UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2015

☐ **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	**45-3864597**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
48 Wall Street – Suite 1100 New York, New York	**10022**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's Telephone Number, including area code: **(646) 205-1603**

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

Title of Each Class	**Name of Each Exchange on Which Registered**
None	None

Securities registered pursuant to Section 12(g) of the Exchange 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 Exchange 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 is a voluntary filer of reports and has filed during the preceding 12 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 website, 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 definite proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

Large accelerated Filer ☐ Accelerated Filer ☐ Non-accelerated Filer ☐ Smaller reporting company ☒

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

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 $177.2 million.

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

Class	**Outstanding at March 23, 2016**
Common stock, $0.0001 par value per share	87,611,370 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 2016 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 December 31, 2015. 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.

TABLE OF CONTENTS

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 within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and subject to the safe harbor created by the Securities Litigation Reform Act of 1995. 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 further adjustment; (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

History

Our Business – General Overview

We are a clinical-stage pharmaceutical company focused on discovering and developing highly targeted cancer therapeutics for a broad range of oncology indications. We are currently developing for use in humans SM-88, our proprietary combination drug product. Combination drug products are commonly referred to as "drug cocktails." We believe SM-88 is a first-in-class oncology therapy that increases the power of the body's innate defenses to utilize oxidative stress to kill cancer cells.

SM-88 is a novel combination of a proprietary novel molecule with three currently-marketed drugs that are generally considered safe for their already approved indications, which are in areas other than cancer treatment.

We believe that SM-88 is capable of synergistically targeting the unique metabolic features of cancer cells and selectively altering the susceptibility of cancer cells to oxidative stress. This selectivity is underscored by evidence indicating that, to date, the SM-88 drug combination drug product has been shown to be nontoxic to noncancerous cells, unlike most current anticancer drugs and treatments. SM-88's therapeutic potential is based on its ability to increase the availability of free radicals at the cancer site and promote their entry into the cell by stripping the cancer cells of their normal barriers to these toxic electrons. The active components of SM-88 are all administered in low doses.

We believe, based on SM-88's mechanism of action and proof-of-concept clinical data, that our drug may ultimately improve overall response rates, clinical outcomes and survival rates in cancer patients. Based on its novel 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.

We consider SM-88 a type of immune-oncology drug using a metabolic pathway, although with a different mechanism than the programmed cell death protein 1, or PD-1, programmed death-ligand 1, or PD-L1, and cytotoxic T-lymphocyte-associated protein 4, or CTLA-4 that have been the subjects of significant research and development by other companies and researchers within the oncology field.

SM-88 is designed to penetrate only living cancer cells, where it introduces multiple mechanisms to kill cancer cells without toxic effects and without involving healthy body tissue. Based upon preliminary data and responses from a phase I clinical trial study and IRB compassionate care studies (described below), we believe that the mechanism of action for SM-88 may induce the transfer of electrons in cancer cells that allow catalyzed external free radicals to react and stress them, creating an engineered metabolic response that results in decreased mucin and decreased defense to reactive oxygen.

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 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 or patients who have relapsed. We believe this development strategy directed at this patient population may allow for faster regulatory approval and may likely require smaller clinical trials, as compared to those indications with more therapeutic options and larger patient populations.

Our initial proof-of-concept clinical trial, we believe, demonstrated that our drug was well-tolerated and showed preliminary activity across a number of different cancer types in terms of tumor regression, biomarker improvement, and in overall survival. Promising results were shown in the 30 enrolled subjects eligible for efficacy evaluation in a proof-of-concept institutional review board (IRB)-approved clinical trial. We cannot predict whether such results will be shown in the future clinical trials and other testing we will be required to undertake in order to obtain regulatory approval of SM-88.

Commencing in January 2012 and concluding in June 2014, we conducted a single-center, open-label, proof-of-concept study for SM-88 in 30 late-stage cancer patients with relapsed or highly refractory disease, including individuals with breast, pancreatic and primary lung cancers, as well as glioblastoma. The trial was conducted under an institutional review board (IRB)-sanctioned compassionate use protocol. In the study, patients received one to ten cycles of treatment, each consisting of daily administration, five days per week, for six weeks. Results from the 30 patients indicated that a complete response was observed in two patients, partial response in six, stable disease in 19 and progressive disease in three. During cycle one, improvements were noted by nearly all subjects in Eastern Cooperative Oncology Group Performance Status, European Organization for Research and Treatment of Cancer Quality of Life and self-reported pain scores. SM-88 was well tolerated, and drug-related adverse events ("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.

We are developing a regulatory and drug development program for SM-88 and are working towards the initiation of our first phase II clinical trial. In September of 2015, we filed an IND with the FDA for our SM-88 drug candidate. In October of 2015, the FDA accepted the IND and concluded that we may proceed with a clinical investigation of SM-88 for breast cancer. We are currently preparing protocols for a phase II breast cancer clinical trial, as well as other phase II trials to be initiated in 2016.

Platform Technology

Our approach is intended to take advantage of the deregulated energy state of tumors to selectively kill cancer cells using electrochemical pathways. While mechanism of action studies are being designed and tested, our IP and drug research program deals with a multi-part process. It is proposed that the high-energy needs of rapidly proliferating tumor cells may be harnessed as a means of stopping cancer cell growth, reducing the size of tumors and eventually destroying those cells. A normal cell uses a process called oxidative phosphorylation to generate approximately 32-high-energy molecules (adenosine triphosphate) from glucose to provide energy for the cell. In contrast, cancer cells use a process called glycolysis that only generates approximately two such high-energy molecules from glucose and requires the additional metabolism of lipids (fats) for energy. This results in a very high-energy requirement for the cancer cells. Cancer cells reproduce rapidly and must synthesize large amounts of proteins to drive their proliferation and, accordingly, their amino acid needs are also quite high. Our approach is to use tumor cells' own exaggerated hunger against them. Our approach is to essentially change the metabolic uptake of the cancer cell. Our SM-88 drug is designed to exploit a cancer's weakness in a manner that we believe has never before been exploited.

SM-88 consists of four drugs in a proprietary combination and is intended as an oral therapy. SM-88 is comprised of three approved drugs, Phenytoin, Methoxsalen, Sirolimus, and a proprietary Tyrosine isomer that we have developed. The components are SM-88 consist of:

- Phenytoin, which stimulates production of reactive lipid species which are associated with apoptosis;
- Methoxsalen, which promotes toxic electron transfer and enhances reactive oxygen species ("ROS") which results mitochondrial directed apoptosis;
- Sirolimus, which is an mTOR inhibitor that decreases insulin actions and results in an increase in tumor cells' demand upon LAT-1 for exogenous amino acids and ROS; and,
- LAT-1, our novel molecule, which is an amino acid exchanger which results in preferential tyrosine uptake.

SM-88 utilizes a proprietary combination of non-nutritive tyrosine analogs that cannot be used in protein synthesis. We believe that the lack of functional tyrosine impairs the synthesis of tyrosine dependent molecules, e.g. mucins, and other essential moieties, making the cancer more vulnerable to cell death.

Our Strengths

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

- Our initial drug candidate, SM-88, is believed to be a first-in-class immuno-modulating-electrochemical-response-modifier cancer therapy;
- SM-88 has demonstrated its potential as an aggressive 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 filed patents for additional drug candidates to provide a pipeline of oncology drug development programs based on our technology platform;
- We currently retain all commercial rights for SM-88 and have undertaken an extensive multinational patent effort to protect those rights;
- Our management team is leveraging its strong track record in the development and commercialization of new technologies and discoveries into the life sciences field; and
- We have a technology base and patent portfolio in the field of targeted electrochemical immuno-oncology.

Our Strategy

Our goal is to develop and commercialize targeted electrochemical immuno-oncology therapies in humans aimed at improving and extending patients' lives. Key elements of our strategy to achieve this goal are to:

- **Successfully advance SM-88 through clinical development, including its phase II clinical trials, a phase III program 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 electrochemical immuno-oncology therapy pipeline** . We plan to expand our R&D efforts to encompass other indications within the oncology field, to investigate other uses and patient populations and to conduct further mechanism studies that could potentially pave the way for adding further drugs to our pipeline of innovative therapies for humans.
- **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, which we are in the process of commencing with regard to SM-88, 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.

Phase I Clinical Trial Study

We recently completed a 30 subject, single-center, open-label, proof-of-concept phase I clinical trial of 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 ("PFS") in patients treated with SM-88;
- Assess secondary measures of efficacy including Objective Response Rate, Duration of Response and Overall Survival ("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, were included in the trial. The patient population was comprised of patients who refused or failed all available anticancer treatments. Sixteen of the 30 subjects had had prior surgery, 10 had had prior radiation therapy and 20 had had prior chemotherapy, including six patients with 3 or more prior regimens, four patients with two prior regimens and 10 patients with one prior regimen. Cancer types, subjects and Response Evaluation Criteria In Solid Tumors 1.1 ("RECIST") status are presented below:

Patient No.	Primary Disease	Sites of Local or Distant Disease	Overall Best Response
1	Invasive ductal carcinoma (breast)	Left breast, lymph nodes, and left chest wall	SD
2	Infiltrating ductal carcinoma (breast)	Lungs, lymph nodes, spine, brain, bone	PR
3	Breast cancer	Lungs, lymph nodes	SD
4	Breast cancer	Lungs, lymph nodes	SD
5	NSLC; large cell neuroendocrine carcinoma	Lymph nodes	SD
6	SCLC	Lungs, lymph nodes, spine, brain	SD
7	Hepatic carcinoma	Lungs, bone	SD
8	NSLC	Lungs, lymph nodes	SD
9	Infiltrating ductal carcinoma (breast)	Lungs, lymph nodes, spine, brain	SD
10	Pancreatic carcinoma	Lungs, lymph node	SD
11	Prostate carcinoma	Bone	SD
12	Breast cancer (bilateral)	Bone	PR
13	Squamous cell carcinoma (throat)	Lymph node	SD
14	Breast cancer	Liver, bone	SD
15	Breast cancer	Lungs, bone	PD
16	Breast cancer	Lungs, lymph nodes, spine, brain	PR
17	Lung adenocarcinoma	None	PR
18	Pancreatic carcinoma	Liver, omentum	SD
19	Prostate carcinoma	Bone	SD
20	Ductal carcinoma (breast)	Bone, lymph node	PD
21	Ductal carcinoma (breast)	Bone, lymph node	PR
22	Pancreatic carcinoma	Lungs	SD
23	Invasive ductal carcinoma (breast)	Bone, lymph nodes	CR
24	Mixed ductal and lobular breast carcinoma (breast)	Bone, lymph nodes	CR
25	Appendiceal carcinoma	Local spread within abdomen	SD
26	Cholangiocarcinoma	Liver	SD
27	NSLC; SCLC	Brain	SD
28	Papillary carcinoma (thyroid)	Lymph node	PR
29	Invasive breast carcinoma	Lymph nodes	PD
30	Colon cancer	Lungs, liver, omentum	SD

