UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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 March 31, 2019

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

For the transition period from _____to _____

Commission File No. 001-38169

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.)**
17 State Street – 7th Floor, New York, NY	**10004**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (212) 461-2315

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value	TYME	Nasdaq Capital Market

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller Reporting Company	☒
Emerging Growth Company	☐		

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

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

The aggregate market value of the voting and non-voting 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 $137,958,473.

The number of shares outstanding of the registrant's common stock on June 4, 2019 was 111,950,937.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by Items 10, 11, 12, 13 and 14 is incorporated by reference into Part III hereof from portions of the Proxy Statement for the registrant's 2019 Annual Meeting of Stockholders.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this Annual Report on Form 10-K are "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the safe harbor created thereby. All statements contained in this Annual Report on Form 10-K other than statements of historical facts, including statements regarding our future results of operations and financial position, our business strategy and plans and our objectives for future operations, are forward-looking statements. The words "believes," "expects," "hopes," "may," "will," "plan," "intends," "estimates," "could," "should," "would," "continue," "seeks," "anticipates," and similar expressions (including their use in the negative), are intended to identify forward-looking statements. Forward-looking statements can also be identified by discussions of future matters such as the development and potential commercialization of our drug candidates (including SM-88 and Tyme-18) and of other new products, the clinical potential and non-toxic safety profiles of our drug candidates, expected releases of interim or final data from our clinical trials, technology enhancements, possible collaborations, the timing, scope and objectives of our ongoing and planned clinical trials and other statements that are not historical. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Item 1A. Risk Factors," and many of which are beyond our control. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this Annual Report on Form 10-K may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, achievements or events and circumstances reflected in the forward-looking statements will occur. We disclaim any intent or duty to update any of these forward-looking statements after completion of this Annual Report on Form 10-K to conform these statements to actual results or revised expectations.

GENERAL

Unless the context otherwise requires, all references in this Annual Report on Form 10-K to the "Company," "TYME," "we," "us" or "our" refer to Tyme Technologies, Inc., together with its subsidiaries.

PART I

ITEM 1. BUSINESS

Executive Summary of Our Business

TYME is an emerging biotechnology company developing cancer metabolism-based therapies (CMBTs ™) that are intended to be effective across a broad range of solid tumors and hematologic cancers, while also maintaining patients' quality of life through relatively low toxicity profiles. Unlike targeted therapies that attempt to regulate specific pathways within cancer, TYME's therapeutic approach is designed to take advantage of a cancer cell's innate metabolic requirements to cause cancer cell death.

Our lead clinical CMBT program, SM-88 (racemetyrosine), is a novel, oral, monotherapy investigational agent that has been studied in clinical trials for over five years within more than 150 cancer patients. TYME recently completed enrollment for two Phase II clinical trials in prostate and pancreatic cancer, and the Company is preparing for pivotal studies for SM-88 in pancreatic cancer during the second half of calendar year 2019. One of these pivotal trials is focused on patients with third-line pancreatic cancer and would be an amendment to the ongoing TYME-88-Panc trial (Part 2). The Company has also partnered with the Pancreatic Cancer Action Network ("PanCAN") to study SM-88 in an adaptive pivotal trial known as Precision Promise SM starting as second-line monotherapy and could expand to first-line combination therapy with standard of care. A Phase II investigator-initiated trial evaluating SM-88 monotherapy in late-stage sarcomas was launched in May 2019 under the direction of principal investigator Dr. Sant Chawla and in collaboration with the Joseph Ahmed Foundation ("JAF"). All of SM-88's current clinical programs study SM-88 in use with three low-dose conditioning agents: methoxsalen, phenytoin, and sirolimus (hereafter, referred to as "MPS"). We are actively evaluating the expansion of our clinical program to other cancers as SM-88 has demonstrated complete or partial responses in 15 different forms of cancer with a well-tolerated safety profile.

In addition to SM-88, the company has a pipeline of pre-Initial New Drug Application ("IND") CMBT product candidates. One candidate, TYME-18, is designed for intra-tumoral injection to increase the permeability of cancer cells. The direct delivery of TYME-18 to the tumor target, in contrast to conventional systemic therapies, aims to localize the effect of the agent to the tumor, while limiting systemic effects and minimizing damage to healthy tissues.

TYME maintains a broad intellectual property portfolio of 162 patent applications granted and/or pending covering our technologies and products, compositions, methods, manufacturing and use with earliest expiration in 2032 not including potential extensions.

SM-88 Mechanism of Action

SM-88 (racemetyrosine) is an orally administered cancer metabolism-based therapy that is chemically altered to be non-functional for fundamental tumor cell processes, including protein synthesis. Scientific literature has broadly published that normal healthy cells do not regularly take up certain non-essential amino acids, specifically tyrosines, while a wide range of cancer cells upregulate methods to consume these metabolites. We believe that, when taken up by a cancer cell, our proprietary modified dysfunctional tyrosine interrupts protein synthesis, reduces key cellular defenses, and ultimately leads to an oxidative stress-related apoptosis or cell death. We also believe this selective cancer uptake of non-essential amino acids is supported by the current safety profile showing minimal observed drug-related serious adverse events (each, an "SAE") in over 150 cancer patients treated with SM-88 to date.

SM-88 is administered with the conditioning agents MPS. The conditioning agents are administered at doses between 5% and 25% of their FDA approved doses in non-cancer indications. We believe the physiologic, but sub-therapeutic doses of these agents may augment the uptake of SM-88 and destabilize cancer cells based on scientific literature of their respective biologic functions.

The Company has established pre-clinical research collaborations with academic institutions, as well as internal pre-clinical initiatives, to broaden the detailed understanding of the mechanisms associated with SM-88. The overall goals of these efforts are to potentially identify patient biomarkers that could be applied to patient selection in clinical trials, as well as identify potential combinations with other anti-cancer mechanisms that could

aid future clinical development. We currently have a research collaboration with Mayo Clinic and could establi sh additional collaborations in the future.

Development Strategy and Key Product Properties

Our goal is to develop CMBTs that may help patients live longer and better lives through next-generation medicines that are both better and safer treatments than current cancer treatment options. Key elements of our strategy to achieve this goal are:

- **Successfully advance SM-88 across a broad range of cancers through clinical development, regulatory approvals and commercial launch globally** .
- **Continue to invest in our technology platform and expand the breadth and depth of our IP portfolio** . We plan to expand our research and development ("R&D") efforts to encompass multiple cancer indications in both solid tumors and hematologic cancers . We have undertaken early development programs for additional delivery systems of our lead oral candidate, SM-88, as well as new investigational CMBTs to treat cancer patients with high unmet medical needs.
- **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 and/or their assets that can augment our expertise and technology, as well as a means to acquire rights or ownership of additional intellectual property ("IP"). We also contemplate exploring global development partners and arrangements, where appropriate.

By using SM-88 to disrupt key aspects of cancer's unique metabolism, our intention is to create an innovative therapeutic approach that is:

- **Broadly effective across different cancer types** – Because a vast majority of cancers use the same metabolic process, known as the Warburg Effect, we believe that they likely also have the same susceptibilities to SM-88 treatment, regardless of physiologic origin;
- **Highly specific to cancer** – As supported by the current safety data reported for over 150 patients, together with recent advances in radiographic imaging that use tyrosine-based agents to selectively image cancer cells, cancer appears to have a high affinity for tyrosine uptake compared to normal cells;
- **Well-tolerated/ broad therapeutic margin** – Safety findings are available for over 150 patients, and only two patients (1%) have reported any drug-related serious adverse events;
- **Suitable for monotherapy or combination therapy** – Although most of TYME's clinical and compassionate use experience has been in monotherapy, SM-88's differentiated mechanism of action (MOA) and safety profile may also allow it to be effective in combination with other cancer therapeutics; and
- **Potentially effective treatment for patients who have failed other therapeutic options** – Current cancer therapies are often intended to inhibit or change a particular aspect of cancer's cellular function, known as selective pressure. However, cancers typically develop resistance mechanisms that can make them less responsive to subsequent selective pressure treatments, while at the same time patients also accumulate treatment-related toxicities that can make them ineligible for subsequent therapies. SM-88 is designed to avoid selective pressure and this fundamental limitation of traditional therapies by utilizing cancer's innate metabolic weaknesses to compromise its defenses, leading to cell death through oxidative stress and exposure to the body's natural immune system. We believe this novel mechanism of action may allow SM-88 to be used in traditional treatment-resistant patients and also limit development of resistance.

We believe we can become a leader in developing and delivering CMBTs with our platform technology for the following reasons:

- Members of our management team have more than ten years of scientific research and clinical development in the field of cancer metabolism-based therapies.
- Oral SM-88 has demonstrated meaningful clinical benefit and well tolerated safety profile, in metastatic cancer patients across 15 different types of solid tumors and hematologic cancers.
- To date, SM-88 has shown significant safety profile and we believe the unique mechanism of action increases prospects for evaluation of the potential of SM-88 as a preferred therapy in combination with existing treatment modalities.
- We currently retain all commercial rights for SM-88 and new pipeline candidates through a strong and growing patent estate of over 57 issued patents and 105 pending patent applications in various countries broadly covering compositions, methods, manufacturing and use in connection with the treatment of cancers.
- We have a technology base and patent portfolio supporting SM-88 and have filed patents applications for additional drug candidates to provide a pipeline of oncology drug development programs based on our CMBT technology platform.

SM-88: Completed Studies

First in Human Study

The initial clinical trial with SM-88, known as the First in Human Study ("FHS"), began in 2012 and was conducted in 30 actively progressing metastatic cancer patients who had failed or refused all available treatments options. The Phase I study was designed to assess the safety of monotherapy SM-88, although the trial was extended beyond the initial six-week period based on reported treatment efficacy, with several patients remaining on treatment for over 12 months. Patients were given SM-88 with conditioning agents melanin, melanotan II, phenytoin, and sirolimus (these conditioning agents will hereafter be referred to as "M2PS").

The results of the FHS were published in the journal, *Investigational New Drugs,* in March 2019, including data from the trial's initiation in January 2012 through September 2017. Patients were treated with monotherapy SM-88 and achieved median overall survival ("OS") of 29.8 months, median progression free survival ("PFS") of 13 months, and a 33% objective response rate ("ORR"). The ORR consisted of four complete responses ("CR") and six partial responses ("PR"), based on Response Evaluation Criteria In Solid Tumors 1.1 ("RECIST"). In addition, 57% of patients (17/30) achieved RECIST stable disease (SD) with a median SD duration of 11 months. Five FHS patients with metastatic cancer survived for over five years after commencing SM-88 treatment. All FHS patients improved or maintained Eastern Cooperative Oncology Group Performance Status ("ECOG PS"), a measure of quality of life, after initiating SM-88 therapy, and OS was comparable for patients who entered the trial with ECOG PS ranging from 0 (asymptomatic) to 2 (unable to perform any work-related activities).

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

2017. One of the re-treated patients experienced a second objective tumor response from SM-88 monotherapy a s measured by RECIST criteria.

We believe that traditional RECIST response criteria, a commonly used clinical endpoint based primarily on computerized tomography ("CT") images, may not fully reflect the therapeutic benefit from SM-88. This is based on the observation in the First in Human Study where a total of 17 of the 30 patients achieved SD with median OS of 29.0 months. Because we believe many patients on SM-88 experience therapeutic benefit without necessarily achieving a CR or PR under RECIST criteria, we commonly refer to "Clinical Benefit," which includes CR, PR and SD designations.

