our pre-Merger company, and the purchaser of the Bridge Note is the manager of GEM.

The closing of the PPO and the closing of the Merger were conditioned upon each other.

All descriptions herein of the subscription agreement for the PPO, PPO Note and PPO Note Escrow Agreement are qualified in their entireties by reference to the texts thereof incorporated by reference herein and listed as exhibits hereto.

Adjustment Shares Escrow Agreement

The Merger Agreement provided that, in the event we raise additional capital in a public or private offering (in one or more closings) for gross proceeds of at least \$20 million (a “Qualified Offering”), based on a pre-money valuation of our Company of at least \$200 million, within five months of the earlier of the (i) date on which the PPO Note has been fully satisfied and (ii) PPO Note Maturity Date, subject to certain conditions (the “Qualified Offering Trigger Termination Date”), we will issue to the holders of record of our Common Stock as of the Closing Date (the “Pre-Merger Company Stockholders”), *pro rata*, 1,333,333 additional restricted shares of our Common Stock (the “Qualified Offering Shares”).

The Merger Agreement further provides that:

- if the pre-money valuation of our Company upon a Qualified Offering is \$150 million or more but less than \$200 million, the Pre-Merger Company Stockholders will surrender to us for cancellation without consideration 1 million shares of our Common Stock;
- if the pre-money valuation of our Company upon a Qualified Offering is \$100 million or more but less than \$150 million, the Pre-Merger Company Stockholders will surrender to us for cancellation without consideration 2 million shares of our Common Stock; and
- if the pre-money valuation of the Company upon a Qualified Offering is less than \$100 million (which Qualified Offering may be rejected in the Company’s sole and absolute discretion) or if no Qualified Offering occurs within five months of the Qualified Offering Trigger Termination Date, the Pre-Merger Company Stockholders will surrender to us for cancellation without consideration 3.5 million shares of our Common Stock.

The Pre-Merger Company Stockholders placed into escrow, (the “Adjustment Shares Escrow Agreement”), 3.5 million shares of our Common Stock (the “Adjustment Shares”) to secure such surrender obligations.

We had the sole authority to determine all matters relating to the Qualified Offering, including the subscription price, pre-money valuation and whether or not to accept any subscriber’s subscription offer. No Qualified Offering occurred by the Qualified Offering Trigger Termination Date. The Adjustment Shares were released to the Company on March 1, 2017, subsequent to the initiation of litigation by the Company to compel the escrow agent’s release of the Adjustment Shares. See Item 3 – “Legal Proceedings.”

Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and other filings with the United States Securities and Exchange Commission, or the SEC, and all amendments to these filings, are available, free of charge, on our website at www.tymetechnologiesinc.com as soon as reasonably practicable following our filing of any of these reports with the SEC. You can also obtain copies free of charge by contacting our Investor Relations department at our office address listed above. The public may read and copy any materials we file with the SEC at the SEC’s Public Reference Room at 100 F Street N.E., Room 1580, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy, and information statements, and other information regarding issuers that file electronically with the SEC at www.sec.gov. The information posted on or accessible through these websites are not incorporated into this filing.

ITEM 1A. RISK FACTORS

Our business is subject to numerous risks. You should carefully consider the following risks and all other information contained in this Annual Report, as well as general economic and business risks, together with any other documents we file with the SEC. If any of the following events actually occur or risks actually materialize, it could have a material adverse effect on our business, operating results and financial condition and cause the trading price of our common stock to decline.

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 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 drug product we may develop in the U.S. or in other countries until we receive approval of a New Drug Application (“NDA”) from the FDA or marketing approval from applicable regulatory authorities outside the U.S. 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 a 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 U.S. 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.

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;
- 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 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;

- 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 IECs 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 the greater rigors 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 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 thirty patients who received SM-88 in our first-in human clinical trials, 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 the patients treated with SM-88 are 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 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-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 proprietary 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. For example, final assays and specifications of our future drug candidates have yet to be developed and the FDA, EMA or other non-U.S. regulatory authorities may require additional analyses to evaluate this aspect of our technology. 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 U.S. 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 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 U.S., 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 U.S.

The fast track program, a provision of the FDA Modernization Act of 1997, is designed to facilitate interactions between a sponsor and the FDA before and during submission of a 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.

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 U.S. 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 U.S. In the European Union, 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 U.S. 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 U.S. 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 U.S., 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, 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' 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;
- 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 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 U.S. 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 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 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 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 U.S., 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 U.S. 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 U.S., the Medicare Prescription Drug, Improvement and Modernization Act of 2003 or 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 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 U.S. 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 or the ATRA, 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;
- 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 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 U.S. 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.

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. As of March 31, 2017, our cash and cash equivalents were \$10,482,977. We believe that, as of March 31, 2017, our available cash and cash equivalents will be sufficient to fund our anticipated level of operations for approximately the next twelve months, but there can be no assurance that this will be the case. 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 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 report, 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.

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 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.

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.

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.

Our corporate headquarters is located in New York. Our current and future, third-party collaborators, future partners, supplies, CROs and investigational sites are or will be, located throughout the U.S. 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 U.S., a variety of risks associated with international operations could materially adversely affect our business. Some of our third-party collaborators, future partners, suppliers, CROs and investigational sites could be located outside the U.S. 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 U.S.;
- 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 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, 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 U.S. 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 U.S. 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 U.S. or in other countries. Changes in either the patent laws or interpretation of patent laws in the U.S. 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 U.S. Publications of discoveries in scientific literature often lag behind the actual discoveries and patent applications in the U.S. 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 or 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 or America Invents Act, the U.S. moved from a “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 this report 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 U.S. 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 U.S. 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.

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 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 U.S., 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 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 U.S. 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 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, referred to as 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 U.S., 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 contain or reduce the costs of medical products and services. For example, one of the most significant health care reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act was enacted in 2010 (“PPACA”). PPACA 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. PPACA, 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.

While the U.S. Supreme Court upheld most of the constitutional elements of PPACA in June 2012, other legal challenges are still pending final adjudication in several jurisdictions. In addition, Congress has also proposed a number of legislative initiatives, including possible repeal of PPACA. At this time, it remains unclear whether there will be any changes made to PPACA, whether to certain provisions or its entirety. We can provide no assurance that PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to health care reform will affect our business.

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.

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 PPACA 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 or 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, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and their respective implementing regulations, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and
- 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.

PPACA, 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, PPACA 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 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 U.S. Food, Drug and Cosmetic Act ("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.

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, 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.

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. 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 the Sarbanes-Oxley Act 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;
- 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 an audit committee that we expect to establish in the future.

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 the Sarbanes-Oxley Act 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 the Sarbanes-Oxley Act of 2002 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 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. Our compliance with Section 404 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. 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 or the JOBS Act, which was enacted in April 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 the Sarbanes-Oxley Act of 2002 or the Sarbanes-Oxley Act'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.

Risks Related to Ownership of Our Common Stock

Our share price is likely to be volatile due to factors beyond our control. There is the possibility that the market price of our common stock may drop below the price paid by investors.

All readers of this report should consider an investment in our common stock as risky and invest in our common stock only if the investor can withstand a significant loss and wide fluctuations in the market value of an investment. Investors 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 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 U.S. 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, if 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 U.S. 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.

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.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish substantial rights.

Until such time, if ever, as we can generate substantial revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, grants and licensing and development agreements in connection with any collaborations. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, then outstanding stockholders' ownership interests in our Company will be diluted and the terms of these new securities may include liquidation or other preferences that adversely affect rights of holders of our common stock. Debt financing, if available at all, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, drug candidates, future revenue streams or grant licenses on terms that are not favorable to us. We cannot give any assurance that we will be able to obtain additional funding if and when necessary or on satisfactory terms. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, scale back or eliminate one or more of our development programs or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

Future issuances of our common stock or rights to purchase our common stock pursuant to our equity incentive plan or outstanding options and warrants could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

We are authorized to grant equity awards, including stock grants and stock options, to our employees, directors and consultants, covering up to 10,000,000 shares of our common stock, pursuant to our 2015 Equity Incentive Plan (the “2015 Plan”) and 750,000 shares of our common stock, pursuant to our 2016 Director Plan (the “2016 Director Plan”) . We plan to register the shares available for issuance or subject to outstanding awards under our 2015 Plan and 2016 Director Plan . Future issuances, as well as the possibility of future issuances, under our 2015 Plan or 2016 Director Plan or other equity incentive plans could cause the market price of our common stock to decrease.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us and our business. Securities and industry analysts may choose not to publish research on our Company. If no, or an insufficient number of, securities or industry analysts provide coverage of our Company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. Further, if one or more of these analysts cease coverage of our Company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board is responsible for appointing the members of our management team, these provisions could, in turn, affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include that:

- our board of directors has the right to expand the size of our board and to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board;
- our certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- stockholders must provide advance notice and additional disclosures in order to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders’ meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer’s own slate of directors or otherwise attempting to obtain control of our company; and
- our board of directors may issue, without stockholder approval, shares of currently undesignated preferred stock; such ability to issue previously undesignated preferred stock makes it possible for our board to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Investors could lose all of their investment in our Company .

An investment in our securities is speculative and involves a high degree of risk. Potential investors should be aware that the value of an investment in our Company may go down as well as up. In addition, there can be no certainty that the market value of an investment in our Company will fully reflect its underlying value. Due to these risks and the other risks described in this report, investors could lose their entire investment in our Company.

Investors may experience dilution of their ownership interests because of the future issuance of additional shares of our common or preferred stock or other securities that are convertible into or exercisable for our common or preferred stock .

In the future, we may issue our authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of our stockholders at the time of such issuances. We are authorized to issue an aggregate of 300,000,000 shares of common stock and 10,000,000 shares of “blank check” preferred stock. We may issue additional shares of our common stock or other securities that are convertible into or exercisable for our common stock in connection with hiring or retaining employees, future acquisitions, future sales of our securities for capital raising purposes or for other business purposes. The future issuance of any such additional shares of our common stock may create downward pressure on the trading price of our common stock. We will need to raise additional capital in the near future to meet our working capital needs and there can be no assurance that we will not be required to issue additional shares, warrants or other convertible securities in the future in conjunction with these capital raising efforts, including at a price (or exercise prices) below the price a stockholder at the time of such securities issuance paid for such stockholder’s stock.

The ability of our board of directors to issue additional stock may prevent or make more difficult certain transactions, including a sale or merger of our Company . Our board is authorized to issue up to 10,000,000 shares of preferred stock with powers, rights and preferences designated by it. (See “Preferred Stock” in “Description of Securities.”) Shares of voting or convertible preferred stock could be issued or rights to purchase such shares could be issued, to create voting impediments or to frustrate persons seeking to affect a takeover or otherwise gain control of our Company. The ability of our board to issue such additional shares of preferred stock, with rights and preferences it deems advisable, could discourage an attempt by a party to acquire control of our Company by tender offer or other means. Such issuances could therefore deprive stockholders of benefits that could result from such an attempt, such as the realization of a premium over the market price for their shares in a tender offer or the temporary increase in market price that such an attempt could cause. Moreover, the issuance of such additional shares of preferred stock to persons friendly to our board could make it more difficult to remove incumbent managers and directors from office even if such change were to be favorable to stockholders generally.

There currently is a limited public trading market for our common stock and there can be no assurance that an active trading market will ever develop. Failure to develop or maintain a trading market could negatively affect the value of our common stock and make it difficult or impossible for a holder of shares of our common stock to sell such shares.

There is currently a limited public trading market for shares of our common stock and an active one may never develop. Our common stock currently is quoted on the QM Tier of OTC Markets. The OTC Markets, generally, is a thinly traded market and lacks the liquidity of certain other public markets with which some investors may have more experience. We may not ever be able to satisfy the listing requirements for our common stock to be listed on a national securities exchange, which is often a more widely-traded and liquid market. Some, but not all, of the factors that may delay or prevent the listing of our common stock on a more widely-traded and liquid market include the following:

- our stockholders’ equity may be insufficient;
- the market value of our outstanding securities may be too low;
- our net income from operations may be too low;
- our common stock may not be sufficiently widely held or held by a sufficiently large number of stockholders;
- we may not be able to secure market makers for our common stock; and
- we may fail to meet other rules and requirements mandated by the several exchanges and markets to have our common stock listed.

Should we fail to satisfy the initial listing standards of the national exchanges or our common stock is otherwise rejected for listing and remains listed on the OTC Markets or is suspended from the OTC Markets, the trading price of our common stock could decline and the trading market for our common stock may be less liquid and our common stock price may be subject to increased volatility.

Our common stock may be subject to the “penny stock” rules of the SEC and the trading market in the securities is limited, which makes transactions in the stock cumbersome and may reduce the value of an investment in the stock.

Rule 15c-9 under the Exchange Act establishes the definition of a “penny stock,” which, for the purposes relevant to us, is any equity security that has a market price of less than \$5.00 per share or with an exercise price of less than \$5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require:

- that a broker or dealer approve a person’s account for transactions in penny stocks; and
- the broker or dealer receives from the investor a written agreement to the transaction, setting the identity and quantity of the penny stock to be purchased.

In order to approve a person’s account for transactions in penny stocks, the broker or dealer must:

- obtain financial information and investment experience objectives of the person;
- make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks; and
- deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form:

Sets forth the basis on which the broker or dealer made the suitability determination; and

Confirms that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker or dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

Generally, brokers may be less willing to execute transactions in securities subject to the “penny stock” rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our common stock.

While our common stock currently has a market price in excess of \$5.00, such may not remain the case and our common stock may, in the future, become subject to the “penny stock” rules.

Our stock may be traded infrequently and in low volumes, so investors may be unable to sell their shares at or near the quoted bid prices if they need to sell their shares.

Until our common stock is listed on a national securities exchange such as the New York Stock Exchange or the Nasdaq Stock Market, we expect our common stock to remain eligible for quotation on the OTC Markets or on another over-the-counter quotation system. In those venues, however, the shares of our common stock may trade infrequently and in low volumes, meaning that the number of persons interested in purchasing our common stock at or near bid prices at any given time may be relatively small or non-existent. An investor may find it difficult to obtain accurate quotations as to the market value of our common stock or to sell the investor’s shares at or near bid prices or at all. In addition, if we fail to meet the criteria set forth in SEC regulations, including those relating to “penny stocks,” various requirements would be imposed by law on broker-dealers who sell our securities to persons other than established customers and accredited investors. Consequently, such regulations may deter broker-dealers from recommending or selling our common stock, which may further affect the liquidity of our common stock. This would also make it more difficult for us to raise capital.

We do not anticipate paying dividends on our common stock.

Cash dividends have never been declared or paid on our common stock and we do not anticipate such a declaration or payment for the foreseeable future. We expect to use future earnings, if any, to fund business growth. Therefore, our stockholders will likely not receive any funds absent a sale of their shares of our common stock. If we do not pay dividends, our common stock may be less valuable because a return on an investment in shares of our common stock will only occur if our stock price appreciates. We cannot assure stockholders of a positive return on their investment when they sell their shares, nor can we assure that stockholders will not lose the entire amount of their investment.

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 29.9% of our outstanding common stock as of May 26, 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.

Compliance with changing regulation of corporate governance and public disclosure will result in additional expenses and pose challenges for our management.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Dodd-Frank Wall Street Reform and Consumer Protection Act, and the rules and regulations promulgated thereunder, the Sarbanes-Oxley Act and SEC regulations have created uncertainty for public companies and significantly increased the costs and risks associated with accessing the U.S. public markets. Our management team will need to devote significant time and financial resources to comply with both existing and evolving standards for public companies, which will lead to increased general and administrative expenses and a diversion of management time and attention from revenue generating activities to compliance activities.

We will need to raise substantial additional capital in the future to fund our operations and we may be unable to raise such funds when needed and on acceptable terms.

When we elect to raise additional funds or additional funds are required, we may raise such funds from time to time through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives. Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on advantageous or reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms advantageous or reasonable to us, we will be prevented from our ability to generate revenues and achieve or sustain profitability will be substantially harmed.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences, which are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, our business, operating results, financial condition and prospects could be materially and adversely affected and we may be unable to continue our operations. These factors raise substantial doubt about our ability to continue as a going concern.

Our common stock is subject to price volatility unrelated to our operations.

The market price of our common stock could fluctuate substantially due to a variety of factors, including market perception of our ability to achieve our planned growth, quarterly operating results of other companies in the same industry, trading volume in our common stock, changes in general conditions in the economy and the financial markets or other developments affecting our competitors or ourselves. In addition, the OTC Market Group, Inc.'s OTC QB tier is subject to extreme price and volume fluctuations in general. This volatility has had a significant effect on the market price of securities issued by many companies for reasons unrelated to their operating performance and could have the same effect on our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal executive offices are located at 44 Wall Street – 12th Floor, New York, New York 10005, where we lease and occupy approximately 700 square feet of office space. We lease these offices under a lease that can be cancelled at any time with 60-days notice. Historically, our costs for this office and related expenses are under \$100,000 per year.

We also maintain an office in Red Bank, New Jersey, where we lease and occupy approximately 150 square feet of office space. The original lease for this office has expired and it is currently rented month-to-month with 30 days termination notice. We estimate our total annual costs for this office at approximately \$6,600 per year.

We believe that our existing facilities are adequate for our current administrative needs. In the future, we may look for additional or alternate space for our operations. We believe that suitable additional or alternative space will be available in the future on commercially reasonable terms. We will rely on clinical research centers, hospitals, contract research organizations and other parties for suitable space and facilities to conduct our clinical trials. We will explore, in the future, establishing a dedicated technical facility, when we believe the need for such a facility has arisen. No assurance can be given that such a facility can be located without difficulty or at a cost favorable to us.

ITEM 3. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on us, our business, operating results or financial condition. The following provides background concerning, and the resolution of, previously disclosed material legal proceedings.

Background. As described in greater detail under “Business – Corporate History; Significant Organizational Events,” “Merger Agreement” and “Adjustment Shares Escrow Agreement,” on March 5, 2015, we entered into a Merger Agreement and certain associated transactions, including capitalized terms used below that were previously detailed and defined under such caption herein. Pursuant to the Merger Agreement, we, Acquisition Sub and Tyme entered into a reverse triangular merger pursuant to which (a) Acquisition Sub merged into Tyme with Tyme as the surviving entity, (b) Tyme became a wholly-owned subsidiary of us, and (c) the Pre-Merger Stockholders of Tyme collectively acquired approximately 79% of our outstanding shares of Common Stock after giving effect to the Merger and the other transactions contemplated by the Merger Agreement.

The shares allocated to our respective stockholders were subject to a number of post-closing adjustments based upon future contingencies. The Merger Agreement required that certain shares then owned by GEM (equal to 3,500,000) would be subject to contingencies and, as a result, they were placed in escrow by GEM pursuant to an escrow agreement and are referred to in this report as Adjustment Shares or the “Escrowed Shares”.

As part of such contingencies and commitments under the Merger Agreement, no Qualified Offering occurred by the Qualified Offering Trigger Termination Date. As a result, as contemplated by the Merger Agreement, the Adjustment Shares were required to be surrendered to us for cancellation under the Adjustment Shares Escrow Agreement.

On November 10, 2015, the Company advised the escrow agent of such facts and demanded the surrender for cancellation of the 3,500,000 shares placed into escrow under the Adjustment Shares Escrow Agreement. Under the Adjustment Shares Escrow Agreement, the depositor of the Escrowed Shares had until November 18, 2015 to challenge the Company’s demand for surrender of the Escrowed Shares.

On November 17, 2015, the Company received notice from the depositor of such 3,500,000 shares disputing the grounds for the surrender for cancellation of those shares.

On January 19, 2016, the Company filed a complaint against the depositor with the Commercial Division of the Supreme Court of New York, New York and on April 1, 2016, the Company filed an amended complaint, which asserted causes of actions for (i) a declaratory judgment declaring that the relevant contracts require the 3,500,000 escrowed Adjustment Shares to be released to the Company; (ii) breach of contract for failure to deliver the 3,500,000 escrowed Adjustment Shares to the Company; (iii) conversion for the depositors willful and malicious interference with the Company’s rights to the Adjustment Shares; and (iv) replevin for the escrow agent’s refusal to surrender the escrowed Adjustment Shares to the Company.

On June 20, 2016, the depositor filed their answer and asserted two counterclaims. The Company moved to dismiss the counterclaims on August 10, 2016, the depositor filed its opposition on September 21, 2016 and the Company filed its reply memorandum of law on October 28, 2016.

Resolution of Legal Proceedings. On February 28, 2017, we, the depositor and CKR Law LLP (“CKR”) entered into a Confidential Settlement and Release Agreement (the “Settlement Agreement”) with respect to, among other things, (a) our complaint filed on or about January 19, 2016 and amended on April 1, 2016 against the depositor with the Commercial Division of the Supreme Court of New York, New York (the “Court”) captioned *Tyme Technologies, Inc. v. GEM Global Yield Fund LLC SCS and CKR Law*

LLP, Index No. 650250/2016, (b) the depositor's counterclaims asserted against us on or about June 20, 2016 as set forth in CKR's and the depositor's answer to the Company's complaint and (c) a Registration Rights Agreement involving the Company and the depositor (the "RRA"), a form of which was filed as Exhibit 10.9 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 11, 2015.

Pursuant to the Settlement Agreement, the depositor directed CKR to surrender to the Company the Escrowed Shares. The Company is not obligated to pay any monetary damages pursuant to the Settlement Agreement. In addition to the foregoing, the Company and GEM agreed to waive and release any claims they may have against each other with respect to the subject matter of the complaint and counterclaim described above. On March 1, 2017, the Company received the Escrowed Shares. The Company and the depositor also entered into a Stipulation of Discontinuance with Prejudice that was filed with the Court on March 2, 2017.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Public market for our common stock

Our common stock was quoted on the over-the counter ("OTC") Markets, QB Tier, under the symbol "TYMI" for each of the periods listed below. OTC Markets securities are not listed and traded on the floor of an organized national or regional stock exchange. Instead, OTC Markets securities transactions are conducted through a telephone and computer network connecting dealers. OTC Markets issuers are traditionally smaller companies that do not meet the financial and other listing requirements of a regional or national stock exchange.

Before September 26, 2014, the common stock of our predecessor was quoted on the OTC Markets, QB Tier, under the symbol of our predecessor, "GGET." Prior to March 12, 2015, there were no reported sales of common stock of our predecessor on the OTC Market. Since March 12, 2015, there have been only a limited number of shares of our common stock reported by OTC Markets as having been traded. There can be no assurance given that a regular and active trading market for our common stock will ever develop.

The following table sets forth, for the periods indicated, the prices of the common stock in the OTC market, as reported and summarized by OTC Markets Group, Inc. These quotations represent inter-dealer quotations, without adjustment for retail markup, markdown, or commission and may not represent actual transactions. There is an absence of an established trading market for our common stock, as the market is limited, sporadic and highly volatile, which may affect the prices listed below.

Quarter Ended	High	Low
March 31, 2015	\$6.75	\$0.10
June 30, 2015	\$8.35	\$6.75
September 30, 2015	\$8.50	\$7.50
December 31, 2015	\$11.25	\$8.48
March 31, 2016	\$6.15	\$6.05
June 30, 2016	\$7.15	\$6.10
September 30, 2016	\$3.60	\$3.50
December 31, 2016	\$4.20	\$2.85
March 31, 2017	\$3.25	\$2.88
April 30, 2017	\$3.10	\$3.10
Through June 8, 2017	\$3.49	\$2.63

Holders; Shares Outstanding

We had a total of 89,341,067 shares of our common stock outstanding on May 26, 2017, held by approximately 196 stockholders of record. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in "street name" by brokers and other nominees.

Limited Anti-dilution Rights of 2017 Private Placement Investors.

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.

Dividend Policy

We have never paid any cash dividends on our common stock and do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain future earnings to fund ongoing operations and future capital requirements. Any future determination to pay cash dividends will be at the discretion of our board of directors and will be dependent upon financial condition, results of operations, capital requirements and such other factors as our board deems relevant. Further, in the event that we issue any shares of a class or series of our preferred stock, the designation of such class or series could limit our ability to pay dividends on our common stock.

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides certain information with respect to all of our equity compensation plans in effect as of March 31, 2017:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights(1)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Issuance Under Equity Compensation Plans(2)
Equity compensation plans approved by stockholders	—	\$ —	—
Equity compensation plans not approved by stockholders	4,254,534	6.15	6,555,000
Total	4,254,534	\$ 6.15	6,555,000

(1) Includes 4,195,000 shares of our common stock issuable under option awards made prior to March 31, 2017 under our 2015 Equity Incentive Plan and 2016 Director Plan at a weighted average exercise price of \$6.15 per share. Also includes 59,534 shares of our common stock issuable upon the exercise of outstanding certain warrants to purchase common stock as of March 31, 2017 at a weighted average exercise price of \$5.00 per share; the warrants described in this sentence are limited to warrants issued in returned for goods or services provided and does not include warrants issued in connection with capital raising transactions, consistent with applicable SEC disclosure obligations.. For a description of the terms of the 2015 Equity Incentive Plan and 2016 Director Plan, please see Note 10 to the consolidated financial statements presented elsewhere herein.

(2) Includes 6,555,000 shares of our common stock issuable under awards eligible to be made (and not outstanding) as of March 31, 2017 under our 2015 Equity Incentive Plan and 2016 Director Plan.

Recent Sales of Unregistered Securities

There are no transactions required to be disclosed that have not already been disclosed within previous SEC filings.

Use of Proceeds from Registered Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

The following tables set forth our selected financial data for the periods indicated. The following statement of operations data for the years ended March 31, 2017 and December 31, 2015 and the selected balance sheet data as of March 31, 2017 and December 31, 2015 are derived from our audited financial statements appearing elsewhere in this report. The statement of operations data for the years ended November 30, 2013 and 2012, and the balance sheet data as of November 30, 2014, 2013 and 2012 have been derived from audited financial statements previously filed with the SEC that are not included herein.

This selected financial data should be read together with the historical financial statements and related notes to those statements, as well as “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” which are included elsewhere in this report.

Our historical results are not necessarily indicative of the results that may be expected in the future, and our interim period results are not necessarily indicative of results to be expected for a full year or any other interim period.