Abbreviations: NSLC = non-small cell lung cancer; SCLC = small cell lung cancer; CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease

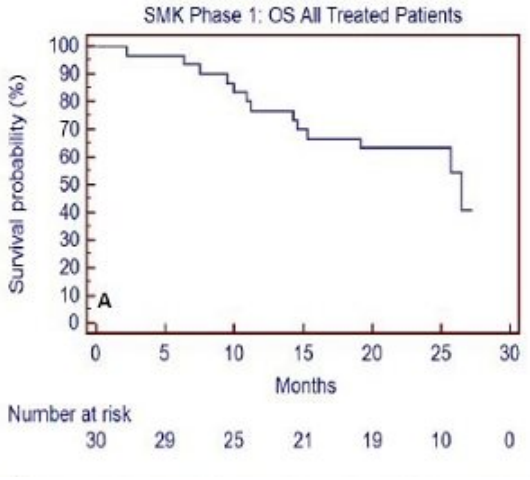
RECIST Results for all Treated Subjects

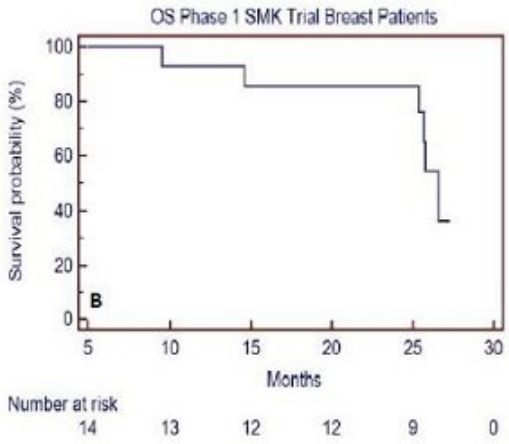
Tumor Response	Number of Subjects n = 30
Complete Response	2
Partial Response	6
Stable Disease	19
Progressive Disease	3
Total Response	27 (90%)

RECIST Results for Subjects with Breast Cancer

Tumor Response	Number of Subjects n = 14
Complete Response	2
Partial Response	4
Stable Disease	5
Progressive Disease	3
Total Response	11 (78.6%)

At the conclusion of this phase I study, as of June 9, 2014, a total of 17 patients out of the 30 treated patients were still alive, including eight of the 14 treated breast cancer patients. Breast cancer patients represented the largest patient sub-group that participated in this phase I study. Kaplan Meier survival curves and individual survival for each patient are presented below:





Current Survivors & OS in Stage 4 Cancer Patients	
Tumor Type	Overall Survival (months)
Appendix	24.4
Breast	27.3
Breast	27.2
Breast	26.0
Breast	26.0
Breast	25.6
Breast	24.5
Breast	24.4
Breast	23.5
Cholangiocarcinoma	24.4
Colon	22.9
Non-Small Cell Lung	24.2
Pancreas	25.4
Prostate	26.5
Prostate	25.6
Small Cell Lung	26.8
Thyroid	23.7

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

Virtually all subjects experienced improvements in Eastern Cooperative Oncology Group Performance Status (ECOG PS), European Organization for Research and Treatment of Cancer (EORTC) Quality of Life ("QoL") questionnaire and self-reported pain scores during Cycle 1. A measureable improvement in self-reported pain was seen in all subjects 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* for all Treated Subjects Following 1 Cycle of SM-88 n=30 Number of Subjects			Pain Scores* for Subjects with Breast Cancer Following 1 Cycle of SM-88 n=14 Number of Subjects		
Score	**Start**	**End**	**Score**	**Start**	**End**
0	4	12	0	1	7
1	6	7	1	3	2
2	3	7	2	2	3
3	5	2	3	2	0
4	3	1	4	0	1
5	2	0	5	1	0
6	3	1	6	2	1
7	3	0	7	2	0
8	0	0	8	0	0
9	0	0	9	0	0
10	1	0	10	1	0

*Pain score scale was the National Institutes of Health, Warren Grant Magnuson Clinical Center, Pain Intensity Instruments, July 2003.

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 our drug is not only unique, but thus far has shown no significant side effects except for cutaneous hyperpigmentation.

We believe that the results of the proof-of-concept clinical trial indicate that SM-88 holds promise as a successful monotherapy and likely has utility in combinations with both cytotoxic and current immuno-therapies. 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.

Our IRB Compassionate Care Studies

In addition to the 30 subject phase I clinical trial, we also performed 53 individual case studies with the Institutional Review Board ("IRB") of New York Downtown Hospital. Cancer types and RECIST status are presented below:

Primary Disease	Number of Patients	Complete Response	Partial Response	Stable Disease	Progressive Disease
Breast Cancer	11	0	4	3	4
Pancreatic Cancer	6	0	0	4	2
Glioma*	5	0	5	0	0
Choleangiocarcinoma	4	0	1	1	2
Prostate Cancer	4	2	1	1	0
Ovarian Cancer	4	0	3	1	0
Colon Cancer*	4	0	1	1	2
Lung Cancer	3	0	0	2	1
Ewing's Sarcoma	2	1	1	0	0
Sarcoma	1	0	1	0	0
Thyroid Cancer	1	0	0	1	0
Urothelial Cancer	1	0	0	1	0
Neuroblastoma	1	0	0	1	0
Renal Cancer	1	0	0	1	0
Alveolar Rhabdomyosarcoma	1	0	0	1	0
Hodgkins Lymphoma	1	1	0	0	0
Germ Cell Tumor	1	0	0	0	1
Lymphoma	1	1	0	0	0
Tonsil Squamous Cell Carcinoma	1	1	0	0	0

*One patient was classified both as Complete Response and Partial Response

RECIST Results for IRB Subjects

Tumor Response	Number of Subjects n = 53
Complete Response	6
Partial Response	17
Stable Disease	18
Progressive Disease	12
Total Response	41(77.4%)

Our Phase II Clinical Trial Strategies

On September 21, 2015, we initiated the next phase of our regulatory and drug development program for SM-88 by submitting an IND to the FDA for a comprehensive, closely monitored, clinical trial in patients with advanced metastatic breast cancer who have failed the usual standard-of-care therapies or have exhausted conventional treatments. On October 23, 2015, the FDA accepted the IND and authorized the phase II trial, including a pharmacokinetic ("PK") study of the four components of SM-88.

We are currently preparing phase II protocols for the breast study as well as for other indications, most likely to include prostate, pancreatic and non-small cell lung cancer. We anticipate that the phase II clinical trials will be multicenter, open-label, randomized, clinical studies. The primary objective of the studies will be to evaluate the overall efficacy, safety, and tolerability of SM-88.

Secondary objectives of the phase II clinical trials may include:

- Evaluation of measures of efficacy, including Objective Response Rate ("ORR"), Duration of Response ("DR"), and Overall Survival ("OS") in subjects with the applicable forms of cancer treated with SM-88.
- Evaluation of the efficacy of SM-88 versus Principal Investigator's ("PI") choice of therapy.
- Determination of the duration of progression-free survival ("PFS") in subjects with the applicable forms of cancer after treatment with SM-88.
- Evaluation of the effect of SM-88 on subject reported outcomes.

Pursuing FDA Fast Track Program/Breakthrough Status

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. However, there can be no assurance that such designation will be granted.

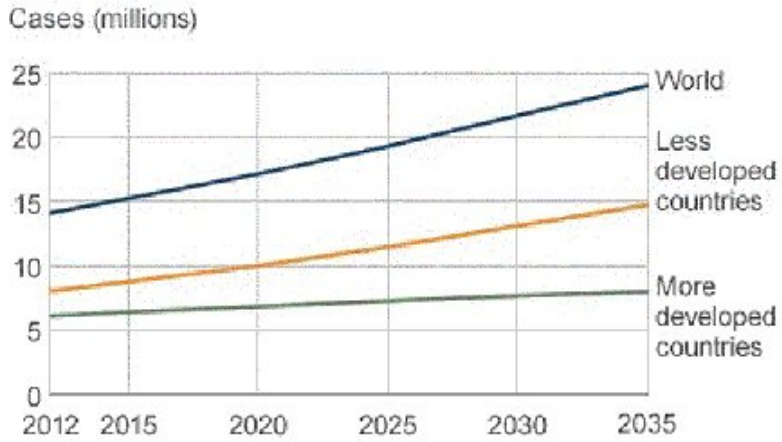
On July 9, 2012, the Food and Drug Administration Safety and Innovation Act ("FDASIA") was signed into law. FDASIA provides a new designation for an expedited FDA review process called Breakthrough Therapy Designation. A breakthrough therapy is a drug that is intended alone or in combination with one 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 term used for a variety of diseases in which abnormal cells divide without control and are able to invade other tissues. Cancer is not just one disease but many diseases. Cancer cells can spread to other parts of the body through the blood and lymph systems. In normal tissues, the rates of new cell growth and cell death are tightly regulated and kept in balance. In cancerous tissues, this balance is disrupted as a result of mutations, causing unregulated cell growth that leads to tumor formation. While tumors can grow slowly or rapidly, the dividing cells will nevertheless accumulate and the normal organization of the tissue will become disrupted. Cancers subsequently can spread throughout the body by processes known as invasion and metastasis. Once cancer spreads to sites beyond the primary tumor, it may be incurable. Cancer cells that arise in the lymphatic system and bone marrow are referred to as hematological malignancies. Cancer cells that arise in other tissues or organs are referred to as solid tumors. The American Cancer Society ("ACS") estimates that solid tumor cancers will account for approximately 1.5 million or 91% of new cancer cases diagnosed annually and will account for approximately 500,000 cancer-related deaths in the U.S. annually. For 2015, the ACS estimated that in the U.S. there were approximately 1.66 million new cases of cancer and 589,000 deaths related to all cancers (solid and hematological).