SM-88 used with M2PS demonstrated a favorable safety profile and was well tolerated. All related adverse events (AEs) for SM-88 were classified as mild or moderate. The most common treatment AEs experienced included hyperpigmentation by 100% of patients (30/30), fatigue by 56.7% of patients (17/30) and pain by 10% of patients (3/30). No dose limiting toxicities were observed.

Compassionate Use Program

In parallel with and following the First in Human Study, we also allowed metastatic cancer patients' access to SM-88 through a compassionate use program. As of March 31, 2017, 76 patients had been treated outside of the FHS with SM-88 (the "Compassionate Use Patients") as part of a compassionate use program under Institutional Review Board ("IRB") supervision. In early 2018, we performed a retrospective analysis on the 53 (of 76) Compassionate Use Patients who had received at least six weeks of treatment. These patients had their scans reviewed by independent radiologists to determine response under RECIST, and 75% of these patients (40 of 53) were deemed to have experienced Clinical Benefit, consisting of 8 CRs, 16 PRs and 16 SD designations.

Through these two programs, patients being treated with SM-88 have achieved CRs or PRs across 15 different cancer types, including some of the most common and difficult to treat cancers, such as pancreatic, prostate, breast, lung, glioma, ovarian, sarcoma and colon cancer. Based on preliminary data from the FHS and the Compassionate Use Patients suggesting SM-88 may have broad potential applicability and acceptable toxicity, we believe that SM-88 may ultimately be utilized as a treatment for a wide range of cancers prior to the end-stage setting.

SM-88 Ongoing Studies

Pancreatic Cancer Trial ("TYME-88-Panc")

TYME-88-Panc is a two-part, open-label clinical trial evaluating SM-88 as an oral monotherapy in late-stage patients with advanced pancreatic cancer. Part 1 was designed to determine optimal dose for pivotal testing and patients were given either a high or low dose of SM-88. Preliminary data from Part 1 was released at the American Society of Clinical Oncology ("ASCO") Gastrointestinal Cancer Symposium on January 18, 2019, and we plan to present additional data at the European Society for Medical Oncology ("ESMO") World Congress on Gastrointestinal Cancer on July 4, 2019. The protocol for Part 2 in patients who have failed two prior lines of systematic therapy is currently being finalized and is intended as a pivotal registration trial.

Part 1 of TYME-88-Panc includes 49 heavily pretreated patients with radiographically progressive metastatic pancreatic cancer, who had received a median of two prior systemic therapies and had significant disease related morbidity before receiving SM-88 used with MPS. Of the 49 patients, 39 patients are evaluable for efficacy, as defined in the protocol. Preliminary results from Part 1 of TYME-88-Panc, using information available as of April 25, 2019, demonstrated overall survival of evaluable patients (N=39) trending to be approximately double the expected survival of this patient population. The expected survival for this patient population would be 2 to 2.5 months. Reported survival of patients progressing after second line therapy was 3 months, based on an analysis of 19 published trials with patients who had progressed after second line treatment (Manax, et al J Clin Oncol 37, 2019 (suppl 4; abstr 226)). In addition, there is an approximate 2 to 4-week transition between second and third line treatments. Thus, based on these considerations, the expected survival for this patient population would be 2 to 2.5 months.

In addition, nine of the first 28 evaluable patients (32%) were still ali ve at 6 months or longer, with an early patient having achieved one year of survival. Monotherapy activity with SM-88 was demonstrated in certain patients based on common measures of anti-tumor activity, including computed tomography ("CT"), positron emis sion tomography ("PET"), and reductions in biomarkers carcinoembryonic antigen ("CEA"), CA-19.9 and circulating tumor cell ("CTC") burden. SM-88 remained well tolerated, showing minimal drug related serious adverse events.

Part 2 of TYME-88-Panc is expected to be a pivotal trial in third-line metastatic pancreatic cancer. The protocol for Part 2 is currently being finalized based on data from Part 1, guidance from the FDA and feedback from Part 1 clinical investigators. Part 2 is poised to begin enrollment in the second half of calendar year 2019.

Phase II Prostate Cancer Trial

On February 14, 2019, we released preliminary results from an ongoing Phase II trial of SM-88 in patients with non-metastatic, biochemical-recurrent prostate cancer at the 2019 ASCO Genitourinary Cancers Symposium. As of January 2019, 23 patients were enrolled and included in the preliminary presentation from the ongoing Phase II trial of SM-88 in prostate cancer. Patients entered the trial with rising prostate-specific antigen levels ("PSA"), detectable CTCs and no radiographically detectable metastases. Study duration, per protocol, was six months, although some patients were granted a waiver to remain on treatment for longer periods. 74% of patients had previously received androgen deprivation therapy as treatment for prostate cancer. In this trial, patients were given SM-88 with micro doses of conditioning agents MPS.

As of January 2019, 87% of patients (20/23) remained free of any local radiographic progression with median duration of therapy of 6.5 months. All patients remained metastases free, as defined by recent FDA draft guidance for use of metastasis-free survival as a trial endpoint. PSA levels generally remained stable during treatment. Median PSA doubling-time, used for assessing disease status in patients with prostate cancer, improved by 34% for patients completing 12 weeks of treatment, from 6.1 months at baseline to 8.2 months. More than half of all patients (12/23) experienced an improvement in PSA doubling time. After 12 weeks, all patients had CTCs below baseline, with a median decrease of 65%. CTCs generally continued to decrease and remained below baseline for the duration of the SM-88 administration.

With a cumulative dosing exposure of 149 months, no drug-related severe or life-threatening adverse events (grade 3 or 4) were observed. The only moderate adverse event (grade 2) possibly-related to SM-88 therapy was fatigue, reported by one patient. The majority of mild adverse events (grade 1) possibly or probably-related to SM-88 therapy were gastrointestinal in nature. No adverse events resulted in dose delay, discontinuation or reduction.

Enrollment in our Phase II prostate cancer trial has been completed and final results are expected in the second half of calendar year 2019.

Investigator-Initiated Phase II Sarcoma Trial

The HopES trial, an investigator-initiated prospective open-label Phase II trial evaluating the efficacy and safety of SM-88 with MPS for the treatment of poor prognosis sarcomas, was initiated in May 2019. Up to 24 evaluable patients will be enrolled in the HopES trial through two patient cohorts. The first cohort will evaluate oral SM-88 as maintenance monotherapy following primary or palliative treatments for Ewing's sarcoma patients with a high risk of relapse or disease progression. The second cohort will determine the clinical benefits of SM-88 as salvage monotherapy for patients with clinically advanced sarcomas. The primary objectives are to measure ORR and PFS. Secondary objectives include duration of response, OS, CBR using RECIST v1.1, and incidence of treatment-emergent adverse events. The Joseph Ahmed Foundation is providing funding and patient support for this trial and the trial is being conducted by principal investigator Dr. Chawla at the Sarcoma Oncology Center in Santa Monica, CA.

Upcoming Studies and Developments

PanCAN Precision Promise Adaptive Phase II/III Trial Platform

We have entered into an agreement for SM-88 to be included in an experimental arm in the novel Precision Promise adaptive pivotal trial platform sponsored by PanCAN. The objective of Precision Promise is to expedite the study and approval of promising therapies for pancreatic cancer by bringing multiple stakeholders together, including academic, industry and regulatory entities.

The primary goal of SM-88's inclusion is to study SM-88 as a monotherapy treatment arm for patients who have failed one prior line of chemotherapy. Additionally, it is planned that SM-88 will be evaluated in combination with gemcitabine (Gemzar ®) and nab-paclitaxel (Abraxane ®) for first-line patients. The second-line monotherapy arm is expected to initiate in the second half of calendar year 2019.

PanCAN is sponsoring Precision Promise and providing funding and other support. While TYME's SM-88 will be included in the trial, we will not oversee, conduct or control the trial.

TYME-18 Preclinical Studies

TYME-18 is a cancer metabolism-based investigational therapy designed for the intra-tumoral delivery of the treatment and increase the permeability of cancer cells while delivering a therapy that will have a selective cytotoxic effect on the tumor. TYME-18 is distinct in composition from SM-88. However, like SM-88, it aims to enhance the susceptibility of a cancer to the highly acidic and toxic tumor microenvironment, while minimizing the impact to normal tissues.

In initial preclinical xenograft mouse studies, TYME-18 was able to completely resolve over 90 percent (11/12 mice) of established colorectal tumors within 12 days versus an average of over 600 percent growth in the control animals. Additionally, there was no detected necrosis of the normal tissue surrounding the tumor site or other identified toxicities in the animals treated with TYME-18. We plan to continue with the development of TYME-18 in solid tumors and to provide details of an IND-enabling program in the second half of calendar year 2019.

Animal Health

Our co-founders, Steve Hoffman and Michael Demurjian, hold certain intellectual property rights with respect to the treatment of cancer in non-humans. Following interest from third parties in creating health partnerships, a committee of independent members of our board of directors has held discussions with our co-founders to obtain intellectual property rights such that the Company could have the ability to pursue cancer therapies in animal health.

Competition

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

The TYME-88-Panc study will be amended to study SM-88 in third-line pancreatic patients. There are no FDA approved third-line pancreatic treatments and there are no active therapies recommended in the ASCO or National Comprehensive Cancer Network guidelines. If commercialized for third-line pancreatic treatment, the competition for SM-88 would be physician choice of therapy, supportive care and/or clinical trials.

Import ant competitive factors include patient safety, effectiveness, quality-of-life and ease of use of products; price and demonstrated cost-effectiveness; marketing effectiveness; payor access and research and development of new products and processes. Most ne w 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 sys tems 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 organ izations and pharmacy benefits managers, we would be required to demonstrate that our products offer not only medical benefits, but also more value as compared with other treatment regimens.

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, development and regulatory plans in addition to proprietary scientific knowledge provide us with certain competitive advantages, we currently have limited financial resources and no revenue source 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 which 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 biopharmaceuticals generally invest far less in R&D and marketing 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. 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 United States, 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 an d 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 ca n we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial products and methods of manufacturing such products, as well as being held valid if challenged.

Tyme maintains a broad intellectual property portfolio of 162 patent applications granted and/or pending, with eight U.S. patents issued as of June 4, 2019. The patents encompass SM-88 as well as inventions that fight cancer and aid in the creation of novel mechanisms to further that effort. 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 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.

We also rely on trademark laws to protect our proprietary rights. Our trademark portfolio currently consists of one domestic trademark: CMBTs (cancer metabolism-based therapies).

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

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

protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

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

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

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

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

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

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

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that the NDA is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most such applications for standard review drugs are reviewed within 10 months from the date the application is accepted for filing. Although the FDA often meets its user fee

performance goals, it can extend these timelines if necessary and its review may not occur on a timely basis at all. The FDA usually refers applications for novel drugs, which present complex questions of safety or efficacy, to an advisory committee - typically a panel that includes clinicians and other experts - for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility o r 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 for the FDA to reconsider the application. If or when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two to six months depending on the type of information that was included. The FDA approval is never guaranteed, and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied.

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.

As of March 31, 2019, we have two active INDs with the U.S. FDA, both associated with SM-88. The two INDs are associated with the relevant FDA departments that oversee our two ongoing clinical trials, the Department of Oncology Products 1 ("DOP1") for our prostate cancer trial, and the Department of Oncology Products 2 ("DOP2") for our pancreatic cancer trial.