	Year ended November 30,		Year Ended December 31,		Year Ended March 31,
	2012	2013	2014	2015	2017
Statement of Operations Data: (in thousands, except share and per share data)					
Operating expenses:					
Research and development	\$ —	\$ —	\$ 761	\$ 3,824	\$ 6,112
General and administrative	—	—	1,823	4,776	9,095
Total operating expenses	(27)	(57)	2,584	8,600	15,207
Loss from operations	(27)	(57)	(2,584)	(8,600)	(15,207)
Interest Expense	—	—	(77)	(3,503)	—
Other Income	—	—	—	376	—
Net loss	\$ (27)	\$ (57)	\$ (2,661)	\$ (11,727)	\$ (15,207)
Basic and diluted loss per option share	\$ 0.0	\$ 0.0	\$ (0.04)	\$ (0.15)	\$ (0.18)
Basic and diluted weighted average shares outstanding	10,983,607	52,000,800	68,000,000	77,848,850	84,454,587

	Year ended November 30,		Year Ended December 31,		Year Ended March 31,
	2012	2013	2014	2015	2017
Balance Sheet Data: (in thousands, except share and per share data)					
Cash and cash equivalents	\$ 16	\$ 0	\$ 0	\$ 4,446	\$ 10,483
Total assets	16	0	0	4,490	10,719
Total liabilities	2	43	97	1,474	3,327
Total stockholders’ equity (deficit)	14	(43)	(97)	3,016	7,392

ITEM 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the “Risk Factors” section of this Annual Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. As used in this report, unless the context suggests otherwise, “we,” “us,” “our,” “the Company” or “Tyme Technologies” refer to Tyme Technologies, Inc.

Overview

Our predecessor was formed in Florida on November 22, 2011 and effective as of September 18, 2014, the predecessor (then constituting a Florida corporation with the name Global Group Enterprises Corp.) reincorporated in the State of Delaware by merging into a wholly-owned Delaware subsidiary, Tyme Technologies, Inc., which was formed on August 22, 2014 specifically for this purpose (the “Reincorporation”). Tyme Technologies, Inc. was the surviving corporation in such merger. As a result of the Reincorporation, among other things, (i) our name changed to Tyme Technologies, Inc., (ii) we changed our jurisdiction of

incorporation from Florida to Delaware, (iii) we increased our authorized capital stock from 250,000,000 shares of common stock, \$0.0001 par value per share, to 300,000,000 shares of common stock, \$0.0001 par value per share, and 10,000,000 shares of preferred stock, \$0.0001 par value per share, (iv) each share of Global Group Enterprises Corp.'s common stock outstanding at the time of the Reincorporation was automatically converted into 4.3334 shares of Tyme Technologies, Inc.'s common stock, with the result that the 12,000,000 shares of common stock outstanding immediately prior to the Reincorporation were converted into 52,000,800 shares of common stock outstanding immediately thereafter. All share and per share numbers in this Annual Report on Form 10-K relating to our common stock prior to the Reincorporation have been adjusted to give effect to this conversion, unless otherwise stated. Subsequent to the Reincorporation, Global Group Enterprises Corp. ceased to exist.

As discussed in "Item 1; Business – Corporate History; Significant Organizational Events," and in the notes to the consolidated financial statements included in this Annual Report on Form 10-K, on March 5, 2015, we entered into a "reverse triangular merger" and related transactions with Tyme Inc., a Delaware corporation ("Tyme"), and other parties that resulted in, among other matters, a change in control of our Company and a change in our fiscal year from a fiscal year ending on November 30th of each calendar year to one ending on December 31st of each calendar year.

On October 27, 2016, our Board of Directors determined to change the fiscal year of the Company from a year ending on December 31 of each year to a year ending on March 31 of each year. The Company's report covering the transition period from January 1, 2016 through March 31, 2016 was filed via transition report on Form 10-QT. As a result of this change, we provided herein disclosures of our results, financial conditions and liquidity for (i) the year ended March 31, 2017 compared to the year ended December 31, 2015; (ii) the three months ended March 31, 2016 compared to three months ended March 31, 2015 and (iii) the year ended December 31, 2015 compared to the year ended December 31, 2014.

We are in the process of evaluating our short- and long-term financing requirements in order to effectuate our business plan. We anticipate that we will seek to raise required capital by the issuance of equity or debt securities, through private or public offerings or by other means. Other than transactions recently concluded and described below under "Recent Financing Developments," we have no arrangements or plans currently in effect and any inability to raise additional funds could have an adverse effect on our ability to execute our business objectives. In addition, no assurance can be given that we will be able to obtain funds on favorable terms, if at all.

Recent Financing Developments

In October of 2016, we raised \$1.47 million through a private placement of 452,314 shares of our common stock.

In March of 2017, we raised \$9.2 million in gross proceeds through a private placement of 3,588,620 shares of our common stock and 3,588,620 common stock purchase warrants (each, a "Warrant"). Each Warrant entitles its holder to purchase one share of common stock (each, a "Warrant Share") at an exercise price of \$3.00 per Warrant Share, subject to adjustment.

In April of 2017, we raised approximately \$2,700,000 in gross proceeds through a private placement of 1,069,603 shares of our common stock and 1,069,603 Warrants.

Critical Accounting Policies and Recent Accounting Pronouncements

While our significant accounting policies are more fully described in Note 2 to the Consolidated Financial Statements appearing elsewhere in this Form 10-K, we believe the following accounting policies are critical to the preparation of our financial statements.

Research and Development Expenses

Research and development costs are expensed as incurred and are primarily comprised of, but not limited to, external research and development expenses incurred under arrangements with third parties, such as contract research organizations ("CROs"), contract manufacturing organizations ("CMOs") and consultants that conduct clinical and preclinical studies, costs associated with preclinical and development activities, costs associated with regulatory operations, depreciation expense for assets used in research and development activities and employee related expenses, including salaries and benefits for research and development personnel. Costs for certain development activities, such as clinical studies, are accrued, over the service period specified in the contract and recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the patterns of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued expense, which are reported in prepaid assets or accounts payable and other current liabilities.

Income Taxes

Our income tax expense, deferred tax assets and liabilities, and liabilities for unrecognized tax benefits reflect management's best estimate of current and future taxes to be paid. We are subject to income taxes in the United States, for Federal and various State jurisdictions. Significant judgments and estimates are required in the determination of the income tax expense.

Deferred income taxes arise from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements, which will result in taxable or deductible amounts in the future. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The assumptions about future taxable income require the use of significant judgment and are consistent with the plans and estimates we are using to manage the underlying businesses. In evaluating the objective evidence that historical results provide, we consider three years of cumulative operating income (loss).

A valuation allowance is provided when, after consideration of all positive and negative evidence that it is less likely than not that the benefit from Federal and State Net Operating Losses (NOLs) will be realizable. In recognition of this risk, we have provided a full valuation allowance on the deferred tax assets related to these NOL carryforwards.

The calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations in various jurisdictions. ASC 740 "Income Taxes" states that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits.

We had unrecognized tax benefits of \$617,233 and \$331,545 at March 31, 2017 and 2016 respectively and no unrecognized tax benefits at December 31, 2015 and 2014. Increases or decreases would not have an effect on the effective tax rate. The tax years, which currently remain subject to examination by major tax jurisdictions as of March 31, 2017 are the period January 1, 2016 through March 31, 2016, years ended December 31, 2015 and 2014 and for the period July 26, 2013 to December 31, 2013. In addition, we had no income tax related penalties or interest for periods presented in these consolidated financial statements. When and if we were to recognize interest and penalties related to unrecognized tax benefits, they would be reported in tax expense.

Stock-Based Compensation

We follow the authoritative guidance for accounting for stock-based compensation in ASC 718, "Compensation-Stock Compensation." The guidance requires that stock-based payment transactions be recognized in the financial statements based on their fair value at the grant date and recognized as compensation expense over the vesting period as services are being provided.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected term of the option, risk-free interest rates, the value of the common stock and expected dividend yield of the common stock. For awards subject to time-based vesting conditions, we recognize stock-based compensation expense equal to the grant date fair value of stock options on a straight-line basis over the requisite service period, which is generally the vesting term. Forfeitures are required to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

We account for stock-based awards issued to non-employees in accordance with ASC 505-50, "Equity-Based Payment to Non-Employees" and accordingly the fair value of the stock options granted to non-employees is remeasured each reporting period until the earlier of: a) the performance commitment date, or b) the date the services required under the arrangement have been completed and the resulting increase or decrease in value, if any, is recognized as expense or income, respectively, during the period the related services are rendered.

Refer to Note 2 to our Consolidated Financial Statements for a discussion of Recent Accounting Pronouncements.

Results of Operations

Year ended March 31, 2017 Compared to Year Ended December 31, 2015

Net loss for the year ended March 31, 2017 was \$15,206,781, compared to \$11,726,818 for the year ended December 31, 2015. The increase in the net loss for the year ended March 31, 2017, as compared to the net loss for the year ended December 31, 2015 is due to increased operating costs and expenses in 2017, as highlighted below.

Revenues and Other Income

During the years ended March 31, 2017 and December 31, 2015, we did not realize any revenues from operations. We do not anticipate recognizing any revenues until such time as one of our products has been approved for marketing by appropriate regulatory authorities or we enter into collaboration or licensing arrangement, none of which is anticipated to occur in the near future.

Operating Costs and Expenses

For the year ended March 31, 2017, operating costs and expenses totaled \$15,206,781, compared to \$8,599,772 for the year ended December 31, 2015, representing an increase of \$6,607,009. Operating costs and expenses were comprised of the following:

- Research and development expenses were \$6,111,587 for the year ended March 31, 2017, compared to \$3,823,966 for the year ended December 31, 2015, representing an increase of \$2,287,621. All research and development expenditures have been incurred in respect of our lead drug candidate, SM-88, and its technology platform. Research and development activities primarily consist of the following:
 - Salary expense for research and development personnel was \$923,816 for the year ended March 31, 2017, compared to \$773,853 for the year ended December 31, 2015, representing a \$149,963 increase between the comparable periods, primarily due to an increase in the number of employees.
 - Consulting and study expenses were \$2,062,290 for the year ended March 31, 2017, compared to \$1,969,617 for the year ended December 31, 2015, representing an increase of \$92,673 between the comparable periods. These types of expenses are anticipated to vary between future accounting periods as we continue to develop our drug candidates and seek governmental approval of such drug candidates.
 - Stock based compensation, primarily related to stock options granted, was \$2,779,073 for the year ended March 31, 2017, compared to \$250,000 for the year ended December 31, 2015, representing a \$2,529,073 increase between the periods, primarily due to option grants to research and development employees.
- General and administrative expenses were \$9,095,194 for the year ended March 31, 2017, compared to \$4,775,806 for the year ended December 31, 2015, representing an increase of \$4,319,388, primarily due to increased stock compensation expense. The general and administrative expenses include:
 - Stock based compensation, primarily related to stock options granted, was \$5,095,813 for the year ended March 31, 2017, compared to \$685,859 for the year ended December 31, 2015, representing a \$4,409,954 increase between the periods, primarily due to option grants to management and board of director members.
 - Legal, professional services, accounting and auditing for the year ended March 31, 2017, was \$2,413,703, compared to \$2,460,469 for the year ended December 31, 2015 representing a decrease of \$46,766.
 - Salary expense for non-research and development personnel was \$978,179 for the year ended March 31, 2017, compared to \$944,561 for the year ended December 31, 2015, representing a \$33,618 increase between the comparable periods.

Other Income/Expenses

Interest expense

For the year ended March 31, 2017, the Company did not incur any interest expense.

For the year ended December 31, 2015 the Company incurred \$3,503,301 of interest expense primarily relating to modification of the Bridge Note. Contemporaneous with the closing of the Merger, the Bridge Note in the principal amount of \$2,310,000 was converted into 2,310,000 shares of Company common stock. On March 5, 2015, the mandatory conversion feature of the Bridge Note was amended to a set fixed conversion amount such that, upon conversion, the Bridge Note purchaser would receive one share of Company common stock for each \$1.00 of principal of the Bridge Note outstanding as of the date of the mandatory conversion. We evaluated the modification to the conversion rate as an inducement to convert the Bridge Note and concluded that it provided the purchaser of the Bridge Note an incremental value of \$3,465,000, which is included as interest expense on the consolidated statement of operations for the period ended March 31, 2015.

Other Income

For the year ended March 31, 2017, the Company did not recognize any other income. Other income for the year ended December 31, 2015 was \$376,255, which primarily represents a gain recorded on the remeasurement of a derivative liability to \$0 as of December 31, 2015. The derivative was originally recorded during the quarter ended March 31, 2015 and based on updated inputs to the valuation model used, we have determined that the derivative liability has no value at December 31, 2015. Changes in the fair value of the derivative are recognized in earnings in the current period.

Income Tax

Our effective tax rate for the years ended March 31, 2017 and December 31, 2015 was zero percent. Our tax rate is affected primarily by state income taxes and changes in valuation allowance.

Three Months Ended March 31, 2016 Compared to Three Months Ended March 31, 2015 (Unaudited)

Net loss for the three months ended March 31, 2016 was \$2,751,127 compared to \$5,601,438 for the three months ended March 31, 2015. The decrease in the net loss for the three months ended March 31, 2016, as compared to the net loss for the 2015 three month period, is primarily due to the elimination of \$3,503,301 in interest expense after the 2015 three month period, which was offset in part by increased operating costs and expenses in the 2016 three month period, as highlighted below.

Revenues and Other Income

During the three month periods ended March 31, 2016 and 2015, we did not realize any revenues from operations. We do not anticipate recognizing any revenues until such time as one of our products has been approved for marketing by appropriate regulatory authorities or we enter into collaboration or licensing arrangement, none of which is anticipated to occur in the near future.

Operating Costs and Expenses

For the three months ended March 31, 2016, operating costs and expenses totaled \$2,751,127 compared to \$2,098,137 for the three months ended March 31, 2015, representing an increase of \$652,990. Operating costs and expenses were comprised of the following:

1. Research and development expenses were \$808,472 for the three months ended March 31, 2016, compared to \$514,317 for the three months ended March 31, 2015, representing an increase of \$294,155. All research and development expenditures have been incurred in respect of our lead oncology drug candidate, SM-88, and its associated technology platform. Research and development activities primarily consist of the following:
 1. Salary expense for research and development personnel was \$212,193 for the three months ended March 31, 2016, compared to \$307,058 for the three months ended March 31, 2015, a decrease of \$94,865 between the comparable periods. The decrease is due to the fact that during the three months ended March 31, 2015, research and development personnel were awarded bonus compensation totaling \$135,560 in connection with the Merger. This decrease is offset by a new hire during the three months ended March 31, 2016.
 2. Consulting and study expenses were \$456,551 for the three months ended March 31, 2016, compared to \$152,259 for the three months ended March 31, 2015, representing an increase of \$304,292 between the comparable periods. These types of expenses are anticipated to vary between future accounting periods as we continue to develop our oncology drug candidates and seek governmental approval of such drug candidates.
 3. For the three months ended March 31, 2016 we incurred compensation expense of \$100,000 related to the Scientific Advisory Board that was established as of September 30, 2015 compared to \$0 for the three months ended March 31, 2015.
2. General and administrative expenses were \$1,942,655 for the three months ended March 31, 2016, compared to \$1,583,820 for the three months ended March 31, 2015, representing an increase of \$358,835, with this increase principally attributed to the recognition of non-cash compensation expense related to stock options of \$1,137,435 for the three months ended March 31, 2016. For the three months ended March 31, 2015, we had no compensation expense related to stock options. The general and administrative expenses for the respective periods include:

1. Transaction costs associated with the Merger, which totaled approximately \$1,000,000 for the three months ended March 31, 2015 and relate to professional fees incurred in respect of legal, investor relations and accounting and auditing of Tyme's financial statements. There were no such transaction costs incurred in the three months ended March 31, 2016.
2. Salary expense for non-research and development personnel was \$243,572 for the three months ended March 31, 2016, compared to \$395,356 for the three months ended March 31, 2015, representing a \$151,784 decrease between the comparable periods. The decrease is due to the fact that during the three months ended March 31, 2015, non-research and development personnel were awarded bonus compensation totaling \$206,690 in connection with the Merger. This decrease is offset by a new full time hire during the three months ended March 31, 2016.
3. Stock based compensation expense related to stock options granted was \$1,137,435 for the three months ended March 31, 2016 compared to \$0 for the three months ended March 31, 2015. No stock options were granted during or prior to the three months ended March 31, 2015.
4. In addition, in the three months ended March 31, 2016, we incurred costs of \$353,362 for legal and accounting fees.

Other income (expense)

Interest charges for the three months ended March 31, 2015 were \$3,503,301, compared to \$0 for the three months ended March 31, 2016. Contemporaneous with the closing of the Merger, the Bridge Note in the principal amount of \$2,310,000 was converted into 2,310,000 shares of Company common stock. On March 5, 2015, the mandatory conversion feature of the Bridge Note was amended to a set fixed conversion amount such that, upon conversion, the Bridge Note purchaser would receive one share of Company common stock for each \$1.00 of principal of the Bridge Note outstanding as of the date of the mandatory conversion. We evaluated the modification to the conversion rate as an inducement to convert the Bridge Note and concluded that it provided the purchaser of the Bridge Note an incremental value of \$3,465,000, which is included as interest expense on the consolidated statements of operations for the three months ended March 31, 2015. We also recorded cash interest expenses of \$38,301 on the Bridge Note during the three months ended March 31, 2015.

Year ended December 31, 2015 Compared to December 31, 2014

Net loss for the year ended December 31, 2015 was \$11,726,818, compared to \$2,660,677 for the year ended December 31, 2014. The increase in the net loss for the year ended December 31, 2014, as compared to the net loss for 2014 is due to increased operating costs and expenses in 2015, as highlighted below.

Revenues and Other Income

During the years ended December 31, 2015 and 2014, we did not realize any revenues from operations. We do not anticipate recognizing any revenues until such time as one of our products has been approved for marketing by appropriate regulatory authorities or we enter into collaboration or licensing arrangement, none of which is anticipated to occur in the near future.

Operating Costs and Expenses

For the year ended December 31, 2015, operating costs and expenses totaled \$8,599,772, compared to \$2,584,116 for the year ended December 31, 2014, representing an increase of \$6,015,656. Operating costs and expenses were comprised of the following:

- Research and development expenses were \$3,823,966 for the year ended December 31, 2015, compared to \$761,359 for the year ended December 31, 2014, representing an increase of \$3,062,607. All research and development expenditures have been incurred in respect of our lead drug candidate, SM-88, and its technology platform. Research and development activities primarily consist of the following:
- Salary expense for research and development personnel was \$773,853 for the year ended December 31, 2015, compared to \$299,880 for the year ended December 31, 2014, representing a \$473,973 increase between the comparable periods, primarily due to a higher salary for the Company's Chief Executive Officer, who primarily provides research and development related services, and an increase in the number of employees.

- Consulting and study expenses were \$1,969,617 for the year ended December 31, 2015, compared to \$382,584 for the year ended December 31, 2014, representing an increase of \$1,587,033 between the comparable periods. These types of expenses are anticipated to vary between future accounting periods as we continue to develop our drug candidates and seek governmental approval of such drug candidates.
- For the year ended December 31, 2015, there was \$653,369 of expenses incurred in connection with the acquisition of manufactured samples to be used in testing. No similar expense was incurred during 2014.
- For the year ended December 31, 2015, we incurred compensation expense, half paid in common shares and half paid in cash, of \$250,000 related to the five Scientific Advisory Board members elected in September 2015. There was no such expense for the year ended December 31, 2014.
- General and administrative expenses were \$4,775,806 for the year ended December 31, 2015, compared to \$1,822,757 for the year ended December 31, 2014, representing an increase of \$2,953,049. We expect our general and administrative expenses, subject to securing ongoing funding, to increase as our operations grow. The general and administrative expenses include:
 - Transaction costs associated with the Merger totaled approximately \$1,000,000 for the year ended December 31, 2015 and relate to professional fees incurred in respect of legal, investor relations and accounting and auditing of Tyme's financial statements. There were no such transaction costs incurred in the year ended December 31, 2014. In addition, in the year ended December 31, 2015, we incurred costs of \$1,468,991 for legal and accounting fees as we continue to implement our business plan.
 - Salary expense for non-research and development personnel was \$944,561 for the year ended December 31, 2015, compared to \$440,269 for the year ended December 31, 2014, representing a \$504,292 increase between the comparable periods. This increase is primarily due to a higher salary in 2015 for the Company's Chief Operating Officer and the addition of a Chief Financial Officer in May 2015. We expect to incur further increases in salary expense for non-research and development personnel as we continue to implement our business plan.
 - Stock based compensation expense related to stock options granted was \$485,859 for the year ended December 31, 2015. No stock options were granted during the year ended December 31, 2014.
 - For the year ended December 31, 2015, we incurred compensation expense, half paid in common shares and half paid in cash, of \$400,000 related to the three members of the Board of Directors and Special Advisor. There was no such expense for the year ended December 31, 2014.

Other income (expense)

Interest charges for the year ended December 31, 2015 was \$3,503,301, compared to \$76,561 for the year ended December 31, 2014. Contemporaneous with the closing of the Merger, the Bridge Note in the principal amount of \$2,310,000 was converted into 2,310,000 shares of Company common stock. On March 5, 2015, the mandatory conversion feature of the Bridge Note was amended to a set fixed conversion amount such that, upon conversion, the Bridge Note purchaser would receive one share of Company common stock for each \$1.00 of principal of the Bridge Note outstanding as of the date of the mandatory conversion. We evaluated the modification to the conversion rate as an inducement to convert the Bridge Note and concluded that it provided the purchaser of the Bridge Note an incremental value of \$3,465,000, which is included as interest expense on the consolidated statement of operations for year ended December 31, 2015. We recorded interest expense of \$38,301 on the Bridge Note during the year ended December 31, 2015.

Other income for the year ended December 31, 2015 was \$376,255, which primarily represents a gain recorded on the remeasurement of a derivative liability to \$0 as of December 31, 2015. The derivative was originally recorded during the quarter ended March 31, 2015 and based on updated inputs to the valuation model used, we have determined that the derivative liability has no value at December 31, 2015. Changes in the fair value of the derivative are recognized in earnings in the current period.

Income Tax

Our effective tax rate for the years ended December 31, 2015 and 2014 was zero percent. Our tax rate is affected primarily by state income taxes and changes in valuation allowance.

Preparation of Financial Statements; Going Concern

Our financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("US GAAP"), which contemplates our continuation as a going concern. We have incurred losses and negative cash flows from operations since inception (July 26, 2013) and have an accumulated deficit of approximately \$33,862,088 as of March 31, 2017. We anticipate incurring additional losses until such time, if ever, that we can generate significant revenues from our products currently in development. Our primary sources of liquidity to date have been the issuance of shares of our common stock, convertible promissory notes and contributed capital by our founders. Substantial additional financing will be needed to fund our operations and to commercially develop our product candidates. There is no assurance that such financing will be available when needed or on acceptable terms. These factors raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued.

The consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded assets amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

At March 31, 2017, we had cash and equivalents of \$10,482,977, and working capital and stockholders' equity of \$7,384,271 and \$7,391,806, respectively.

Liquidity and Capital Resources

Liquidity and Capital Requirements Outlook

We anticipate requiring additional capital in order to fund the development of our product candidates, as well as to engage in strategic transactions. The most significant funding needs are anticipated to be in connection with preparing for and conducting immediate Phase II clinical trials of our SM-88 drug candidate for prostate cancer and pancreatic cancer and additional or related studies and investigations. We are evaluating the expansion of our clinical program to other forms of cancer beyond those noted above.

To meet our short and long-term liquidity needs, we currently expect to use existing cash balances and a variety of other means, including potential issuances of debt or equity securities in public or private financings, option exercises, and partnerships and/or collaborations. The demand for the equity and debt of biopharmaceutical companies like ours is dependent upon many factors, including the general state of the financial markets. During times of extreme market volatility, capital may not be available on favorable terms, if at all. Our inability to obtain such additional capital could materially and adversely affect our business operations.

While we will continue to seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all, and our negotiating position in capital generating efforts may worsen as existing resources are used.

Additional equity financing may be dilutive to our stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business; and our stock price may not reach levels necessary to induce option exercises. If we are unable to raise the funds necessary to meet our long-term liquidity needs, we may have to delay or discontinue the development of certain or all of our drug candidates or raise funds on terms that we currently consider unfavorable. These factors raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued.

Cash Flows

Net cash used in or provided by operating, investing and financing activities from continuing operations were as follows:

	Year Ended March 31, 2017	Three Months Ended March 31, 2016	Three Months Ended March 31, 2015 (unaudited)	Year Ended December 31, 2015	Year Ended December 31, 2014
Net cash used in operating activities	\$ (5,861,127)	\$ (1,373,257)	\$ (2,281,683)	\$ (6,610,156)	\$ (1,515,586)
Net cash used in investing activities	\$ —	\$ —	\$ —	\$ —	\$ (2,710)
Net cash provided by financing activities	\$ 10,238,795	\$ 3,032,282	\$ 5,598,339	\$ 11,046,716	\$ 1,435,400

Operating Activities

Our cash used in operating activities in the year ended March 31, 2017 totaled \$5,861,127 which is the sum of (i) our net loss of \$15,206,781, adjusted for non-cash expenses totaling \$8,076,368 (which includes adjustments for equity-based compensation, depreciation and amortization and the issuance of common stock for services), and (ii) changes in operating assets and liabilities of \$1,269,286.

Our cash used in operating activities in the three months ended March 31, 2016 totaled \$1,373,257 which is the sum of (i) our net loss of \$2,751,127, adjusted for non-cash expenses totaling \$1,138,497 (which includes adjustments for equity-based compensation, depreciation and amortization and the issuance of common stock for services), and (ii) changes in operating assets and liabilities of \$239,373.

Our cash used in operating activities in the three months ended March 31, 2015 totaled \$2,281,683 which is the sum of (i) our net loss of \$5,601,438, adjusted for non-cash expenses totaling \$4,141,074 (which includes adjustments for equity-based compensation, depreciation and amortization and the issuance of common stock for services), and (ii) changes in operating assets and liabilities of \$(821,319).