Despite significant improvements in cancer diagnosis and treatment, cancer rates continue to increase globally and are a leading cause of death. According to the International Agency for Research on Cancer, the specialized cancer agency of the World Health Organization, annual cancer rates around the world are projected to increase by over 56% from 14.1 million cases in 2012 to 22 million new cases in the year 2030. According to the CDC, cancer is the second leading cause of death in the U.S., exceeded only by heart disease. The overall five-year survival expectancy is currently approximately 66% and there are an estimated 13 million people currently suffering from cancer in the U.S.



Cancer cases worldwide. *Source:* American Cancer Society

Cancer Costs

Of the nation's 10 most expensive medical conditions, cancer has the highest per person-estimated cost of treatment. According to a National Institutes of Health analysis, medical costs associated with cancer reached $125 billion in 2010 and are projected to increase another 27% by 2020, to approximately $158 billion in the U.S. Based upon data published by the National Cancer Institute, treatment costs increase significantly with cancer disease progression.

When estimating projections for the cost of cancer in the U.S. from 2010-2020, cancer prevalence was estimated by phase of care (initial year following diagnosis, continuing and last year of life) and tumor site, for 13 cancers in men and 16 cancers in women and projected through 2020. Cancer prevalence was calculated from cancer incidence and survival models estimated from Surveillance, Epidemiology and End Results (SEER) Program data. Annualized net costs were estimated from recent SEER Medicare linkage data, which included claims through 2006 among beneficiaries aged 65 years and older with a cancer diagnosis.

The table below provides estimates of expenditures on cancer treatment in 2010 and projected for 2020.

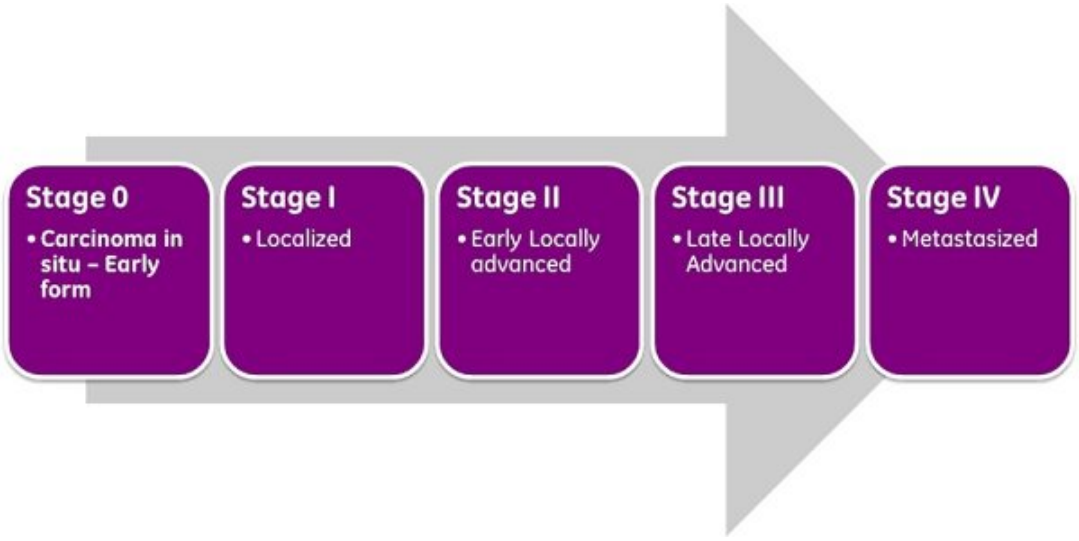
A Snapshot of Estimates of the National Expenditures for Cancer Care in 2010 and 2020 (Costs in 2010 U.S. Billion Dollars)

Cancer Site	2010	2020 Projection
Breast	$16.50	$20.50
Colorectal	$14.14	$17.41
Lung	$12.12	$14.73
Lymphoma	$12.14	$15.26
Prostate	$11.85	$16.34
Leukemia	$5.44	$6.95
Ovary	$5.12	$6.03
Brain	$4.47	$5.53
Bladder	$3.98	$4.91
Kidney	$3.80	$5.12
Head/Neck	$3.64	$4.34
Uterus	$2.62	$3.05
Melanoma	$2.36	$3.16
Pancreas	$2.27	$2.83
Stomach	$1.82	$2.26
Cervix	$1.55	$1.54
Esophagus	$1.33	$1.76
All sites	$124.57	$157.77

Note: This is based on a study that estimated and projected cost of cancer care, segregated by cancer site, through the year 2020 using the most recently available U.S. population projections, cancer incidence, survival and cost of care data.
Data Source: Mariotto AB, Yabroff KR, Shao Y, Feuer EJ, Brown ML. Projections of the Cost of Cancer Care in the U.S.: 2010-2020. J Natl Cancer Inst. 2011 Jan.

Stages of Cancer

Most types of cancer are classified into four stages, with an additional Stage 0 to distinguish those forms that may later lead to cancer ("pre-cancer" stage). The diagram below illustrates the progression of the disease:



Data Source: WWW.MD-HEALTH.COM. Accessed 29 September 2014.

Stage 0 . Also known as carcinoma in situ, this is an early form of cancer where there is a flat lesion but no invasion of malignant cells into the surrounding tissue. Although this can develop into full-blown cancer, some doctors do not consider this as cancer but "pre-cancer."

Stage I . Tumors in this stage are usually smaller than 2 centimeters (cm) and are localized to their site of origin. Lymph nodes are not affected and there is no sign of metastasis (spreading to other parts of the body).

Stage II . Tumors in this stage measure 2-5 cm, but are still localized to their site of origin since they have not invaded other tissues or metastasized. Local lymph nodes may be affected. Stage II tumors are considered to be locally advanced tumors.

Stage III . Tumors in this stage are fairly large, measuring more than 5 cm. This late, locally advanced stage affects nearby lymph nodes and it may be difficult to differentiate from stage II cancer.

Stage IV . Tumors in this stage may be of any size, affecting nearby lymph nodes and showing evidence of metastasis to other organs or regions of the body. A secondary cancer may develop during this stage. The overall physical and mental health of the patient may be affected and the historical survival rate is very low.

Survival

Stage IV cancer usually carries a grim prognosis, as compared to earlier stages of the disease. The five-year survival rate for patients in this stage may depend on different factors such as the type of cancer, age of patient, overall general health, the type of treatment used and will-power to overcome the disease.

A five-year survival rate can be expressed as the percentage of patients who will likely live up to five years after the disease, based on research performed in patients with the same type and stage of cancer. For example, a 60% five-year survival rate indicates that it is estimated that 60 out of every 100 patients will live for five years after diagnosis while the rest (40 of 100) will most likely die.

The five-year survival rate is just an estimate and not an exact number, since many factors influence the progression of one's disease. The following table summarizes the five-year survival rates of different types of stage IV cancers:

Five-Year Cancer Survival Rates

Cancer Type	Survival Rate (%)
Brain	Less than 20%
Breast	16%
Colon	8-15%
Liver:	
Primary	30%
Secondary Tumor	0%
Lung	50%
Ovarian	17%
Pancreatic	4%
Prostate	33%
Skin	15-20%
Stomach	5%

Data Source: WWW.MD-HEALTH.COM.
Accessed 29 September 2014

Cancer Treatments

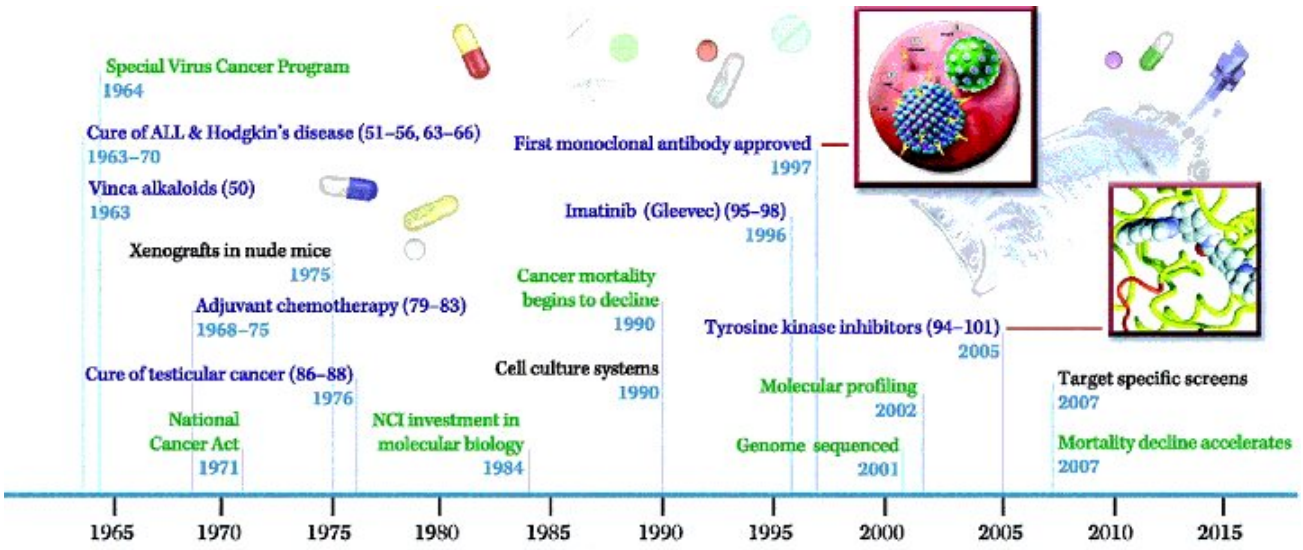
The most common methods of treating patients with cancer are surgery, radiation and drug therapy. For patients with localized disease, surgery and radiation therapy are particularly effective. Drug therapies are generally used by physicians for treating patients with metastatic cancer or for cancers that cannot otherwise be treated through surgery, such as most hematological malignancies. The goal of the various drug therapies is to damage and kill cancer cells or to interfere with the molecular and cellular processes that control the development, growth and survival of cancer cells. In many cases, drug therapy entails the administration of a combination of drugs. Over the past several decades, drug therapy has evolved from non-specific drugs that kill both healthy and cancerous cells, to drugs that target specific molecular pathways involved in cancer.

An early approach to pharmacological cancer treatment was to develop drugs, referred to as chemotherapeutic or cytotoxic drugs, that kill rapidly proliferating cancer cells through non-specific mechanisms, such as disrupting cell metabolism or causing damage to cellular components required for tumor survival and rapid growth. While these drugs have been effective in the treatment of some cancers, cytotoxic drug therapies frequently act in an indiscriminate manner, killing healthy cells along with cancerous cells. Due to their mechanism of action, many cytotoxic drugs have a relatively narrow therapeutic window or a dose range above which the toxicity causes unacceptable or even fatal levels of damage and below which the drugs are not effective in eradicating cancer cells.