In February 2019, we participated in a Type C meeting with the FDA. During that meeting we received guidance on our planned pivotal trial for SM-88 in third line pancreatic cancer. The trial is planned to be a randomized study comparing SM-88 to a control arm. The control arm will consist of physician's choice of therapies. The primary end point will be overall survival.

Priority Review/Standard Review (U.S.) and Related Requirements

The FDA may grant an NDA 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. There can be no assurance that we would be able to satisfy the eligibility criteria for priority review or to receive regulatory approval under either standard review.

Breakthrough Therapy Approvals

The Food and Drug Administration Safety and Innovation Act provides another 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 substant ial 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.

Fast Track Program

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

The 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 ("ANDA") 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 studies 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 a currently approved drug, if new clinical investigations conducted or sponsored by the applicant are determined by the FDA to be essential to the approval of the new or supplemental NDA.

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 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

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

Other Healthcare Laws and Compliance Requirements

In the U.S., our activities are potentially subject to regulation by federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the U.S.

Department of Health and Human Services (for example, the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice and state and local governments.

United States Adopted Names (USAN) Council

In the first calendar quarter of 2019, we were notified that United States Adopted Names (USAN) Council has approved the use of the nonproprietary generic name, racemetyrosine, for SM-88.

European Regulation and Review

EU Approval Process

The European Medicines Agency ("EMA") is a decentralized scientific agency of the European Union ("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 is similar to the U.S. and likewise generally involves satisfactorily completing each of the following:

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

Preclinical Studies

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

Clinical Trial Approval

Pursuant to the Clinical Trials Directive 2001/20/EC, as amended, a system for the approval of clinical trials in the EU has been implemented through national legislation of the Member States. Under this system, approval must be obtained from the competent national authority of each European Member State in which a study is planned to be conducted. To this end, a CTA is submitted, which must be supported by an investigational medicinal product dossier ("IMPD") and further supporting information prescribed by the Clinical Trials Directive

and other applicable guidance documents. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application in that country.

An EU regulation on clinical trials was adopted by the European Parliament and the Council of Ministers in 2014. The new regulation aims to simplify consent rules, streamline application procedures by creating a centralized process for approval, provide more transparency and harmonize performance of clinical trials throughout the EU Member States. The new regulations are anticipated to take effect in 2020, with one-year transition period during which a new CTA can be authorized either according to the old Clinical Trials Directive 2001/20/EC or the new 536/2014 Regulation, as requested by the sponsor.

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 three procedures: (i) a centralized authorization procedure, (ii) a mutual recognition procedure, (iii) a decentralized 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 coordination 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

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 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 however, that we would be able to satisfy any of these requirements or receive any approval or accelerated evaluation.

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 is 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 nine months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization shall be valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization that 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 ceases 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 before the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. However, this period may be reduced to six years if at the end of the fifth year it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify continued market exclusivity. Market exclusivity can be revoked only in very selected cases, such as consent from the marketing authorization holder, inability to supply sufficient quantities of the product, demonstration of "clinically relevant superiority" by a similar medicinal product or, after a review by the Committee for Orphan Medicinal Products, requested by a Member State in the fifth year of the marketing exclusivity period (if the designation criteria are believed to no longer apply). Medicinal products designated as orphan drugs are eligible for incentives made available by the EU and by its Member States to support research into and the development and availability of orphan drugs. It is not our current intention to pursue orphan drug designation for SM-88.

Regulatory Data Protection

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

This regime consists of a regulatory data protection period of eight years plus a concurrent market exclusivity of ten years plus an additional market exclusivity of one additional 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 that, 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 P IP.

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 have entered into limited term supply arrangements for certain SM-88 components related to supply for our clinical activities in order to secure favorable pricing terms. 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 before submission of an NDA to the FDA.

Our current intention is that, during the ongoing development of SM-88, we will transition the needed manufacturing, CMC and GMP programs towards commercial manufacturing. The overall manufacturing program includes, but is not limited to, the development of product and process specifications, producing and validating standards and the development of suitable analytical methods for test and release, as well as stability testing. Before and during the use of contract manufacturers, we (or qualified designee) will conduct audits to ensure compliance with the mutually agreed process descriptions and cGMP regulations. Our manufacturers themselves must co mply 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 anticipate scaling the manufacturing pro cess to a suitable size. Increasing scale involves several steps and may involve modification of the process, in which case modifications to our CMC sections will occur, with continuous submissions to the FDA and EU regulatory authorities.

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

SM-88 is currently used with the conditioning agents methoxsalen, phenytoin, and sirolimus (“MPS”). Methoxsalen, phenytoin, and sirolimus each previously received regulatory approval in areas other than cancer treatment. SM-88 and the three agents within MPS 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 do not believe unusual equipment could be required in the manufacturing process.

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

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

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

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

Employees

As of March 31, 2019, we had a total of 15 employees, all full-time and 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 15 employees, seven perform research and development activities and eight perform general and administrative functions. Our Chief Executive Officer, Steve Hoffman, is also our Chief Science Officer and, as such, may be considered engaged in R&D activities, for purposes of the immediately preceding sentence, as well as his being categorized as serving in an administrative capacity. Based upon their roles and activities with the Company, certain other employees may also be categorized as serving in more than one role. Where necessary, we have entered into consulting contracts to provide us with subject matter expertise. We believe there is a sufficient number of available 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 office is located at 17 State Street, 7th floor, New York, NY 10004. We also have another office located at One Pluckemin Way, Bedminster, NJ 07921. Our telephone number is 212-461-2315. Our website address is *www.tymeinc.com* .

Corporate History; Significant Organizational Events

We were originally incorporated in Florida as Global Group Enterprises Corp. on November 22, 2011. Effective as of September 18, 2014, we reincorporated in the State of Delaware and later engaged in a merger and certain other transactions. 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, ("Common Stock") to 300,000,000 shares of Common Stock and 10,000,000 shares of "blank check" preferred stock, par value $0.0001 per share; and
- we entered into a subsequent merger in 2015, whereby we acquired our current clinical-stage pharmaceutical business.

At-the-Market Sales of Common Stock

On November 2, 2017, we entered into an equity distribution agreement with Canaccord Genuity Inc. ("Canaccord"), pursuant to which we may, from time to time, sell shares of our common stock having an aggregate offering price of up to $30,000,000 through Canaccord, as our sales agent, in an at-the-market offering (the "ATM"). Since initiation, we have sold 3,927,248 shares of our common stock under this equity distribution agreement for net proceeds of $11,492,261 after commissions of $359,866 and other transaction expenses.

Underwritten Securities Offering

On March 6, 2018, TYME closed an underwritten public offering of 10.4 million shares of its Common Stock, at a public offering price of $2.25 per share and received net proceeds, after deducting underwriting discounts and commissions, but before our expenses of the offering, of approximately $21.89 million.

On April 2, 2019, the Company closed an underwritten registered offering of 8,000,000 shares of its common stock, par value $0.0001 per share, and warrants to purchase up to 8,000,000 shares of its common stock with an exercise price of $2.00 per share at a combined purchase price of $1.50 per share of common stock and accompanying warrant. The net proceeds to the Company, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company, was approximately $11 million. The Company intends to use the net proceeds from the offering for research and further development of its lead clinical program SM-88 and for general corporate purposes, including capital expenditures, working capital and general and administrative expenses. The Company may also use a portion of the net proceeds to acquire or invest in businesses, products and

technologies that are complementary to its own, although it has no current plans, commitments or agreements with respect to any acquisitions as of the date hereof.

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.tymeinc.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 SEC also maintains a website that contains all the materials we file with, or furnish to, the SEC. Its website is www.sec.gov .

The contents of our website are not incorporated by reference into this Form 10-K or any other document we file with the SEC, and any reference to our website is intended to be an inactive textual reference only.

Corporate Governance Developments

In April 2018, our Board of Directors ("Board") and holders of a majority of the Company's outstanding common stock approved and implemented changes to our certificate of incorporation that (a) implemented a classified Board, (b) authorized the Board to exclusively fill any and all vacancies occurring on our Board, (c) authorized our Board to exclusively have the power to change, and set, the size of our Board and (d) authorized our Board to have the exclusive power to call a special meetings of our stockholders. Additionally, our Board may pursue certain other structural defenses such as a stockholder rights plan.

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 Owning Our Stock

The ownership interests in our Company held by our two founders 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 Co-Founder, Chief Executive Officer, Chief Science Officer and a director, beneficially owned 23.6% and Michael Demurjian, our Co-founder, beneficially owned 23.7% of our outstanding common stock as of June 4, 2019. 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 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.

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

Our share pric e is likely to be volatile due to factors beyond our control and may drop below prices 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 purchaser 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 factors affecting our drug discovery and development objectives as well as changes in our operating performance or prospects. In addition, the stock market has recently experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. Some of the factors that may cause the market price of our common stock to fluctuate include, but are not limited to:

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

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 and no revenue source. To the extent that we raise additional capital through the sale of equity equity-linked securities or convertible debt securities as we expect we will, 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. For example, pursuant an underwritten registered offering that closed on April 2, 2019, we issued warrants, the exercise price of which is subject to downward adjustment in certain circumstances where we sell equity securities at a sales price less than the warrant price. Such warrants also impose restrictions on our ability to enter into certain fundamental transactions. 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 12.5% of our shares of common stock outstanding from time to time pursuant to our 2015 Equity Incentive Plan, as amended (the "2015 Plan") and up to 2,750,000 shares of our common stock, pursuant to our amended and restated 2016 Director Plan (the "2016 Director Plan"). Future issuances, as well as the possibility of future issuances, under our 2015 Plan or 2016 Director Plan or other equity incentive plans could cause the market price of our common stock to decrease.

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

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us and our business. Securities and industry analysts may choose not to publish research on our Company. If an insufficient number of securities or industry analysts provide coverage of our Company, the trading price for our stock would likely be negatively impacted. 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. Because our board is responsible for appointing the members of our management team, the se provisions could, in turn, affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions:

- establish a board of directors having three classes of directors with a three-year term of office that expires as to one class each year, commonly referred to as a "staggered board";
- limit the manner in which stockholders can remove directors from our Board;
- exclusively empower the Board to fill any and all vacancies on the Board;
- authorize the board of directors to exclusively have the power to change and set the size of the board of directors;
- limit who may call stockholder meetings;
- include advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and for nominations to our Board, which include, among other things, requirements for proposing stockholders to disclose information about derivative or short positions; and
- authorize our Board to 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 establish a "poison pill" and 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 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, to raise needed financing, we are likely to 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 also have an effective "shelf" registration statement on Form S-3 that allows us to issue securities in registered offerings as well as an available ATM Financing Facility that allows us to sell shares of our Common Stock through a placement agent at market prices. 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 we regularly evaluate our capital needs and available sources of financing. 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 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 advisab le, 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 t he 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.

Our common stock has historically been characterized by low and/or erratic trading volume, and the intraday per share price of our common stock has fluctuated from $1.65 to $4.64 between April 1, 2018 and March 31, 2019, the date of our last completed fiscal year.