Our cash used in operating activities in the year ended December 31, 2015 totaled \$6,610,156 which is the sum of (i) our net loss of \$11,726,818, adjusted for non-cash expenses totaling \$4,728,851 (which includes adjustments for equity-based compensation, depreciation and amortization and the issuance of common stock for services), and (ii) changes in operating assets and liabilities of \$387,811.

Our cash used in operating activities in the year ended December 31, 2014 totaled \$1,515,586 which is the sum of (i) our net loss of \$2,660,677, adjusted for non-cash expenses totaling \$6,969 (which includes adjustments for equity-based compensation, depreciation and amortization and the issuance of common stock for services), and (ii) changes in operating assets and liabilities of \$1,138,122.

Investing Activities

During the year ended March 31, 2017, we spent \$0 for property and equipment.

We had no net cash used in investing for the three month ended March 31, 2016 and 2015.

During the year ended December 31, 2015, we spent \$0 for property and equipment.

During the year ended December 31, 2014, we spent \$2,710 for property and equipment.

Financing Activities

During the year ended March 31, 2017, our financing activities consisted of the following:

- In October 2016, we raised \$1.47 million through a private placement of 452,314 shares of our common stock
- In March of 2017, we raised \$9.2 million in gross proceeds through a private placement of 3,588,620 shares of our common stock and 3,588,620 common stock purchase warrants (each, a "Warrant"). Each Warrant entitles its holder to purchase one share of common stock (each, a "Warrant Share") at an exercise price of \$3.00 per Warrant Share, subject to adjustment; and

During the three months ended March 31, 2016, our financing activities consisted primarily of the following:

- Pursuant to a Securities Purchase Agreement, dated as of February 2, 2016, for the aggregate consideration of \$3,100,000, the Company sold and issued to two individuals an aggregate of: (x) 775,000 shares of the common stock, par value \$0.0001 per share, of the Company and (y) 461,384 common stock purchase warrants. Each warrant entitles its holder to purchase one share of common stock at an initial exercise price of \$5.00 per warrant share (subject to adjustment) at any time during the period commencing on February 2, 2016 and terminating on the tenth anniversary of such date. No registration rights were granted to the purchasers of the shares and warrants.

During the three months ended March 31, 2015, our financing activities consisted primarily of the following:

- Contemporaneous with the closing of the Merger, the Company completed a private placement of 2,716,000 shares of Company common stock for gross proceeds of \$6,790,000 (of which, \$4,265,000 was tendered in cash and the remaining subscription price paid by the delivery of the three-month PPO Note in the principal amount of \$2,500,000).
- Gross proceeds of \$960,000 through the additional funding under and the corresponding amendment and restatement of the Bridge Note.
- In 2014, Tyme and Luminant granted cash advances totaling \$355,766 to certain of their then stockholders/members. Effective as of the consummation of the Merger during the three months ended March 31, 2015, these non-interest bearing advances were settled.

During the year ended December 31, 2015, our financing activities consisted primarily of the following:

- On December 23, 2015, pursuant to a Securities Purchase Agreement, dated as of December 18, 2015, for the aggregate consideration of \$3,000,000, the Company sold and issued to a total of three individuals and entities an aggregate of: (x) 750,000 shares of the common stock, par value \$0.0001 per share, of the Company and (y) 446,500 common stock purchase warrants. Each warrant entitles its holder to purchase one share of common stock at an initial exercise price of \$5.00 per warrant share (subject to adjustment) at any time during the period commencing on December 23, 2015 and terminating on the tenth anniversary of such date. No registration rights were granted to the purchasers of the shares and warrants.
- Effective as of December 21, 2015, pursuant to a Securities Acquisition Agreement, dated as of December 18, 2015, the Company issued to a law firm, in satisfaction of \$200,000 of payables due such law firm, an aggregate of (x) 50,000 shares of common stock and (y) 29,767 warrants. No registration rights were granted to the purchasers of the law firm shares and warrants.

During the year ended December 31, 2014, our financing activities consisted primarily of the following:

- On July 11, 2014, the Company entered into a Securities Purchase Agreement and received \$1,100,000 in proceeds from the issuance of a convertible promissory note (the "Bridge Note") of the Company, from an investor who is an affiliate of GEM. On November 24, 2014, the holder of the Bridge Note loaned the Company an additional \$250,000.
- Proceeds of \$200,000 from issuance of convertible notes.

Subsequent Events

Between April 1 and April 18, 2017, the Company raised approximately \$2,700,000 in gross proceeds through a private placement of 1,069,603 shares of common stock and 1,069,603 warrants, each of which entitles its holder to purchase one share of Common Stock at \$3.00 per share, subject to adjustment. The Company also received \$150,000 payment on stock subscription receivable.

Seasonality

The Company does not believe that its operations are seasonal in nature.

JOBS Act

For as long as we remain an “emerging growth company” under the Jumpstart Our Business Startups Act of 2012 (“JOBS Act”), we will, among other things:

- be exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act, which requires that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;
- be permitted to omit the detailed compensation discussion and analysis from proxy statements and reports filed under the Exchange Act and instead provide a reduced level of disclosure concerning executive compensation; and
- be exempt from any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation or a supplement to the auditor’s report on the financial statements.

We currently intend to take advantage of most or all of the reduced regulatory and reporting requirements that will be available to us so long as we qualify as an “emerging growth company.” Among other things, this means that our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an emerging growth company, which may increase the risk that weaknesses or deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as an emerging growth company, we may elect not to provide in our public reports and filings with the SEC certain information, including financial information and information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC, which may make it more difficult for investors and securities analysts to evaluate our Company. As a result, investor confidence in our Company and the market price of our common stock could be materially and adversely affected.

Section 107 of the JOBS Act also provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an “emerging growth company” can delay the adoption of new or revised accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Contractual Obligations and Commitments

At our current stage of development and at a stage where we have yet to secure material and recurring amounts of financial funding, we do not have any significant contractual obligations. We plan to enter into longer term obligations once we have a credible level of clarity on the financial resources consistently available to us.

Purchase Commitments

We have no material non-cancelable purchase commitments with contract manufacturers or service providers as we have generally contracted on a cancelable basis.

Off-Balance Sheet Arrangements

We do not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined by applicable SEC regulations. Accordingly, our operating results, financial condition, and cash flows are not subject to off-balance sheet risks.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market risk is the potential loss arising from adverse changes in market rates and market prices such as interest rates, foreign currency exchange rates, and changes in the market value of equity instruments. We do not believe we are currently exposed to any material market risk. As of March 31, 2017, we had \$10,482,977 of cash on hand in a U.S. bank account.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Tyme Technologies, Inc.

We have audited the accompanying consolidated balance sheet of Tyme Technologies, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of March 31, 2017 and March 31, 2016, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year ended March 31, 2017, the three months ended March 31, 2016 and the year ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Tyme Technologies, Inc. and subsidiaries as of March 31, 2017 and 2016, and the results of their operations and their cash flows for the year ended March 31, 2017, the three months ended March 31, 2016, and the year ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses from operation, negative cash flows and an accumulated deficit as of March 31, 2017. These conditions, along with other matters described in Note 1, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We also have audited the adjustments to the 2014 consolidated financial statements to retrospectively apply the impact of the reverse merger, as described in Note 1 to the consolidated financial statements. In our opinion, such adjustments are appropriate and have been properly applied. We were not engaged to audit, review, or apply any procedures to the 2014 consolidated financial statements of the Company other than with respect to such adjustments and, accordingly, we do not express an opinion or any other form of assurance on the 2014 financial statements taken as a whole.

/s/ GRANT THORNTON LLP

New York, New York
June 12, 2017

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of
Tyme Technologies, Inc. and Subsidiaries (formerly Tyme Inc. and Subsidiary)

We have audited, before the effects of the adjustments to retrospectively apply the change in accounting described in Note 1, the consolidated statements of operations and cash flows of Tyme Technologies, Inc. and Subsidiaries (formerly Tyme Inc. and Subsidiary) (the "Company") for the year ended December 31, 2014 (the 2014 financial statements before the effects of the adjustments discussed in Note 1 are not presented herein). The 2014 consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the 2014 consolidated financial statements, before the effects of the adjustments to retrospectively apply the change in accounting described in Note 1, present fairly, in all material respects, the financial position of Tyme Technologies, Inc. and Subsidiaries (formerly Tyme Inc. and Subsidiary) as of December 31, 2014, and the results of its operations and its cash flows for the year then ended in conformity with U.S. generally accepted accounting principles.

We were not engaged to audit, review, or apply any procedures to the adjustments to retrospectively apply the change in accounting described in Note 1 and, accordingly, we do not express an opinion or any other form of assurance about whether such adjustments are appropriate and have been properly applied. Those adjustments were audited by Grant Thornton LLP.

The fiscal year 2014 consolidated financial statements before the effects of the adjustments to retrospectively apply the change in accounting described in Note 1, were prepared assuming that the Company will continue as a going concern. For the year ended December 31, 2014, the Company incurred losses and negative cash flows since inception and had a stockholders' deficit of \$2,473,316. The Company continues to anticipate incurring additional losses until such time, if ever, that it can generate significant revenues from its product candidates currently in development. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plan in regards to these matters is described in Note 1. The 2014 consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ WithumSmith+Brown, PC
New Brunswick, New Jersey
April 15, 2015

Tyme Technologies, Inc. and Subsidiaries
Consolidated Balance Sheets

	March 31, 2017	March 31, 2016
Assets		
Current assets		
Cash and cash equivalents	\$ 10,482,977	\$ 6,105,309
Prepaid and other assets	228,362	226,098
Total current assets	10,711,339	6,331,407
Property and equipment, net	7,535	11,816
Total assets	<u>\$ 10,718,874</u>	<u>\$ 6,343,223</u>
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and other current liabilities	\$ 2,948,468	\$ 1,676,918
Derivative liability	378,600	—
Insurance note payable	—	232,100
Total current liabilities	3,327,068	1,909,018
Total liabilities	3,327,068	1,909,018
Commitments and contingencies (See Note 8)		
Stockholders' equity		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized at March 31, 2017 and 2016, 0 shares issued and outstanding at March 31, 2017 and 2016	—	—
Common stock, \$0.0001 par value, 300,000,000 shares authorized, 91,692,641 issued and 88,192,641 outstanding at March 31, 2017, and 300,000,000 authorized, 87,611,370 issued and 84,111,370 outstanding at March 31, 2016	9,172	8,763
Common stock, \$0.0001 par value, 58,823 shares subscribed	6	—
Additional paid in capital	41,419,714	23,080,749
Subscription receivable	(174,998)	—
Accumulated deficit	(33,862,088)	(18,655,307)
Total stockholders' equity	7,391,806	4,434,205
Total liabilities and stockholders' equity	<u>\$ 10,718,874</u>	<u>\$ 6,343,223</u>

The Notes to the Consolidated Financial Statements are an integral part of these statements.

Tyme Technologies, Inc. and Subsidiaries
Consolidated Statements of Operations

	Year Ended March 31, 2017	Three Months Ended March 31, 2016	2015 (Unaudited)	Year Ended December 31, 2015	2014
Operating expenses:					
Research and development	\$ 6,111,587	\$ 808,472	\$ 514,317	\$ 3,823,966	\$ 761,359
General and administrative	9,095,194	1,942,655	1,583,820	4,775,806	1,822,757
Total operating expenses	15,206,781	2,751,127	2,098,137	8,599,772	2,584,116
Loss from operations	(15,206,781)	(2,751,127)	(2,098,137)	(8,599,772)	(2,584,116)
Interest expense	—	—	3,503,301	3,503,301	76,561
Other income	—	—	—	(376,255)	—
Loss before income taxes	(15,206,781)	(2,751,127)	(5,601,438)	(11,726,818)	(2,660,677)
Income tax expense	—	—	—	—	—
Net loss	(15,206,781)	(2,751,127)	(5,601,438)	(11,726,818)	(2,660,677)
Loss attributable to non-controlling interests	—	—	—	—	(10,851)
Loss attributable to controlling interests	<u>\$ (15,206,781)</u>	<u>\$ (2,751,127)</u>	<u>\$ (5,601,438)</u>	<u>\$ (11,726,818)</u>	<u>\$ (2,649,826)</u>
Basic and diluted loss per common share	<u>\$ (0.18)</u>	<u>\$ (0.03)</u>	<u>\$ (0.08)</u>	<u>\$ (0.15)</u>	<u>\$ (0.04)</u>
Basic and diluted weighted average shares outstanding	<u>84,454,587</u>	<u>83,796,260</u>	<u>73,400,081</u>	<u>77,848,850</u>	<u>68,000,000</u>

The Notes to the Consolidated Financial Statements are an integral part of these statements.

Tyme Technologies, Inc. and Subsidiaries
Consolidated Statements of Stockholders' Equity
For the Year Ended March 31, 2017, Three Months Ended March 31, 2016, and Year Ended December 31, 2015

	Common Stock		Subscribed Shares	Subscribed Amount	Additional Paid-in capital	Subscription Receivable	Accumulated Deficit	Non- controlling Interests	Due from Stockholders/ Members	Total Stockholders' Equity (Deficit)
	Shares	Amount								
Balance at January 1, 2014	68,000,000	\$ 6,800	—	\$ —	\$ —	\$ —	\$ (1,527,536)	\$ 1,976,693	\$ (1,306,238)	\$ (850,281)
Conversion of \$1.126 million convertible debt plus accrued interest of \$26,242 into 3,624,400 shares of common stock	3,624,400	—	—	—	1,152,242	—	—	—	—	1,152,242
Surrender of 3,624,400 common stock by two principal stockholders of the Company	(3,624,400)	—	—	—	—	—	—	—	—	—
Capital contributions	—	—	—	—	—	—	—	35,000	—	35,000
Advances to stockholders/members	—	—	—	—	—	—	—	—	(149,600)	(149,600)
Luminant stockholder loans assigned in buyout of noncontrolling interests by certain stockholders of Tyme	—	—	—	—	(1,100,072)	—	—	—	1,100,072	—
Contribution of noncontrolling interests	—	—	—	—	2,000,842	—	—	(2,000,842)	—	—
Net Loss attributable to noncontrolling interests prior to contribution of noncontrolling interests	—	—	—	—	—	—	—	(10,851)	—	(10,851)
Net loss	—	—	—	—	—	—	(2,649,826)	—	—	(2,649,826)
Balance, January 1, 2015	68,000,000	\$ 6,800	—	—	\$ 2,053,012	\$ —	\$ (4,177,362)	—	\$ (355,766)	\$ (2,473,316)
Repayment of stockholder loans	—	—	—	—	—	—	—	—	355,766	355,766
Common stock issued as part of the Merger	12,724,000	1,272	—	—	(1,272)	—	—	—	—	—
Issuance of common stock and warrants for services	300,000	30	—	—	824,970	—	—	—	—	825,000
Issuance of common stock and warrants in private placement offering for cash, net of associated expense	2,466,000	247	—	—	7,230,703	—	—	—	—	7,230,950
Issuance of common stock in private placement offering in exchange for subscription receivable	1,000,000	100	—	—	2,499,900	(2,500,000)	—	—	—	—
Issuance of common stock upon conversion of Bridge Note and accrued interest	2,310,000	231	—	—	2,404,243	—	—	—	—	2,404,474
Incremental value of the modification to Bridge Note conversion rate as an inducement to convert	—	—	—	—	3,465,000	—	—	—	—	3,465,000
Stock based compensation	36,370	5	—	—	324,995	—	—	—	—	325,000
Fair value of price protection feature associated with shares issued under the PPO and Bridge Note conversion	—	—	—	—	(376,300)	—	—	—	—	(376,300)
Amortization of employee stock options	—	—	—	—	485,859	—	—	—	—	485,859
Proceeds from the collection of stock subscription receivable	—	—	—	—	—	2,500,000	—	—	—	2,500,000
Net loss	—	—	—	—	—	—	(11,726,818)	—	—	(11,726,818)
Balance, January 1, 2016	86,836,370	\$ 8,685	—	\$ —	\$ 18,911,110	\$ —	\$ (15,904,180)	\$ —	\$ —	\$ 3,015,615
Issuance of common stock in private placement offering for cash, net of associated expense	775,000	78	—	—	3,032,204	—	—	—	—	3,032,282
Stock based compensation	—	—	—	—	1,137,435	—	—	—	—	1,137,435
Net loss	—	—	—	—	—	—	(2,751,127)	—	—	(2,751,127)
Balance, April 1, 2016	87,611,370	\$ 8,763	—	\$ —	\$ 23,080,749	\$ —	\$ (18,655,307)	\$ —	\$ —	\$ 4,434,205
Issuance of common stock and warrants in private placement offering for cash, net of associated expenses	3,529,797	353	—	—	9,000,537	—	—	—	—	9,000,890
Issuance of common stock in private placement offering in exchange for stock subscription receivable	7,692	1	—	—	24,998	(24,999)	—	—	—	—
Issuance of common stock and warrants in private placement offering for cash, net of associated expense	452,314	45	—	—	1,469,960	—	—	—	—	1,470,005
Stock Subscription Receivable Private placement of \$9.2M	—	—	58,823	6	149,993	(149,999)	—	—	—	—
Derivative liability	—	—	—	—	(378,600)	—	—	—	—	(378,600)
Stock based compensation	—	—	—	—	7,721,837	—	—	—	—	7,721,837
Issuance of common stock for services	75,000	8	—	—	250,242	—	—	—	—	250,250
Issuance of stock to Scientific Advisory Board members	16,468	2	—	—	99,998	—	—	—	—	100,000
Net loss	—	—	—	—	—	—	(15,206,781)	—	—	(15,206,781)
Balance, March 31, 2017	91,692,641	\$ 9,172	58,823	\$ 6	\$ 41,419,714	\$ (174,998)	\$ (33,862,088)	\$ —	\$ —	\$ 7,391,806

The Notes to the Consolidated Financial Statements are an integral part of these statements.

Tyme Technologies, Inc. and Subsidiaries
Consolidated Statements of Cash Flows

	Year Ended March 31, 2017	Three Months Ended March 31, 2016	2015 (unaudited)	Year Ended, December 31 2015	2014
Cash flows from operating activities:					
Net loss	\$ (15,206,781)	\$ (2,751,127)	\$ (5,601,438)	\$ (11,726,818)	\$ (2,660,677)
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation	4,281	1,062	1,074	4,292	4,293
Issuance of common stock for services	350,250	—	625,000	825,000	—
Stock—based compensation	—	—	50,000	325,000	—
Amortization of employees, directors and consultants stock options,	7,721,837	1,137,435	—	485,859	—
Inducement for conversion of Bridge Note to common shares	—	—	3,465,000	3,465,000	—
Gain on remeasurement of derivative liability	—	—	—	(376,300)	—
Loss on disposal of fixed assets	—	—	—	—	2,676
Changes in operating assets and liabilities:					
Prepaid and other assets	(2,264)	36,786	(244,020)	109,421	(30,025)
Accounts payable and other current liabilities	1,271,550	202,587	(577,299)	278,390	1,168,147
Net cash used in operating activities	(5,861,127)	(1,373,257)	(2,281,683)	(6,610,156)	(1,515,586)
Cash flows from investing activities:					
Purchases of property and equipment	—	—	—	—	(2,710)
Net cash used in investing activities	—	—	—	—	(2,710)
Cash flows from financing activities:					
Insurance note payments	(232,100)	—	—	—	—
Capital contributions – non-controlling interest	—	—	—	—	35,000
Repayment from (advances to) stockholders/members	—	—	355,766	355,766	(149,600)
Change in due to officer	—	—	17,623	—	—
Proceeds from Bridge Note	—	—	960,000	960,000	1,350,000
Proceeds from private placement offering of common stock and warrants, net	10,470,895	3,032,282	4,264,950	7,230,950	—
Proceeds from issuance of convertible notes	—	—	—	—	200,000
Proceeds from the collection of stock subscription receivable	—	—	—	2,500,000	—
Net cash provided by financing activities	10,238,795	3,032,282	5,598,339	11,046,716	1,435,400
Net increase (decrease) in cash	4,377,668	1,659,025	3,316,656	4,436,560	(82,896)
Cash and cash equivalents — beginning of period	6,105,309	4,446,284	9,724	9,724	92,620
Cash and cash equivalents — end of period	\$ 10,482,977	\$ 6,105,309	\$ 3,326,380	\$ 4,446,284	\$ 9,724
Supplemental Cash Flow Information:					
Cash paid for interest and income taxes are as follows:					
Interest	\$ —	\$ —	\$ —	\$ —	\$ —
Income taxes	\$ —	\$ —	\$ —	\$ 675	\$ —
Noncash investing and financing activities:					
Financing of insurance premiums	\$ —	\$ 232,100	\$ —	\$ —	\$ —
Conversion of the Bridge Note and all accrued interest into shares of common stock	\$ —	\$ —	\$ 2,404,474	\$ 2,404,474	\$ —
Subscribed and subscription receivable shares in conjunction with private placement offering	\$ 174,998	\$ —	\$ 2,500,000	\$ 2,500,000	\$ —
Inducement for conversion of Bridge Note to common shares	\$ —	\$ —	\$ 3,465,000	\$ 3,465,000	\$ —
Derivative liability associated with the price protection feature of shares of common stock issued	\$ 378,600	\$ —	\$ 376,300	\$ 376,300	\$ —
Conversion of \$1.126 million of convertible debt into 3,624,400 shares of common stock; simultaneously, stockholders surrendered an equal amount of their own common stock, thereby having no change in the total number of shares outstanding	\$ —	\$ —	\$ —	\$ —	\$ 1,152,242
Luminant member advances assigned in buyout of noncontrolling interest	\$ —	\$ —	\$ —	\$ —	\$ 1,100,072
Contribution of noncontrolling interests by stockholders of Tyme Inc.	\$ —	\$ —	\$ —	\$ —	\$ 2,000,842

The Notes to the Consolidated Financial Statements are an integral part of these statements.

Tyme Technologies, Inc. and Subsidiaries
Notes to Consolidated Financial Statements

(Notes relating to the three month period ending March 31, 2015 are unaudited)

Note 1. Nature of Business

Tyme Technologies, Inc. ("Tyme Tech") and its wholly owned subsidiaries, Tyme Inc. ("Tyme") and Luminant Biosciences, LLC ("Luminant") (collectively, the "Company") have historically operated on a fiscal year ending December 31 of each year.

The unaudited consolidated financial statements have been prepared on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position, results of operations and cash flows for the three months ended March 31, 2015.

The accompanying consolidated financial statements include the results of operations of Tyme Tech and its wholly owned subsidiaries, Tyme and Luminant. Luminant conducted the initial research and development of the Company's therapeutic platform. Since January 1, 2014, the majority of the Company's research and development activities and other business efforts have been conducted by Tyme.

Tyme Tech was incorporated in the State of Florida on November 22, 2011, and, effective as of September 18, 2014, the Company (then constituting a Florida corporation with the name Global Group Enterprises Corp.) reincorporated in the State of Delaware by merging into its wholly-owned Delaware subsidiary, Tyme Technologies, Inc., which was formed on August 22, 2014 specifically for this purpose (the "Reincorporation"). Tyme Technologies, Inc. was the surviving corporation in such merger.

On March 5, 2015, Tyme Tech consummated a reverse triangular merger with Tyme (the "Merger"). (See Reverse Triangular Merger below.) The Merger resulted in Tyme becoming a wholly-owned subsidiary of Tyme Tech. Tyme is a clinical-stage biopharmaceutical company focused on the development and commercialization of highly targeted cancer therapeutics with a broad range of oncology indications for humans. Tyme was incorporated in Delaware in 2013 and its operations to date have been directed primarily toward developing business strategies, research and development activities and preparing for clinical trials for human oncologic product candidates. In June of 2016, the Company initiated a Phase Ib/II clinical study subject to United States Food and Drug Administration (the "FDA") review for SM-88 use in human prostate cancer patients and as of March 31, 2017, such study was progressing as a Phase II program. The Company is also evaluating the expansion of its Phase II program to other types of cancer, including pancreatic cancer.

Reverse Triangular Merger

On March 5, 2015, Tyme Tech consummated a reverse triangular merger whereby a newly formed subsidiary formed specifically for the transaction merged with and into Tyme. The Merger resulted in Tyme becoming a wholly-owned subsidiary of Tyme Tech and the stockholders of Tyme as of immediately prior to the effective date of the Merger (the "Pre-Merger Tyme Stockholders"), receiving, in the aggregate, common stock of the Company equal to approximately 79% of the total number of shares of Company common stock outstanding immediately following such issuance to such former Tyme stockholders (34,000 shares of Company common stock for every one share of Tyme common stock outstanding as of the closing of the Merger). The Merger resulted in the Company issuing a total of 68,000,000 shares of common stock to the Pre-Merger Tyme Stockholders and 12,724,000 shares to the Tyme Tech stockholders as of the date of the Merger. (See Note 7. Stockholders' Equity.)

The Merger Agreement contained representations and warranties and pre- and post-closing covenants of each party and customary closing conditions. Breaches of the representations and warranties under the Merger Agreement are subject to indemnification provisions. Each of the Pre-Merger Tyme Stockholders initially received in the Merger 95% of the shares to which each such stockholder was entitled under the terms of the Merger Agreement, with the remaining 5% of such shares being held in escrow for two years to satisfy post-closing claims for indemnification by the Company ("Indemnity Shares"), pursuant to an Indemnification Shares Escrow Agreement. As the Company and the indemnification representative are aware of no post-closing claims during the two-year period, a joint instruction was sent on April 7, 2017 asking for the release of the Indemnity Shares. The Company expects all of the Indemnity Shares to be distributed to the Pre-Merger Tyme Stockholders on a *pro rata* basis in June of 2017.