The next approach to pharmacological cancer treatment was to develop drugs such as monoclonal antibodies (or targeted therapeutics) which are antibodies that are derived from a single-parental cell clone, that target specific biological molecules in the human body that play a role in rapid cell growth and the spread of cancer. Included in this category are small molecule drugs as well as large molecule drugs, also known as biologics. With heightened vigilance and new diagnostic tests, targeted therapies (including monoclonal antibodies such as Herceptin®, Rituxan®, Erbitux® and Avastin®, as well as small molecules such as Nexavar® and Tarceva®) have resulted in improvements in overall survival for many cancer patients. More recently, antibodies have been developed that are optimized regarding their effector function, also known as FC optimized antibody drugs, such as obinutuzumab. These molecules are designed to engage NK-cells and macrophages more effectively in the elimination of cancer cells.

Cancer immunotherapy plays an increasing role among emerging cancer drug therapies. The intention of the cancer immunotherapy is to harness the body's own immune system to fight tumor cells or, in some cases, re-establish or remove certain blockades or promote certain signaling cascades. There are different approaches, such as vaccinations, checkpoint inhibitors, immunomodulators, T-cell and NK-cell engagers like bispecific antibodies or cellular therapies involving the induction of a patient's own T-cells to express chimeric antigen receptors. Ipilimumab (Yervoy®) and sipuleucel-T (Provenge®) were the first cancer immunotherapies to enter the market.

The chart below shows the gradual evolution of cancer therapy and highlights the recent focus on developing targeted therapies or "magic bullets," that are designed to kill cancer cells while sparing normal tissue, thus reducing toxicity.



Evolution of cancer pharmacotherapy. *Source*: American Association for Cancer Research (AACR)

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 for us to adequately enable us to 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 competition comes from other commercial and research enterprises working in the field of cancer research. Those pharmaceutical and biotechnology companies, academic institutions and government research institutes around the globe that are working towards new treatments in the field of oncology, collectively form the competitive nature in cancer R&D.

We plan to position SM-88 to compete with products manufactured by other companies in highly competitive markets throughout the world.

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 and 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.

Currently, we already have one patent issued in the U.S., as well as four patent applications pending. We have begun the process of pursuing foreign patent applications corresponding to two of these patent applications and intend to pursue foreign patent applications corresponding to the others. 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, adverse events (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 GCPs. 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 or 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. 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.

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 particular 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 whether or not we should pursue 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.

EU Approval Process

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 labelling;
- 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.

Pediatric Studies

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. This period may, however, 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 2 ("EOP2"), we will scale-up the manufacturing, CMC and GMP program towards commercial manufacturing. The overall CMC program includes the development of production 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 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.

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 an FDA-audited contract manufacturer and holder of an FDA Drug Master File. 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. 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 would 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 through-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. Smaller amounts of drug substance were also produced during this time for various research and development activities. Future work involving the drug substance is planned to involve development and validation of the anticipated commercial manufacturing route. This will involve the use of a different regulatory starting material than had been utilized for the recent cGMP drug substance manufacturing campaign. This new starting material is readily available and process chemistry is well understood.

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. In addition, additional drug product forms may be developed, if necessary.

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 these sources 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, these other sources are readily available.

Employees

As of February 29, 2016, we had a total of nine 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 nine employees, six perform research and development activities and three 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 as well as his being categorized, for purposes of the immediately preceding sentence, 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 48 Wall Street - Suite 1100, 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. Our initial intention was to distill, bottle, market and distribute alcoholic beverages (primarily an ultra-premium vodka), but we never acted on such intention, other than initial planning. 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 subcaptions 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.

The effects of the foregoing merger and associated financing transactions are described below.

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. 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. Any of the Indemnity Shares remaining in escrow at the end of such two-year period shall be distributed to the pre-Merger Tyme stockholders on a *pro rata* basis. 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 also agreed, subject to one exception discussed below, not to register under the Securities Act for resale any of the shares of our Common Stock issued to the pre-Merger Tyme stockholders for the two years following the closing of the Merger. Notwithstanding the restriction on registering shares of our Common Stock received in the Merger by the pre-Merger Tyme stockholders, we did agree to register 9% of the shares of our Common Stock issued in connection with the Merger to the pre-Merger Tyme stockholders.

In addition, two of the pre-Merger Tyme stockholders who each are currently serving as executive officers and directors of our Company and are holders of 10% or more of our Common Stock (the "Restricted Stockholders") entered into a Lock-Up and No Shorting Agreement (each, a "Lock-Up Agreement"), whereby they agreed to certain restrictions on the sale or disposition (including pledges) of shares of our Common Stock held by them for one year following the closing of the Merger. The Lock-Up Agreements exclude the shares which we agreed to register for all of the pre-Merger Tyme stockholders discussed in the immediately preceding paragraph, as well as an additional one million shares each which they are permitted to sell only in private transactions.

All descriptions of the Merger Agreement, Indemnification Shares Escrow Agreement and Lock-Up Agreements herein are qualified in their entireties 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 entireties 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 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 private placement offering (the "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 PPO was exempt from registration under Section 4(2) of the Securities Act. The sole investor in the PPO was GEM Global Yield Fund LLC SCS, a "société en commaudite 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 provides 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 have 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 and we have sought a return of the Adjustment Shares from escrow. 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 and Commercialization of Our Drug Candidates.

Our proprietary lead combination drug product, SM-88, is in the early stages of clinical development. We are currently finalizing our regulatory and drug development program for SM-88 and working towards the initiation of our first phase II clinical trial. 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 a limited phase I clinical trial for SM-88. We have not yet developed our commercialization strategy and marketing plan. In additional, 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 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;
- delay or failure to obtain regulatory approval or agreement to commence a clinical trial in any of the countries where enrollment is planned;
- inability to obtain sufficient funds required to execute our clinical and regulatory development plans;
- clinical holds on or other regulatory objections to, a new or ongoing clinical trial;
- delay or failure to supply regulatory-required data and other information to regulators, including the FDA and EMA;
- delay or failure in the testing, validation, manufacture and delivery of sufficient supplies of SM-88 for our clinical trials;
- delay or failure to reach agreement on acceptable clinical trial terms or clinical trial protocols with prospective investigational sites or clinical research organizations ("CRO"), the terms of which can be subject to extensive negotiation and may vary significantly among different sites or CROs;
- delays or failures of third parties, including other agents, consultants and advisors, to provide required resources and services and submit data and information to us and the applicable regulators; and
- delay or failure to obtain institutional review board or independent ethics committee ("IEC") approval to conduct a clinical trial at a prospective investigational site.

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

- slower than expected rate of subject recruitment and enrollment;
- slower than projected IRB/IEC review and approval;
- the Data Monitoring Committee ("DMC") for a clinical trial requires the clinical trial be delayed or stopped or requests major or minor modifications to the clinical trial;
- failure of subjects to complete their full participation in clinical trial or return for post-treatment follow-up;
- unforeseen safety issues, including severe or unexpected drug-related adverse effects experienced by subjects, including the possibility of death;
- lack of SM-88 efficacy during the clinical trials;
- poor trial design for one or more of our clinical trials;
- withdrawal of participation by a principal investigator 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 IEUs for re-review, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by the FDA, the EMA, other regulatory authorities or the IRB/IEC overseeing the clinical trial, due to a number of factors, which include but are not limited to:

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

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

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

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

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

The results of previous clinical trials may not be predictive of future results, our progress in 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 may still suffer significant setbacks in subsequent registration clinical trials. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

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 adverse event (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 shareholder 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 December 31, 2015, our accumulated deficit was approximately $15,904,000. 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. We believe that our available cash and cash equivalents will be sufficient to fund our anticipated level of operations for the next six-to-nine 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. 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 have anti-dilution protection that could result in additional dilution to our stockholders generally. These provisions provide that if we raise certain funds before March 2018 at a per share price less than $.050 per share, anti-dilution protections will apply. See Item 1 – "Business – Corporate History; Significant Organizational Events." 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 keyman 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 February 29, 2016, 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. 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 newly 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 December 31, 2015, 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 segregation of duties over cash disbursements, oversight of our outside accounting firm by management, disclosures and the preparation of financial statements. In addition, at the present time, we do not have an audit committee.

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 March 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"). We plan to register the shares available for issuance or subject to outstanding awards under our 2015 Plan. Future issuances, as well as the possibility of future issuances, under our 2015 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 15g-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 own of record approximately 31.3% of our outstanding common stock as of February 1, 2016. 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 48 Wall Street - Suite 1100, New York, New York 10005, where we lease and occupy approximately 1,100 square feet of office space. We lease these offices under a three-month lease that provides for automatic renewals, unless either party gives notice of non-renewal. The current term of our lease expires on March 31, 2016 and we anticipate renewing the lease for an additional three-month term. Historically, our costs for this office are approximately $46,000 per year.

We also maintain an office in Red Bank, New Jersey, where we lease and occupy approximately 150 square feet of office space. We lease this office under a lease, expiring in March of 2016. 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. When our current lease term expires, we may exercise our renewal option or 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

Except as set forth below, 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.

As described in greater detail under "Business – Corporate History; Significant Organizational Events," on March 5, 2015, we entered into a Merger Agreement and certain associated transactions, including capitalized terms used below that are detailed and defined under such caption. 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 former shareholders 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.

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 are required to be surrendered to us for cancellation under the Adjustment Shares Escrow Agreement.

On November 10, 2015, we made demand of the escrow agent holding the Adjustment Shares for their surrender for cancellation. On November 17, 2015, GEM challenged such demand. On December 2, 2015, we filed a complaint against GEM with the Supreme Court of New York, seeking, among other things, a declaratory judgment directing GEM to deliver to us the 3,500,000 Adjustment Shares for cancellation.

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 is currently quoted on the OTC Markets, QB Tier, under the symbol "TYMI." 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.

Previously and until September 26, 2014, our common stock was quoted on the OTC Markets, QB Tier, under the symbol "GGET." Prior to March 12, 2015, there were no reported sales of our common stock on the OTC Market. Since such date, 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 over-the-counter 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, 2015	$8.50	$7.50
December 31, 2015	$11.25	$8.48

Holders

We had a total of 87,611,370 shares of our common stock outstanding on March 23, 2016, held by 41 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.

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 information required by this item will be included in an amendment to this Annual Report on Form 10-K or incorporated by reference from our definitive proxy statement to be filed pursuant to Regulation 14A.