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

Historically, the public market for our common stock has been characterized by low and/or erratic trading volume, often resulting in price volatility. For the fiscal year ended March 31, 2019, the average daily trading volume for our common stock was approximately 496,059 shares. In addition, the price of our common stock has been volatile. Our common stock had a closing price of $2.20 on April 2, 2018, and ended fiscal year 2019 at a closing price of $1.76. During the fiscal year 2019, our common stock had a low trading price of $1.76, which occurred on March 29, 2019, and had a high closing price of $4.21, which occurred on December 12, 2018.
The market price of our common stock is subject to wide fluctuations due to factors that we cannot control, including the results of preclinical and clinical testing of our products under development, decisions by collaborators regarding product development, regulatory developments, market conditions in the pharmaceutical and biotechnology industries, future announcements concerning our competitors, adverse developments concerning proprietary rights, public concern as to the safety or commercial value of any products and general economic conditions.

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

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.

Compliance with changing regulation of corporate governance and public disclosure is costly and will 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 continue to devote significant time and financial resources to comply with both existing and evolving standards for public companies, and, as a result, we will continue to incur costs with compliance activities and require that management dedicate significant time and attention to compliance activities, which may impact their ability to focus on revenue-generating 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.

We regularly evaluate our capital needs and available sources of financing. 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 as we expect we will, 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.

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

Our proprietary lead drug product, SM-88, is in clinical development in three principal areas. We are currently participating in the advancement of Phase II and/or Pivotal clinical trials for pancreatic cancer, prostate cancer, and sarcoma. Clinical drug development is expensive, time-consuming and uncertain, and we may ultimately not be able to obtain regulatory approval for the commercialization of our lead candidate.

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

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the U.S. Food and Drug Administration (the "FDA"), the European Medicines Agency (the "EMA"), national competent authorities in Europe and other non-U.S. regulatory authorities, which establish regulations that differ from country to country. We are not permitted to market SM-88 and any other drug product we may develop in the United States or in other countries until we receive approval of a New Drug Application (an "NDA") from the FDA or marketing approval from applicable regulatory authorities outside the United States. Since SM-88 is in clinical development, it is subject to the risk of failure inherent in the drug development process. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA or EMA. Obtaining approval of an NDA or a Marketing Authorization Application ("MAA") can be a lengthy, expensive and uncertain process. In addition, failure to comply with the FDA, EMA and/or other non-U.S. regulatory requirements prior to or following 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 manufacturing;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending NDAs or supplements to approved NDAs in the United States and refusal to grant marketing approvals in other jurisdictions, such as a MAA in the EU.

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

- the drug candidate may be deemed unsafe or ineffective;
- future 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 limited experience with completing 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 initializing and conducting our small-scale completed Phase Ib clinical trial and the ongoing Phase II clinical trials for SM-88. We have initiated our commercialization strategy and marketing plan. In addition, our executive team does not all have 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 at TYME (whether Phase II, III, or otherwise), obtaining marketing approval, manufacturing product on a commercial scale or conducting sales and marketing activities. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

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

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

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

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

SM-88 is in clinical development. We are conducting several Phase II trials and expect to soon initiate or have SM-88 included in Phase II/III clinical trials and their successful completion 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 plans and expected future revenue could be adversely affected and could result in our inability to continue our operations.

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 or Independent Ethics Committee (“IEC”) review and approval;
- the Data Monitoring Committee (“DMC”) for a clinical trial requires the clinical trial be delayed or stopped or requests major or minor modifications to the clinical trial;
- failure of subjects to complete their full participation in clinical trial or return for post-treatment follow-up;
- unforeseen safety issues, including severe or unexpected drug-related adverse effects experienced by subjects, including the possibility of death;
- lack of SM-88 efficacy during the clinical trials;
- poor trial design for one or more of our clinical trials;
- withdrawal of participation by a Principal Investigator (“PI”) in one or more of our clinical trials;
- withdrawal of participation by one of our Clinical Research Organizations (“CRO”);
- 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 suspend or terminate 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 prospecti ve clinical trial protocols to reflect such changes mandated by regulatory authorities. Amendments may require us to renegotiate terms with CROs or clinical trial sites or to resubmit clinical trial protocols and other documents to IRBs or IECs for re-revi ew, 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 num ber of factors, which include, but are not limited to:

- failure to conduct the clinical trial in accordance with regulatory requirements or compliance with the clinical protocol;
- unforeseen safety issues or any determination that a clinical trial presents unacceptable health risks to subjects;
- lack of adequate funding to continue the clinical trial due to higher or additional unforeseen costs or other business decisions; and
- upon a breach or pursuant to the terms of any agreement with or for any other reason by, current or future collaborators that have responsibility for the clinical development of SM-88.

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

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

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

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

Drug candidates that have shown promising results in early clinical trials(such as our First in Human Study) and compassionate use programs (such as our Compassionate Use Patients) may still suffer significant setbacks in subsequent clinical trials. Many companies in the pharmaceutical industry, including those with greater resources and experience than TYME, as well as those that have conducted large-scale clinical trials under an IND (in contrast to our limited number of First in Human Study patients and Compassionate Use Patients, all of whom were treated outside of an IND approved clinical trial) have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials. In light of these factors, and the fact that our dosage and method of delivery from our First in Human Study and Compassionate Use Patients differ from our current Phase II trials, and may differ from future Phase II or subsequent trials, no assurance can be given that our ongoing or future Phase II (or subsequent) trials may produce results similar to our First in Human Study or those experienced by Compassionate Use Patients.

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

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

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

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

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

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

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

If there are changes in the application of legislation or regulatory policies or if problems are discovered with SM-88 or our manufacturer(s) or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include imposing fines on us, imposing restrictions on the drug or its manufacture and requiring us to recall or remove the drug from the market. The

regulators could also suspend or withdraw our marketing authorizations, requiring us to conduct additional clinical trials , change our drug labeling or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell SM-88 may be impaired and we may incur substantial additional expense to comply with regulatory requirements, which could adversely affect our business, financial condition and the results of operations and the value of our share price.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all.

In addition to SM-88, we are researching other drug platforms, such as TYME-18. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing. Results of preclinical studies and early-stage clinical trials may not be predictive of future results. Preclinical studies and early-stage clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules and may not advance to later-stage clinical trials. Furthermore, the results of an early-stage clinical trial may not be predictive of the results of later-stage, large scale efficacy clinical trials.

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

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

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

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

diffi culties 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 count ry may delay or have negative effects on the process for regulatory approval in other countries. We do not have any drug candidates approved for sale in any jurisdiction, including international markets and we therefore do not have experience in obtaining regulatory approval. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to create stockholder value for SM-88 will be harmed.

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

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

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

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

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

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate SM-88 as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. In the EU, the European Commission may designate a drug candidate as an orphan medicinal drug if it is a medicine for the diagnosis, prevention or treatment of life-threatening or very serious conditions that affects not more than five in 10,000

persons in the EU or it i s 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 excl usivity 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 regulat ory requirements and process for obtaining marketing approval.

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

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

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

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

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 involvement in Phase II/III trials 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 SM-88 drug product and/or the agents used with SM-88.
- 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 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 m arketing 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 with drawal 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.
- 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.
- SM-88 drug substance is being manufactured by a FDA-approved, third party and to date that manufacturer 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 the existing drug in the United States. We believe this cGMP manufacturer has sufficient capacity to meet our projected needs into the near future. In the event of a catastrophic event or this manufacturer is unable to meet our needs, we will, due to the nature of the drug substance and the modifications required for this drug substance, need to find an alternative source of supply, which will likely result in time delays in the clinical development process. We believe that replacement for this supplier, in the event it becomes necessary, is not impossible, but would cause us to lose time that could otherwise be devoted to development. Currently, we do not have an arrangement in place for a secondary supplier for this drug substance.

We currently have very limited marketing, sales or distribution infrastructure. If we are unable to develop full 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 very limited 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 competi tion 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.

Further, 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, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, was adopted in March 2010 ("Health Care Reform Law"). The Health Care Reform Law is a far-reaching 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 costs and restrictions impacted by the Health Care Reform Law may impact our competitiveness or availability opportunity.

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 recruiting subjects 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 prices we set. Our successful commercialization will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement and pricing policies.

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

In the United States, there have been a number of proposals for increased federal and state government regulation of, or involvement in, the pricing and/or purchasing of drugs. For example, a rule proposed by the Trump administration would eliminate rebates that pharmaceutical companies pay to pharmacy benefit managers, which insurance companies and large employers use to negotiate lower drug prices; and the Prescription Drug Price Relief Act, introduced in the Senate in January 2019, would require the HHS Secretary to assure that Americans don't pay more for prescription drugs than the median price of five countries (Canada, UK, France, Germany and Japan).There have also been state legislative efforts to address drug costs, which generally have focused on increasing transparency about drug costs and limiting drug prices. Some such legislation has been subject to legal challenges.

In addition, the Health Care Reform Law made changes affecting the pharmaceutical industry by increasing the mandated Medicaid rebate from 15.1% to 23.1%, expanding the rebate to apply to drugs sold to Medicaid managed care organizations, and increasing the types of entities eligible for the federal 340B drug discount program. The Health Care Reform Law also requires pharmaceutical manufactures to pay a 50% point of service discount to Medicare Part D beneficiaries when they are in the Medicare Part D coverage gap; and beginning in 2019, that discount increases to 70%, as a result of the Balanced Budget Act of 2018. Also, pharmaceutical manufacturers are required to pay an annual non-tax deductible health care reform fee (which is assessed in proportion to prior year branded pharmaceutical sales to certain government programs). If the Health Care Reform Law is not further amended, repealed or replaced, certain of its components will continue to be phased in until 2022. While we anticipate continued efforts to invalidate, modify, repeal or replace the Health Care Reform Law, we expect that certain aspects of the Law could, nonetheless, negatively impact drug reimbursement, which could negatively affect the price we may charge for, and market acceptance of, any products we develop that receive regulatory approval. Moreover, growing state budgetary pressures increase the likelihood that changes in healthcare reimbursement at the state level in response to changes made to, or invalidation, repeal or replacement of, the Health Care Reform Law and/or changes in payment mechanisms of federally supported benefit programs, would be adverse to us. Potential repeal of the Health Care Reform Law, ongoing legislative, regulatory and administrative policy changes to that law, the results of congressional and state elections, and pending litigation challenging certain aspects of the Health Care Reform Law or its funding continue to create uncertainty about the effects of the Health Care Reform Law. The time frames for conclusion, final outcomes and ultimate impact of these developments are uncertain. Given the inherent difficulty of foreseeing the nature and scope of future changes to the Health Care Reform Law and how states, businesses and individuals will respond to those changes, the Company cannot predict the impact, but it is reasonably possible that invalidation, repeal or replacement of, or other changes to, that law and/or states' responses to such changes could have a significant adverse effect on the Company's business, results of operations, financial position, prospects, and cash flow.

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 of 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 health care products. 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, in the EU, marketing approval of SM-88 and other drug products we may develop, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval. With respect to other countries outside of the United States, too, risks include changes in medical reimbursement policies and programs and pricing restrictions in key markets; multiple regulatory requirements that could restrict the Company's ability to manufacture and sell its products in key markets; trade protection measures and import or export licensing requirements; foreign exchange

rate fluctuations; and diminished protection of intellectual property in some countries., Recently, sev eral important multinational organizations, including the United Nations (UN), World Health Organization (WHO) and Organization for Economic Cooperation and Development (OECD), have issued reports and policy recommendations relating to international pharm aceutical pricing (e.g., 2016 UN High Level Panel Report on Access to Medicines). Late in 2018, reports critical of the pharmaceutical industry's pricing practices were published by the OECD and WHO; these will exert additional pricing pressures. In addit ion, instability, disruption, or destruction in a region could affect the Company's ability to sell its products there.