Contemporaneous with the closing of the Merger, among other matters, the Company completed a private placement offering (the “PPO”) of 2,716,000 shares of Company common stock (the “PPO Shares”) for gross proceeds of \$6,790,000 (of which, \$4,264,000 was tendered in cash and the remaining subscription price paid by the delivery of a three-month promissory note in the principal amount of \$2,500,000 (“PPO Note”). In addition, a Tyme convertible promissory note in the principal amount of \$2,310,000 (the “Bridge Note”) was converted into 2,310,000 shares (the “Bridge Note Shares”) of Company common stock. The foregoing aggregate 79% ownership of the post-Merger Company by the former Tyme stockholders was calculated giving effect to the issuances of Company common stock in the PPO, the conversion of the Bridge Note and surrender of stock for cancellation by certain stockholders of the Pre-Merger Company. The purchaser of the PPO Shares and party receiving the Bridge Shares upon conversion of the Bridge Note were granted certain registration rights with respect to such shares (such shares being collectively referred to as the PPO/Bridge Note Conversion Registrable Shares”). The PPO Note was originally secured by the escrow of 5,000,000 shares of Company common stock pursuant to a Subscription Note Shares Escrow Agreement, dated as of March 5, 2015 (the “Subscription Note Escrow Agreement”). As originally provided in the Subscription Note Escrow Agreement, to the extent that the PPO Note was not paid at or prior to its maturity date of June 5, 2015, the escrowed shares would be forfeited for cancellation at the rate of one share for every \$0.50 of PPO Note principal not paid. The Company received a payment of \$1,250,000 in June 2015 and the maturity date on the remaining principal amount of the PPO Note was extended to July 6, 2015 pursuant to an Omnibus Amendment, dated as of June 5, 2015 (the “First Omnibus Amendment”). The Company entered into a Second Omnibus Amendment as of July 23, 2015 (the “Second Omnibus Amendment”), pursuant to which the terms of certain agreements entered into in connection with the Merger were modified and amended. Under the Second Omnibus Amendment, (x) the Company agreed to the extension of the maturity date of the remaining \$1,250,000 outstanding amount due under the PPO Note to a date five business days following the Company providing the maker of the PPO Note of written evidence that an Investigational New Drug Application for the Company’s SM-88 drug candidate has been submitted by the Company to the FDA, (y) the holder of all of the PPO/Bridge Note Conversion Registrable Shares irrevocably waived any liquidated damages with respect to the date of filing or the effective date of the registration statement contemplated by a Registration Rights Agreement entered into in connection with the consummation of the Merger and PPO and (z) the amount of shares that the former-Tyme stockholders may include in such registration statement was increased to 15% of the total number of shares such stockholders received in connection with the Merger.

The Merger established a public forum for the Company. Subject to executing on the Company’s goals, management envisages that the public forum may help the Company secure necessary future funding in the public markets as the Company further develops its business as a clinical-stage biopharmaceutical enterprise focused on the development and commercialization of highly targeted cancer therapeutics for humans with a broad range of oncology indications.

The transaction costs associated with the Merger relate to professional fees incurred in respect of legal, investor relations, accounting and audit. All such transaction costs total approximately \$1,000,000 and are included in general and administrative expense for the three months ended March 31, 2015 and for the year ended December 31, 2015.

For accounting purposes, the acquisition of Tyme by Tyme Tech was considered a reverse acquisition, an acquisition transaction where the acquired company, Tyme, is considered the acquirer for accounting purposes, notwithstanding the form of the transaction. The primary reason the transaction was treated as a purchase by Tyme rather than a purchase by Tyme Tech was because Tyme Tech was a public reporting shell company with limited operations and Tyme’s stockholders gained majority control of the outstanding voting power of the Company’s equity securities through their collective ownership of a majority of the outstanding shares of Company common stock. Consequently, reverse acquisition accounting has been applied to the transaction.

The capital structure, including the number and type of shares issued appearing in the consolidated balance sheets for the periods presented, reflects that of the legal parent or accounting acquiree, Tyme Tech, including the shares issued to effect the reverse acquisition after the Merger and the capital structure of Tyme modified by the 34,000-for-1 exchange ratio in the Merger for the periods prior to the consummation of the Merger. As a result of the Merger and its accounting treatment as a reverse acquisition, stockholders’ equity has been retrospectively adjusted as of the earliest period presented in these consolidated financial statements. These adjustments include an increase of \$6,798 to the par value of common stock issued, a decrease of \$2,008 to additional paid-in capital and an increase in accumulated deficit of \$4,790 as of January 1, 2014. There was no change to total stockholders’ equity (deficit) as a result of the Merger.

Going Concern

The Company has incurred losses and negative cash flows from operations since inception (July 26, 2013) and has an accumulated deficit of \$33,862,088 as of March 31, 2017. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant revenues from its products currently in development. The Company's primary sources of liquidity to date have been the issuance of common stock, convertible promissory notes and contributed capital by its founders. Substantial additional financing will be needed by the Company to fund its operations and to seek applicable FDA and foreign governmental authorization to commercially market its product candidates. There is no assurance that such financing will be available when needed or on acceptable terms. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued.

The consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded assets amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Management is evaluating different strategies to obtain the required additional funding for future operations. These strategies may include, but are not limited to, additional funding from current or new investors, officers and directors; borrowings of debt; public or private offerings of the Company's equity or debt securities; partnerships and/or collaborations. There can be no assurance that any of these future-funding efforts will be successful.

Note 2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Significant Accounting Policies

Principles of Consolidation

The Company's consolidated financial statements include the accounts of Tyme Tech and its subsidiaries, Tyme and Luminant. All intercompany transactions and balances have been eliminated in consolidation.

Risks and Uncertainties

The Company is subject to those risks associated with any specialty pharmaceutical company that has substantial expenditures for research and development. There can be no assurance that the Company's research and development projects will be successful, that products developed will obtain necessary regulatory approval or that any approved product will be commercially viable. In addition, the Company operates in an environment of rapid technological change and is largely dependent on the services of its employees and consultants, as well as third party contractors.

Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of revenues and expenses during the reporting period. Significant items subject to such estimation include the fair value of the Company underlying the conversion feature of the senior secured bridge notes, derivative value associated with the price protection feature of shares of Company common stock issued in connection with the PPO and Bridge Note conversion and stock-based compensation. Actual results could differ from such estimates.

Cash and Cash Equivalents

The Company considers all highly-liquid investments that have maturities of three months or less when acquired to be cash equivalents. The Company's cash and cash equivalents consisted of \$10,482,977 at March 31, 2017 and \$6,105,309 at March 31, 2016.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentration of credit risk consist primarily of cash. Cash is deposited with major banks and, at times, such balances with any one financial institution may be in excess of FDIC insurance limits. The Company exceeded the FDIC limit of \$250,000 by \$10,232,977 at March 31, 2017 and \$5,855,309 at March 31, 2016. Although the Company has exceeded the federally insured limit, it has not incurred losses related to these deposits. Management monitors the Company's accounts with these institutions to minimize credit risk.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, including cash, accounts payable and other current liabilities approximates fair value given their short-term nature. The fair value of the derivative liability is discussed below.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

Fair value should be based on the assumptions that market participants would use when pricing an asset or liability and is based on a fair value hierarchy that prioritizes the information used to develop those assumptions. The fair value hierarchy gives the highest priority to quoted prices in active markets (observable inputs) and the lowest priority to the Company's assumptions (unobservable inputs). Fair value measurements should be disclosed separately by level within the fair value hierarchy. For assets and liabilities recorded at fair value, it is the Company's policy to maximize the use of observable inputs and minimize the use of unobservable inputs when developing fair value measurements, in accordance with established fair value hierarchy.

Fair value measurements for assets and liabilities where there exists limited or no observable market data are based primarily upon estimates, and often are calculated based on the economic and competitive environment, the characteristics of the asset or liability and other factors. Therefore, the results cannot be determined with precision and may not be realized in an actual sale or immediate settlement of the asset or liability. Additionally, there may be inherent weaknesses in any calculation technique, and changes in the underlying assumptions used, including discount rates and estimates of future cash flows, could significantly affect the results of current or future values.

Additionally, from time to time, the Company may be required to record at fair value other assets on a nonrecurring basis, such as assets held for sale and certain other assets. These nonrecurring fair value adjustments typically involve application of lower-of-cost-or-market accounting or write-downs of individual assets.

Fair value guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Level 3 valuations are for instruments that are not traded in active markets or are subject to transfer restrictions and may be adjusted to reflect illiquidity and/or non-transferability, with such adjustment generally based on available market evidence. In the absence of such evidence, management's best estimate is used.

An adjustment to the pricing method used within either Level 1 or Level 2 inputs could generate a fair value measurement that effectively falls in a lower level in the hierarchy. The Company had no assets or liabilities classified as Level 1 or Level 2 for the year ended March 31, 2017, the three months ended March 31, 2016 and the year ended December 31, 2015 and 2014 and there were no material re-measurements of fair value with respect to financial assets and liabilities, during those periods, other than those assets and liabilities that are measured at fair value on a recurring basis. There were no transfers between Level 1 and Level 2 in any of the periods reported.

Assets and liabilities measured at fair value on a recurring basis as of March 31, 2017 are summarized below:

	Level 1	Level 2	Level 3	Total
March 31, 2017				
Liabilities:				
Derivative liability – anti-dilution feature	\$ —	\$ —	\$ 378,600	\$ 378,600
Total	\$ —	\$ —	\$ 378,600	\$ 378,600

The change in the fair value of the derivative liability for the year ended March 31, 2017 was de minimis.

The fair value of the derivative liability as of March 31, 2017 was estimated using a Monte Carlo simulation model using the following assumptions:

Volatility	70%
Risk-Free Interest Rate	0.83%
Expected Term in Years	4.7 months
Dividend Rate	0.00%
Fair Value of Common Stock Share	\$1.78

Prepaid Assets

Prepaid assets represent expenditures made in advance of when the economic benefit of the cost will be realized, and which will be expensed in future periods with the passage of time.

Property and Equipment, Net

Property and equipment are recorded at cost and are depreciated on a straight-line basis over their estimated useful lives. The Company estimates a life of five to seven years for equipment and furniture and fixtures. Upon sale or retirement, the cost and related accumulated depreciation are removed from the accounts and the resulting gain or loss is reflected in results of operations. Repairs and maintenance costs are expensed as incurred.

Impairment of Long-Lived Assets

The Company assesses the recoverability of its long-lived assets, which include fixed assets, whenever significant events or changes in circumstances indicate impairment may have occurred. If indicators of impairment exist, projected future undiscounted cash flows associated with the asset are compared to its carrying amount to determine whether the asset's value is recoverable. Any resulting impairment is recorded as a reduction in the carrying value of the related asset in excess of fair value and a charge to operating results. For the year ended March 31, 2017, the three months ended March 31, 2016 and the year ended December 31, 2015 and 2014, the Company determined that there were no triggering events requiring an impairment analysis.

Research and Development

Research and development costs are expensed as incurred and are primarily comprised of, but not limited to, external research and development expenses incurred under arrangements with third parties, such as contract research organizations ("CROs"), contract manufacturing organizations ("CMOs") and consultants that conduct clinical and preclinical studies, costs associated with preclinical and development activities, costs associated with regulatory operations, depreciation expense for assets used in research and development activities and employee related expenses, including salaries and benefits for research and development personnel. Costs for certain development activities, such as clinical studies, are accrued, over the service period specified in the contract and recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the patterns of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued expense, which are reported in prepaid assets or accounts payable and other current liabilities.

Income Taxes

Income tax expense, deferred tax assets and liabilities, and liabilities for unrecognized tax benefits reflect management's best estimate of current and future taxes to be paid. The Company is subject to income taxes in the United States, for Federal and various State jurisdictions. Significant judgments and estimates are required in the determination of the income tax expense.

Deferred income taxes arise from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements, which will result in taxable or deductible amounts in the future. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

A valuation allowance is provided when, after consideration of all positive and negative evidence that it is less likely than not that the benefit from Federal and State Net Operating Losses (NOLs) will be realizable. In recognition of this risk, the Company has provided a full valuation allowance on the deferred tax assets related to these NOL carryforwards. The assumptions about future taxable income require the use of significant judgment and are consistent with the plans and estimates we are using to manage the underlying businesses. In evaluating the objective evidence that historical results provide, we consider three years of cumulative operating income (loss).

The calculation of tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations in various jurisdictions. ASC 740 "Income Taxes" states that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits.

The Company had unrecognized tax benefits of \$617,233 and \$331,545 at March 31, 2017 and 2016, respectively and no unrecognized tax benefits at December 31, 2015 and 2014. Increases or decreases in such benefits would have no effect on the effective tax rate. The tax years, which currently remain subject to examination by major tax jurisdictions as of March 31, 2017 are the period January 1, 2016 through March 31, 2016, years ended December 31, 2015 and 2014 and for the period July 26, 2013 to December 31, 2013. In addition, the Company had no income tax related penalties or interest for periods presented in these consolidated financial statements. When and if the Company were to recognize interest and penalties related to unrecognized tax benefits, they would be reported in tax expense.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views their operations and manages their business in one segment.

Derivative Liabilities

Accounting standards require presentation of derivative liabilities at fair value. Derivative liabilities are adjusted to reflect fair value at the end of each reporting period, with any change in the fair value being recorded in results of operations as a component of other income or expense.

Basic and Diluted Loss Per Share

The Company calculates net loss per share in accordance with ASC Topic 260, "Earning per Share". Basic net loss per share is computed by dividing net loss attributable to the Company by the weighted average number of shares of Company common stock outstanding for the period, and diluted earnings per share is computed by including common stock equivalents outstanding for the period. During the periods presented, the calculation excludes any potential dilutive common shares and any equivalents as they would have been anti-dilutive as the Company incurred losses for the periods then ended.

Stock-based Compensation

The Company follows the authoritative guidance for accounting for stock-based compensation in ASC 718, Compensation-Stock Compensation. The guidance requires that stock-based payment transactions be recognized in the financial statements based on their fair value at the grant date and recognized as compensation expense over the vesting period as services are being provided. (See Note 10, Equity Incentive Plan.)

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected term of the option, risk-free interest rates, the value of the common stock and expected dividend yield of the common stock. For awards subject to time-based vesting conditions, the Company recognizes stock-based compensation expense equal to the grant date fair value of stock options on a straight-line basis over the requisite service period, which is generally the vesting term. Forfeitures are required to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The Company accounts for stock-based awards issued to non-employees in accordance with ASC 505-50, "Equity-Based Payment to Non-Employees" and accordingly the fair value of the stock options granted to non-employees is remeasured each reporting period until the earlier of: a) the performance commitment date, or b) the date the services required under the arrangement have been completed and the resulting increase or decrease in value, if any, is recognized as expense or income, respectively, during the period the related services are rendered.

Recent Accounting Pronouncements

In May 2017, the FASB issued ASU No. 2017-09, Compensation - Stock Compensation, which is intended to reduce both (1) diversity in practice and (2) cost and complexity when applying the guidance in Topic 718, Compensation—Stock Compensation, to a change to the terms or conditions of a share-based payment award. The amendments in this Update are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017 with early adoption permitted. The Company has chosen to early adopt ASU No. 2017-09, Compensation – Stock Compensation. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In February 2017, the FASB issued Update No. 2017-05, Other Income-Gains and Losses from the Derecognition of Nonfinancial Assets (Subtopic 610-20): Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets. This update is meant to clarify the scope of ASC Subtopic 610-20, Other Income-Gains and Losses from the Derecognition of Nonfinancial Assets and to add guidance for partial sales of nonfinancial assets. This guidance is to be applied using a full retrospective method or a modified retrospective method as outlined in the guidance and is effective at the same time as Update 2014-09. Further, the Company is required to adopt this guidance at the same time that it adopts the guidance in Update 2014-09. The Company is currently evaluating the provisions of this guidance and assessing its potential impact on the Company's financial condition and results of operations.

In January 2017, the FASB issued ASU 2017-01, amending Business Combinations: Clarifying the Definition of a Business, to clarify the definition of a business with the objective of providing a more robust framework to assist management when evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The standard will be effective for the Company for its fiscal year beginning April 1, 2018, including interim periods within that fiscal year, with early application permitted. The amendments are to be applied prospectively to business combinations that occur after the effective date.

In August 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update or ASU, 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"), which amended the existing accounting standards for the statement of cash flows. The amendments provide guidance on eight classification issues related to the statement of cash flows. The Company is required to adopt the guidance in the first quarter of fiscal 2019 and early adoption is permitted. The amendments should be applied retrospectively to all periods presented. For issues that are impracticable to apply retrospectively, the amendments may be applied prospectively as of the earliest date practicable. The Company is currently in the process of assessing the impact of ASU 2016-15 on its statement of cash flows.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses* ("ASU 2016-13"), which introduces a new model for recognizing credit losses on financial instruments based on an estimate of current expected credit losses. ASU 2016-13 will apply to (1) loans, accounts receivable, trade receivables, and other financial assets measured at amortized cost, (2) loan commitments and other off-balance sheet credit exposures, (3) debt securities and other financial assets measured at fair value through other comprehensive income, and (4) beneficial interests in securitized financial assets. ASU 2016-13 will be effective in fiscal years beginning after December 15, 2019 including interim periods within those fiscal years. The Company is currently in the process of assessing the impact of ASU 2016-13 on the Company's financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting* (“ASU 2016-09”), which provides for simplification of certain aspects of employee share-based payment accounting including income taxes, classification of awards as either equity or liabilities, accounting for forfeitures and classification on the statement of cash flows. ASU 2016-09 will be effective for the Company in the first quarter of 2017 and will be applied either prospectively on the area covered in this update. The Company is currently in the process of assessing the impact of ASU 2016-09 on the Company’s consolidated financial statements and disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* (“ASU 2016-02”). The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 is effective for annual periods beginning after December 15, 2019, and for interim periods within fiscal years beginning after December 15, 2020, with early adoption permitted. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact that the standard will have on its consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments - Overall (Subtopic 825-10), Recognition and Measurement of Financial Assets and Financial Liabilities* (“ASU 2016-1”), which addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. ASU 2016-01 will be effective for the Company for annual periods and interim periods within those annual periods beginning after December 15, 2018 and early adoption is not permitted. The Company does not anticipate that the adoption of this standard will have a material impact on its consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17, *Income Taxes (Topic 740)*. The amendments in this update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The Company did not retrospectively adjust the prior periods within the Balance Sheet. The early adoption ASU 2015-17 did not have a material impact on the Company’s financial position, results of operations or liquidity. The reason for the change is to simplify the presentation of deferred income taxes.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern*, which provides guidance on determining when and how reporting entities must disclose going-concern uncertainties in their financial statements. The new standard requires management to perform interim and annual assessments of an entity’s ability to continue as a going concern within one year of the date of issuance of the entity’s financial statements (or within one year after the date on which the financial statements are available to be issued, when applicable). Further, an entity must provide certain disclosures if there is “substantial doubt about the entity’s ability to continue as a going concern.” This guidance is effective for annual reporting periods ending after December 15, 2016, and for annual periods and interim periods thereafter, with early adoption permitted. The Company has adopted this ASU during the year ended March 31, 2017. Management has evaluated the impact of the adoption of these changes and has determined there is no material impact on the consolidated financial statements.

Note 3. Net Loss Per Common Share

The following table sets forth the computation of basic and diluted net loss per common share for the periods indicated (in thousands, except share and per share data):

	Year Ended March 31, 2017	Three Months Ended March 31, 2015 (Unaudited)		Year Ended December 31, 2015 2014	
Basic and diluted net loss per common share calculation					
Net loss	\$ (15,206,781)	\$ (2,751,127)	\$ (5,601,438)	\$ (11,726,818)	\$ (2,660,677)
Weighted average common shares outstanding — basic and diluted	84,454,587	83,796,260	73,400,081	77,848,850	68,000,000
Net loss per share of common stock — basic and diluted	\$ (0.18)	\$ (0.03)	\$ (0.08)	\$ (0.15)	\$ (0.04)

The following outstanding securities at March 31, 2017, 2016 and 2015 (unaudited) and December 31, 2015 and 2014 have been excluded from the computation of diluted weighted average shares outstanding, as they would have been anti-dilutive:

	Year Ended March 31, 2017	Three Months Ended March 31, 2016 (Unaudited)	Year Ended December 31, 2015	Year Ended December 31, 2014
Stock options	4,039,444	350,000	150,000	—
Warrants	4,556,038	937,651	476,267	—
Total	8,595,482	1,287,651	626,267	—

Note 4. Property and Equipment, Net.

Property and equipment, net consisted of the following:

	March 31, 2017	March 31, 2016
Machinery and equipment	\$ 21,463	\$ 21,463
Less: accumulated depreciation	13,928	9,647
	<u>\$ 7,535</u>	<u>\$ 11,816</u>

Depreciation expense was \$4,281 for the year ended March 31, 2017, \$1,062 and \$1,074 for the three months ended March 31, 2016 and 2015, respectively, and \$4,292 and \$4,293 for the year ended December 31, 2015 and 2014, respectively.

Note 5. Accounts Payable and Other Current Liabilities.

Accounts payable and other current liabilities consisted of the following:

	March 31, 2017	March 31, 2016
Legal	\$ 1,443,084	\$ 795,478
Consulting	60,317	44,056
Accounting and auditing	69,738	143,357
Research and development	644,546	324,787
Board of Directors and Scientific Advisory Board compensation	487,500	337,500
Insurance	232,100	12,925
Other	11,183	18,815
	<u>\$ 2,948,468</u>	<u>\$ 1,676,918</u>

Note 6. Debt.

Insurance Note Payable

The Company entered into an agreement to finance director and officer insurance totaling \$232,100 for the policy year ending in March 2017. The balance at March 31, 2017 and March 31, 2016 was \$0 and \$232,100, respectively.

Bridge Notes Payable

On July 11, 2014, Tyme received \$1,100,000 in proceeds from the issuance of a convertible promissory note (the “Bridge Note”) from an affiliate of GEM Global Yield Fund, LLC SCS (“GEM”). The Bridge Note bears interest at a rate of 10% per year, maturing fifteen months from the date of issue and was secured by all assets of Tyme. The Bridge Note was mandatorily convertible into Company common stock upon the closing of the PPO. To secure certain obligations relating to the Bridge Note and the then proposed merger, Tyme issued in the name of the purchaser of the Bridge Note shares of the Company’s stock which were placed into escrow shares of Company common stock. These shares were not deemed outstanding, but would either be delivered to the Bridge Note purchaser or returned to Tyme for cancellation pursuant to the terms of a Termination Shares Escrow Agreement, dated as of July 11, 2014, among Tyme, the purchaser of the Bridge Note and the escrow agent. Subsequently, such escrow concerning the Bridge Note was terminated in accordance with the applicable provisions of the Termination Shares Escrow Agreement, those shares of Company common stock were released by the escrow agent to the Company, and the Company then cancelled those shares of common stock.

On November 24, 2014, the purchaser of the Bridge Note loaned Tyme an additional \$250,000. In connection with the funding of such loan, the Bridge Note was amended and restated to reflect a principal amount of \$1,350,000.

On January 15, 2015, the purchaser of the Bridge Note loaned Tyme an additional \$960,000. In connection with the funding of such further loan, the Bridge Note was amended and restated to reflect a principal amount of \$2,310,000. On March 5, 2015, the Bridge Note was further amended and restated to the effect that the mandatory conversion feature was amended to a set fixed conversion amount such that, upon mandatory conversion, the Bridge Note purchaser would receive one share of Company common stock (each, a "Bridge Note Conversion Share") for each \$1.00 of principal of the Bridge Note outstanding as of the date of the mandatory conversion. The Company evaluated the modification to the conversion rate as an inducement to convert the Bridge Note and concluded that it provided the purchaser of the Bridge Note an incremental value of \$3,465,000, which is included as interest expense on the consolidated statements of operations for the three months ended March 31, 2015 and the year ended December 31, 2015.

Derivative Liability - PPO

The investor in the PPO and the Bridge Note holder has been granted anti-dilution protection with respect to the PPO Shares and Bridge Note Conversion Shares such that, if within two years after the closing of the Merger, the Company shall issue additional shares of Company common stock or common stock equivalents, for a consideration per share less than \$0.50 per share (the "Lower Price"), each such investor and holder will be entitled to receive from the Company additional shares ("Lower Price Shares") of Company common stock in an amount such that, when added to the number of shares initially purchased by such investor or received upon conversion of the Bridge Note, will equal the number of shares that such investor's PPO subscription amount would have purchased or the Bridge Note holder would have received upon conversion of the Bridge Note at the Lower Price. GEM was the sole investor in the PPO and designee of the Bridge Note holder who received the Bridge Note Conversion Shares.

The Company has determined that this anti-dilution protection is a freestanding financial instrument that will be carried as a liability at fair value. At the time of the merger, in the quarter ended March 31, 2015, management measured this derivative at fair value and recognized a derivative liability of \$376,300 on the consolidated balance sheet, with the offset recorded against additional paid-in capital. The derivative is valued primarily using models based on unobservable inputs that represent management's best estimate of what market participants would use in pricing the liability at the measurement date and thus are classified as Level 3. The model incorporates various assumptions related to the Company's stock price and ascribes a probability based on management's expectation that such assumptions would occur. Changes in the fair values of the derivative are recognized in earnings in the current period. As of December 31, 2015, the Company determined that the likelihood of the anti-dilution provisions being met was remote based on the Company's current stock price and the length of time remaining until maturity, and therefore, the anti-dilution protection had no value. As of March 5, 2017, the anti-dilution provisions expired without the triggering of any such protection. The write down of the \$376,300 derivative liability was recorded as other income.

Note 7. Stockholders' Equity.

Preferred Stock

The Company is authorized to issue up to 10,000,000 shares of preferred stock, each with a par value of \$0.0001. Shares of Company preferred stock may be issued from time to time in one or more series and/or classes, each of which will have such distinctive designation or title as shall be determined by the Company's board of directors prior to the issuance of any shares of such series or class. The Company preferred stock will have such voting powers, full or limited or no voting powers and such preferences and relative, participating, optional or other special rights and such qualifications, limitations or restrictions thereof, as shall be stated in such resolution or resolutions providing for the issue of such series or class of Company preferred stock as may be adopted from time to time by the Company's board of directors prior to the issuance of any shares thereof. No shares of Company preferred stock are currently issued or outstanding and the Company's board of directors has not designated any class or series of Company preferred stock for use in the future.

Common Stock

Voting

Each holder of Company common stock is entitled to one vote for each share thereof held by such holder at all meetings of stockholders (and written action in lieu of meetings). The number of authorized shares of Company common stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of majority of the combined number of issued and outstanding shares of the Company.

Dividends

Dividends may be declared and paid on the Company common stock from funds lawfully available therefore, as and when determined by the board of directors.

Liquidation

In the event of the liquidation, dissolution, or winding-up of the Company, holders of Company common stock will be entitled to receive all assets of the Company available for distribution to its stockholders.