Recent Sales of Unregistered Securities

We issued, effective as of February 2, 2016, to a total of two individuals, for the aggregate consideration of $3,100,000, (i) 775,000 shares of our common stock and (ii) 461,384 ten-year common stock purchase warrants entitling its holder to purchase one share of our common stock at a purchase price of $5.00 per share.

We also issued, effective as of December 31, 2015, an aggregate of 9,999 shares of our common stock to our three independent directors, an advisor to our board of directors and the five members of our scientific and medical advisory board, in accordance with our independent director compensation policy, our agreement with such advisor and our scientific and medical advisory board compensation policy.

We also issued, effective December 23, 2015, to a total of three individuals and entities, for the aggregate consideration of $3,000,000, (i) 750,000 shares of our common stock and (ii) 466,500 ten-year common stock purchase warrants entitling its holder to purchase one share of our common stock at a purchase price of $5.00 per share.

Effective December 21, 2015, we issued to a law firm, in satisfaction of $200,000 of outstanding fees for services rendered, (i) 50,000 shares of our common stock and (ii) 29,767 ten-year common stock purchase warrants entitling its holder to purchase one share of our common stock at a purchase price of $5.00 per share.

We believe that the issuance of these shares was exempt from the registration requirements of the Securities Act of 1933 under Section 4(2) of the Securities Act as such issuance did not involve any public offering.

Use of Proceeds from Registered Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

We were originally formed in Florida on November 22, 2011, to produce, market and sell an ultra-premium vodka product to retailers. We were not successful in our efforts and we turned our efforts towards seeking, investigating and, if such investigation warranted, engaging in a business combination with a private entity whose business presented an opportunity for our stockholders.

Effective as of September 18, 2014, we (then constituting a Florida corporation with the name Global Group Enterprises Corp.) reincorporated in the State of Delaware by merging into our 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) we changed our name 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 "blank check" 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." the notes to the consolidated financial statements included in this Annual Report on Form 10-K and in "Recent Developments" below, 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, which is the fiscal year basis for the financial statements presented herewith.

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. We have no such arrangements or plans currently in effect and our inability to raise funds could have a severe adverse effect on our ability to become a viable company. In addition, no assurance can be given that we will be able to obtain funds on favorable terms, if at all.

Recent Developments

On March 5, 2015, we entered into and completed the Merger and associated transaction. For further details concerning these transactions, see "Item 1; Business – Corporate History; Significant Organizational Events."

As a result of the Split-Off Transaction and Merger, we discontinued our pre-Merger business and acquired the business of Tyme, a research and development company focused on developing drug candidates for the treatment of cancer in humans. We intend to continue the existing business operations of Tyme as our wholly-owned subsidiary. At the present time, we do not intend to operate any other business other than Tyme, although such operations may be conducted through one or more direct and/or indirect subsidiaries as we believe appropriate.

In connection with the consummation of the Merger, we changed our fiscal year from a fiscal year ending on November 30 th of each calendar year to one ending on December 31 st of each calendar year, which is the historical fiscal year of Tyme and which is the fiscal year basis for the financial statements presented herewith.

At the point of Merger and since inception, we were essentially a "public reporting shell" with no substantive business operations. As such, we had negligible revenues and operating profits that require separate identification.

The transaction costs associated with the Merger relate to professional fees incurred in respect of legal, investor relations and accounting and audit of Tyme's financial statements. All of such transaction costs, being associated with the final Merger, have been expensed as incurred and total approximately $1,000,000.

For accounting purposes, the acquisition of Tyme by our Company 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 our Company was because we were a public reporting shell company with limited operations and Tyme's stockholders gained majority control of the outstanding voting power of our equity securities through their collective ownership of a majority of the outstanding shares of Company common stock. Consequently, reverse acquisition accounting will be applied to the transaction. No goodwill or intangible assets were recognized in conjunction with the completion of the Merger.

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 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. 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).

We believe that it is not more likely than not that the benefit from Federal and State NOLs will be realized. 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 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 no unrecognized tax benefits at December 31, 2015 and 2014. The increases or decreases in such benefits would be reflected as increases or decreases to income tax expense in the period in which new information is available. The tax years, which currently remain subject to examination by major tax jurisdictions as of December 31, 2015, are the years ended December 31, 2015 and 2014 and for the period from 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.

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 Topic 505-50 "Equity-Based Payment to Non-Employees" and accordingly the value of the stock compensation to non-employees is measured on the earlier of: a) the performance commitment date, or b) the date the services required under the arrangement have been completed.

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

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 $15,904,000 as of December 31, 2015. 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.

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.

Results of Operations

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 $2,649,826 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.

    - 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.

Liquidity and Capital Resources

At December 31, 2015, we had cash of $4,446,284, working capital of $3,002,737 and stockholders' equity of $3,015,615.

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

	Year Ended December 31,	
	2015	2014
Net cash used in operating activities	$ (6,610,156)	$ (1,515,586)
Net cash used in investing activities	—	(2,710)
Net cash provided by financing activities	11,046,716	1,435,400

Operating Activities

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 before noncontrolling interests of $11,726,818, adjusted for non-cash expenses totaling $4,728,851 (which includes adjustments for equity-based compensation, depreciation and amortization, a gain on the remeasurement of a derivative liability and noncash conversion), 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 before noncontrolling interests of $2,660,667, adjusted for non-cash expenses totaling $6,969 (which includes adjustments for depreciation and amortization and a loss on disposal of fixed assets), and (ii) changes in operating assets and liabilities providing $1,138,122.

Investing Activities

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 December 31, 2015, our financing activities consisted 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 PPO Note in the principal amount of $2,500,000). Payment under the PPO Note of $1,250,000 was received in June of 2015 and payment of the remaining $1,250,000 was received in October 2015.

- We raised gross proceeds of $960,000 in January 2015 through the additional funding under and the corresponding amendment and restatement of the Bridge Note.

- Tyme and Luminant obtained from and granted cash advances to certain of their then stockholders/members. Effective as of the consummation of the Merger, these non-interest bearing advances were settled.

- On December 23, 2015, the Company sold 750,000 shares of the Company's common stock, par value $0.0001 per share, and 446,500 common stock purchase warrants for net proceeds of $2,966,000.

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.

Liquidity and Capital Requirements Outlook

Liquidity

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 one or more phase II clinical trials of our SM-88 drug candidate and related studies and investigations. The IND for SM-88 for a study involving breast cancer patients was accepted by the FDA in October of 2015. We are evaluating the expansion of the phase II program to other forms of cancer.

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. In addition, we expect to seek as appropriate grants for scientific and clinical studies. There can be no assurance that we will be successful in qualifying for or obtaining such grants

We believe that our current cash balances will be sufficient to fund the business through the next six to nine months.

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 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.

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.

Although we are still evaluating the JOBS Act, we currently intend to take advantage of some 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 may 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

Through December 31, 2015, we do not have any off-balance sheet arrangements, as defined by applicable SEC regulations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, we are not required to provide the information required by Item 7A.

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 December 31, 2015, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for 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 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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit 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 audit provides 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 December 31, 2015, and the results of their operations and their cash flows for 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 December 31, 2015. 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
March 30, 2016

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 balance sheet Tyme Technologies, Inc. and Subsidiaries (formerly Tyme Inc. and Subsidiary) (the "Company") as of December 31, 2014, and the related consolidated statement of operations, stockholders' equity (deficit), and cash flows for the year then ended (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. As of and 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

	December 31, 2015	December 31, 2014
Assets		
Current assets		
Cash and cash equivalents	$ 4,446,284	$ 9,724
Prepaid and other assets	30,784	140,205
Total current assets	4,477,068	149,929
Property and equipment, net	12,878	17,170
Total assets	$ 4,489,946	$ 167,099
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable and other current liabilities	$ 1,474,331	$ 1,290,415
Current maturities of senior secured bridge notes	—	1,350,000
Total current liabilities	1,474,331	2,640,415
Total liabilities	1,474,331	2,640,415
Commitments and contingencies (See Note 10)		
Stockholders' equity (deficit)		
Preferred stock, $0.0001 par value, 10,000,000 and 0 shares authorized at December 31, 2015 and December 31, 2014, respectively, 0 shares issued and outstanding at December 31, 2015 and December 31, 2014	—	—
Common stock, $0.0001 par value, 300,000,000 shares authorized, 86,836,370 shares issued and outstanding at December 31, 2015, and 71,400,000 shares issued and 68,000,000 shares outstanding at December 31, 2014	8,685	6,800
Additional paid in capital	18,911,110	2,053,012
Accumulated deficit	(15,904,180)	(4,177,362)
Due from stockholders/members	—	(355,766)
Total stockholders' equity (deficit)	3,015,615	(2,473,316)
Total liabilities and stockholders' equity (deficit)	$ 4,489,946	$ 167,099

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 December 31,	
	2015	2014
Revenues	$ —	$ —
Operating expenses:		
Research and development	3,823,966	761,359
General and administrative	4,775,806	1,822,757
Total operating expenses	8,599,772	2,584,116
Loss from operations	(8,599,772)	(2,584,116)
Interest expense	3,503,301	76,561
Other income	(376,255)	—
Loss before income taxes	(11,726,818)	(2,660,677)
Income tax expense	—	—
Net loss	(11,726,818)	(2,660,677)
Loss attributable to noncontrolling interests	—	(10,851)
Loss attributable to controlling interests	$ (11,726,818)	$ (2,649,826)
Basic and diluted loss per common share	$ (0.15)	$ (0.04)
Basic and diluted weighted average shares outstanding	77,848,850	68,000,000

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

Tyme Technologies, Inc. and Subsidiaries
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
For the Years Ended December 31, 2015 and 2014

	Common Stock		Additional Paid-in capital	Subscription receivable	Accumulated deficit	Non-Controlling Interests	Due from Stockholders/ Members	Total Stockholders' Equity (Deficit)
	Shares	Amount						
Balance, 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, December 31, 2015	86,836,370	$ 8,685	$ 18,911,110	$ —	$ (15,904,180)	$ —	$ —	$ 3,015,615

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 December 31,	
	2015	2014
Cash flows from operating activities:		
Net loss	$ (11,726,818)	$ (2,660,677)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	4,292	4,293
Issuance of common stock for services	825,000	—
Stock-based compensation	325,000	—
Amortization of employee stock options	485,859	—
Inducement for conversion of Bridge Note to common shares	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	109,421	(30,025)
Accounts payable and other current liabilities	278,390	1,168,147
Net cash used in operating activities	(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:		
Capital contributions - noncontrolling interest	—	35,000
Repayment from (advances to) stockholders/members	355,766	(149,600)
Proceeds from Bridge Note	960,000	1,350,000
Proceeds from private placement offering of common stock and warrants, net	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	11,046,716	1,435,400
Net increase (decrease) in cash	4,436,560	(82,896)
Cash and cash equivalents - beginning of period	9,724	92,620
Cash and cash equivalents - end of period	$ 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:		
Conversion of the Bridge Note and all accrued interest into shares of common stock	$ 2,404,474	$ —
Issuance of subscription receivable for shares issued in conjunction with private placement offering	$ 2,500,000	$ —
Inducement for conversion of Bridge Note to common shares	$ 3,465,000	$ —
Derivative liability associated with the price protection feature of shares of common stock issued in PPO and Bridge Note conversion	$ 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.