The Company is currently subject to numerous government laws and regulations and could become subject to new laws and regulations. The costs of compliance with such laws and regulations, or the negative results of non-compliance, could adversely affect the business, cash flow, results of operations, financial position and prospects of the Company. These laws and regulations could include (a) additional health care reform laws in the United States or other countries, including additional mandatory discounts or fees applicable to drug manufacturers; (b) new anti-bribery and corruption laws; (c) new laws, regulations and judicial or other governmental decisions affecting pricing, drug reimbursement, and access or marketing within or across jurisdictions; (d) new data privacy regulations and enforcement; (e) new global regulatory requirements for reporting payments and other value transfers to healthcare professionals; and (f) importation restrictions, embargos, trade sanctions and legislative or other regulatory changes affecting trade.

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.

We hold clinical trial insurance for our ongoing SM-88 clinical trials. 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 current and 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 judgm ents 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 some of our management team has experience in creating and marketing various products, most members of our executive team have not 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 employees, advisors and consultants currently and in the past, this lack of experience by our chief executive and some operating officers could result in delays in obtaining necessary regulatory approvals, both in conducting clinical trials and final marketing approvals; additional costs; and the possibility that approvals will not be obtained due to the failure to comply with the regulatory approval process. Such delays, costs and/or failure would likely adversely affect our business, financial condition and results of operations and could possibly cause us to cease our operations in their entirety

Risks Related to our Financial Condition and Need for Additional Capital

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

We are a clinical-stage pharmaceutical company with a limited operating history. We have incurred significant losses since our inception. As of March 31, 2019, our accumulated deficit was $85,814,696. 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 and any other drug candidates we may develop, 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 from operations 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 s upport clinical development and the market demand for SM-88, if approved;
- launching and commercializing SM-88, either directly or with a collaborator or distributor;
- establishing sales, marketing and distribution capabilities in the United States and in other markets, such as the EU;
- obtaining market acceptance of SM-88 as a viable treatment option;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and/or developing new drug candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

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

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

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

- the number and characteristics of drug candidates that we pursue;
- the scope, progress, timing, cost and results of nonclinical and clinical development and research;
- the costs, timing and outcome of our seeking and obtaining FDA, EMA and other non-U.S. regulatory approvals;
- the costs associated with manufacturing SM-88, as well as other potential drug candidates, and establishing sales, marketing and distribution capabilities;
- our ability to maintain, expand and defend the scope of our IP portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other IP rights;
- the extent to which we acquire or in-license other products or technologies;
- our need and ability to hire additional administrative, managerial, scientific, operational and medical personnel;

- the effect of competing products that may limit market penetration of SM-88 and any other drug candidates we may develop;
- the amount and timing of revenues, if any, we receive from commercial sales of SM-88 or any other drug candidates for which we receive marketing approval in the future;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and the economic and other terms, timing of and ultimate success of any future collaboration, licensing or other arrangements, including the timing of achievement of milestones and receipt of any milestone or royalty payments under such agreements.

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

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. All of these projected milestone timelines 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 third party suppliers for SM-88 and for the com ponents of MPS used with SM-88. Supplies are obtained through limited term supply agreements under individual purchase orders. At this time, no supply agreements place exceeds 18 months. 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 qualificatio ns 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 periodically 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 may be more established companies with a competitive advantage due to their larger size and cash resources or greater clinical development and commercialization capabilities and, as a result, we may not be able to obtain favorable terms for our arrangements;
- 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 employee s. While we may, in the future, seek to obtain key man insurance on Mr. Hoffman and/or such other executives and employees, we may not be able to obtain the insurance at favorable rates or at all. Any insurance proceeds we may receive under such "key perso n" 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 produ cts in our pipeline would be adversely affected without his continued involvement.

We are highly reliant on our executives, but certain of them, including our chief executive and science officer, Steven Hoffman, and our chief medical officer, Giuseppe Del Priore, have other business interests to which they devote their attention. From time to time, these other interests may distract their attention from our company, generate reputational risk for our company or give rise to conflicts of interest that must be resolved through the exercise of sound judgment consistent with their fiduciary duties to us. Our ability to attract and retain investors, collaborators, and employees could be adversely affected by damage to our reputation resulting from various sources, such as our executives' other business interests, employee misconduct, litigation, or regulatory outcomes.

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

As of March 31, 2019, we had 15 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, including the potential development of new products, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and recruit and train additional qualified personnel. Future growth would impose significant added responsibilities on management. Due to our limited financial resources and the limited experience of our management team in managing a life sciences company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Some members of our current management have 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, New York with another office in Bedminster, New Jersey. Our current and future, third-party collaborators, future partners, supplies, CROs and investigational sites are or will be, located throughout the United States or internationally and may be located near major high-risk terrorist targets, earthquake faults, flood and fire zones. The ultimate impact on us, our significant partners and suppliers as well as our and their general infrastructures being located near major high-risk terrorist targets, earthquake faults, flood and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major terrorist attack, earthquake, fire, flood or other natural or manmade disaster.

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

- economic weakness, including inflation or political instability in particular non-U.S. economies and markets;
- differing regulatory requirements for drug approvals in non-U.S. countries;
- differing, and in some cases, more stringent data protection requirements in non-U.S. countries, such as the EU General Data Protection Regulation;
- potentially reduced protection for IP rights;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import/export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires.

We may seek approvals of our drug candidates in the EU and United Kingdom. On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the EU, commonly referred to as Brexit. Negotiations are taking place to determine the future terms of the UK's relationship with the EU, including the terms of withdrawal, the terms of future trading and relations and any potential transition periods. The impact of Brexit on the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the EU is uncertain, and could prevent or delay us from commercializing our product candidates in the United Kingdom or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or EU for our product candidates, which could significantly and materially harm our business.

We may be party to legal proceedings that could have a material adverse effect on the Company's liquidity, financial position, and results of operations, as well as its reputation.

The Company has limited experience in litigation and other legal proceedings, but any lawsuit brought against us or legal proceeding that we may bring to enforce our rights could result in substantial costs, divert the time and attention of our management, result in counterclaims (whether meritorious or as a litigation tactic), result in substantial monetary judgments or settlement costs and harm our reputation, any of which could seriously harm our business. For example, during the fourth quarter of fiscal year 2019, we, along with our CEO and CFO, were named in a securities lawsuit by a purported stockholder, in which the plaintiff alleged to represent a class of stockholders and asserted claims under the Securities Exchange Act of 1934, as amended. Though such complaint was voluntarily dismissed by the plaintiff, we could be subject to lawsuits in the future and any litigation or claim against us, even without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, and harm our reputation.

Additionally, we may seek to enforce our rights under contractual arrang ements and otherwise. Even if successful, litigation or other legal proceedings to enforce our rights could be expensive and time consuming and could divert management's attention from managing our business.

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 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.

Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. 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. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding patients in our clinical trials or other studies or our employees, could harm our reputation, require us to comply with federal and/or state breach notification laws, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. There can be no assurance that the security measures we have implemented to protect our information technology systems and infrastructure will prevent service interruptions or security breaches that could adversely affect our business.

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

- economic weakness, including inflation or political instability in particular non-U.S. economies and markets;
- differing regulatory requirements for drug approvals in non-U.S. countries;
- potentially reduced protection for IP rights;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import/export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires.

Use of social media could give rise to liability, breaches of data security, or reputational harm.

We and our employees use social media to communicate externally. There is risk that the use of social media by us or our employees to communicate about our product candidates or business may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us or our product candidates in social media could seriously damage our reputation, brand image, and goodwill. Any of these events could have a material adverse effect on our business, prospects, operating results, and financial condition and could adversely affect the price of our common stock.

Risks Related to Intellectual Property

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

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

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

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

term of another patent that is commonly owned or names a common inventor. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights is highly uncertain.

Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. We may become involved in opposition, interference, derivation, inter parties review or other proceedings that challenge our patent rights or the patent rights of others and the outcome of any proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of or invalidate our patent rights, allowing third parties to commercialize our technology or drug products and compete directly with us, without payment to us or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

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

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

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

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 cou ld 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 app roved 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 ou r business.

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

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

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

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

Although we will try to ensure that our employees and outside contractors do not use the proprietary information or the know-how of others in their work for us and we have no knowledge of any instances of wrongful use or disclosure by our employees and outside contractors to date, we may be subject to claims that we or these employees and outside contractors have used or disclosed IP, including trade secrets or other proprietary information from their former employers or clients. Litigation may be necessary to defend our Company against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable IP rights, personnel or consulting services. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to IP claims may cause us to incur significant expenses and could distract our scientific and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. Should this occur and securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce resources available to us for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other IP-related proceedings could adversely affect our ability to compete in the marketplace.

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

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

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

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

Risks Related to Government Regulations

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

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future revenue and profitability and the future revenue and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, the Health Care Reform Law contains a number of provisions, including those governing enrollments in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which have affected existing government healthcare programs and resulted in the development of new programs. The Health Care Reform Law, among other things:

- imposes a non-deductible annual fee on entities that manufacture or import certain branded prescription drugs;
- increases the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;
- requires collection of rebates for drugs paid by Medicaid managed care organizations; and
- provides for a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

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

- our ability to set a price we believe is fair for our drug products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

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

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

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

On October 12, 2017, President Trump signed an executive order directing federal agencies to take certain steps intended to make it easier for individuals and small businesses to collectively buy health insurance through association health plans, which are not subject to all of the requirements under the Health Care Reform Law (the "October 2017 Executive Order"). On the same date, he announced that cost-sharing reduction payments from the U.S. government for low-income health insurance enrollees' copayments and deductibles (the "CSR Payments") would cease effective immediately. Cessation of the CSR Payments and other changes ordered could have significant adverse impacts, including, but not limited to, insurance premium increases and increased uncertainty in the health insurance markets.

On December 12, 2017, President Trump signed the Tax Cuts and Jobs Act into law, revoking the tax penalty that applied to individuals who did not comply with the Health Care Reform Law's requirement to have health insurance coverage (known as the "individual mandate").

Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Health Care Reform Law -mandated fees, including the tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices.

Judicial challenges to the Health Care Reform Act, the January 2017and October 2017 Executive Orders, The Tax Cuts and Jobs Act, cessation of the CSR Payments and other executive action and legislation, could result in increased uncertainty with respect to the pharmaceutical, biotechnology and other life science industries and may materially harm our business, financial condition and results of operations. Further, we can provide no assurance that the Health Care Reform Law, as currently enacted or as amended in the future, or other related laws will not adversely affect our business, financial condition or results of operations. Nor can we predict how future federal or state legislative or administrative changes relating to health care reform will affect our business, financial condition or results of operations.