Escrow Shares

Pursuant to the Merger Agreement, the Company would have been required to issue 1,333,333 shares of Company common stock to the Pre-Merger Company stockholders in the event that the Company conducted an offering of at least \$20,000,000 at a pre-money Company valuation between \$200,000,000 and \$400,000,000 with such offering proceeds placed in escrow on or before the date which was five months following the consummation of the Merger. As this offering did not occur, these 1,333,333 shares were not issued. The Merger Agreement further provided that, if the pre-money valuation on which the raised funds were placed into escrow was less than \$200,000,000, or if no money was raised within such five month period, up to 3,500,000 shares of Company common stock were required to be surrendered for cancellation. Such 3,500,000 shares (the "Escrowed Shares") were placed into escrow pursuant to an Adjustment Shares Escrow Agreement entered into at the time of Merger Closing (the "Adjustment Shares Escrow Agreement"). The date on which the offering funds were required to be placed into escrow was extended under the terms of the Second Omnibus Amendment to November 5, 2015. No offering was consummated, nor were any offering funds placed into escrow. On November 10, 2015, the Company advised the escrow agent of such facts and demanded the surrender for cancellation of the 3,500,000 shares placed into escrow under the Adjustment Shares Escrow Agreement. Under the Adjustment Shares Escrow Agreement, the depositor of the Escrowed Shares had until November 18, 2015 to challenge the Company's demand for surrender of the Escrowed Shares.

On November 17, 2015, the Company received notice from the depositor of such 3,500,000 shares disputing the grounds for the surrender for cancellation of those shares. Until resolved by court order or otherwise, the 3,500,000 shares shall remain in escrow. On January 19, 2016, the Company filed a complaint against the depositor with the Commercial Division of the Supreme Court of New York, New York and on April 1, 2016, the Company filed an amended complaint, which asserts causes of actions for (i) a declaratory judgment declaring that the relevant contracts require the 3,500,000 escrowed Adjustment Shares to be released to the Company; (ii) breach of contract for failure to deliver the 3,500,000 escrowed Adjustment Shares to the Company; (iii) conversion for the depositors willful and malicious interference with the Company's rights to the Adjustment Shares; and (iv) replevin for the escrow agent's refusal to surrender the escrowed Adjustment Shares to the Company.

On June 20, 2016, the depositor filed their answer and asserted two counterclaims. The first counterclaim alleges that the Company purportedly breached its obligation to allow the depositor to provide additional financing by refusing to allow the depositor to purchase 17,200,000 shares at a price of \$1.1626 per share. The depositor alleges that it was damaged by at least \$144,000,000 based upon the differential between the depositor's proposed share purchase price and the then-current market value of the Company's Common stock. The depositor's second counterclaim alleges that the Company purportedly breached its fiduciary duties to the depositor as a stockholder of the Company, by rejecting the depositor's proposed financing described above. The Company believes the depositor's counterclaims are without merit and intends to vigorously defend these claims and seek the return of the 3,500,000 escrowed Adjustment Shares in accordance with the terms set out in the Merger Agreement and the Adjustment Shares Escrow Agreement. The Company moved to dismiss the counterclaims on August 10, 2016, the depositor filed its opposition on September 21, 2016 and the Company filed its reply memorandum of law on October 28, 2016.

On February 28, 2017, we, GEM Global Yield Fund LLC SCS (on behalf of it and its affiliates, collectively, "GEM"), and CKR Law LLP ("CKR") entered into a Confidential Settlement and Release Agreement (the "Settlement Agreement") with respect to, among other things, (a) our complaint filed on or about January 19, 2016 and amended on April 1, 2016 against GEM with the Commercial Division of the Supreme Court of New York, New York (the "Court") captioned *Tyme Technologies, Inc. v. GEM Global Yield Fund LLC SCS and CKR Law LLP*, Index No. 650250/2016, (b) GEM's counterclaims asserted against us on or about June 20, 2016 as set forth in CKR's and GEM's answer to the Company's complaint and (c) a Registration Rights Agreement involving the Company and GEM (the "RRA"), a form of which was filed as Exhibit 10.9 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 11, 2015.

Pursuant to the Settlement Agreement, GEM directed CKR to surrender to the Company the Escrowed Shares. The Company is not obligated to pay any monetary damages pursuant to the Settlement Agreement. In addition to the foregoing, the Company and GEM agreed to waive and release any claims they may have against each other with respect to the subject matter of the complaint and counterclaim described above. The parties also agreed to terminate the RRA. On March 1, 2017, the Company received the Escrowed Shares. The Company and the depositor also entered into a Stipulation of Discontinuance with Prejudice that was filed with the Court on March 2, 2017. The Escrowed Shares were cancelled by the Company on May 25, 2017.

Registration Rights Agreement

In connection with the PPO, the Company entered into a Registration Rights Agreement (the "Registration Rights Agreement") with the purchaser in the PPO and the holder of the Bridge Note, pursuant to which the Company agreed to promptly, but no later than 90 days following the maturity date of the PPO Note (such maturity date initially being 90 calendar days after the closing of the PPO), file a registration statement with the SEC (the "Registration Statement") covering (a) all of the PPO Shares issued in the PPO, (b) the Bridge Note Conversion Shares issued upon conversion of the Bridge Note, (c) the Lower Price Shares, if any, and (d) any shares of the Company common stock issued or issuable with respect to the PPO Shares, Conversion Shares and Lower Price Shares upon any stock split, dividend or other distribution, recapitalization or similar event. The Merger Agreement provided that the Registration Statement may also cover 9% of the total number of shares issued to the Pre-Merger Tyme Stockholders in connection with the Merger. The required filing date of the Registration Statement to avoid the imposition of liquidated damages was extended by an additional 31 days pursuant to the First Omnibus Amendment.

The Registration Rights Agreement was further modified by the Second Omnibus Amendment to the effect of (x) the holder of all of the PPO/Bridge Note Conversion Registrable Shares agreeing to irrevocably waive any right to damages for the late filing and/or effectiveness of the registration statement contemplated by the Registration Rights Agreement and (y) the total number of shares that can be registered by the former Tyme stockholders was increased to 15% of the total number of shares issued to them in connection with the Merger.

Pursuant to the Settlement Agreement (as defined under "Escrow Shares"), the Registration Rights Agreement was terminated effective February 28, 2017.

Securities Purchase Agreements

On December 23, 2015, pursuant to a Securities Purchase Agreement, dated as of December 18, 2015, for the aggregate consideration of \$3,000,000, before deducting offering costs of \$34,000, the Company sold and issued in a private placement an aggregate of: (i) 750,000 shares of the Company's common stock, par value \$0.0001 per share, and (ii) 446,500 common stock purchase warrants. Each Warrant entitles its holder to purchase one share of common stock at an initial exercise price of \$5.00 at any time during the period commencing on December 23, 2015 and terminating on the tenth anniversary of such date. No registration rights were granted to the purchasers of these shares or warrants. The warrants are included within additional paid-in capital on the statement of stockholders' equity and will not be subject to remeasurement.

On February 2, 2016, pursuant to a Securities Purchase Agreement, for the aggregate consideration of \$3,100,000, before deducting offering costs of \$67,718, the Company sold and issued in a private placement an aggregate of: (i) 775,000 shares of the Company's common stock, par value \$0.0001 per share, and (ii) 461,384 common stock purchase warrants. Each Warrant entitles its holder to purchase one share of common stock at an initial exercise price of \$5.00 at any time during the period commencing on February 2, 2016 and terminating on the tenth anniversary of such date. No registration rights were granted to the purchasers of these shares or warrants. The warrants are included within additional paid-in capital on the statement of stockholders' equity and will not be subject to remeasurement.

In October 2016, the Company raised \$1.47 million through a private placement of 452,314 shares of our common stock.

On March 10, 2017, the Company raised \$9.2 million in gross proceeds through a private placement ("March 2017 Private Placement") of 3,588,620 shares of our common stock and 3,588,620 common stock purchase warrants (each, a "Warrant"). Each Warrant entitles its holder to purchase one share of common stock (each, a "Warrant Share") at an exercise price of \$3.00 per Warrant Share, subject to adjustment. The warrants expire two years from the date of issuance and vest immediately. The warrants are included within additional paid-in capital on the statement of stockholders' equity and will not be subject to remeasurement.

Investors in the March 2017 Private Placement have limited anti-dilution protection. This provision provides that if the Company were to 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 the Company to issue additional securities to the March 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. The provision has been accounted for as a derivative liability with a fair value of \$378,600 and will be subject to remeasurement (see Note 2).

At March 31, 2017 4,496,504 common stock purchase warrants relating to securities purchase agreements were outstanding and exercisable.

The following summarizes the common stock warrant activity for the years ended March 31, 2017 and March 31, 2016:

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

Note 8. Commitments and Contingencies.

Contract Service Providers

In the course of the Company’s normal business operations, it enters into agreements and arrangements with contract service providers to assist in the performance of its research and development and clinical research activities. Substantially all of these agreements and arrangements are on an as needed basis.

Employment Agreement

On March 5, 2015, the Company entered into employment agreements with its Chief Executive Officer and Chief Operating Officer. Under these agreements, each of such two executive officers will be entitled to an annual base salary of \$450,000 and such performance bonuses as the Company’s board of directors may determine, from time to time, in its sole discretion. The base salaries will be reviewed annually (commencing in 2016) by the Company’s board of directors; provided that the base salaries may not be decreased from their then current levels due to any board review. The employment agreements each have a term of five years; provided, however, that, commencing on the first anniversary of the dates of the agreements and on each anniversary thereafter, the term shall automatically be extended by one year, such that, at any time during the term of the agreement, the remaining employment term shall never be less than four years and one day. If employment is terminated by the Company without Cause or by the executive for Good Reason, the executive will be entitled to receive (i) base salary as in effect at the time of such termination to the extent such amount has accrued through the termination date and remains unpaid, (ii) any fully earned and declared but unpaid performance bonus as of the termination date, (iii) an amount equal to the sum of base salary the executive would have received from the date of such termination through the then applicable expiration date, which shall be payable in the same amounts and at the same intervals as if the employment period had not ended and (iv) any unpaid expenses as of the termination date. If the employment is terminated for “Cause,” or in the case of the executive’s death or disability, the executive will only be entitled to his base salary through the termination date, plus any accrued and unpaid performance bonus as of the termination date.

On March 15, 2017, the Company entered into a letter agreement with Ben R. Taylor, pursuant to which he became President and Chief Financial Officer of the Company effective April 3, 2017, which provides for an annual salary of \$450,000 and a term which is scheduled to expire on the one-year anniversary of the effective date of the letter agreement unless earlier terminated. The letter agreement (i) could renew for an additional one-year period unless timely notice of nonrenewal is given or the letter agreement is earlier terminated, (ii) provides for severance benefits equal to six months of salary in the event of termination by the Company without “cause” or by the executive for “good reason” (as such terms are defined in the letter agreement) and (iii) contemplates the establishment of a performance bonus opportunity based upon the achievement of performance criteria and goals approved by the Board. Pursuant to the letter agreement, the Company granted to Mr. Taylor, effective March 27, 2017 (the “Grant Date”), a nonqualified stock option to Mr. Taylor, which enables Mr. Taylor to purchase up to 1,500,000 shares of Common Stock of the Company at an exercise price per share of \$2.95. The Option vests in four equal annual installments on each anniversary of the Grant Date.

Legal Proceedings

Other than discussed below, the Company is not involved in any legal proceeding that it expects to have a material effect on its business, financial condition, results of operations or cash flows.

As described in Note 7, Stockholders’ Equity, the Merger Agreement further provided that, if the pre-money valuation on which the raised funds were placed into escrow was less than \$200,000,000, or if no money was raised within such five month period, up to 3,500,000 shares of Company common stock were required to be surrendered for cancellation. Such 3,500,000 shares were placed into escrow pursuant to an Adjustment Shares Escrow Agreement entered into at the time of Merger Closing. The date on which the offering funds were required to be placed into escrow was extended under the terms of the Second Omnibus Amendment to November 5, 2015. No offering was consummated, nor were any offering funds placed into escrow by November 5, 2015. On November 10, 2015, the Company advised the escrow agent of such facts and demanded the surrender for cancellation of the 3,500,000 shares placed into escrow under the Adjustment Shares Escrow Agreement. Under the Adjustment Shares Escrow Agreement, the depositor of such escrowed shares had until November 18, 2015 to challenge the Company’s demand for surrender of the Escrowed Shares.

On November 17, 2015, the Company received notice from the depositor of such 3,500,000 shares disputing the grounds for the surrender for cancellation of those shares. Until resolved, by court order or otherwise, the 3,500,000 shares shall remain in escrow. In our complaint, we requested, among other things, that GEM return 3,500,000 shares to the Company that were held in escrow (the “Escrowed Shares”) pursuant to an escrow agreement executed on or about March 5, 2015 and amended on or about June 5, 2015, under which CKR was the escrow agent and held the Escrowed Shares.

On January 19, 2016, the Company filed a complaint against the depositor with the Commercial Division of the Supreme Court of New York, New York and on April 1, 2016, the Company filed an amended complaint, which asserts causes of actions for (i) a declaratory judgment declaring that the relevant contracts require the 3,500,000 escrowed Adjustment Shares to be released to the Company; (ii) breach of contract for failure to deliver the 3,500,000 escrowed Adjustment Shares to the Company; (iii) conversion for the depositors willful and malicious interference with the Company’s rights to the Adjustment Shares; and (iv) replevin for the escrow agent’s refusal to surrender the escrowed Adjustment Shares to the Company.

On February 28, 2017, we, GEM Global Yield Fund LLC SCS (on behalf of it and its affiliates, collectively, “GEM”), and CKR Law LLP (“CKR”) entered into a Confidential Settlement and Release Agreement (the “Settlement Agreement”) with respect to, among other things, (a) our complaint filed on or about January 19, 2016 and amended on April 1, 2016 against GEM with the Commercial Division of the Supreme Court of New York, New York (the “Court”) captioned *Tyme Technologies, Inc. v. GEM Global Yield Fund LLC SCS and CKR Law LLP*, Index No. 650250/2016, (b) GEM’s counterclaims asserted against us on or about June 20, 2016 as set forth in CKR’s and GEM’s answer to the Company’s complaint and (c) a Registration Rights Agreement involving the Company and GEM (the “RRA”), a form of which was filed as Exhibit 10.9 to the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on March 11, 2015.

Pursuant to the Settlement Agreement, GEM directed CKR to surrender to the Company the Escrowed Shares. The Company is not obligated to pay any monetary damages pursuant to the Settlement Agreement. In addition to the foregoing, the Company and GEM agreed to waive and release any claims they may have against each other with respect to the subject matter of the complaint and counterclaim described above. The parties also agreed to terminate the RRA. On March 1, 2017, the Company received the Escrowed Shares. The Company and the depositor also entered into a Stipulation of Discontinuance with Prejudice that was filed with the Court on March 2, 2017.

Note 9. Related Party Transactions.

Due from Stockholders/Members

Effective as of the consummation of and in anticipation of the Merger, the non-interest bearing advances made to such stockholders/members was settled by the bonus compensation payments of \$342,250 payable to such stockholders being retained by the Company in lieu of payment. The balance of \$13,516 was settled during March 2015 by personal reimbursement made by the stockholders to the Company.

Sale of Excess Ingredient Materials

During the three months ending March 31, 2016, Steve Hoffman, the Company's President and Chief Executive Officer, purchased excess ingredient materials from the Company for a cost of \$170,000, which was the pro rata cost of obtaining the items. The income from this was recorded as an offset to Research and Development expense on the consolidated statements of operations, where the cost of such materials was originally recorded.

Legal

The Company was provided legal service by Drinker, Biddle & Reath LLP ("DBR"). A partner of DBR is a Board of Director member and received, and is entitled to receive, equity compensation payable to non-employee directors generally under the 2016 Director Plan. See note 10 below concerning the 2016 Director Plan. During the year ending March 31, 2017, the three months ended March 31, 2016 and 2015 (unaudited), and the years ended December 31, 2015 and 2014, approximately \$1,477,000, \$111,000, \$0, \$0, and \$0, respectively, have been incurred as legal expenses associated with DBR, and the Company had approximately \$1,303,000 and \$94,000 in accounts payable and accrued expenses payable to DBR at March 31, 2017 and March 31, 2016, respectively.

Note 10. Equity Incentive Plan.

On March 5, 2015, the Company's Board of Directors adopted and the Company's stockholders approved, the Company's 2015 Equity Incentive Plan (the "2015 Plan"). A reserve of 10,000,000 shares of Company common stock has been established for issuance under the 2015 Plan. No more than an aggregate of 3,333,333 shares of common stock may be awarded during the twelve month period starting March 5 of each succeeding year. Awards under the 2015 Plan may include, but need not be limited to, one or more of the following: options, stock appreciation rights, restricted stock, performance grants, stock bonuses, and any other type of award deemed by the administrator to be consistent with the purposes of the 2015 Plan. The exercise price of all options awarded under the 2015 Plan must be no less than 100% of the fair market value of the Company common stock as determined on the date of the grant and have a term of no greater than ten years from the date of grant. As of March 31, 2017, there were 5,832,718 shares available for grant under the 2015 Plan.

On May 9, 2016, the Board approved the establishment of a stock option plan for non-executive members of the Board (the "2016 Director Plan"), which includes: (i) (A) for current members, an immediate stock option grant of 25,000 shares at fair market value (as defined in the 2016 Director Plan to generally mean the closing stock price per share on the date of grant); or (B) for future members initially appointed, an immediate stock option grant of 25,000 shares at fair market value; and (ii) beginning with the 2017 annual meeting, for members who are reelected as members of the Board, an annual stock option grant of 10,000 shares at fair market value. Each of these stock option awards will vest 50% on the date of grant and 50% on the first anniversary of the date of grant. These stock option awards are in addition to the annual payment of \$50,000 in cash fees to non-employee directors.

Stock Options

As of March 31, 2017, there was approximately \$13,375,000 of total unrecognized compensation related to non-vested stock options. The cost is expected to be recognized over the remaining weighted average remaining service period of four years.

During the year ended March 31, 2017, the three months ended March 31, 2016 and 2015 (unaudited), and the year ended December 31, 2015 and 2014, approximately \$7,725,000, \$1,137,000, \$0, \$811,000, and \$0, respectively, have been recognized as stock based compensation. During the year ended March 31, 2017, the three months ended March 31, 2016 and 2015 (unaudited), and the year ended December 31, 2015 and 2014, approximately \$5,100,000, \$1,137,000, \$0, \$811,000, and \$0 have been recognized in general and administrative expense. During the year ended March 31, 2017 approximately \$2,625,000 have been recognized in research and development expense. There was no such expense recorded in research and development expense for the three months ended March 31, 2016 and 2015 (unaudited), and the years ended December 31, 2015 and 2014.

The Company uses the Black-Scholes option pricing model to determine the fair value of stock options granted. In accordance with ASC 718 for employees, the compensation expense is amortized on a straight-line basis over the requisite service period, which approximates the vesting period.

The expected volatility of options granted has been determined using the method described under ASC 718 using the expected volatility of similar companies. The expected term of options granted to employees in the current fiscal period has been based on the contractual term of the agreement as prescribed by ASC 718 Share-Based Payment.

The assumptions utilized to estimate the fair value of stock options granted are presented in the following table:

	Year Ended March 31, 2017	Three Months Ended March 31, 2015 (Unaudited)		Year Ended December 31, 2015 2014	
		2016	2015 (Unaudited)	2015	2014
Risk free interest rate	1.57% - 2.49%	1.4%	N/A	1.65%	N/A
Expected volatility	80.74% - 92.33%	79.0%	N/A	82.9%	N/A
Expected term	5 - 10 years	5 years	N/A	5 years	N/A
Dividend yield	0.0%	0.0%	N/A	0.0%	N/A

The following is a summary of the activity of the Company's stock options under the 2015 Plan and 2016 Director Plan as of March 31, 2017:

	Number of Options	Weighted Average Exercise Price
Outstanding at March 31, 2016	350,000	\$ 9.61
Granted	4,045,000	\$ 6.19
Exercised	—	\$ —
Forfeited/Cancelled	(355,556)	\$ 10.02
Outstanding at March 31, 2017	4,039,444	\$ 6.15
Options exercisable at March 31, 2017	1,346,389	\$ 7.56

Weighted-average grant date fair value of options granted during the year ended March 31, 2017 is \$5.34.

Range of Exercise Price	Stock Options Outstanding				Stock Options Vested			
	Number Outstanding at March 31, 2017	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value	Number Vested at March 31, 2017	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value
\$1.93 - \$7.75	4,039,444	\$6.15	9.25	\$16,000	1,346,389	\$7.56	8.51	\$16,000

The intrinsic value is calculated as the excess of the market value of March 31, 2017 over the exercise price of the options is approximately \$16,000. The market value as of March 31, 2017 was \$2.88 as reported by the OTC Market, Inc.

Stock Grants

On March 10, 2015, the Company adopted an independent director compensation policy and also adopted a compensation policy with respect to a special advisor to the Company's board of directors. Under such independent director compensation policy, each of those directors meeting the NASDAQ stock market definition of independent director is entitled to receive annual compensation in the amount of \$100,000, one-half to be paid in cash on a quarterly basis, in arrears, and the remaining one-half of the compensation to be paid in the form of Company common stock on a quarterly basis, in arrears, with the shares valued at the closing sale price of the Company common stock on the last trading day of the applicable quarterly period. The special advisor at such time was being compensated in the same manner as the independent directors. Effective as of September 30, 2015, the Company established a Scientific and Medical Advisory Board and a compensation policy for the advisory board's members, substantially identical to the compensation policy described above in this paragraph for the Company's independent directors, was adopted. In May 2016, the Company replaced the stock component of the previous independent director compensation policy with the 2016 Director Plan and the Company likewise has determined to extend similar awards to the special advisor and members of the Scientific and Medical Advisory Board.

The Company's compensation expense for stock awards was \$112,500, \$100,000, \$50,000, \$325,000 and \$0 for the years ended March 31, 2017, three months ended March 31, 2016 and 2015 (unaudited), and the year ended December 31, 2015, and 2014, respectively. The accrued expense for stock awards earned but not yet issued is \$112,500 and \$100,000 at March 31, 2017 and March 31, 2016, respectively.

The Company's compensation expense for cash awards was \$262,500, \$100,000, \$50,000, \$325,000 and \$0 for the years ended March 31, 2017, three months ended March 31, 2016 and 2015 (unaudited), and the year ended December 31, 2015 and 2014, respectively. The accrued expense for cash awards was \$375,000 and \$237,500 at March 31, 2017 and March 31, 2016, respectively.

Note 11. Income Taxes.

The Company provides for income taxes under ASC 740. Under ASC 740, the liability method is used in accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities, and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

The Company has not recorded a current or deferred income tax expense or benefit since its inception.

The Company's loss before income taxes was \$15,206,781, \$2,751,127, \$5,601,438, \$11,726,818, and \$2,660,677 for the year ended March 31, 2017, three months ended March 31, 2016 and 2015 (unaudited), and year ended December 31, 2015 and 2014, respectively, and was generated entirely in the United States.

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets are comprised of the following:

	Year Ended March 31, 2017	Three Months Ended March 31, 2015 (Unaudited)		Year Ended December 31, 2015 2014	
Net operating loss carryforward	\$ 5,747,394	\$ 4,443,724	\$ 1,730,737	\$ 4,316,110	\$ 1,330,660
Research and development credit carryforward	310,727	238,449	—	198,490	—
Stock options - NQSOs	3,178,381	—	—	—	—
Accruals	803,242	142,640	—	—	—
Other temporary differences	6,568	6,878	(3,702)	62,928	—
Gross deferred tax assets	10,046,312	4,831,691	1,727,035	4,577,528	1,330,660
Deferred tax valuation allowance	(10,046,312)	(4,831,691)	(1,727,035)	(4,577,528)	(1,330,660)
Net deferred taxes	\$ —	\$ —	\$ —	\$ —	\$ —

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on the Company's history of operating losses since inception, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of March 31, 2017. The valuation allowance increased by \$5,214,621 for the period April 1, 2016 through March 31, 2017 due primarily to the generation of net operating losses during the period and filing in additional jurisdictions.

A reconciliation of income tax benefit computed at the statutory federal income tax rate to income taxes as reflected in the financial statements is as follows:

	Year Ended March 31, 2017	Three Months Ended March 31,		Year Ended December 31,	
		2016	2015	2015	2014
U.S. statutory income tax rate	34%	34%	34%	34%	35.0%
State income taxes, net of federal benefit	—	4.9	6.0	7.9	5.0
Stock options	—	(14.1)	—	—	—
Permanent differences	—	—	—	(12.8)	—
Non-deductible transaction costs	—	—	(6.0)	—	—
Bond premium on repurchase	—	—	(20.0)	—	—
Tax rate change	(5.4)	(21.7)	—	—	—
Provision to return true-up	7.3	15.6	(7.0)	8.0	—
R&D credit carryforwards	0.8	1.5	—	1.8	—
Valuation allowance	(36.7)	(20.2)	(7.0)	(38.9)	(40.0)
Effective tax rate	—%	—%	—%	—%	—%

As of March 31, 2017, the Company had U.S. federal net operating loss carryforwards of \$16,904,097 net of uncertain tax positions, which may be available to offset future income tax liabilities and will begin to expire at various dates starting in 2033. As of March 31, 2017, none of the Company's state net operating losses have value due to the apportionment rule in the states where state income tax returns are currently filed. As of March 31, 2017, the Company had federal research and development tax credit carryforwards of \$310,727, available to reduce future tax liabilities which will begin to expire at various dates starting in 2030.

Under the provisions of the Internal Revenue Code, the NOL carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, as well as similar state tax provisions. This could limit the amount of NOLs that the Company can utilize annually to offset future taxable income or tax liabilities. The amount of the annual limitation, if any, will be determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has completed several financing transactions since its inception which may have resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code, or could result in a change in control in the future.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	Year Ended March 31, 2017	Three Months Ended March 31,		Year Ended December 31,	
		2016	2015	2015	2014
Gross unrecognized tax benefits at beginning of year	\$ 331,545	\$ —	\$ —	N/A	N/A
Increases in tax positions for current period	285,688	331,545	—	N/A	N/A
Gross unrecognized tax benefits at end of year	\$ 617,233	\$ 331,545	\$ —	N/A	N/A

As of March 31, 2017, the Company had \$617,233 of unrecognized tax benefits, which were offset with the net operating loss and valuation allowance on the consolidated balance sheet. None of the gross unrecognized tax benefits would affect the effective tax rate at March 31, 2017, if recognized. In addition, the Company did not record any penalties or interest related to uncertain tax positions for the periods presented in these consolidated financial statements.