Note 1. Nature of Business and Basis of Presentation.

The accompanying consolidated financial statements include the results of operations of Tyme Technologies, Inc. ("Tyme Tech") and its wholly owned subsidiaries, Tyme Inc. ("Tyme") and Luminant Biosciences, LLC ("Luminant") (collectively, the "Company"). 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 and all of the Company's patent and patent application rights are held by Tyme.

Tyme Tech was incorporated in the State of Florida on November 22, 2011, to engage in the business of producing, marketing and selling an ultra-premium vodka product to retailers. Management determined to cease the ultra-premium vodka business and attempt to acquire other assets or business operations that would maximize shareholder value. 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. 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 its product candidates. Tyme, and now the Company, has focused its research and development efforts on a proprietary platform technology for which it retains global intellectual property ("IP") and commercial rights. The Company is currently formulating its regulatory and drug development program for its lead drug candidate, SM-88, and working towards the initiation of its first phase II clinical trial. Subsequent to December 31, 2015, the Company's Investigational New Drug Application for its SM-88 drug candidate for breast cancer patients (the "IND") was accepted by the United States Food and Drug Administration (the "FDA"). The Company is also evaluating the expansion of its phase II program to other types of 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 time of the Merger, 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 8. 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. Any of the Indemnity Shares remaining in escrow at the end of such two-year period shall be distributed to the pre-Merger Tyme stockholders on a pro rata basis.

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 right to damages, including 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. (See Note 8. Stockholders' Equity - Subscription Receivable.)

At the point of Merger and since inception, Tyme Tech was essentially a "public reporting shell" with no substantive business operations. As such, Tyme Tech had no revenues and operating profits that require separate identification.

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 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.

In conjunction with the reverse acquisition, Tyme Tech changed its fiscal year-end from November 30 to December 31, the historical fiscal year-end of Tyme. 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 approximately $15,904,000 as of December 31, 2015. 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.

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; a public offering 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.

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.

Note 2. Summary of 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.

Use of Estimates

The preparation of the consolidated financial statements in conformity with US 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. As of December 31, 2015, the Company's cash and cash equivalents consisted of $4,446,284 deposited in two checking accounts at two financial institutions.

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 approximately $3,946,284 at December 31, 2015. 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 carrying amount of the senior secured bridge notes payable as of December 31, 2014 approximated fair value because the interest rates on these instruments were reflective of rates that the Company could obtain on unaffiliated third party debt with similar terms and conditions.

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. The Company's derivative liability is classified as a Level 3 instrument. (See Note 7. Derivative Liability.)

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 during the years 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 years, 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.

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 or when a triggering event occurs.

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 included in operating expenses. 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 years 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 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 the Company by its 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

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, the Company determines deferred tax assets and liabilities on the basis of the differences between the financial statements and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that it believes that these assets are more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If the Company determines that it would be able to realize our deferred tax assets in the future in excess of their net recorded amount, the Company would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions in accordance with ASC 740 on the basis of a two-step process in which (1) the Company determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, the Company recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority.

The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statement of operations. Accrued interest and penalties are included on the related tax liability line in the consolidated balance sheet.

The Company had no unrecognized tax benefits at December 31, 2015 and 2014. The tax years which currently remain subject to examination by major tax jurisdictions as of December 31, 2015, December 31, 2015 and 2014 and for the period from 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.

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 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 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. At December 31, 2015 and 2014, the calculation excludes any potential dilutive common shares and any equivalents as they would have been anti-dilutive as the Company had 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 12. 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 Topic 505-50 “Equity-Based Payment to Non-Employees” and accordingly the value of the stock compensation to non-employees is measured on the earlier of: a) the performance commitment date, or b) the date the services required under the arrangement have been completed.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (“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 No. 2015-17, *Balance Sheet Classification of Deferred Taxes* ("ASU 2015-17"), which eliminates the current requirement to present deferred tax liabilities and assets as current and noncurrent in a classified balance sheet. Instead, entities will be required to classify all deferred tax assets and liabilities as noncurrent. ASU 2015-17 will be effective for the Company for annual periods beginning after December 15, 2017, and interim periods within fiscal years beginning after December 15, 2018, with early adoption permitted. The Company does not anticipate that the adoption of this standard will have a material impact on its consolidated financial statements.

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 does not anticipate that the adoption of this standard will have a material impact on its consolidated financial statements, other than potentially on the footnote disclosures.

In June 2014, the FASB issued ASU No. 2014-12, *Compensation - Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide that a Performance Target Could be Achieved after the Requisite Service Period* , ("ASU 2014-12"). ASU 2014-12 requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. ASU 2014-12 is effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. The Company does not anticipate that the adoption of this standard will have a material impact on its consolidated financial statements.

Note 3. Net Loss Per Common Share

The following table sets forth the computation of basic and diluted net loss per share for the periods indicated:

	Year Ended December 31, 2015	Year Ended December 31, 2014
Basic and diluted net loss per common share calculation:		
Net loss attributable to controlling interests	$ (11,726,818)	$ (2,649,826)
Weighted average common shares outstanding	77,848,850	68,000,000
Net loss per share of common stock—basic and diluted	$ (0.15)	$ (0.04)

There are 3,500,000 shares in escrow, subject to cancellation, that have not been included in basic weighted average common shares outstanding for the year ended December 31, 2015 (See Note 8. Stockholders' Equity.)

The following outstanding securities at 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 December 31, 2015	Year Ended December 31, 2014
Stock options	150,000	—
Warrants	496,500	—
Total	646,500	—

Note 4. Property and Equipment, Net.

Property and equipment, net consisted of the following:

	December 31, 2015	December 31, 2014
Machinery and equipment	$ 21,463	$ 21,463
Less: accumulated depreciation	8,585	4,293
	$ 12,878	$ 17,170

Depreciation expense was $4,292 and $4,293 for the years 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:

	December 31, 2015	December 31, 2014
Interest	$ —	$ 56,174
Legal	781,933	844,602
Consulting	50,947	43,314
Accounting and auditing	157,129	272,913
Research and development	241,259	58,750
Board of Directors and Scientific Advisory Board compensation	225,000	—
Other	18,063	14,662
	$ 1,474,331	$ 1,290,415

Note 6. Debt.

Convertible/Bridge Notes Payable

On August 2, 2013, Tyme entered into a Convertible Promissory Note Agreement (the "Convertible Note Agreement") to be funded in a series of loans up to a maximum principal amount of $997,000 ("Convertible Notes"). As of December 31, 2013, Tyme had received $997,000 in proceeds under the Convertible Notes. The Convertible Notes accrued interest at a rate of 2.5% per year. Principal repayments were to commence on April 30, 2014 equal to 1/24th of the then outstanding balance, with the entire principal amount due and payable on April 30, 2016. The lender opted not to collect principal payments in anticipation of converting the Convertible Notes.

The Convertible Note Agreement provided that if, prior to April 30, 2014, Tyme entered into any financing transaction with the lender or an affiliate thereof, upon the closing of such transaction, the outstanding principal balance of the Convertible Notes would automatically convert on a dollar-for-dollar basis into the securities being issued and sold at a conversion price equal to the purchase price per share implied by a pre-investment valuation of Tyme equal to $20,000,000 ("Conversion Price"). The Convertible Note Agreement further provided that if Tyme entered into an agreement with a third party, other than the lender or affiliate thereof, into any debt or equity financing, exclusive license of any portion of the IP Rights, a sale of substantially all of the assets of Tyme, or subsidiary thereof, or any transaction or series of transactions resulting in the current stockholders holding less than a majority of the voting interests, then, at the lender's option, effective immediately prior to closing of the third party transaction, the outstanding principal balance of the Convertible Notes would have been converted on a dollar-for-dollar basis into shares of common stock. The Convertible Note Agreement provided that in the case of conversion of principal under either scenario, Tyme would have no further obligations or liabilities under the Convertible Notes.

In January 2014, the lender increased the aggregate principal amount of the Convertible Notes from $997,000 to $1,126,000 and advanced funds to Tyme to that effect, such that the total amount funded to the Company was equal to the increased principal amount of the Convertible Notes.

On August 28, 2014, the lender converted the Convertible Notes in the aggregate principal amount of $1,126,000 plus accrued interest of $26,242, into shares of Tyme common stock (3,624,400 shares of the Company common stock). Simultaneous with the issuance of shares to the lender, the two principal stockholders of the Company, as capital contributions, surrendered to Tyme for cancellation an equal number of shares. The net effect of such issuance and cancellations resulted in no change in the total number of shares of Company common stock issued (71,400,000) and outstanding (68,000,000) at such time.

For the years ended December 31, 2015 and 2014, the Company recorded interest expense on the Convertible Notes amounting to $0 and $20,387, respectively.

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 but placed into escrow 3,400,000 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.

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 a further $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 effect that the mandatory conversion feature be 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 Bridge Note, including accrued interest, was converted at the time of the Merger. 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 statement of operations for the year ended December 31, 2015.

The Company recorded interest expense of $38,301 and $56,174 during the years ended December 31, 2015 and 2014, respectively, on the Bridge Note. The aggregate outstanding principal and accrued interest balance at December 31, 2015 and 2014 was $0 and $1,406,174, respectively.

Note 7. Derivative Liability.

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 a result, a gain of $376,300 was recorded in Other income in the Consolidated Statements of Operations to reflect the remeasurement of the derivative liability to $0.