If we fail to comply with healthcare and privacy laws and 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 patients' rights are, and other healthcare issues and will be, applicable to our business. We could be subject to healthcare fraud and abuse, privacy and security, and transparency 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 th e 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, ite ms or services relating to healthcare matters;
- the federal physician self-referral law, commonly known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services reimbursed by Medicare or Medicaid if the physician or a member of the physician's family has a financial relationship with the entity and which also prohibits the submission of any claims for reimbursement for designated health services furnished pursuant to a prohibited referral;
- the federal transparency requirements under the Health Care Reform Law, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the U.S. Department of Health and Human Services ("HHS") information related to physician payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family members;
- HIPAA, the Health Information Technology for Economic and Clinical Health Act ("HITECH") and their respective implementing regulations, which govern the conduct of certain electronic healthcare transactions and are designed to protect the security and privacy of protected health information; and state, local and foreign 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.
- As our operations expand, we may become subject to the EU General Data Protection Regulation ("GDPR"). The GDPR, together with the national legislation of the EU member states governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting.

The Health Care Reform Law, among other things, amended the intent standard of the federal Anti-Kickback Statute and criminal healthcare fraud statutes to a stricter standard such that a person or entity no longer needs to have actual knowledge of a violation of this statute or specific intent to violate it to be convicted. In addition, the Health Care Reform Law codified case law held 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, fraud and abuse, and transparency laws may prove costly.

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the Foreign Corrupt Practices Act ("FCPA") and other anti-corruption laws that apply in countries where we operate or may do business in the future. The FCPA and these other laws generally prohibit us, our officers and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We may in the future operate in jurisdictions that pose a high risk of potential FCPA violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

Because our business is heavily regulated, it therefore involves significant interaction with public officials. We have or will have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government and the purchasers of pharmaceuticals are government entities; therefore, any dealings with these prescribers and purchasers are subject to regulation under the FCPA.

We are also subject to other laws and regulations, including regulations administered by the governments of the United States, United Kingdom, and authorities in the EU, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, which we collectively refer to as Trade Control Laws.

There is no assurance that we will be completely effective in ensuring our compliance, or the compliance of our employees, agents, suppliers, manufacturers, contractors, or collaborators, with all applicable anti-corruption laws, including the FCPA or other legal requirements, including Trade Control Laws. If we are not in compliance with the FCPA, the Bribery Act and other anti-corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Any of the foregoing could have an adverse impact on our reputation in the industry as well as our business, financial condition, results of operations and liquidity.

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

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

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

The filing of an ANDA as described abov e 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 we are found to have promoted such off-label uses prior to FDA approval for the applicable indication(s) (or to have promoted SM-88 for any use prior to initial FDA approval), we may receive warning letters and become subject to significant liability, which would materially harm our business. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred and our reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA prohibitions on the sale or marketing of our products or significant fines and penalties and the imposition of these sanctions could also affect our reputation and position within the industry.

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

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

Being a public company is expensive and administratively burdensome.

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

- maintain and evaluate a system of internal controls over financial reporting in compliance with the requirements of Section 404 of SOX and the related rules and regulations of the SEC and the Public Company Accounting Oversight Board;
- maintain policies relating to disclosure controls and procedures;
- prepare and distribute periodic reports, proxy statements, Forms 8-K and other reports and filings in compliance with our obligations under applicable federal securities laws;

- 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 cost 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. Compliance with these rules and regulations may require us to hire additional financial reporting, internal controls and other finance personnel and will involve significant 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, particularly directors willing to serve on our audit committee.

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

As a public company, we will incur significant legal, accounting, insurance and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also have incurred and will incur costs associated with SOX and related rules implemented by the SEC. We will continue to incur ongoing periodic expenses in connection with the administration of our organizational structure. The expenses incurred by public companies generally for reporting and corporate governance purposes have been increasing. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. 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.

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

In the United States, there have been and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future revenue and profitability and the future revenue and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, on December 22, 2017, President Trump signed into law new federal tax legislation that includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Since the enactment of the Tax Act, there have been additional amendments to certain provisions of the ACA, and we expect the current Trump administration may continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. It is uncertain the extent to which any such changes may impact our business or financial condition.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn and Matthew Bellina Right to Try Act of 2017 (the "Right to Try Act"), was signed into law. The law, among other things, provides a federal framework for certain patients with life-threatening diseases to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.
There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance

companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls m ay 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.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

The recently enacted Tax Cuts and Jobs Act of 2017 (the "Tax Act") federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is unknown if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is likewise uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including most recently beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal executive offices are located at 17 State Street, 7th Floor, New York, New York 10004, where we lease and occupy approximately 4,752 square feet of office space, with a lease term expiring August 30, 2020. Our costs for this space are approximately $250,000 per year plus certain tax, utilities and other expenses.

We also maintain a two year lease for an office in Bedminster, New Jersey, where we lease and occupy ap proximately 1,962 square feet of office space. We estimate our total annual costs for this office at approximately $42,000 per year.

We believe that our existing facilities are adequate for our current and near-term growth of our administrative operations. We will rely on clinical research centers, hospitals, contract research organizations and other parties for suitable space and facilities to conduct our clinical trials. We will explore, in the future, establishing a dedicated technical facility, when we believe the need for such a facility has arisen. No assurance can be given that such a facility can be located without difficulty or at a cost favorable to us.

ITEM 3. LEGAL PROCEEDINGS

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

During the fourth quarter of fiscal year 2019, we, along with our CEO and CFO, were named in a securities lawsuit by a purported stockholder. The plaintiff alleged to represent a class of stockholders for the period from March 14, 2018 through January 18, 2019, inclusive, and asserted claims under Securities Exchange Act of 1934, as amended, Section 10(b) (and Rule 10b-5) against all defendants and Section 20(a) control person liability against the individual defendants. In general, the plaintiff's allegations focus on events during the period from March 14, 2018 through January 18, 2019 and contends that the defendants provided inadequate or misleading disclosure at various times during the period concerning its Phase II clinical trial for SM-88 in pancreatic cancer. On March 28, 2019, the plaintiff voluntarily dismissed the complaint against all defendants without prejudice.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ADDITIONAL ITEM. EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers and their positions as of May 30, 2019 were:

	Title and Business Experience	Age
Steve Hoffman	Mr. Hoffman has served as Chief Executive Officer of our wholly-owned subsidiary, Tyme, Inc. since its formation in July 2013, and a manager of our wholly-owned subsidiary, Luminant Biosciences, LLC, since its formation in September 2011. In such roles and continuing with his current position as Chief Executive Officer and Chief Science Officer of the Company, which commenced in March 2015, he supervises the development of our product candidates.	56
Ben R. Taylor	Mr. Taylor has served as President and Chief Financial Officer since April 2017.	42
Dr. Giuseppe Del Priore	Dr. Del Priore has served as Chief Medical Officer since November 2015. Dr. Del Priore also served on our Advisory Board from April 2015 to November 2015.	56
Dr. Jonathan Eckard	Dr. Eckard has served as Chief Scientific Affairs Officer since August 2017 and assumed the role of Chief Business Officer in March 2019.	45
Michele Korfin	Ms. Korfin has served as our Chief Commercial Officer since October 2018 and assumed the role of Chief Operating Officer in March 2019.	47
James Biehl	Mr. Biehl has served as our Chief Legal Officer and Secretary since September 2018 and served on our Board from 2017 until September 2018.	55
Barbara C. Galaini	Ms. Galaini has served as our Principal Accounting Officer since August 2018 and our Corporate Controller since April 2018.	61

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 has been traded on the Nasdaq Capital Market under the symbol "TYME" since July 27, 2017. Prior to July 27, 2017, our common stock was quoted on the over-the counter ("OTC") Markets, QB Tier, under the symbol "TYME." Our transfer agent is Continental Stock and Transfer and Trust Company.

The closing price of TYME stock as of June 4, 2019 was $1.11.

Holders; Shares Outstanding

We had a total of 111,950,937 shares of our common stock outstanding on June 4, 2019, held by approximately 190 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 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 Plan

Reference is made to the information in Item 12 of this report under the caption "Equity Compensation Plans in effect as of March 31, 2019," which is incorporated herein by this reference.

Share Repurchases

During the twelve months ended March 31, 2019, we did not repurchase any shares of common stock.

ITEM 6. SELECTED FINANCIAL DATA

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information under this item.

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," "TYME" or "Tyme Technologies" refer to Tyme Technologies, Inc., together with its subsidiaries.

Overview

TYME is an emerging biotechnology company developing cancer metabolism-based therapies (CMBTs) that are intended to be effective across a broad range of solid tumors and hematologic cancers, while also maintaining patients' quality of life through relatively low toxicity profiles. Unlike targeted therapies that attempt to regulate specific pathways within cancer, TYME's therapeutic approach is designed to take advantage of a cancer cell's innate metabolic requirements to cause cancer cell death.

Our lead clinical CMBT program, SM-88 (racemetyrosine), is a novel, oral, monotherapy investigational agent that has been studied in clinical trials for over five years within more than 150 cancer patients. TYME recently completed enrollment for two Phase II clinical trials in prostate and pancreatic cancer, and the Company is preparing for pivotal studies for SM-88 in pancreatic cancer during the second half of calendar year 2019. One of these pivotal trials is focused on patients with third-line pancreatic cancer and would be an amendment to the ongoing TYME-88-Panc trial (Part 2). The Company has also partnered with the Pancreatic Cancer Action Network ("PanCAN") to study SM-88 in an adaptive pivotal trial known as Precision Promise ^{SM} starting as second-line monotherapy and could expand to first-line combination therapy with standard of care. A Phase II investigator-initiated trial evaluating SM-88 monotherapy in late-stage sarcomas was launched in May 2019, under the direction of principal investigator Dr. Sant Chawla and in collaboration with the Joseph Ahmed Foundation ("JAF"). All of SM-88's current clinical programs study SM-88 in use with three low-dose conditioning agents: methoxsalen, phenytoin, and sirolimus (hereafter, referred to as "MPS"). We are actively evaluating the expansion of our clinical program to other cancers as SM-88 has demonstrated complete or partial responses in 15 different forms of cancer with a well-tolerated safety profile.

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. The financial information presented in this section is in conformity with accounting principles generally accepted in the United States of America ("GAAP").

Research and Development Expenses

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

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 federal income taxes in the United States, as well as in various U.S. state jurisdictions. Significant judgments and estimates are required in the determination of the income tax expense.

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

A valuation allowance is provided when, after consideration of available positive and negative evidence, that it is not more likely than not that the benefit from deferred tax assets will be realizable. In recognition of this risk, we have provided a full valuation allowance against the net deferred tax assets.

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

We had unrecognized tax benefits of $127,000 and $469,000 at March 31, 2019 and 2018, respectively. Increases or decreases would not have an effect on the effective tax rate. As of March 31, 2019, the Company had gross U.S. federal net operating loss carryforwards of approximately $50.8 million, which may be available to offset future income tax liabilities and will begin to expire at various dates starting in 2033. As of March 31, 2019, none of the Company's state net operating losses have value due to the apportionment rule in the states where state income tax returns are currently filed. As of March 31, 2019, the Company had gross federal research and development tax credit carryforwards of $0.8 million, available to reduce future tax liabilities which will begin to expire at various dates starting in 2030.

The Company files federal income tax returns in the United States, and various state jurisdictions. The federal and state income tax returns are generally subject to tax examinations for the period January 1, 2015 through

March 31, 2018. 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 perio d. In addition, we had no income tax related penalties or interest for periods presented in these consolidated financial statements. When and if we were to recognize interest and penalties related to unrecognized tax benefits, they would be reported in tax expense.