The Company files income tax returns in the United States, and various state jurisdictions. The federal and state income tax returns are generally subject to tax examinations for the period January 1, 2016 through March 31, 2016, the years ended December 31, 2015 and 2014, and the period July 26, 2013 to December 31, 2013. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities to the extent utilized in a future period.

Note 12. Quarterly Information (unaudited)

	June 30, 2016	September 30, 2016	December 31, 2016	March 31, 2017
Fiscal Year Ended March 31, 2017				
Operating expenses:				
Research and development	\$ 1,585,540	\$ 1,130,468	\$ 1,745,681	\$ 1,649,898
General and administrative	4,425,786	1,990,471	1,245,268	1,433,669
Total operating expenses	6,011,326	3,120,939	2,990,949	3,083,567
Loss from operations	(6,011,326)	(3,120,939)	(2,990,949)	(3,083,567)
Loss before income taxes	(6,011,326)	(3,120,939)	(2,990,949)	(3,083,567)
Income tax expense	—	—	—	—
Net loss	(6,011,326)	(3,120,939)	(2,990,949)	(3,083,567)
Basic and diluted loss per common share	\$ (0.07)	\$ (0.04)	\$ (0.04)	\$ (0.04)
Basic and diluted weighted average shares outstanding	84,119,728	84,177,838	84,517,074	85,089,905

	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015	March 31, 2016
Fiscal Year Ended March 31, 2016					
Operating expenses:					
Research and development	\$ 514,317	\$ 790,692	\$ 1,357,394	\$ 1,161,563	\$ 808,472
General and administrative	1,583,820	959,594	958,922	1,273,470	1,942,655
Total operating expenses	2,098,137	1,750,286	2,316,316	2,435,033	2,751,127
Loss from operations	(2,098,137)	(1,750,286)	(2,316,316)	(2,435,033)	(2,751,127)
Interest expense	3,503,301	—	—	—	—
Other income	—	—	—	(376,255)	—
Loss before income taxes	(5,601,438)	(1,750,286)	(2,316,316)	(2,058,778)	(2,751,127)
Income tax expense	—	—	—	—	—
Net loss	(5,601,438)	(1,750,286)	(2,316,316)	(2,058,778)	(2,751,127)
Basic and diluted loss per common share	\$ (0.08)	\$ (0.02)	\$ (0.03)	\$ (0.03)	\$ (0.03)
Basic and diluted weighted average shares outstanding	73,400,081	86,007,313	86,013,196	82,189,523	83,796,260

On October 27, 2016, the Board of Directors of Tyme Tech approved a change in fiscal year end from December 31 to March 31 of each year. As a result of the change in fiscal year, Tyme Tech filed with the Securities and Exchange Commission (“SEC”) a transition report on Form 10-QT on November 8, 2016 (the “Transition Report”) reporting the results for the three months periods ending March 31, 2016 and March 31, 2015 (unaudited). As a result of an audit of the financial statements for the Transition Report, certain adjustments were made to the condensed consolidated financial statements contained in the Transition Report compared to what was reported on the Company’s Form 10-Q for the quarter ended March 31, 2016, filed with the SEC on May 10, 2016. The Company evaluated the materiality of these adjustments and concluded that they were not material, individually or in the aggregate, to any of the previously issued financial statements.

Note 13. Subsequent Events.

The Company evaluates events or transactions that occur after the balance sheet date but prior to the issuance of consolidated financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure.

Between April 1 and April 18, 2017, the Company raised approximately \$2,700,000 in gross proceeds through a private placement of 1,069,603 shares of common stock and 1,069,603 warrants, each of which entitles its holder to purchase one share of Common Stock at \$3.00 per share, subject to adjustment. The Company also received \$150,000, payment on stock subscription receivable.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

There were no disagreements with either Grant Thornton LLP or WithumSmith+Brown, PC.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2017 as required by Rules 13a-15(b) and 15d-15(b) of the Exchange Act. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our Principal Executive Officer and Principal Financial Officer have concluded that at March 31, 2017, due to the material weaknesses in our internal control over financial reporting noted below, our disclosure controls and procedures were not effective. We intend to implement remedial measures designed to address these material weaknesses.

Management’s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Management assessed the effectiveness of our internal control over financial reporting as of March 31, 2017. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework issued in 2013. Based on the evaluation of our disclosure controls and procedures as of March 31, 2017, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date due to the material weakness described below, our disclosure controls and procedures were not effective for the reasons set forth below. A material weakness is a deficiency, or a combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company’s annual or interim financial statements will not be presented or detected on a timely basis.

The matters involving internal controls and procedures that our management considered to be material weaknesses under the standards of the Public Company Accounting Oversight Board were:

- inadequate segregation of duties consistent with control objectives; and
- ineffective controls over period end financial disclosure and reporting processes, including inadequate management oversight of outside accounting firm.

The aforementioned material weaknesses were identified by Messrs. Hoffman and Taylor in connection with their review of our financial statements as of March 31, 2017. In addition, our management noted further internal control deficiencies, including those relating to segregation of duties over cash disbursements and the prompt analysis of the financial impact of all transactions to which we are a party.

Our management believes that the material weaknesses set forth above did not have an effect on our financial results.

Management’s Remediation Initiatives

In an effort to remediate the identified material weaknesses and other deficiencies and enhance our internal controls, we have initiated, or plan to initiate, the following series of measures:

- We retained an accounting and financial reporting advisory firm with significant experience with publicly held companies to assist management in the accounting function and with implementing and enhancing our internal controls over financial reporting. As we secure additional working capital, we will create additional positions in order to segregate duties consistent with control objectives and will increase our personnel resources and technical accounting expertise within the accounting function.
- We intend to initiate periodic meetings with our outside accounting firm to discuss operating results, significant transactions, conclusions reached regarding technical accounting matters and financial reporting disclosures.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to exemptions provided to issuers that are non-accelerated filers or qualify as an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during our fourth fiscal quarter ended March 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

We recently hired 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 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 anticipate that a number of changes in our financial controls and procedures will be made in the ensuing periods.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors

The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 is incorporated by reference to the information contained in our definitive Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item 12 is incorporated by reference to the information contained in our Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item 13 is incorporated by reference to the information contained in our Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item 14 is incorporated by reference to the information contained in our Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) DOCUMENTS FILED AS PART OF THIS REPORT

The following is a list of our financial statements included in this Annual Report on Form 10-K under Item 8 of Part II hereof:

1. FINANCIAL STATEMENTS AND SUPPLEMENTAL DATA

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of March 31, 2017, March 31, 2016

Consolidated Statements of Operations for the year ended March 31, 2017; the three months ended March 31, 2016 and March 31, 2015 (unaudited); and the years ended December 31, 2015 and December 31, 2014

Consolidated Statements of Stockholders' Equity (Deficit) for the years ended March 31, 2017 and March 31, 2016; and the years ended December 31, 2015 and December 31, 2014.

Consolidated Statements of Cash Flows for the years ended March 31, 2017, March 31, 2016, March 31, 2015, December 31, 2015 and December 31, 2014.

Notes to Consolidated Financial Statements as of March 31, 2017 and March 31, 2016 and December 31, 2015 and December 31, 2014.

(b) EXHIBITS

Exhibit Number	Description
2.1	Agreement and Plan of Merger and Reorganization, dated as of March 5, 2015, by and among Tyme Technologies, Tyme Acquisition Corp., Tyme, Inc. and other signatories thereto. [Incorporated by reference to Exhibit 2.1 to our Current Report on Form 8-K (Date of Report: March 5, 2015), filed with the SEC on March 11, 2015.]
2.2	Agreement and Plan of Merger, dated September 12, 2014, between Global Group Enterprises Corp. and Tyme Technologies, Inc. [Incorporated by reference to Exhibit 2.1 to our Current Report on Form 8-K (Date of Report: September 12, 2014), filed with the SEC on September 19, 2014.]
3.1	Amended and Restated Certificate of Incorporation of Tyme Technologies, Inc. [Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K (Date of Report: September 12, 2014), filed with the SEC on September 19, 2014.]
3.2	Articles of Merger of Global Group Enterprises Corp. with and into Tyme Technologies, Inc., filed with the Secretary of State of the State of Florida on September 18, 2014. [Incorporated by reference to Exhibit 3.3 to our Current Report on Form 8-K (Date of Report: September 12, 2014), filed with the SEC on September 19, 2014.]
3.3	Certificate of Merger of Global Group Enterprises Corp. with and into Tyme Technologies, Inc., filed with the Secretary of State of the State of Delaware on September 18, 2014. [Incorporated by reference to Exhibit 3.4 to our Current Report on Form 8-K (Date of Report: September 12, 2014), filed with the SEC on September 19, 2014.]
3.4	Certificate of Merger of Tyme Acquisition Corp. with and into Tyme Inc., filed with the Secretary of State of the State of Delaware on March 5, 2015. [Incorporated by reference to Exhibit 3.4 to our Current Report on Form 8-K (Date of Report: March 5, 2015), filed with the SEC on March 11, 2015.]
3.5	By-Laws of Tyme Technologies, Inc. [Incorporated by reference to Exhibit 3.2 to our Current Report on Form 8-K (Date of Report: September 12, 2014), filed with the SEC on September 19, 2014.]
3.6	Form of Warrant Certificate, dated as of February 2, 2016. [Incorporated by reference to Exhibit A to the Form of Securities Purchase Agreement, dated as of February 2, 2016, filed as Exhibit 10.1 to our Current Report on Form 8-K (Date of Report: February 2, 2016), filed with the SEC on February 8, 2016.]

Exhibit Number	Description
3.7	Form of Warrant Certificate, dated as of December 18, 2015, between Tyme Technologies, Inc. and the purchaser parties thereto. [Incorporated by reference to Exhibit A to the Form of Securities Purchase Agreement, dated as of December 18, 2015, filed as Exhibit 99.1 to our Current Report on Form 8-K (Date of Report: December 23, 2015), filed with the SEC on December 30, 2015.]
3.8	Form of Warrant. [Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K (Date of Report: March 21, 2017), filed with the SEC on March 22, 2017.]
10.1	Split-Off Agreement, dated as of March 5, 2015, among Global Group Enterprises Corp., Tyme Technologies, Inc. and Andrew Keck. [Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K (Date of Report: March 5, 2015), filed with the SEC on March 11, 2015.]
10.2	General Release Agreement, dated as of March 5, 2015, among Global Group Enterprises Corp., Tyme Technologies, Inc. and Andrew Keck. [Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K (Date of Report: March 5, 2015), filed with the SEC on March 11, 2015.]
10.3	Lock-Up and No Shorting Agreement, dated as of March 5, 2015, between Tyme Technologies, Inc. and Steven Hoffman. [Incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K (Date of Report: March 5, 2015), filed with the SEC on March 11, 2015.]
10.4	Lock-Up and No Shorting Agreement, dated as of March 5, 2015, between Tyme Technologies, Inc. and Michael Demurjian. [Incorporated by reference to Exhibit 10.4 to our Current Report on Form 8-K (Date of Report: March 5, 2015), filed with the SEC on March 11, 2015.]
10.6†	2015 Equity Incentive Plan of Tyme Technologies, Inc. [Incorporated by reference to Exhibit 10.8 to our Current Report on Form 8-K (Date of Report: March 5, 2015), filed with the SEC on March 11, 2015.]
10.7	License Agreement, dated as of July 9, 2014, between Steven Hoffman and Tyme Inc. [Incorporated by reference to Exhibit 10.11 to our Current Report on Form 8-K (Date of Report: March 5, 2015), filed with the SEC on March 11, 2015.]
10.8†	Employment Agreement, dated as of March 5, 2015, between Tyme Technologies, Inc. and Steven Hoffman. [Incorporated by reference to Exhibit 10.12 to our Current Report on Form 8-K (Date of Report: March 5, 2015), filed with the SEC on March 11, 2015.]
10.9†	Employment Agreement, dated as of March 5, 2015, between Tyme Technologies, Inc. and Michael Demurjian. [Incorporated by reference to Exhibit 10.13 to our Current Report on Form 8-K (Date of Report: March 5, 2015), filed with the SEC on March 11, 2015.]
10.10	Please see Exhibit 3.7 .
10.11†*	Employment Letter Agreement, dated as of March 15, 2017, between Tyme Technologies, Inc. and Ben R. Taylor.
10.12†*	Option Agreement, dated as of March 27, 2017, between Tyme Technologies, Inc. and Ben R. Taylor.
21.1*	List of Subsidiaries
24.1*	Power of Attorney (Included in Signature Page of Form 10-K)
31.1*	Rule 13(a)-14(a)/15(d)-14(a) Certification of Principal Executive Officer.
31.2*	Rule 13(a)-14(a)/15(d)-14(a) Certifications of Principal Financial Officer.
32.1*	Rule 1350 Certification of Chief Executive Officer.
32.2*	Rule 1350 Certifications of Chief Financial Officer.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Schema Document.
101.CAL*	XBRL Calculation Linkbase Document.
101.DEF*	XBRL Definition Linkbase Document.
101.LAB*	XBRL Label Linkbase Document.
101.PRE*	XBRL Presentation Linkbase Document.

† Management contract or compensatory plan or arrangement

* Filed herewith

SIGNATURES

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

Dated: June 12, 2017

TYME TECHNOLOGIES, INC.

By: /s/ Steve Hoffman
Steve Hoffman
Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Steve Hoffman, Michael Demurjian or Ben R. Taylor as his true and lawful attorneys-in-fact, each with the power of substitution, for him in any and all capacities, to sign any amendments to this Report on Form 10-K and to file same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
<u>/s/ Steve Hoffman</u> Steve Hoffman	Chief Executive Officer and Director (Principal Executive Officer)	June 12, 2017
<u>/s/ Michael Demurjian</u> Michael Demurjian	Chief Operating Officer and Director	June 12, 2017
<u>/s/ Ben R. Taylor</u> Ben R. Taylor	Chief Financial Officer and President (Principal Financial Officer and Principal Accounting Officer)	June 12, 2017
<u>/s/ Gerald Sokol</u> Gerald Sokol	Director	June 12, 2017
<u>/s/ Paul L. Sturman</u> Paul L. Sturman	Director	June 12, 2017
<u>/s/ David Carberry</u> David Carberry	Director	June 12, 2017
<u>/s/ Timothy C. Tyson</u> Timothy C. Tyson	Director	June 12, 2017
<u>/s/ James Biehl</u> James Biehl	Director	June 12, 2017

TYME TECHNOLOGIES, INC.
48 Wall Street – Suite 1100
New York, New York 10005

March 15, 2017

Ben Roberts Taylor

Dear Ben:

This letter (this “ **letter agreement** ”) sets forth our agreement with respect to your employment with Tyme Technologies, Inc., a Delaware corporation (the “ **Company**, ” “ **we** ” or “ **us** ” as applicable).

1. Employment. Subject to Section 13(a) below, you will be employed by the Company upon the terms and conditions set forth in this letter agreement for the period effective on the business day immediately succeeding satisfaction of the Funding Condition described in Section 13(a) (the “ **Effective Date** ”) and ending as provided in Section 4 (the “ **Employment Period** ”).

2. Position and Duties. During the Employment Period, you will serve as President and Chief Financial Officer of the Company and will have the usual and customary duties, responsibilities and authority of a person in such position and such other duties assigned to you by the Board of Directors of the Company (the “ **Board** ”), the Chief Executive Officer of the Company (the “ **CEO** ”) and/or the Board’s Audit Committee (the “ **Audit Committee** ”), in all cases that are consistent with your position. You will report directly to the CEO and the Audit Committee. Except as otherwise provided herein, you will devote your full working time, efforts and attention to, and diligently and conscientiously perform the duties of, such position. In addition to performing such duties for the Company, you may be required to perform similar duties for the Company’s existing subsidiaries or affiliates, and/or any subsidiaries and/or affiliates which may be formed or acquired from time to time including, but not limited to, Tyme Inc., a Delaware corporation, and Luminant Biosciences, LLC (collectively, all such subsidiaries and/or other “affiliates” of the Company (as defined in Rule 405 under the Securities Act of 1933, as amended) shall be referred to as the “ **Affiliates** ”).

3. Compensation.

(a) During the Employment Period, your base salary will be \$450,000.00 per annum (your “ **Base Salary** ”), such Base Salary to be prorated during partial years of employment. Your Base Salary will be payable in regular installments in accordance with the Company’s general payroll practices and subject to withholding and other payroll taxes. Your Base Salary may be reviewed annually (beginning on or about January 1, 2018) by the Board in its sole discretion; provided, however, that your Base Salary shall not be decreased by the Board

.

(b) You will also be entitled, conditioned upon your continued employment with the Company or one of the Affiliates through and including the applicable date of payment, to receive a performance bonus based upon Board-determined satisfaction of individual and Company goals to be established by the Board (your “ **Performance Bonus** ”), in such amount(s), for such period(s) and based on such criteria as determined from time to time by the Board in the Board’s sole discretion. The Board shall establish a Performance Bonus plan during first or second quarter of the Company fiscal year ending on March 31, 2018.

(c) In connection with your entering into this letter agreement, we shall grant to you, on within four business days following the Effective Date (the “ **Grant Date** ”), under the Company’s 2015 Equity Incentive Plan (the “ **2015 Plan** ”), an option (the “ **Option** ”) to purchase up to 1,500,000 shares (each, an “ **Option Share** ”) of the common stock, par value \$0.0001 per share (the “ **Common Stock** ”). The Option shall be evidenced by a Stock Option Agreement in the form attached as **Exhibit A** to this letter agreement (the “ **Stock Option** ”). The Option shall contain a per Option Share purchase (exercise) price on the Grant Date as set forth in the Stock Option and shall be consistent with the 2015 Plan. The Option shall have a term of ten years and shall vest in four equal annual installments beginning on the one-year anniversary of the Grant Date (each, a “ **Vesting Date** ”), provided that you are employed by the Company on the relevant Vesting Date, and otherwise subject to the provisions of the 2015 Plan. For the avoidance of doubt, in the event you terminate employment with the Company prior to full vesting of the Option, the unvested portion of the Option will expire and terminate in full as of such termination and you will not have any right to exercise the unvested portion of the Option; provided, however, that if such termination is a termination by the Company without Cause under Section 5(a) below, the portion of the Option that would have vested on the next Vesting Date but for such separation without Cause shall vest. The number of Option Shares and purchase price shall be adjusted in the event of any stock splits, mergers, consolidations or similar transactions. In the event of any conflict between the provisions of this paragraph 3(c) and the provisions of the Stock Option, the provisions of the Stock Option shall govern.

(d) During the Employment Period, you will be entitled to participate in all employee benefit programs, including without limitation health/medical insurance, for which senior executive employees of the Company are generally eligible, subject to applicable law and the terms of the applicable plans and policies, as may be amended from time to time, in the sole discretion of the Board. The Company reserves the right to amend or cancel any employee benefit plans at any time in its sole discretion, subject to the terms of such employee benefit plan and applicable law. During the Employment Period, you will be entitled to four weeks paid vacation during each calendar year, with such vacation time pro-rated for any partial years during the Employment Period; provided, however, that no carry-over of unused vacation time shall be permitted and no compensation shall be paid for any such unused vacation time, unless applicable law requires otherwise.

(e) The Company agrees to reimburse you for all reasonable out-of-pocket business expenses incurred by you on behalf of the Company during the Employment Period, provided that you properly account to the Company for all such expenses in accordance with the policies of the Company and the rules, regulations and interpretations of the U.S. Internal Revenue Service relating to reimbursement of business expenses (“ **Expenses** ”), and provided further any Expense in excess of \$1,000 shall require advance approval of the CEO.

4. Termination. The Employment Period shall begin on the Effective Date and will end on the one-year anniversary thereof (the “ **Expiration Date** ”), unless sooner terminated as provided below or extended as provided below. Unless the Employment Period has been terminated in accordance with the following sentence of this Section 4 or one party has given at least 60 days’ advance, written notice that you or the Company seek to terminate the employment arrangement on the Expiration Date, the Expiration Date shall automatically be extended by one additional year. Notwithstanding the foregoing, the Employment Period (i) will terminate automatically upon your death, (ii) may be terminated by the Company upon Notice of Termination (as defined in Section 5(f) below) delivered to you as a result of your Disability (as defined in Section 5(h) below), (iii) may be terminated by the Company at any time for Cause (as defined in Section 5(g) below) or without Cause and (iv) may be terminated by you with or without Good Reason (as defined in Section 5(i) below) upon written notice.

5. Severance.

(a) If the Employment Period is terminated by the Company without Cause or by you for Good Reason, you will be entitled to receive (i) your Base Salary as in effect at the time of such termination to the extent such amount has accrued through the Termination Date (as defined in Section 5(f) below) and remains unpaid, (ii) any fully earned and declared but unpaid Performance Bonus as of the Termination Date, (iii) an amount equal to one-half of your Base Salary, as in effect at the time of your separation, which shall be payable in the same amounts and at the same intervals as such payments would have been made if still employed, (iv) any unpaid Expenses as of the Termination Date, and (v) accelerated vesting, if applicable, as provided in Section 3(c) above. Upon delivery of the payments and benefits described in this Section 5(a), the Company shall have no further obligation to you under this letter agreement or otherwise with respect to your employment with the Company, except where required by applicable law. The Company’s obligation to make the payments and provide the benefits to you described in clauses (iii) and (v) of this Section 5(a) is conditioned upon your executing and delivering, no later than 21 days after it is provided to you (or such greater time as may be required by applicable law), and not timely revoking, a release relating to your employment by the Company in favor of the Company, its Affiliates and their respective stockholders, officers, members, managers, directors, employees, and subsidiaries substantially in the form attached as Exhibit B.

(b) If the Employment Period is terminated by the Company for Cause or by you other than for Good Reason, the Company will pay you (i) your Base Salary as in effect at the time of such termination to the extent such amount has accrued through the Termination Date and remains unpaid, (ii) any fully earned and declared but unpaid Performance Bonus as of the Termination Date, and (iii) any unpaid Expenses as of the Termination Date. Upon delivery of the payment described in this Section 5(b), the Company will have no further obligation to you under this letter agreement or otherwise with respect to your employment with the Company, except where required by applicable law.

(c) If the Employment Period is terminated upon your Disability or death, the Company will pay you or your estate or succession, whichever is applicable, (i) your Base Salary as in effect at the time of such termination to the extent such amount has accrued through the Termination Date and remains unpaid, (ii) any fully earned and declared but unpaid Performance

Bonus as of the Termination Date, and (iii) any unpaid Expenses as of the Termination Date. Upon delivery of the payments described in this Section 5(c), the Company shall have no further obligation to you under this letter agreement or otherwise with respect to your employment with the Company, except where required by applicable law.

(d) If the Employment Period concludes on the one-year anniversary of the Effective Date by reason of non-renewal of the Employment Period, or on the second anniversary of the Effective Date by reason of the natural end of the Employment Period, the Company will pay you (i) your Base Salary as in effect at the time of such termination to the extent such amount has accrued through the Termination Date and remains unpaid, (ii) any fully earned and declared but unpaid Performance Bonus as of the Termination Date, and (iii) any unpaid Expenses as of the Termination Date. Upon delivery of the payment described in this Section 5(d), the Company will have no further obligation to you under this letter agreement or otherwise with respect to your employment with the Company, except where required by applicable law. For clarity, upon any termination pursuant to this Section 5(d), you shall not be entitled to any vesting of the Option except for such vesting that occurs on or before the Expiration Date.

(e) Except as otherwise required by law or as specifically provided herein, all of your rights to salary, severance, fringe benefits, bonuses and any other amounts hereunder (if any) accruing after the termination of the Employment Period will cease upon the earlier of the date of such termination and your last day of active service. In the event the Employment Period is terminated, your sole remedy, and the sole remedy of your successors, assigns, heirs, representatives and estate, will be to receive the payments described in this letter agreement.

(f) Any termination of the Employment Period by the Company (other than termination upon your death) or by you must be communicated by written notice (in either case, a “**Notice of Termination**”) to you. For purposes of this letter agreement, “**Termination Date**” means (i) if the Employment Period is terminated by your death, the date of your death, (ii) if the Employment Period is terminated upon your Disability, by the Company or by you, the date specified in the Notice of Termination (which may not be earlier than the date of such Notice), (iii) upon any non-renewal (effective on the one-year anniversary of the Effective Date) or natural expiration (effective on the second anniversary of the Effective Date) of the Employment Period, such applicable anniversary of the Effective Date, and (iv) for any other termination by the Company or you, the date specified in the Notice of Termination (which may not be earlier than the date of such Notice). Notwithstanding anything contained herein to the contrary, any termination of the Employment Period by you must be communicated to the Company no less than 30 days prior to the intended Termination Date.

(g) For purposes of this letter agreement, “**Cause**” means any one of the following: (i) a breach by you of this letter agreement, (ii) your conviction of, guilty plea to, or confession of guilt of, a felony or other crime that, in the Company’s reasonable judgment, impacts your suitability for employment, (iii) materially fraudulent, dishonest or illegal conduct by you in the performance of services for or on behalf of the Company or any of its Affiliates, (iv) any conduct by you in material violation of Company policy, (v) any conduct by you that is materially detrimental to the reputation of the Company or any of its Affiliates, (vi) your misappropriation of funds of the Company or any of its Affiliates, (vii) your gross negligence or

willful misconduct, (viii) your failure or refusal to comply with written directions of the Board, the Audit Committee or CEO, (ix) your making statements or other communications to analysts, regulatory authorities, the press or other third parties that are unauthorized or inconsistent with the instructions of the Board, the Audit Committee, or the CEO, (x) your making statements or other communications to analysts, regulatory authorities, the press or other third parties inconsistent with the Company's approved, publicly disclosed strategies, or that would cause competitive or regulatory harm to the Company in the Board's discretion, but in all cases except where such statement is approved in advance by the Board or protected by applicable law, (xi) your engaging in conduct involving an act of moral turpitude, (xii) a breach of your duty of loyalty to the Company or its Affiliates, or (xiii) your misrepresentation of your prior professional or academic standing, credentials or accomplishments.