Note 8. 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

Authorized, Issued and Outstanding

The Company is authorized to issue 300,000,000 shares of common stock, each with a par value of $0.0001, of which 86,836,370 shares were issued and outstanding at December 31, 2015 and 71,400,000 shares were issued and 68,000,000 shares were outstanding at December 31, 2014. Included in the shares issued and outstanding at December 31, 2015 are 3,500,000 shares that are in escrow, subject to cancellation, as discussed further below. The 3,400,000 shares issued but not outstanding at December 31, 2014 were held in escrow to secure certain obligations of Tyme to the holder of the Bridge Note.

Prior to the Merger, the Company conducted a 4.3334-for-1 forward stock split. The Merger resulted in the Company issuing a total of 68,000,000 shares of Company common stock to the Pre-Merger Tyme stockholders and 12,274,000 shares to the Tyme Tech stockholders as of the date of the Merger. As a result of the Merger and its accounting treatment as a reverse acquisition, stockholders' equity (deficit) has been presented to reflect such stock split and stock issuances as of the earliest period presented in these consolidated financial statements. (See Note 1. Nature of Business and Basis of Presentation - Reverse Triangular Merger.)

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.

Subscription Receivable

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 $6,765,000 of which $4,265,000 was paid in cash. The remaining subscription price was paid by the delivery of a three-month promissory note in the principal amount of $2,500,000 (the "PPO Subscription Note"). (See Note 1. Nature of Business and Basis of Presentation - Reverse Triangular Merger.) On June 5, 2015, in accordance with the First Omnibus Amendment, the Company received $1,250,000, representing one-half of the principal amount of the PPO Subscription Note, and the maturity date of the PPO Subscription Agreement was extended to July 6, 2015. The First Omnibus Amendment, among other matters, also made corresponding adjustments to the Subscription Note Escrow Agreement and authorized the release of 2,500,000 of the 5,000,000 shares of Company common stock initially placed into escrow under such agreement.

Effective as of July 23, 2015 and pursuant to a Second Omnibus Amendment (the "Second Omnibus Amendment"), the maturity date of the PPO Subscription Note was further extended to the fifth business day following the date on which the Company notifies the maker of the PPO Subscription Note that the Company had filed with the United States Food and Drug Administration (the "FDA") an Investigational New Drug Application (an "IND") for the Company's SM-88 drug candidate. Such IND was received by the FDA on September 21, 2015, and notice of such was given on September 25, 2015. The Company received the balance of the PPO Subscription Note on October 16, 2015 and the remaining 2,500,000 shares were released from escrow.

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 conducts 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 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 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. On December 2, 2015, the Company filed a complaint against the depositor with the Supreme Court of New York, seeking, among other things, a declaratory judgment directing the depositor to deliver to the Company the 3,500,000 Adjustment Shares for cancellation.

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 former stockholders of Tyme 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 irrevocable 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.

Securities Purchase Agreement

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.

Securities Issued for Services

On March 5, 2015, as a condition of the Merger Agreement, pursuant to a Consulting Agreement, the Company issued 250,000 fully vested, non-forfeitable shares to an Investor Relations firm for services provided in conjunction with the merger. The value of these shares was $625,000, based on the price of the shares issued as part of the Merger. No registration rights were granted related to these shares.

On 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 (i) 50,000 shares of the Company's common stock, par value $0.0001 per share, and (ii) 29,767 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 18, 2015 and terminating on the tenth anniversary of such date. No registration rights were granted related to 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.

Note 9. 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 $11,726,818 and $2,660,677 for the years 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 December 31, 2015	Year Ended December 31, 2014
Net operating loss carryforward	$ 4,316,110	$ 1,330,660
Research and development credit carryforward	198,490	—
Other temporary differences	62,928	—
Gross deferred tax assets	4,577,528	1,330,660
Deferred tax valuation allowance	(4,577,528)	(1,330,660)
	$ —	$ —

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 December 31, 2015 and 2014. The valuation allowance increased by $3,246,868 and $1,064,660 for the years ended December 31, 2015 and 2014, respectively, due primarily to the generation of net operating losses during the periods.

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:

	December 31, 2015	December 31, 2014
U.S. statutory income tax rate	34.0%	35.0%
State income taxes, net of federal benefit	7.9	5.0
Permanent differences	(12.8)	—
Rate change and provision to return true-up	8.0	—
R&D credit carryforwards	1.8	—
Valuation allowance	(38.9)	(40.0)
Effective tax rate	—%	—%

As of December 31, 2015 and 2014, the Company had U.S. federal net operating loss carryforwards of $10,005,274 and $3,312,651, respectively, which may be available to offset future income tax liabilities and will begin to expire at various dates starting in 2033. As of December 31, 2015 and 2014, the Company also had U.S. state net operating loss carryforwards of $17,467,895 and $0, respectively, which may be available to offset future income tax liabilities and will begin to expire at various dates starting in 2033.

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 shareholders 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.

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 years ended December 31, 2015 and 2014 and for the period from July 26, 2013 through 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 10. 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 Agreements

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 the executive is terminated without "Cause" (as defined in the agreements) or for "Good Reason" (as defined in the agreements), the executive will be entitled to receive his base salary plus any accrued but unpaid performance bonus, with the base salary payable at the same intervals as the base salary would have been payable if the termination had not occurred. 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 May 15, 2015, the Company appointed a new Chief Financial Officer. The new officer has entered into an employment agreement with the Company that requires the officer to expend one-third of his working time to the Company for which he will be compensated at the rate of $80,000 per annum. The new officer was also granted a five-year option to purchase 150,000 shares of Company common stock at $7.75 per share. The option vested with respect to 75,000 shares on November 15, 2015 and the remaining 75,000 shares will vest on May 15, 2016. Vesting is dependent upon the new officer being in the Company's employment on the applicable vesting date. (See Note 12. Equity Incentive Plan – Stock Options.) On January 27, 2016, the Company entered into a new employment agreement with the Chief Financial Officer. (See Note. 13. Subsequent Events).

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 8. 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 "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 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. On December 2, 2015, the Company filed a complaint against the depositor with the Supreme Court of New York, seeking, among other things, a declaratory judgment directing the depositor to deliver to the Company the 3,500,000 Adjustment Shares for cancellation.

Note 11. Related Party Transactions.

Due from Stockholders/Members

Tyme and Luminant obtained from and granted cash advances to certain of their stockholders/members. These net advances were non-interest bearing and had no terms for repayment. At December 31, 2015 and 2014, amounts due to the Company totaled $0 and $355,766 and were reflected as a reduction of stockholders equity.

Effective as of the consummation of and in anticipation of the Merger, the non-interest bearing advances of $355,766 made to such stockholders/members were settled by payments received from such stockholders.

Sale of Excess Ingredient Materials

On December 17, 2015, the Company's board of directors approved a future sale of certain excess ingredient materials which the Company believes will expire, terminate and/or lose potency prior to any anticipated use by the Company. The sale of such excess ingredients will be made to Steve Hoffman, the Company's President and Chief Executive Officer, at the pro rata cost of obtaining such items. In his capacity as a director, Mr. Hoffman abstained from voting on this matter. (See Note. 13 Subsequent Events.)

Note 12. 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 months following the 2015 Plan adoption. 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 on the date of the grant and have a term of no greater than ten years from the date of grant. As of December 31, 2015, there were 9,813,630 shares available for grant under the 2015 Plan.

Stock Options

As of December 31, 2015, there was $281,841 of total unrecognized compensation related to non-vested stock options. The cost is expected to be recognized over the remaining period of the options which are expected to vest through May 2016.

During the years ended December 31, 2015 and 2014, $485,859 and $0, respectively, has been recognized as stock based compensation in general and administrative expense.

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 assumptions utilized to determine such values are presented in the following table:

	December 31, 2015	December 31, 2014
Risk free interest rate	1.65%	N/A
Expected volatility	82.90%	N/A
Expected term	5 years	N/A
Dividend yield	0%	N/A

Risk-free interest rate —Based on the daily yield curve rates for U.S. Treasury obligations with maturities which correspond to the expected term of the Company's stock options.

Expected volatility —Because the Company has a limited trading history in its common stock, expected volatility is based on that of comparable public development stage biotechnology companies.

Expected term —The expected option term represents the period that stock-based awards are expected to be outstanding. The Company is currently using the contractual term of five years as the expected term due to its limited history of granting stock options.

Dividend yield —The Company has not paid any dividends on common stock since its inception and does not anticipate paying dividends on its common stock in the foreseeable future.

Forfeitures —ASC 718 requires forfeitures to be estimated at the time of grant and revised if necessary, in subsequent periods if actual forfeitures differ from those estimates. Due to its limited history of granting stock options, the Company is not applying any forfeiture rate.

The following is a summary of the status of the Company's stock options as of December 31, 2015:

	Number of Options	Weighted Average Exercise Price
Outstanding at December 31, 2014	—	$ —
Granted	150,000	7.75
Exercised	—	—
Forfeited/Cancelled	—	—
Outstanding at December 31, 2015	150,000	$ 7.75
Grant date fair value	$ 5.12	

	Stock Options Outstanding				Stock Options Vested		
Range of Exercise Price	Number Outstanding at December 31, 2015	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value	Number Vested at December 31, 2015	Weighted Average Exercise Price	Aggregate Intrinsic Value
$ 7.75	150,000	$ 7.75	4.4	$ 525,500	75,000	$ 7.75	$262,500

The intrinsic value is calculated as the excess of the market value of December 31, 2015 over the exercise price of the option. The market value as of December 31, 2015 was $11.25 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 is 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, five individuals were appointed as members of such advisory board and a compensation policy for the advisory board's members, substantially identical to the compensation policy for the Company's independent directors, was adopted.

Accordingly, as compensation with respect to the year ended December 31, 2015, the Company issued to its three independent directors, special advisor and five advisory board members an aggregate of 36,370 shares of Company common stock (7,248 shares as of March 31, 2015, 5,884 shares as of June 30, 2015, 13,239 shares as of September 30, 2015 and 9,999 shares as of December 31, 2015), which were valued at the closing sale price of the Company common stock on the last trading day of each of the quarters ended during 2015 ($6.90 per share with respect to the quarter ended March 31, 2015, $8.50 per share with respect to the quarters ended June and September 30, 2015 and $11.25 with respect to the quarter ended December 31, 2015). Total stock compensation expense related to these stock grants was $325,000 for the year ended December 31, 2015.

Note 13. Subsequent Events.