Stock-Based Compensation

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

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected term of the option, risk-free interest rates, the value of the common stock and expected dividend yield of the common stock. For awards subject to time-based vesting conditions, we recognize stock-based compensation expense equal to the grant date fair value of stock options on a straight-line basis over the requisite service period, which is generally the vesting term. The Company accounts for forfeitures as they occur, rather than estimating forfeitures as of an award's grant date.

We accounted for stock-based awards issued to non-employees in accordance with ASC 505-50, "Equity-Based Payment to Non-Employees" and accordingly the fair value of the stock options granted to non-employees was remeasured each reporting period until the earlier of: a) the performance commitment date, or b) the date the services required under the arrangement have been completed and the resulting increase or decrease in value, if any, was recognized as expense or income, respectively, during the period the related services are rendered. Effective July 1, 2018, the Company adopted ASU 218-07 and, as such, the fair value of options granted to non-employees is estimated at the date of grant only.

The expected volatility of options granted has been determined using the method described under ASC 718 using the expected volatility of similar companies. The expected term of options granted to employees in the current fiscal period has been based on the term by using the simplified method as allowed under SAB No. 110. The expected term of options granted to non-employees and consultants is based on the grant's full contractual life. Effective July 1, 2018, the Company adopted ASU 2018-07 and, as such, the expected term is determined using the simplified method for options granted to non-employees and consultants.

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

Results of Operations

Year ended March 31, 2019 Compared to Year Ended March 31, 2018

Net loss for the year ended March 31, 2019 was $32,983,000 compared to $18,969,000 for the year ended March 31, 2018. The increase in the net loss for the year ended March 31, 2019, as compared to the net loss for the year ended March 31, 2018 is due to increased operating costs and expenses in 2019, as highlighted below.

Cash used in operating activities for the year ended March 31, 2019 was $20,116,000 compared to $11,879,000 for the year ended March 31, 2018. See Cash Flows section below for further details.

Revenue

During the years ended March 31, 2019 and March 31, 2018, 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 arrangements, none of which is anticipated to occur in the near future.

Operating Expenses

For the year ended March 31, 2019, operating costs and expenses totaled $31,777,000, compared to $19,360,000 for the year ended March 31, 2018, representing an increase of $12,417,000, of which $6,037,000 relates to increased R&D study and consulting expenses, $2,471,000 to severance expense $1,810,000 to salaries and related employee costs, $873,000 to stock based compensation and $1,226,000 to professional fees and other general and administrative expenses. Operating costs and expenses by function were comprised of the following:

- Research and development expenses were $14,719,000 for the year ended March 31, 2019, compared to $8,840,000 for the year ended March 31, 2018, representing an increase of $5,879,000, primarily attributable to the increase in study and consulting expenses. Substantially 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:
    - Study and consulting expenses were $9,554,000 for the year ended March 31, 2019, compared to $3,517,000 for the year ended March 31, 2018, representing an increase of $6,037,000 between the comparable periods. The increase is mainly attributable to expanded clinical activities, primarily our pancreatic and prostate cancer clinical trials and the pre-clinical testing, which was expanded in fiscal year 2019. The study costs are anticipated to vary between future accounting periods as we continue to develop our drug candidates and seek governmental approval of such drug candidates.
    - Salary and salary related expenses for research and development personnel was $2,307,000 for the year ended March 31, 2019, compared to $1,727,000 for the year ended March 31, 2018, representing an increase of $580,000 between comparable periods, primarily due to costs associated with increased employee base.
    - Included in research and development expense for the year ended March 31, 2019 is $2,844,000 of stock based compensation related to stock options granted to research and development personnel compared to $3,566,000 for the year ended March 31, 2018, representing a decrease of $722,000 between the comparable periods, primarily due to fully-vested option grants that resulted in a one-time compensation expense, which was partially offset by the amortization of expense related to options granted to employees during fiscal year 2019.
- General and administrative expenses were $14,587,000 for the year ended March 31, 2019, compared to $10,520,000 for the year ended March 31, 2018, representing an increase of $4,067,000, of which $1,595,000 (39%) relates to stock-based compensation (non-cash) and the remainder primarily relates to increased headcount and increased professional services. The general and administrative expenses include:
    - Stock based compensation related to stock options granted was $5,719,000 for the year ended March 31, 2019, compared to $4,124,000 for the year ended March 31, 2018, representing an increase of $1,595,000, primarily attributable to the modification of vesting provisions of certain grants previously issued and the issuance of options to members of the Board of Directors (“Board) and employees in fiscal year 2019, partially offset by options which became fully vested in fiscal year 2018.
    - Legal, professional services, accounting and auditing expenses for the year ended March 31, 2019, was $3,834,000, compared to $3,481,000 for the year ended March 31, 2018 representing an increase of $353,000 primarily related to increase in investor relations and communications activity in fiscal year 2019.
    - Salary and salary related expenses for non-research and development personnel was $3,245,000 for the year ended March 31, 2019, compared to $2,015,000 for the year ended March 31, 2018, representing an increase of $1,230,000 between the comparable periods due to costs associated with an increased employee base and contractual compensation adjustments.

- Severance expense was $2,471,000 for the year ended March 31, 2019. On March 15, 2019, we entered into a Release Agreement related to the separation of employment of our Chief Operating Officer. The Agreement provides for salary continuance for five years, reimbursement of health benefits for three years and a modification to his outstanding stock options to extend the post-termination exercise period for his vested options from three months to five years. The severance expense was recorded at its present v alue and included $0.4 million relating to stock option modification. There was no severance expense for the year ended March 31, 2018.

Other Income/Expenses

For the year ended March 31, 2019, the Company incurred $7,000 of interest expense related to its insurance note payable. For the year ended March 31, 2018, the Company did not enter into debt financing arrangements, and as such did not incur any interest expense.

Other income for the year ended March 31, 2019 was $90,000, which represents interest income earned on bank deposits. Other income for the year ended March 31, 2018 was $390,000, which represents a non-cash gain recorded on the remeasurement of a derivative liability due to the expiration of anti-dilution protection on warrants. Certain holders of our outstanding securities that acquired our securities in March and April 2017 private placement transactions had limited anti-dilution protection that could have resulted in additional dilution to our stockholders. The anti-dilution protection expired without additional shares issued. The resulting change in the fair value of the derivative was recognized as other income for the period.

Warrant Modification

Warrant modification expense for the year ended March 31, 2019 was $1,289,000, representing the incremental value of the maturity extension of the 3,483,521 outstanding March and April 2017 Private Placement warrants as compared to the original warrants, both valued on the modification dates which is reflected in warrant modification expense in the consolidated statement of operations. There was no warrant modification expense for the year ended March 31, 2018.

Income Tax

Our effective tax rate for the years ended March 31, 2019 and 2018 was zero percent.

Liquidity and Capital Resources

Liquidity and Capital Requirements Outlook

The Company has historically funded its operations primarily through equity offerings of its common stock. On November 2, 2017, the Company entered into an equity distribution agreement (“Equity Distribution Agreement”) with Canaccord Genuity Inc. (“Canaccord”), to commence an at-the-market offering (the “ATM Financing Facility”) pursuant to which the Company may, from time to time, sell shares of the Company’s common stock, having an aggregate offering price up to $30,000,000, through Canaccord, as the Company’s sales agent. In the year ended March 31, 2018, the Company raised approximately $6,152,000 in gross proceeds through the ATM. During the fiscal year ending March 31, 2019, the Company raised approximately $5,844,000 in gross proceeds from the facility. At March 31, 2019, there remained approximately $17.9 million of availability to sell shares through the facility.

In March 2018, the Company raised approximately $21,890,000 of net proceeds (after underwriting discounts and commissions but before expenses) through an underwritten registered public offering of 10,350,000 shares of our common stock. The most recent offering was completed subsequent to March 31, 2019 on April 2, 2019, when the Company closed on an underwritten registered offering of 8,000,000 shares of its common stock, par value $0.0001 per share, and warrants to purchase up to 8,000,000 shares of its common stock with an exercise price of $2.00 per share at a combined purchase price of $1.50 per share of common stock and accompanying warrant. The net proceeds to the Company, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company, were approximately $11 million. The proceeds of the offering are being used for continued and new clinical trials, continued development of compounds, and other general corporate purposes.

We anticipate requiring additional capit al to further fund the development of our product candidates, as well as to engage in potential partnerships or collaborations. The most significant funding needs continue to be in connection with conducting immediate Phase II clinical trials of our SM-88 drug candidate for pancreatic cancer and prostate cancer, participating in an investor-initiated clinical trial of SM-88 in sarcoma, and conducting additional or related studies and investigations, including small-scale pre-clinical studies related to the mechanism of action of our lead clinical program SM-88 and other potential drug candidates. The Company's financing needs also relate to expenses of its participation in the Precision Promise adaptive pivotal pancreatic trial platform sponsored by PanCAN. Precision Promise is expected to launch in the second half of calendar year 2019. The greater scale of these trials is expected to lead to increased costs, including providing SM-88 for use by the subjects. If we determine to move beyond the pre-clinical s tage for any of our pre-clinical trials or if we amend Part 2 of the Company's ongoing Tyme-88-Panc trial and proceed with Phase II or significantly expand currently active clinical trials, our liquidity requirements will be increased.

Primarily as a result of its active clinical trials, the launch of the Precision Promise trial, and the initiation of Part 2 of the Company's ongoing Phase II trial in pancreatic cancer, as well as other business developments, the Company currently anticipates that its quarterly cash usage, or "cash burn rate", will increase in fiscal 2020 compared to fiscal 2019 and is expected to approximate $5.0 million to $6.0 million per quarter.

As of March 31, 2019, the Company had cash on hand of approximately $14.3 million and a working capital of approximately $9.8 million. TYME received an additional $11 million in proceeds, after deducting underwriting discounts and commissions and estimated offering expenses from financing activities that closed on April 2, 2019.

Management has concluded that substantial doubt does not exist regarding the Company's ability to satisfy its obligations as they come due during the twelve-month period following the issuance of these financial statements. This conclusion is based on the Company's assessment of qualitative and quantitative conditions and events, considered in aggregate as of the date of issuance of these financial statements that are known and reasonably knowable. Among other relevant conditions and events, the Company has considered its operational plans, liquidity sources, obligations due or expected, funds necessary to maintain the Company's operations, and potential adverse conditions or events as of the issuance date of these financial statements.

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

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

Additional equity financing, which we expect to raise, may be dilutive to our stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business; and our stock price may not reach levels necessary to induce option exercises. If we are unable to raise the funds necessary to meet our long-term liquidity needs, we may have to delay or discontinue the development of certain or all of our drug candidates or raise funds on terms that we currently consider unfavorable.

Cash Flows

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

	Year Ended March 31, 2019	Year Ended March 31, 2018
Net cash used in operating activities	$ (20,116,000)	$ (11,879,000)
Net cash used in investing activities	$ (16,000)	$ —
Net cash provided by financing activities	$ 5,458,000	$ 30,372,000

Operating Activities

Our cash used in operating activities in the year ended March 31, 2019 totaled $20.1 million which is the sum of (i) our net loss of $33.0 million, adjusted for non-cash expenses totaling $10.3 million (which includes equity-based compensation, warrant modification expense, severance stock option modification, and depreciation and amortization), and (ii) changes in operating assets and liabilities of $2.6 million.