(h) For purposes of this letter agreement "**Disability**" means any accident, sickness, incapacity or other physical or mental condition that prevents you, with or without accommodation, from performing the essential functions of your position for either (i) 90 consecutive days or (ii) 120 days during any period of 365 consecutive days, in all cases consistent with applicable law. During the time periods specified above, the Company will continue to provide you with the compensation stated in Section 3 above.

(i) For purposes of this letter agreement, "**Good Reason**" means the failure of the Company to make all payments due you under this letter agreement and the continuation thereof for more than 30 calendar days after your notice to the Company of such failure and demand for such outstanding payment(s).

6. Confidential Information.

(a) You will not disclose or use at any time any Confidential Information (as defined below in Section 6(c)), whether or not such information is developed by you, except to the extent that such disclosure or use is required in the performance or exercise by you in good faith of (i) duties assigned to you under this letter agreement or otherwise by the Board, (ii) rights as an employee, officer, director or shareholder of the Company or any of its Affiliates or (iii) rights under any agreement with the Company or any Affiliates.

(b) You will deliver to the Company at the termination of the Employment Period, or at any time the Company may request, all memoranda, notes, plans, designs, records, reports, computer files and software and other documents and data (and copies thereof) that are Confidential Information or Work Product (as defined below) or information relating to the business of the Company or its Affiliates which you may then possess or have under your control.

(c) As used in this letter agreement, the term "**Confidential Information**" means information that is not generally known or available to the public and that is used, developed or obtained by the Company or any Affiliate in connection with its or their businesses, including but not limited to (i) information, observations and data concerning the business or affairs of the Company or its Affiliates, (ii) products or services, (iii) fees, costs and pricing structures, (iv) designs, (v) analyses, (vi) drawings, designs, photographs, artwork and reports, (vii) computer software, including operating systems, applications and program listings, (viii)

flow charts, manuals and documentation, (ix) data bases, (x) accounting and business methods, (xi) inventions, devices, new developments, methods and processes, whether patentable or unpatentable and whether or not reduced to practice, (xii) other copyrightable works, (xiii) all production methods, processes, technology and trade secrets, (xiv) Company product and product candidate formulae and any trade secrets with respect to such products and product candidates, including formulations, chemical compositions, mechanisms of action and medical dosages, and (xv) all similar and related information in whatever form. Confidential Information shall also include all patient information, data and other Protected Health Information ("PHI"), as that term is defined in 45 CFR parts 160 and 164.

(d) Notwithstanding the provisions of this letter agreement to the contrary, you will have no liability to the Company for disclosure of any specific Confidential Information (other than PHI) if such Confidential Information:

(i) is in the public domain or becomes publicly known in the industry in which the Company operates or is disclosed by the Company other than as the result of a breach of this letter agreement or any other agreement by you; or

(ii) is required to be disclosed by law, court order, or similar compulsion or in connection with any legal proceeding; provided however, that such disclosure will be limited to the extent so required and, subject to the requirements of law, you will give the Company as much advance notice as is reasonably possible of your intent to so disclose such Confidential Information and will cooperate with the Company in seeking confidentiality protections.

(e) Additionally, notwithstanding any other provision of this Agreement, you understand that:

(i) You will not be held criminally or civilly liable under any federal or state trade secret law or this Agreement for any disclosure of Confidential Information that:

(A) you make: (y) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (z) solely for the purpose of reporting or investigating a suspected violation of law; or

(B) you make in a complaint or other document that is filed under seal in a lawsuit or other proceeding.

(ii) If you file a lawsuit for retaliation by the Company for reporting a suspected violation of law you may disclose Confidential Information to your attorney and use the Confidential Information in the court proceeding if you:

(A) file any document containing the Confidential Information under seal; and

(B) do not disclose the Confidential Information, except pursuant to court order.

7. Inventions and Patents. You agree that all inventions, innovations, improvements, technical information, trade secrets, systems, software developments, ideas, results, methods, designs, artwork, analyses, drawings, reports, copyrights, service marks, trademarks, trade names, logos, medicinal and product candidate formulations and dosages, chemical compositions, mechanisms of action, medical procedures and all similar or related information (whether patentable or unpatentable) which relate to the Company's or any of its Affiliates' businesses, research and development or existing products (or products under development) or services and which are conceived, developed or made by you (whether or not during usual business hours and whether or not alone or in conjunction with any other person) during your employment with the Company, together with all intellectual property rights therein, including, but not limited to, any patent applications, patents, trademark, trade name and service mark applications or registrations, copyrights and applications and reissues thereof that may be granted for or upon any of the foregoing, as well as any improvements to any inventions, technology, or trade secrets of the Company (collectively referred to herein as "Work Product"), is the exclusive property of the Company and/or its Affiliates. For the avoidance of doubt and without limiting the foregoing, (x) the Company or any of its Affiliates shall be the sole owner of all right, title and interest in such Work Product, including all intellectual property rights relating to such Work Product, without you retaining any license or other residual right whatsoever, and (y) any rights to any new or an existing Work Product are automatically and hereby conveyed, assigned and transferred to the Company pursuant to this agreement. You hereby waive and renounce to all moral rights related, directly or indirectly, to any such existing or new Work Product. You will take reasonable steps to promptly disclose such Work Product to the Board and perform all actions reasonably requested by the Board (whether during or after the Employment Period) to establish and confirm such ownership (including the execution and delivery of assignments, consents, powers of attorney and other instruments) and to provide reasonable assistance to the Company and its Affiliates in connection with the prosecution of any applications for patents, trademarks, trade names, service marks or reissues thereof or in the prosecution or defense of interferences relating to any Work Product.

8. Non-Compete; Non-Solicitation; Non-Disparagement.

(a) You acknowledge that, in the course of your employment with the Company, you will become familiar with the Company's and its Affiliates' trade secrets and with other Confidential Information concerning the Company and its Affiliates and that your services will be of special, unique and extraordinary value to the Company and its Affiliates. Therefore, you agree that, during the Restriction Period (as defined in Section 8(b) below) and for a period of three years following such Restriction Period, you will not (x) anywhere in the United States or anywhere the Company or any of its Affiliates conducts business or (y) anywhere the Company or any of its Affiliates has spent time and resources in connection with expanding its business, directly or indirectly, either on your own behalf or on behalf of any other person, firm or entity:

(i) own, manage, operate, provide services to, consult with, provide financing to, join, control or participate in the ownership, management, operation or control of, or the provision of financing to, any business wherever located (whether in corporate, proprietorship or partnership form or otherwise), if such business is engaged in the business of manufacturing, marketing, sale, research or development of pharmaceuticals for cancer utilizing

a methodology or mechanism that is similar to methodologies or mechanisms used by the Company (collectively, “ **Specified Therapies** ”); provided, however, that this Section 8(a)(i) shall not prohibit you from working, after the Restriction Period for an entity that engages in the manufacture, sale, marketing or distribution of pharmaceutical products so long as neither you nor such employer is involved in the manufacturing, marketing, sale or research or development of therapeutics or pharmaceuticals for any of the Specified Therapies.

(ii) say anything or otherwise communicate to a competitor, actual or potential customer of the Company or any Affiliate, the media, or other third party which is harmful to the reputation of the Company or any of its Affiliates or which could be reasonably expected to lead any person to cease to deal with the Company or any of its Affiliates on substantially equivalent terms to those previously offered or at all.

(b) For purposes of this letter agreement, “ **Restriction Period** ” means (i) the Employment Period and any other period during which you are employed by the Company or any of its Affiliates, whether pursuant to this Agreement or otherwise, and (ii) a period of six months following your separation from employment, regardless of the reason for your separation and whether caused by you or the Company.

(c) Nothing in Section 8(a) will prohibit you from being a passive owner of not more than 2% of the outstanding stock of a publicly-traded corporation, so long as you have no active participation in the business of such corporation.

(d) During the Restriction Period and for a period of three years following the Restriction Period, you also will not:

(i) induce or attempt to induce any customer, supplier or other business relation of the Company or any of its Affiliates to cease doing business with the Company or any of its Affiliates, or in any way interfere with the relationship between any such customer, supplier or business relation, on the one hand, and the Company or any Affiliates, on the other hand;

(ii) engage, employ, solicit or contact with a view to the engagement or employment of, any employee, officer or manager of, or full-time consultant to, the Company or any Affiliates or any person was an employee, officer or manager of, or consultant to, the Company or any Affiliates, if he or she has been in such a role at any time within the immediately prior three months; or

(iii) assist any individual or entity to engage in the conduct referenced in clauses (i) and (ii) immediately above.

(e) The Company, on behalf of itself and all Affiliates, agrees that during the Restriction Period they and their executive officers (or other persons acting on their behalf) will not say anything which is harmful to your reputation or which could be reasonably expected to lead any person to cease to deal with you or engage you in any consulting or employment position; provided, however, that the restriction in this sentence shall not include statements made internally within the Company or any Affiliates, statements made to their attorneys or

other business advisors, for legitimate business purposes, or statements made to any third party in related to the restrictions contained in this Section 8.

(f) You acknowledge that your agreement to the provisions of this Section 8 is in consideration of, and a condition precedent to, your employment with the Company and your receipt of the payments described in Section 3. Further, you acknowledge that the restrictions contained in this Section 8 are in addition to, and not in lieu of, restrictions contained in other applicable agreements, including the Stock Option attached as Exhibit A.

9. Enforcement.

(a) Because the employment relationship between you and the Company is unique and because you have access to Confidential Information, you acknowledge and agree that (i) the covenants set forth in Sections 6 and 8 are reasonable and necessary in order to protect the legitimate interests of the Company and you are receiving adequate consideration hereunder; (ii) the Company will not have any adequate remedy at law if you violate the terms hereof or fail to perform any of my obligations under Sections 6 or 8; (iii) money damages would be an inadequate remedy for any breach of Section 6 or 8 of this letter agreement, and your breach of Section 6 or 8 will constitute irreparable harm and injury to the Company for which it has no adequate remedy at law; and (iv) the Company shall have the right, in addition to any other rights it may have under applicable law, to obtain from any court of competent jurisdiction preliminary and permanent injunctive relief (without posting a bond or other security) to restrain any breach or threatened breach of, or otherwise to specifically enforce any such covenant or any of the other obligations under Sections 6 or 8 of this Agreement, as well as to obtain damages, costs and reasonable attorneys' fees incurred by the Company in enforcing its rights under this letter agreement and an equitable accounting of all earnings, profits and other benefits arising from such violation, which rights shall be cumulative and in addition to any other rights or remedies to which the Company may be entitled.

(b) If you violate any of the restrictions or obligations contained in Section 8, then the Restriction Period and any applicable period following the Restriction Period shall not run in your favor from the time of the commencement of any such violation until such time as such violation shall be cured by you, and the restrictions contained in that Section will be extended for a period equal to the period that you were in breach.

(c) You acknowledge and agree that if you breach any of the provisions of this letter agreement, the Company will have the right and remedy to require you to account for and pay over to the Company or its designee, all compensation, profits, monies, accruals, increments or other benefits you derive or receive as a result of such breach. This right and remedy will be in addition to, and not in lieu of, any other rights and remedies available to the Company under law or in equity.

(d) Sections 6 and 8 of this letter agreement will expressly survive termination of this agreement. You acknowledge and agree that (i) any claims that you may have against the Company will not be a defense to enforcement of the restrictions set forth in Sections 6 or 8 and (ii) the circumstances of your termination of employment with the Company will have no impact on your obligations under Sections 6 or 8.

10. Notices. All notices, requests, demands, claims, and other communications hereunder will be in writing. Any notice, request, demand, claim or other communication hereunder will be deemed duly given (i) upon delivery, if delivered personally to the recipient, against written receipt therefor, or (ii) upon the first business day after the date sent, if sent priority next-day delivery to the intended recipient by reputable express courier service (charges prepaid) and addressed to the intended recipient as set forth below:

If to the Company, to:

Steve Hoffman, Chief Executive Officer
Tyme Technologies, Inc.
44 Wall Street – 12th Floor
New York, New York 10005

and with a copy to:

Drinker Biddle & Reath LLP
105 College Road East, P.O. Box 627
Princeton, NJ 08542-0627
Attention: Jim Biehl, Esq.

If to you, to the address shown on the first page.

Any party hereto may send any notice, request, demand, claim or other communication hereunder to the intended recipient at the address set forth above using any other means, but no such notice, request, demand, claim or other communication will be deemed to have been duly given unless and until it actually is received and acknowledged by the intended recipient. Any party hereto may change the address (or add new parties and their addresses) to which notices, requests, demands, claims, and other communications hereunder are to be delivered by giving the other parties hereto notice in the manner set forth in this Section 10.

11. Representations and Warranties. You hereby represent and warrant to the Company that (a) all information provided by you to the Company through or in connection with any employment questionnaire is true and accurate in all respects and does not omit any material information necessary to make such furnished information not misleading, (b) the execution, delivery and performance of this letter agreement by you does not and will not conflict with, breach, violate or cause a default under any agreement, contract or instrument to which you are a party or any judgment, order or decree to which you are subject, (c) you are not a party to or bound by any employment agreement, consulting agreement, non-compete agreement, confidentiality agreement or similar agreement with any other person or entity that is inconsistent with the provisions of this letter agreement, (d) upon the execution and delivery of this letter agreement by the Company and you, this letter agreement will be a valid and binding obligation of you enforceable in accordance with its terms and (e) you are fully able to perform those services described in this letter agreement. The Company hereby represents and warrants to you that (i) the execution, delivery and performance of this letter agreement by the Company does not and will not conflict with, breach, violate or cause a default under any agreement, contract or instrument to which it is a party or any judgment, order or decree to which it is

subject and (ii) upon the execution and delivery of this letter agreement by the Company and you, this agreement will be a valid and binding obligation of the Company enforceable in accordance with its terms.

12. Lock-Up Agreement. In connection with a registration with the United States Securities and Exchange Commission under the Securities Act of the public sale of shares of Common Stock, you shall not to sell, make any short sale of, loan, grant any option for the purchase of, or otherwise dispose of any securities of the Company (other than those included in the registration) without the prior written consent of the Company or such underwriters, as the case may be, for such period of time prior to the effective date of such registration and continuing through and following the effective date of such registration (not to exceed 180 days) as the Company or the underwriters, as the case may be, shall specify. You agree that the Company may instruct its transfer agent to place stop-transfer notations in its records to enforce the provisions of this Section. You shall execute a form of agreement reflecting the foregoing restrictions as requested by the underwriters managing such offering.

13. General Provisions.

(a) Conditioned on Closing of Financing. The effectiveness of his letter agreement is expressly conditioned upon the closing and funding, prior to March 24, 2017, of an equity securities financing transaction involving the Company through an agreement dated March 10, 2017 (the “SPA”), for which investor SPA signature pages were being held by the Company in escrow prior to the execution of this letter agreement and in which the Company ultimately receives at least \$8 million in gross proceeds in accordance with, or on economic terms at least as favorable to, the economic terms set forth in the SPA (the “**Funding Condition**”). In the event that such closing under the SPA does not occur by March 24, 2017, this letter agreement shall be of no force and effect, and neither party to the letter agreement shall have further obligations to the other hereunder, except for the obligation not to use or disclose confidential information of the other consistent with applicable law.

(b) No Interference. For clarity, the Company confirms that nothing in this letter agreement is intended to prevent, impede or interfere with your right, without notice to the Company, to (a) file a charge or complaint with any agency which enforces anti-discrimination, workplace safety, securities, or other laws; (b) communicate with, cooperate with or provide truthful information to any governmental agency, or participate in any government investigation; or (c) testify truthfully in any court or administrative proceeding.

(c) Severability. It is the desire and intent of the parties hereto that the provisions of this letter agreement be enforced to the fullest extent permissible under the laws and public policies applied in each jurisdiction in which enforcement is sought. Accordingly, if any particular provision of this letter agreement will be adjudicated by a court of competent jurisdiction to be invalid, prohibited or unenforceable for any reason, such provision, as to such jurisdiction, will be ineffective, without invalidating the remaining provisions of this agreement or affecting the validity or enforceability of this letter agreement or affecting the validity or enforceability of such provision in any other jurisdiction. Notwithstanding the foregoing, if such provision could be more narrowly drawn so as not to be invalid, prohibited or unenforceable in such jurisdiction, it will, as to such jurisdiction, be so narrowly drawn, without invalidating the

remaining provisions of this letter agreement or affecting the validity or enforceability of such provision in any other jurisdiction.

(d) Complete Agreement. This letter agreement and any schedules or exhibits expressly constitute the entire agreement among the parties hereto with respect to the subject matter hereof and supersedes and pre-empts any prior understandings, agreements or representations by or among the parties, written or oral, which may have related to the subject matter hereof in any way. Except as specified herein, you have no other rights with respect to service for or employment by the Company.

(e) Successors and Assigns. This letter agreement will be binding upon Employee's heirs, executors, administrators and other legal representatives and may be assigned by the Company and its successors to any Person, including, but not limited to, any successor or parent of the Company or any Affiliate. The Company also may assign this letter agreement in connection with any sale or merger (whether a sale or merger of stock or assets or otherwise) of the Company or the business of the Company. Employee expressly consents to the assignment of the restrictions and requirements set forth in this letter agreement to any new owner of the Company's business, purchaser of the Company or any other permitted assignee, and any such assignment (even if involving a termination and rehiring for official purposes) shall not constitute a termination without Cause hereunder. Employee may not assign, pledge, or encumber Employee's interest in this Agreement, or any part thereof, without the written consent of the Company.

(f) Governing Law. This letter agreement will be governed by and construed in accordance with the domestic laws of New York, without giving effect to the choice of law provisions thereof. The parties agree that the exclusive venue for all disputes under this agreement shall be the federal and state courts sitting in New York County, New York.

(g) Amendment and Waiver. The provisions of this letter agreement may be amended and waived only with the prior written consent of the Company (with the approval of the Board) and you, and no course of conduct or failure or delay in enforcing the provisions of this letter agreement will affect the validity, binding effect or enforceability of this letter agreement or any provision hereof.

(h) Headings. The section headings contained in this agreement are inserted for convenience only and will not affect in any way the meaning or interpretation of this agreement.

(i) Counterparts. This letter agreement may be executed in counterparts, each of which will be deemed an original and all of which together will constitute one and the same instrument.

(j) 409A Provision.

(i) For purposes of this letter agreement the term “ **termination of employment** ” and similar terms relating to your termination of employment mean a “ **separation from service** ” as that term is defined under Section 409A of the Internal Revenue Code of 1986, as amended, and the final regulations issued thereunder (“ **Section 409A** ”). For purposes of

Section 409A, each installment payment provided under this Agreement shall be treated as a separate payment. The Company and you intend that this letter agreement comply in form and operation with the requirements of Section 409A. To the extent permitted by applicable Department of Treasury/Internal Revenue Service guidance, or law or regulation, the Company and you will take reasonable actions to reform this letter agreement or any actions taken pursuant to their operation of this letter agreement in order to comply with Section 409A. Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under this Agreement comply with Section 409A and in no event shall the Company be liable for all or any portion of any taxes, penalties, interest or other expenses that may be incurred by you on account of non-compliance with Section 409A.

(ii) Notwithstanding any other provision of this Agreement, if any payment or benefit provided to you in connection with your termination of employment is determined to constitute “nonqualified deferred compensation” within the meaning of Section 409A and you are determined to be a “specified employee” as defined in Section 409A(a)(2)(b)(i), then such payment or benefit shall not be paid until the first payroll date to occur following the six-month anniversary of the termination date or, if earlier, on your death (the “Specified Employee Payment Date”). The aggregate of any payments that would otherwise have been paid before the Specified Employee Payment Date shall be paid to you in a lump sum on the Specified Employee Payment Date and thereafter, any remaining payments shall be paid without delay in accordance with their original schedule.

* * *

If this letter agreement correctly expresses our mutual understanding, please sign and date this letter agreement at the signature block on the succeeding page, and return it to us.

Very truly yours,

Tyme Technologies, Inc.

By: _____
Name: Steve Hoffman
Title: Chief Executive Officer

The terms of this letter agreement are
accepted and agreed to as of the date
first set forth above by:

Ben Roberts Taylor

Tyme Technologies, Inc.

Nonqualified Stock Option Agreement

Tyme Technologies, Inc., a Delaware corporation (the “**Company**”), pursuant to the Company’s 2015 Equity Incentive Plan (the “**Plan**”), has granted to Ben Roberts Taylor (the “**Optionee**”) a nonqualified stock option (the “**Option**”) to purchase a total of 1,500,000 shares (each, a “**Share**”) of the common stock, par value \$0.0001 per share (the “Common Stock”), of the Company, at an exercise price equal to the trailing five day average trade price of a share of Common Stock (the “**Exercise Price**”), on the terms and conditions set forth in this Option Agreement (this “**Agreement**”) and, in all respects, subject to the terms and conditions of the Plan. The effective date of grant of the Option is [REDACTED], 2017 (the “**Date of Grant**”). Unless otherwise defined herein, the capitalized terms defined in the Plan shall have the same defined meanings in this Agreement.

1. Duration. Subject to the earlier termination as provided in this Agreement or under the Plan, the Option shall expire and shall no longer be exercisable as of the close of business on March [REDACTED], 2027 (the “**Termination Date**”).

2. Written Notice of Exercise. The Option may be exercised only by delivering to the President or Secretary of the Company, at the Company’s principal executive offices, of a written notice of exercise substantially in the form described in paragraph 8(b) of this Agreement, accompanied by this Agreement.

3. Anti-Dilution Provisions.

(a) If there is any stock dividend, stock split or combination of shares of Common Stock, the number and amount of Shares then subject to the Option shall be proportionately and appropriately adjusted as determined by the Committee, whose determination shall be final, conclusive and binding upon Optionee and the Company.

(b) If there is any other change in the Common Stock, including a recapitalization, reorganization, sale or exchange of assets, exchange of shares, offering of subscription rights, or a merger or consolidation in which the Company is the surviving corporation, an adjustment, if any, shall be made in the Shares then subject to the Option as the Board of Directors or Committee may deem equitable, and whose determination shall be final, conclusive and binding upon Optionee and the Company. Failure of the Board of Directors or the Committee to provide for an adjustment pursuant to this paragraph 3(b) prior to the effective date of any Company action referred to in this paragraph 3(b) shall be conclusive evidence that no adjustment is required in consequence of such action.

(c) If the Company is merged into or consolidated with any other corporation and the Company is not the surviving corporation, or if the Company sells all or substantially all of the Company’s assets to any other corporation, then either:

(i) the Company shall cause provisions to be made for the continuance of the Option after such event or for the substitution for the Option of an option covering the number and class of securities which the Optionee would have been entitled to receive in such merger, consolidation or if the Optionee had been the holder of record of a number of shares of Common Stock equal to the number of Shares covered by the unexercised portion of the Option immediately prior to such merger, consolidation or sale; or

(ii) the Company shall give to Optionee written notice of the Company's election not to cause any provision to be made under the preceding clause (i) and, then only in such event the Option shall become exercisable in full (or, at the election of the Optionee, in part) at any time during a period to be designated by the Company, ending not more than one business day prior to the effective date of the merger, consolidation or sale, in which case the Option shall not be exercisable to any extent after the expiration of such period.

Notwithstanding the provisions of this paragraph 3(c), in no event shall the Option be exercisable after the Termination Date.

4. Investment Representation and Legend of Certificates . Optionee acknowledges that, for any period in which a registration statement with respect to the Option and/or Shares under the Securities Act of 1933, as amended (the “**Securities Act**”), is not effective, Optionee shall hold the Option and will purchase and/or own the Shares for investment purposes only and not for resale or distribution. The Company shall have the right to place upon the face and/or reverse side of any stock certificate or certificates evidencing the Shares such legend as the Committee may prescribe for the purpose of preventing disposition of such Shares in violation of the Securities Act.

5. Non Transferability. The Option shall not be transferable by Optionee, other than by (a) will, the laws of descent or distribution or (b) pursuant to a proceeding under title 11 of the U.S. Bankruptcy Code or similar insolvency proceeding, and is exercisable during the lifetime of Optionee only by Optionee, except as otherwise specifically provided in this Agreement or the Plan. The terms of this Agreement shall be binding upon the executors, administrators, heirs, successors and assigns of Optionee.

6. Certain Rights Not Conferred by Option. Optionee shall not, by virtue of holding the Option, be entitled to any rights of a stockholder in the Company.

7. Expenses. The Company shall pay all original issue and transfer taxes with respect to the issuance of the Shares pursuant hereto and all other fees and expenses necessarily incurred by the Company in connection therewith.

8. Exercise of Options.

(a) Notwithstanding anything to the contrary contained in this Agreement, the Option shall become exercisable according to the following schedule, provided that the Optionee is employed by the Company on such dates:

1-year anniversary of the Date of Grant	375,000 shares
2-year anniversary of the Date of Grant	375,000 shares
3-year anniversary of the Date of Grant	375,000 shares
4-year anniversary of the Date of Grant	375,000 shares

(b) Notwithstanding the foregoing, upon a termination of the Optionee's employment without Cause by the Company, additional vesting shall occur as set forth in Section 3(c) of Optionee's Employment Agreement.

(c) The Option shall be exercisable, in whole or part and from time to time, but subject to the exercise schedule set forth in paragraph 8(a) of this Agreement, by written notice of such exercise, delivered to the President or Secretary of the Company, at the Company's principal office by personal delivery, against written receipt therefor, or by pre-paid, certified or registered mail, return receipt requested. Such notice shall specify the number of Shares for which the Option is being exercised (which number, if less than all of the Shares then subject to exercise, shall be 100 or an integral multiple thereof) and shall be accompanied by:

(i) payment of the full exercise price for the Shares for which the Option is being exercised; and

(ii) this Agreement.