Employment Agreement

The Company entered into a new employment arrangement, set forth in a letter agreement, dated as of January 27, 2016, with Robert Dickey IV, Vice President - Finance and Chief Financial Officer. The new employment arrangement supersedes the prior letter agreement with Mr. Dickey which was dated as of May 15, 2015. As part of the new employment agreement, Mr. Dickey has been granted a five year option to purchase up to 200,000 shares of the Company's common stock at a per share purchase price of $11.00, the closing price of the common stock on the date of the new agreement. One-half of the shares subject to such option vested immediately upon grant and the remaining 100,000 shares subject to the option will vest on July 27, 2016, provided that Mr. Dickey is still employed by the Company on said vesting date. The option granted to Mr. Dickey under the prior agreement has not been terminated and remains exercisable in accordance with its terms.

Securities Purchase Agreement

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 a total of two individuals 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.

Sale of Excess Ingredient Materials

On March 24, 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 items. The income from this will be recorded as an offset to Research and Development expense on the Consolidated Statements of Operations, where the cost of such materials was originally recorded.

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

On November 13, 2015, we engaged Grant Thornton LLP as our new independent registered public accounting firm to audit our financial statements, commencing with our fiscal year ending December 31, 2015. We previously reported in our Current Report on Form 8-K (Date of Report: October 8, 2015), as filed with the Securities and Exchange Commission on October 14, 2015, our termination of our prior independent registered public accounting firm, WithumSmith+Brown, PC.

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 December 31, 2015 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, 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 December 31, 2015. 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 December 31, 2015, 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 reasonably 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:

- lack of a functioning audit committee resulting in ineffective oversight in the establishment and monitoring of required internal controls and procedures;
- inadequate segregation of duties consistent with control objectives; and
- ineffective controls over period end financial disclosure and reporting processes.

The aforementioned material weaknesses were identified by Messrs. Hoffman and Dickey in connection with their review of our financial statements as of December 31, 2015. 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:

- Assuming we are able to 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. In the meantime, beginning in our fiscal quarter ended September 30, 2015, 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.

- We intend to design and implement centralized and automated enhancements to the processing of invoices to assure standardized supplier setup and proper entry by invoice type into our accounts payable system. These enhancements will also incorporate adherence to signing authorities as part of check run processing and ensure adequate segregation of duties as well as the completion of timely month end reconciliation procedures for accounts payable and accrued expenses.

- We also plan to appoint one or more independent directors to an audit committee, which will undertake audit oversight and other duties normally performed by audit committees of public companies.

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. However, for as long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

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 December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

As noted above, we intend to form an audit committee. We anticipate that such audit committee will discuss with management, including our Chief Financial Officer, and our independent registered public accounting firm, the status of our financial controls and procedures and determine what changes are necessary to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with US GAAP. 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 December 31, 2015 and 2014

Consolidated Statements of Operations for the years ended December 31, 2015 and 2014

Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2015 and 2014

Consolidated Statements of Cash Flows for the years ended December 31, 2015 and 2014

Notes to Consolidated Financial Statements as of December 31, 2015 and 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.]

Exhibit Number	Description
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.]
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.]
10.5	Form of Subscription Agreement between Tyme Technologies, Inc. and GEM Global Yield Fund LLC SCS. [Incorporated by reference to Exhibit 10.5 to our Current Report on Form 8-K (Date of Report: March 5, 2015), filed with the SEC on March 11, 2015.]
10.6	Subscription Note of GEM Global Yield Fund LLC SCS, dated March 5, 2015, in the amount of $2.5 million and payable to Tyme Technologies, Inc. [Incorporated by reference to Exhibit 10.6 to our Current Report on Form 8-K (Date of Report: March 5, 2015), filed with the SEC on March 11, 2015.]
10.7	Subscription Note Shares Escrow Agreement, dated March 5, 2015, between GEM Global Yield Fund LLC SCS and Tyme Technologies, Inc. and CKR Law LLP (as Escrow Agent). [Incorporated by reference to Exhibit 10.7 to our Current Report on Form 8-K (Date of Report: March 5, 2015), filed with the SEC on March 11, 2015.]
10.8†	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.]
10.9	Form of Registration Rights Agreement, dated as of March 5, 2015, among Tyme Technologies, Inc. and the other parties thereto. [Incorporated by reference to Exhibit 10.9 to our Current Report on Form 8-K (Date of Report: March 5, 2015), filed with the SEC on March 11, 2015.]
10.10	Indemnification Shares Escrow Agreement, dated as of March 5, 2015, among Tyme Technologies, Inc., Steven Hoffman (as Indemnification Representative) and CKR Law LLP. [Incorporated by reference to Exhibit 10.10 to our Current Report on Form 8-K (Date of Report: March 5, 2015), filed with the SEC on March 11, 2015.]
10.11	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.]
10.12†	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.]
10.13†	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.]
10.14	Consulting Agreement, dated as of March 5, 2015, between Tyme Technologies, Inc. and Beryllium Advisory Consulting, Limited Liability Company. [Incorporated by reference to Exhibit 10.14 to our Current Report on Form 8-K (Date of Report: March 5, 2015), filed with the SEC on March 11, 2015.]
10.15	Adjustment Shares Escrow Agreement, dated as of March 5, 2015, among Tyme Technologies, Inc., the depositor parties thereto, CKR Law LLP (as Escrow Agent). [Incorporated by reference to Exhibit 10.15 to our Current Report on Form 8-K (Date of Report: March 5, 2015), filed with the SEC on March 11, 2015.]
10.16	10% Secured Convertible Promissory Note of Tyme Inc. in the principal amount of $1,100,000, issued on July 11, 2014. [Incorporated by reference to Exhibit 10.16 to our Current Report on Form 8-K (Date of Report: March 5, 2015), filed with the SEC on March 11, 2015.]
10.17	Amended and Restated 10% Secured Convertible Promissory Note of Tyme Inc. in the principal amount of $1,350,000 issued on November 24, 2014. [Incorporated by reference to Exhibit 10.17 to our Current Report on Form 8-K (Date of Report: March 5, 2015), filed with the SEC on March 11, 2015.]
10.18	Second Amended and Restated 10% Secured Convertible Promissory Note of Tyme Inc. in the principal amount of $2,310,000 issued on January 15, 2015. [Incorporated by reference to Exhibit 10.18 to our Current Report on Form 8-K (Date of Report: March 5, 2015), filed with the SEC on March 11, 2015.]

Exhibit Number	Description
10.19	Letter Agreement, dated as of March 5, 2015, among Christopher Brown, Tyme Technologies, Inc. and Tyme Inc. [Incorporated by reference to Exhibit 10.19 to our Current Report on Form 8-K (Date of Report: March 5, 2015), filed with the SEC on March 11, 2015.]
10.20†	Employment Agreement, dated as of May 15, 2015, between Tyme Technologies, Inc. and Robert Dickey. [Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K (Date of Report: May 15, 2015), filed with the SEC on May 20, 2015.]
10.21†	Option Agreement dated as of May 15, 2015, between Tyme Technologies, Inc. and Robert Dickey. [Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K (Date of Report: May 15, 2015), filed with the SEC on May 20, 2015.]
10.22	Omnibus Amendment, dated as of June 5, 2015, among Tyme Technologies, Inc., Christopher Brown and GEM Global Yield Fund LLC SCS. [Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K (Date of Report: June 5, 2015), filed with the SEC on June 10, 2015.]
10.23	Second Omnibus Amendment, dated as of July 23, 2015, among Tyme Technologies, Inc., Christopher Brown and GEM Global Yield Fund LLC SCS. [Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K (Date of Report: July 23, 2015), filed with the SEC on July 23, 2015.]
10.24	Form of Securities Purchase Agreement, dated as of February 2, 2016, among Tyme Technologies, Inc. and the purchaser parties thereto. [Incorporated by reference to 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.]
10.25	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.]
10.26	Employment Agreement, dated as of January 27, 2016, between Tyme Technologies, Inc. and Robert Dickey IV. [Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K (Date of Report: January 27, 2016), filed with the SEC on February 2, 2016.]
10.27	Option Agreement, dated as of January 27, 2016, between Tyme Technologies, Inc. and Robert Dickey IV. [Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K (Date of Report: January 27, 2016),filed with the SEC on February 2, 2016.]
10.28	Option Agreement, dated as of May 15, 2015 between Tyme Technologies, Inc. and Robert Dickey IV. [Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed with the SEC on May 20, 2015.]
10.29	Form of Securities Purchase Agreement, dated as of December 18, 2015, between Tyme Technologies, Inc. and the purchaser parties thereto. [Incorporated by reference to 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.]
10.30	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.]
10.31	Securities Acquisition Agreement, dated as of December 18, 2015, between Tyme Technologies, Inc. and the purchaser parties thereto. [Incorporated by reference to Exhibit 99.2 to our Current Report on Form 8-K (Date of Report: December 23, 2015), filed with the SEC on December 30, 2015.]
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.
99.1	Press Release of Tyme Technologies, Inc., dated November 23, 2015. [Incorporated by reference to Exhibit 99.1 to our Quarterly Report on Form 10-Q for September 30, 2015, filed with the SEC on November 23, 2015.]
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: March 30, 2016

TYME TECHNOLOGIES, INC.

By: /s/ Steve Hoffman
Steve Hoffman
President and
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 or Robert Dickey IV 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
/s/ Steve Hoffman Steve Hoffman	Chief Executive Officer and Director (Principal Executive Officer)	March 30, 2016
/s/ Robert Dickey IV Robert Dickey IV	Vice-President - Finance and Chief Financial Officer (Principal Financial Officer)	March 30, 2016
/s/ Patrick G. LePore Patrick G. LePore	Director	March 30, 2016
/s/ Gerald H. Sokol Gerald H. Sokol	Director	March 30, 2016
/s/ Tim Tyson Tim Tyson	Director	March 30, 2016

EXHIBIT 21.1

List of Subsidiaries

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

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

EXHIBIT 31.1

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 December 31, 2015 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 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 me 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 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: March 30, 2016

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

EXHIBIT 31.2

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

I, Robert Dickey IV, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2015 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 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 me 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 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: March 30, 2016

/s/ Robert Dickey IV
Robert Dickey IV
Vice-President - Finance and Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

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

In connection with the Annual Report on Form 10-K of Tyme Technologies, Inc. (the "Company") for the fiscal year ended December 31, 2015, 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 at and for the periods presented therein.

Date: March 30, 2016

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

EXHIBIT 32.2

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 December 31, 2015, to which this Certification is being filed as an exhibit thereto (the "Report"), I, Robert Dickey IV, 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 at and for the periods presented therein.

Date: March 30, 2016

/s/ Robert Dickey IV
Robert Dickey IV
Vice-President - Finance and Chief Financial Officer
(Principal Financial Officer)