(c) The form of payment of the Exercise Price for Shares purchased pursuant to each exercise of the Option shall be paid in full at the time of each purchase in one or a combination of the following methods:

(i) cash;

(ii) check (subject to collection);

(iii) in the discretion of the Committee, surrender to the Company of other shares of Common Stock owned by the Optionee which:

(A) have a Fair Market Value on the date of surrender equal to the aggregate exercise price of the Shares as to which the Option is being exercised; and

(B) have been owned of record by Optionee for at least six months;

(iv) in the discretion of the Committee, commencing upon the date on which all of the Shares subject to the Option are exercisable in accordance with the exercise schedule set forth in paragraph 8(a) of this Agreement, by "cashless exercise," by means of exercising the Option in full and receiving such number of Shares having a Fair Market Value on the date of such cashless exercise equal to the difference between:

(A) the Fair Market Value of the Shares issuable upon exercise of the Option in full on the date of such cashless exercise; and

(B) the exercise price of the Option multiplied by the number of Shares issuable upon exercise of the Option in full; or

(v) in the discretion of the Committee, but, in all cases, subject to applicable law, by:

(A) delivery to the Company of a promissory note containing such terms and conditions determined by the Committee, in the Committee's sole discretion, but at a rate of interest at least equal to the imputed interest specified under Section 483 or Section 1274, whichever is applicable, of the Code, and secured by the Shares issuable upon exercise of the Option for which the promissory note is being delivered and otherwise in compliance with applicable law (including, without limitation, state corporate law and federal margin requirements);

(B) assignment to the Company of the net proceeds (to the extent necessary to pay such exercise price) to be received from a registered broker upon the sale of the Shares or assignment of the net proceeds (to the extent necessary to pay such exercise price) of a loan from such broker in such amount; or

(C) such other consideration and method of payment for the issuance of stock to the extent permitted under applicable law and satisfying the requirements of Rule 16b-3 promulgated pursuant to the Exchange Act.

(d) No Shares shall be delivered upon exercise of the Option until all laws, rules and regulations that the Committee may, in its sole discretion, deem applicable have been complied with. If a registration statement under the Securities Act is not then in effect with respect to the Shares issuable upon such exercise, the Company may require as a condition precedent that Optionee, upon exercising the Option, deliver to the Company a written representation and undertaking, satisfactory in form and substance to the Committee, that, among other things, Optionee is acquiring the Shares for Optionee's own account for investment purposes only and not with a view to the distribution thereof.

(e) Optionee shall not be considered a record holder of the Shares so purchased for any purpose until the date on which Optionee is actually recorded as the holder of such Shares in the records of the Company.

9. Continued Employment. Nothing herein shall be deemed to create any employment or consultancy or guaranty of continued employment or consultancy or limit in any way the Company's right to terminate Optionee's employment or consultancy at any time.

Tyme Technologies, Inc.

By: _____
Steven Hoffman, President

OPTIONEE ACKNOWLEDGEMENT

OPTIONEE ACKNOWLEDGES AND AGREES THAT THE EXERCISABILITY OF THE SHARES SUBJECT TO THIS AGREEMENT AND THE OPTION IS EARNED ONLY BY CONTINUING EMPLOYMENT OR CONSULTANCY AT THE WILL OF THE COMPANY (NOT THROUGH THE ACT OF BEING HIRED, BEING GRANTED THE OPTION OR ACQUIRING SHARES HEREUNDER). OPTIONEE FURTHER ACKNOWLEDGES AND CONFIRMS THAT NOTHING IN THIS AGREEMENT, NOR IN THE PLAN WHICH IS INCORPORATED HEREIN BY REFERENCE, SHALL CONFER UPON OPTIONEE ANY RIGHT WITH RESPECT TO CONTINUATION OF EMPLOYMENT OR CONSULTANCY BY THE COMPANY, NOR SHALL IT INTERFERE IN ANY WAY WITH OPTIONEE'S OR THE COMPANY'S RIGHT, SUBJECT TO OPTIONEE'S AND THE COMPANY'S RIGHTS UNDER OTHER AGREEMENTS, IF ANY, WITH THE COMPANY, TO TERMINATE EMPLOYMENT OR CONSULTANCY AT ANY TIME, WITH OR WITHOUT CAUSE.

Optionee acknowledges receipt of a copy of the Plan and certain information related to this Plan and Company and represents that Optionee is familiar with the terms and provisions of the Plan, and hereby accepts the Option subject to all of the terms and provisions of the Plan. Optionee has reviewed the Plan and this Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Agreement and fully understands all of the terms and provisions of the Option and this Agreement. Optionee hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Committee upon any questions rising under the Plan. Optionee further agrees to notify the Company upon any change in the residence address indicated below.

Accepted and agreed as of the Date
of Grant as first set forth above:

Name: Ben Roberts Taylor
Address:

EXHIBIT B

Form of Release

RELEASE

This Release is delivered by Ben R. Taylor on this ____ day of _____, 20__.

DEFINITIONS

A. As used herein, unless otherwise specified, the term "Employer" shall mean Tyme Technologies, Inc.

B. As used herein, unless otherwise specified, the term "Employee" shall mean Ben R. Taylor.

RECITALS

WHEREAS, Employee's employment ended on _____, 20__; and

WHEREAS, it is a condition to the Employee's receipt of certain post-employment benefits ("Conditional Benefits") under the Employment Agreement, dated as of **[INSERT DATE]**, 2017 (the "Employment Agreement"), between Employee and Employer that Employee execute this Release.

NOW THEREFORE, in consideration of the promises, representations and mutual covenants contained in this Release, and for other good and valuable consideration, the sufficiency of which is hereby acknowledged, it is agreed as follows:

1. Consideration. Employee acknowledges that the Conditional Benefits are in excess of any earned wages or benefits due and owing Employee, and would not be paid or provided unless Employee executed this Release. Employee acknowledges and agrees that the Conditional Benefits are adequate and independent consideration for Employee executing this Release and releasing any and all claims against Employer and other Released Parties (as defined below).

2. Release of All Claims. In consideration of the above, and the other promises set forth in this Release, Employee fully and forever waives, releases, acquits and discharges Employer and each and every of its subsidiaries and related or affiliated entities (together, the "Entities"), and each of the Entities' current and former directors, officers, shareholders, members, partners, employees, and attorneys (collectively, the "Released Parties") from and for all manner of claims, actions, suits, charges, grievances and/or causes of action, in law or in equity, existing by reason of and/or based upon any fact or set of facts, known or unknown, existing from the beginning of time through the date of Employee's execution of this Release relating to and/or arising out any matter or subject, including but not limited to the Employment Agreement, Employee's employment with Employer and/or the cessation of Employee's

employment with Employer (collectively, the "Released Claims"). The Released Claims include, but are not limited to, all claims, actions, suits, charges, grievances and/or causes of action for wages, compensation, liquidated damages, commissions, bonuses, benefits, sums of money, damages of every type, costs, attorney fees, judgments, executions, wrongful discharge, breach of contract, breach of implied contract, breach of the covenant of good faith and fair dealing, tortious interference with contract or business relationships, assault, battery, invasion of privacy, misappropriation of trade secrets, promissory estoppel, unjust enrichment, loss of consortium, violation of the penal statutes, negligent or intentional infliction of emotional distress, negligence, defamation, retaliation and/or discrimination and/or harassment on account of age, sex, sexual orientation, creed, religion, race, color, national origin, sensory disability, mental disability, physical disability, veteran or military status, marital status, or any other classification recognized under all applicable discrimination laws, or any other claim or cause of action, which has or could have been alleged under the common law, civil rights statutes, Title VII of the Civil Rights Act of 1964 ("Title VII"), the Age Discrimination in Employment Act ("ADEA"), the Family and Medical Leave Act ("FMLA"), the Employee Retirement Income Security Act ("ERISA"), the Rehabilitation Act of 1973, the Older Workers Benefits Protection Act ("OWBPA"), the Americans with Disabilities Act ("ADA"), the Consolidated Omnibus Budget Reconciliation Act ("COBRA"), the Workers Adjustment Retraining Notification Act ("WARN"), the Equal Pay Act ("EPA"), the Uniformed Services Employment and Reemployment Rights Act ("USERRA"), the National Labor Relations Act ("NLRA"), the New York State Human Rights Law, the New York City Human Rights Law, the New York State Labor Law, and all other federal, state, local statutes, ordinances, and laws, and every type of relief, (legal, equitable and otherwise) available to Employee. Subject to Section 10 below, Employee covenants and agrees that he will not pursue or allege any claim, matter or cause of action in violation of, and/or released under, this Release. Notwithstanding the foregoing, nothing in this Release shall be construed as releasing Employer from its obligation to pay those amounts due to Employee under Section 5(a) of the Employment Agreement, subject to the terms and conditions thereof, which obligation is not a Released Claim. Nor is this Release intended to release claims arising from facts occurring after Employee executes this Release or that may not be released as a matter of law.

3. Covenant Not to Sue. Employee agrees that neither he nor any person or entity on his behalf shall commence, maintain or prosecute any lawsuit or court complaint against Employer or any of the other Released Parties with respect to any act, omission or other matter that is released by the provisions of the preceding Section. This Section shall not operate to waive any rights that may not legally be waived, nor shall it preclude Employee from bringing an action under this Agreement, and it shall in all respects be subject to Section 10 below.

Employee affirms that, as of this date, he has not taken or initiated any Court complaint against any of the Released Parties concerning his separation from the Company and/or any payment, benefit or compensation that he maintains she is owed or otherwise entitled to, and no such action is pending.

4. Confidentiality. To the fullest extent permitted by law, Employee agrees to keep confidential all facts, opinions, and information which relate in any way to Employee's employment and/or cessation of employment with Employer, as well as the terms of this Release; provided however, Employee may discuss the terms of this Release with (a) his spouse, legal representative, and/or tax preparer, each of whom must also agree to maintain

confidentiality and comply with this Paragraph 4 of the Release, and (b) a government agency in connection with a government investigation.

5. Return of Employer's Property. Employee represents that he has returned to Employer any and all property, records, papers, documents and writings, in whatever form, of Employer in Employee's possession and/or control, and that he has not retained any copies thereof, in whatever form.

6. Cooperation.

(a) In the event Employee is served with a subpoena or is required by court order or otherwise to testify in any type of proceeding involving the Employer and related to a Released Claim, Employee shall immediately advise Employer in writing of same.

(b) Employee agrees to cooperate with Employer in any internal investigation, administrative, regulatory, or judicial proceeding or any dispute with a third party. Employee's cooperation may include being available to Employer upon reasonable notice for interviews and factual investigations, appearing at Employer's request to give testimony without requiring service of a subpoena or other legal process, volunteering to Employer pertinent information, and turning over to Employer all relevant documents which are or may come into Employee's possession. Employee understands that in the event Employer asks for Employee's cooperation in accordance with this provision, Employer will reimburse him/her for reasonable travel expenses (including lodging and meals) upon submission of receipts acceptable to Employer.

7. ADEA Notice and Acknowledgement. Employee acknowledges that he has carefully read this Release and fully understands its contents. Prior to signing this Release, Employee has been advised in writing hereby and has had an opportunity to consult with his attorney of choice concerning the terms and conditions of this Release with regard to any claim or right Employee may have under the ADEA or otherwise. Employee has been offered at least 21 days to review and consider this Release, and no revisions to this Release, whether material or not, have restarted the running of that period. Employee may voluntarily and knowingly waive this 21 day period, or any part thereof, if he signs this Release prior to the expiration of 21 days. After signing this Release, Employee shall have seven days from the signing date to revoke this Release. This Release shall not be effective (including for purposes under the Employment Agreement) until after the seven-day revocation period has expired without Employee's revocation. Any revocation must be made in writing and delivered to the Chief Executive Officer of Employer. Until all applicable periods set forth in this Section 7 have expired without revocation, Employer shall not be required to make any payment or provide any benefits to Employee, which payment or benefits are, under the Employment Agreement, contingent upon the signing and delivery to the Company and non-revocation of this Release. By signing this Release, Employee agrees and understands that he is waiving and releasing any and all rights he may have to pursue claims against Employer, from the beginning of time up to the date of his execution of this Release, including, without limitation, all ADEA claims.

8. No Further Payments, Benefits or Rights. Employee acknowledges that, other than the Conditional Benefits, he has received payment in full of all of the compensation, benefits and/or payments of any kind due to him from Employer and/or any other Released

Parties, including all compensation, bonuses, expense reimbursements, payments to or from benefit plans, unused accrued vacation time, personal time, severance, sick pay or any other payment under a plan, program, practice or promise of the Employer or that of any other Released Party. Employee further acknowledges that he is not, and shall not be, entitled to receive from Employer or any other Released Party any payments, benefits or perquisites (whether monetary and non-monetary) other than those expressly described in this Agreement.

9. Governing Law. New York law shall govern this Release, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of New York or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of New York.

10. Non-Interference. For clarity, Employer confirms that nothing in this Release – including in the Confidentiality, General Release, and Covenant Not to Sue provisions – is intended to prevent, impede or interfere with Employee's right, without notice to Employer, to (a) file a charge or complaint with any agency which enforces anti-discrimination, workplace safety, securities, or other laws; (b) communicate with, cooperate with or provide truthful information to any governmental agency, or participate in any government investigation; (c) testify truthfully in any court or administrative proceeding; or (d) receive and retain any monetary award from a government administered whistleblower award program for providing information directly to a government agency. However, Employee understands that, by signing this Agreement and not revoking it, he has waived her right to recover any money from Employer or any other Released Parties, other than the Conditional Benefits.

11. Successors and Assigns. This Release shall be inure to the benefit of the successors and assigns of Employer.

12. Severability. If any portion of this Release is ruled unenforceable, all remaining portions of this Release shall remain valid.

13. No Reliance; No Waiver. Employee represents that he is not relying on any representation, statement, or promise of Employer or any other party in giving this Release. This Release may not be amended, modified, waived, or terminated except in a writing signed by Employee and an authorized representative of Employer.

14. Headings. The paragraph and section headings in this Release are inserted merely for the convenience of reference only and shall not be used to construe, affect or modify the terms of any paragraph or provision of this Release.

EMPLOYEE WITHOUT ANY DURESS OR COERCION FREELY, KNOWINGLY AND VOLUNTARILY ENTERS INTO, AND GIVES THIS RELEASE. EMPLOYEE UNDERSTANDS AND AGREES WITH ALL OF THE PROVISIONS AND THE TERMS STATED IN THIS RELEASE AND HAS BEEN AFFORDED SUFFICIENT AND REASONABLE TIME TO CONSIDER WHETHER TO ENTER INTO THIS RELEASE. EMPLOYER ADVISES EMPLOYEE TO CONSULT WITH AN ATTORNEY OF EMPLOYEE'S CHOOSING PRIOR TO EXECUTING THIS RELEASE WHICH CONTAINS A RELEASE AND WAIVER.

Ben R. Taylor

Date

Tyme Technologies, Inc.

Nonqualified Stock Option Agreement

Tyme Technologies, Inc., a Delaware corporation (the “**Company**”), pursuant to the Company’s 2015 Equity Incentive Plan (the “**Plan**”), has granted to Ben R. Taylor (the “**Optionee**”) a nonqualified stock option (the “**Option**”) to purchase a total of 1,500,000 shares (each, a “**Share**”) of the common stock, par value \$0.0001 per share (the “Common Stock”), of the Company, at an exercise price per share of Common Stock equal to \$2.95 (the “**Exercise Price**”), on the terms and conditions set forth in this Option Agreement (this “**Agreement**”) and, in all respects, subject to the terms and conditions of the Plan. The effective date of grant of the Option is March 27, 2017 (the “**Date of Grant**”). Unless otherwise defined herein, the capitalized terms defined in the Plan shall have the same defined meanings in this Agreement.

1. Duration. Subject to the earlier termination as provided in this Agreement or under the Plan, the Option shall expire and shall no longer be exercisable as of the close of business on March 27, 2027 (the “**Termination Date**”).

2. Written Notice of Exercise. The Option may be exercised only by delivering to the President or Secretary of the Company, at the Company’s principal executive offices, of a written notice of exercise substantially in the form described in paragraph 8(b) of this Agreement, accompanied by this Agreement.

3. Anti-Dilution Provisions.

(a) If there is any stock dividend, stock split or combination of shares of Common Stock, the number and amount of Shares then subject to the Option shall be proportionately and appropriately adjusted as determined by the Committee, whose determination shall be final, conclusive and binding upon Optionee and the Company.

(b) If there is any other change in the Common Stock, including a recapitalization, reorganization, sale or exchange of assets, exchange of shares, offering of subscription rights, or a merger or consolidation in which the Company is the surviving corporation, an adjustment, if any, shall be made in the Shares then subject to the Option as the Board of Directors or Committee may deem equitable, and whose determination shall be final, conclusive and binding upon Optionee and the Company. Failure of the Board of Directors or the Committee to provide for an adjustment pursuant to this paragraph 3(b) prior to the effective date of any Company action referred to in this paragraph 3(b) shall be conclusive evidence that no adjustment is required in consequence of such action.

(c) If the Company is merged into or consolidated with any other corporation and the Company is not the surviving corporation, or if the Company sells all or substantially all of the Company’s assets to any other corporation, then either:

(i) the Company shall cause provisions to be made for the continuance of the Option after such event or for the substitution for the Option of an option covering the number and class of securities which the Optionee would have been entitled to receive in such merger, consolidation or if the Optionee had been the holder of record of a number of shares of Common Stock equal to the number of Shares covered by the unexercised portion of the Option immediately prior to such merger, consolidation or sale; or

(ii) the Company shall give to Optionee written notice of the Company's election not to cause any provision to be made under the preceding clause (i) and, then only in such event the Option shall become exercisable in full (or, at the election of the Optionee, in part) at any time during a period to be designated by the Company, ending not more than one business day prior to the effective date of the merger, consolidation or sale, in which case the Option shall not be exercisable to any extent after the expiration of such period.

Notwithstanding the provisions of this paragraph 3(c), in no event shall the Option be exercisable after the Termination Date.

4. Investment Representation and Legend of Certificates . Optionee acknowledges that, for any period in which a registration statement with respect to the Option and/or Shares under the Securities Act of 1933, as amended (the “**Securities Act**”), is not effective, Optionee shall hold the Option and will purchase and/or own the Shares for investment purposes only and not for resale or distribution. The Company shall have the right to place upon the face and/or reverse side of any stock certificate or certificates evidencing the Shares such legend as the Committee may prescribe for the purpose of preventing disposition of such Shares in violation of the Securities Act.

5. Non Transferability. The Option shall not be transferable by Optionee, other than by (a) will, the laws of descent or distribution or (b) pursuant to a proceeding under title 11 of the U.S. Bankruptcy Code or similar insolvency proceeding, and is exercisable during the lifetime of Optionee only by Optionee, except as otherwise specifically provided in this Agreement or the Plan. The terms of this Agreement shall be binding upon the executors, administrators, heirs, successors and assigns of Optionee.

6. Certain Rights Not Conferred by Option. Optionee shall not, by virtue of holding the Option, be entitled to any rights of a stockholder in the Company.

7. Expenses. The Company shall pay all original issue and transfer taxes with respect to the issuance of the Shares pursuant hereto and all other fees and expenses necessarily incurred by the Company in connection therewith.

8. Exercise of Options.

(a) Notwithstanding anything to the contrary contained in this Agreement, the Option shall become exercisable according to the following schedule, provided that the Optionee is employed by the Company on such dates:

1-year anniversary of the Date of Grant	375,000 shares
2-year anniversary of the Date of Grant	375,000 shares
3-year anniversary of the Date of Grant	375,000 shares
4-year anniversary of the Date of Grant	375,000 shares

(b) Notwithstanding the foregoing, upon a termination of the Optionee's employment without Cause by the Company, additional vesting shall occur as set forth in Section 3(c) of Optionee's Employment Agreement.

(c) The Option shall be exercisable, in whole or part and from time to time, but subject to the exercise schedule set forth in paragraph 8(a) of this Agreement, by written notice of such exercise, delivered to the President or Secretary of the Company, at the Company's principal office by personal delivery, against written receipt therefor, or by pre-paid, certified or registered mail, return receipt requested. Such notice shall specify the number of Shares for which the Option is being exercised (which number, if less than all of the Shares then subject to exercise, shall be 100 or an integral multiple thereof) and shall be accompanied by:

(i) payment of the full exercise price for the Shares for which the Option is being exercised; and

(ii) this Agreement.

(c) The form of payment of the Exercise Price for Shares purchased pursuant to each exercise of the Option shall be paid in full at the time of each purchase in one or a combination of the following methods:

(i) cash;

(ii) check (subject to collection);

(iii) in the discretion of the Committee, surrender to the Company of other shares of Common Stock owned by the Optionee which:

(A) have a Fair Market Value on the date of surrender equal to the aggregate exercise price of the Shares as to which the Option is being exercised; and

(B) have been owned of record by Optionee for at least six months;

(iv) in the discretion of the Committee, commencing upon the date on which all of the Shares subject to the Option are exercisable in accordance with the exercise schedule set forth in paragraph 8(a) of this Agreement, by "cashless exercise," by means of exercising the Option in full and receiving such number of Shares having a Fair Market Value on the date of such cashless exercise equal to the difference between:

(A) the Fair Market Value of the Shares issuable upon exercise of the Option in full on the date of such cashless exercise; and

(B) the exercise price of the Option multiplied by the number of Shares issuable upon exercise of the Option in full; or

(v) in the discretion of the Committee, but, in all cases, subject to applicable law, by:

(A) delivery to the Company of a promissory note containing such terms and conditions determined by the Committee, in the Committee's sole discretion, but at a rate of interest at least equal to the imputed interest specified under Section 483 or Section 1274, whichever is applicable, of the Code, and secured by the Shares issuable upon exercise of the Option for which the promissory note is being delivered and otherwise in compliance with applicable law (including, without limitation, state corporate law and federal margin requirements);

(B) assignment to the Company of the net proceeds (to the extent necessary to pay such exercise price) to be received from a registered broker upon the sale of the Shares or assignment of the net proceeds (to the extent necessary to pay such exercise price) of a loan from such broker in such amount; or

(C) such other consideration and method of payment for the issuance of stock to the extent permitted under applicable law and satisfying the requirements of Rule 16b-3 promulgated pursuant to the Exchange Act.

(d) No Shares shall be delivered upon exercise of the Option until all laws, rules and regulations that the Committee may, in its sole discretion, deem applicable have been complied with. If a registration statement under the Securities Act is not then in effect with respect to the Shares issuable upon such exercise, the Company may require as a condition precedent that Optionee, upon exercising the Option, deliver to the Company a written representation and undertaking, satisfactory in form and substance to the Committee, that, among other things, Optionee is acquiring the Shares for Optionee's own account for investment purposes only and not with a view to the distribution thereof.

(e) Optionee shall not be considered a record holder of the Shares so purchased for any purpose until the date on which Optionee is actually recorded as the holder of such Shares in the records of the Company.

9. Continued Employment. Nothing herein shall be deemed to create any employment or consultancy or guaranty of continued employment or consultancy or limit in any way the Company's right to terminate Optionee's employment or consultancy at any time.

Tyme Technologies, Inc.

By: /s/ Steven Hoffman
Steven Hoffman, President

OPTIONEE ACKNOWLEDGEMENT

OPTIONEE ACKNOWLEDGES AND AGREES THAT THE EXERCISABILITY OF THE SHARES SUBJECT TO THIS AGREEMENT AND THE OPTION IS EARNED ONLY BY CONTINUING EMPLOYMENT OR CONSULTANCY AT THE WILL OF THE COMPANY (NOT THROUGH THE ACT OF BEING HIRED, BEING GRANTED THE OPTION OR ACQUIRING SHARES HEREUNDER). OPTIONEE FURTHER ACKNOWLEDGES AND CONFIRMS THAT NOTHING IN THIS AGREEMENT, NOR IN THE PLAN WHICH IS INCORPORATED HEREIN BY REFERENCE, SHALL CONFER UPON OPTIONEE ANY RIGHT WITH RESPECT TO CONTINUATION OF EMPLOYMENT OR CONSULTANCY BY THE COMPANY, NOR SHALL IT INTERFERE IN ANY WAY WITH OPTIONEE'S OR THE COMPANY'S RIGHT, SUBJECT TO OPTIONEE'S AND THE COMPANY'S RIGHTS UNDER OTHER AGREEMENTS, IF ANY, WITH THE COMPANY, TO TERMINATE EMPLOYMENT OR CONSULTANCY AT ANY TIME, WITH OR WITHOUT CAUSE.

Optionee acknowledges receipt of a copy of the Plan and certain information related to this Plan and Company and represents that Optionee is familiar with the terms and provisions of the Plan, and hereby accepts the Option subject to all of the terms and provisions of the Plan. Optionee has reviewed the Plan and this Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Agreement and fully understands all of the terms and provisions of the Option and this Agreement. Optionee hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Committee upon any questions rising under the Plan. Optionee further agrees to notify the Company upon any change in the residence address indicated below.

Accepted and agreed as of the Date
of Grant as first set forth above:

/s/ Ben R. Taylor

Name: Ben R. Taylor
Address:

List of Subsidiaries

Tyme, Inc., a Delaware Corporation (“Tyme”)

Luminant Biosciences, LLC (a wholly-owned subsidiary of Tyme)

Certification of Principal Executive Officer
Pursuant to Rule 13a-14 or 15d-14 of the Securities Exchange Act of 1934

I, Steve Hoffman, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended March 31, 2017 of Tyme Technologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: June 12, 2017

/s/ Steve Hoffman
Steve Hoffman
Chief Executive Officer
(Principal Executive Officer)

Certification of Principal Financial Officer
Pursuant to Rule 13a-14 or 15d-14 of the Securities Exchange Act of 1934

I, Ben R. Taylor, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended March 31, 2017 of Tyme Technologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: June 12, 2017

/s/ Ben R. Taylor
Ben R. Taylor
President and Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

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

In connection with the Annual Report on Form 10-K of Tyme Technologies, Inc. (the "Company") for the fiscal year ended March 31, 2017, to which this Certification is being filed as an exhibit thereto (the "Report"), I, Steve Hoffman, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (a) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C 78m(a) or 78o(d)); and
- (b) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: June 12, 2017

/s/ Steve Hoffman

Steve Hoffman
Chief Executive Officer
(Principal Executive Officer)

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

In connection with the Annual Report on Form 10-K of Tyme Technologies, Inc. (the "Company") for the fiscal year ended March 31, 2017, to which this Certification is being filed as an exhibit thereto (the "Report"), I, Ben R. Taylor, President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (a) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C 78m(a) or 78o(d)); and
- (b) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: June 12, 2017

/s/ Ben R. Taylor

Ben R. Taylor
President and Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)