Our cash used in operating activities in the year ended March 31, 2018 totaled $11.9 million which is the sum of (i) our net loss of $19.0 million, adjusted for non-cash expenses totaling $7.3 million (which includes equity-based compensation, depreciation and amortization and the issuance of common stock for services), and (ii) changes in operating assets and liabilities of $.2 million.

Investing Activities

During the year ended March 31, 2019 investing activities included $16 thousand for the purchase of property and equipment.

Financing Activities

During the year ended March 31, 2019, our finance activities mainly consisted of the following:

- In the year ended March 31, 2019, the Company raised approximately $5.7 million in net proceeds after sales commissions and expenses of the offering through the ATM Financing Facility via the sale of 2,383,884 shares of our common stock.

During the year ended March 31, 2018, our financing activities consisted of the following:

- In the year ended March 31, 2018, the Company raised approximately $5.8 million in net proceeds after sales commissions and expenses of the offering through the ATM Financing Facility via sale of 1,543,364 shares of our common stock.
- In March 2018, we raised approximately $21.7 million in net proceeds after underwriting commissions and discounts and expenses of the offering through a public offering of 10,350,000 shares of our common stock.
- In April 2017, we raised $2.6 million in net proceeds through a private placement of 1,069,603 shares of our common stock and 1,069,603 Warrants. Each Warrant entitles its holder to purchase one Warrant Share at an exercise price of $3.00 per Warrant Share, subject to adjustment.

Subsequent Events

On April 2, 2019, the Company closed on an underwritten registered offering of 8,000,000 shares of its common stock, par value $0.0001 per share, and warrants to purchase up to 8,000,000 shares of its common stock with an exercise price of $2.00 per share at a combined purchase price of $1.50 per share of common stock and accompanying warrant. The net proceeds to the Company, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company, was approximately $11 million.

Seasonality

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

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 with the exception of certain purchase commitments discussed below.

Purchase Commitments

The Company has entered into three contracts with manufacturers to supply certain components used in SM-88 in order to achieve favorable pricing on supplied products. These contracts have non-cancellable elements related to the scheduled deliveries of these products in future periods. Payments are made by us to the manufacturer when the products are delivered and of acceptable quality. The contracts are structured to match clinical supply needs for our ongoing trials and we expect the timing of associated payments to predominately occur during fiscal year 2019. Total outstanding future obligations associated with the contracts were $2.0 million at March 31, 2019.

In May 2019, the Company increased the work scope of one of the contracts resulting in a commitment increase of $495,000.

Leases

The Company has a two-year lease for office space in New Jersey with a monthly rent of $2,289 for the first six months and $4,292 for the remaining term expiring February 2021. Future rent payments are $40,000 and $47,000 for fiscal years 2020 and 2021, respectively.

The Company has a two-year lease for office furniture in New Jersey with future rent payments of $19,000 and $17,000 for fiscal years 2020 and 2021, respectively.

The Company subleases office space in New York, the rent obligation has been prepaid through August 30, 2020. Rent expense, primarily for the New York office, including short term rentals was approximately $243,000 and $93,000 for the years ended March 31, 2019 and 2018 respectively.

Off-Balance Sheet Arrangements

We do not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined by applicable SEC regulations.

ITEM 7A. QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information under this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

REPORT OF INDEPENDENT REGIST ERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Tyme Technologies, Inc.

Opinion on the financial statements
We have audited the accompanying consolidated balance sheets of Tyme Technologies, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of March 31, 2019 and 2018, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended March 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of March 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended March 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of March 31, 2019 based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), and our report dated June 12, 2019 expressed an unqualified opinion.

Basis for opinion
These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2015.

New York, NY
June 12, 2019

Tyme Technologies, Inc. and Subsidiaries
Consolidated Balance Sheets

	March 31, 2019	March 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 14,302,328	$ 28,975,822
Prepaid rent	242,755	6,450
Prepaid clinical costs	592,134	149,400
Prepaid expenses and other current assets	1,001,898	616,905
Total current assets	16,139,115	29,748,577
Property and equipment, net	10,363	3,239
Prepaid rent, net of current portion	101,148	—
Prepaid clinical costs, net of current portion	1,266,025	1,266,025
Total assets	$ 17,516,651	$ 31,017,841
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and other current liabilities (including $325,000 and $384,000 of related party accounts payable, respectively)	$ 3,692,308	$ 2,817,090
Severance payable	523,261	—
Accrued bonuses	1,495,248	1,248,690
Insurance note payable	597,339	480,094
Total current liabilities	6,308,156	4,545,874
Long-term liabilities		
Severance payable	1,540,613	—
Total liabilities	7,848,769	4,545,874
Commitments and contingencies (See Note 9)		
Stockholders' equity		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized, 0 shares issued and outstanding	—	—
Common stock, $0.0001 par value, 300,000,000 shares authorized, 103,946,048 issued and outstanding at March 31, 2019, and 300,000,000 authorized, 101,226,479 issued and outstanding at March 31, 2018	10,397	10,125
Additional paid in capital	95,472,181	79,293,423
Accumulated deficit	(85,814,696)	(52,831,581)
Total stockholders' equity	9,667,882	26,471,967
Total liabilities and stockholders' equity	$ 17,516,651	$ 31,017,841

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

Tyme Technologies, Inc. and Subsidiaries
Consolidated Statements of Operations

	Years Ended March 31,	
	2019	2018
Operating expenses:		
Research and development	$ 14,719,481	$ 8,839,661
General and administrative (including $977,000 and $1,619,000 of related party legal expenses, respectively)	14,586,165	10,520,217
Severance expense	2,470,906	—
Total operating expenses	31,776,552	19,359,878
Loss from operations	(31,776,552)	(19,359,878)
Warrant modification expense	(1,289,125)	—
Other income, net	82,562	390,385
Loss before income taxes	(32,983,115)	(18,969,493)
Net loss	$ (32,983,115)	$ (18,969,493)
Basic and diluted loss per common share	$ (0.32)	$ (0.21)
Basic and diluted weighted average shares outstanding	102,354,050	90,567,476

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

Tyme Technologies, Inc. and Subsidiaries
Consolidated Statements of Stockholders' Equity
For the Years Ended March 31, 2019 and 2018

	Common Stock				Additional			Total
	Shares	Amount	Subscribed Shares	Subscribed Amounts	Paid-in capital	Subscription Receivable	Accumulated Deficit	Stockholders' Equity
Balance, April 1, 2017	91,692,641	$ 9,172	58,823	$ 6	$ 41,419,714	$ (174,998)	$ (33,862,088)	$ 7,391,806
Issuance of common stock and warrants in private placement offering for cash, net of associated expenses of $130,300	1,069,603	107	—	—	2,596,993	—	—	2,597,100
Issuance of common stock from at-the-market financing facility, net of associated expenses of $327,939	1,543,364	154	—	—	5,823,863	—	—	5,824,017
Issuance of common stock in public offering for cash, net of associated expenses of $1,547,972	10,350,000	1,035	—	—	21,739,425	—	—	21,740,460
Proceeds from collection of stock subscription receivable	58,823	6	(58,823)	(6)	—	174,998	—	174,998
Stock based compensation	—	—	—	—	7,689,334	—	—	7,689,334
Issuance of common stock upon exercise of options and warrants	12,048	1	—	—	35,529	—	—	35,530
Derivative liability	—	—	—	—	(11,785)	—	—	(11,785)
Retirement and cancellation of shares of common stock	(3,500,000)	(350)	—	—	350	—	—	—
Net loss	—	—	—	—	—	—	(18,969,493)	(18,969,493)
Balance, March 31, 2018	101,226,479	$ 10,125	—	—	$ 79,293,423	—	$ (52,831,581)	$ 26,471,967
Issuance of common stock from at-the-market financing facility, net of associated expenses of $175,306	2,383,884	238	—	—	5,668,006	—	—	5,668,244
Exercise of options	100,000	10	—		269,990	—	—	270,000
Cashless exercise of warrants	235,685	24	—	—	(24)	—	—	—
Warrant modification	—	—	—	—	1,289,125	—	—	1,289,125
Severance stock based compensation	—	—	—	—	388,282	—	—	388,282
Stock based compensation	—	—	—	—	8,563,379	—	—	8,563,379
Net loss	—	—	—	—	—	—	(32,983,115)	(32,983,115)
Balance, March 31, 2019	103,946,048	$ 10,397	—	—	$ 95,472,181	—	$ (85,814,696)	$ 9,667,882

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

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

	Years Ended, March 31	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (32,983,115)	$ (18,969,493)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	8,420	4,296
Amortization of employees, directors and consultants stock options	8,563,379	7,689,334
Warrant modification expense	1,289,125	—
Severance stock based compensation	388,282	—
Gain on remeasurement of derivative liability	—	(390,385)
Changes in operating assets and liabilities:		
Prepaid rent	(337,453)	(6,450)
Prepaid clinical costs	(442,734)	(1,415,425)
Prepaid and other assets	433,334	91,551
Accounts payable and other current liabilities	654,229	(131,378)
Severance payable	2,063,874	—
Accrued bonuses	246,558	1,248,690
Net cash used in operating activities	(20,116,101)	(11,879,260)
Cash flows from investing activities:		
Purchase of property & equipment	(15,544)	—
Net cash used in investing activities	(15,544)	—
Cash flows from financing activities:		
Insurance note payments	(480,093)	—
Issuance of common stock from at-the-market financing facility (net of expenses)	5,668,244	5,824,017
Proceeds from exercise of stock options	270,000	35,530
Proceeds from private placement offering of common stock and warrants, net of issuance costs	—	2,597,100
Proceeds from the collection of stock subscription receivable	—	174,998
Proceeds from public offering, net of issuance of costs	—	21,740,460
Net cash provided by financing activities	5,458,151	30,372,105
Net (decrease) increase in cash	(14,673,494)	18,492,845
Cash and cash equivalents — beginning of year	28,975,822	10,482,977
Cash and cash equivalents — end of year	$ 14,302,328	$ 28,975,822
Supplemental Cash Flow Information:		
Cash paid for interest and income taxes are as follows:		
Interest	$ 7,415	$ —
Income taxes	$ —	$ —
Noncash investing and financing activities:		
Financing of insurance premiums	$ 597,339	$ 480,094
Deferred expenses related to post year end financing	$ 220,988	$ —
Cashless exercise of 1,086,271 warrants for 235,685 shares of common stock	$ —	$ —
Derivative liability associated with the price protection feature of shares of common stock issued	$ —	$ 11,785
Retirement and cancellation of shares of common stock	$ —	$ 350

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

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

Note 1. Nature of Business

Tyme Technologies, Inc. ("Tyme Tech") is a Delaware corporation headquartered in New York, NY, with wholly owned subsidiaries, Tyme Inc. and Luminant Biosciences, LLC ("Luminant") (collectively, "TYME" or the "Company"). Prior to 2014, Luminant conducted the initial research and development of the Company's therapeutic platform. Since January 1, 2014, the majority of the Company's research, development and other business activities have been conducted by Tyme Inc., which was incorporated in Delaware in 2013.

TYME is an emerging biotechnology company developing cancer metabolism-based therapies (CMBTs ™) that are intended to be effective across a broad range of solid tumors and hematologic cancers, while maintaining patient's quality of life with relatively low toxicity profiles. Unlike targeted therapies that attempt to regulate specific pathways within cancer, TYME's therapeutic approach is designed to take advantage of a cancer cell's innate metabolic requirements to cause cancer cell death.

The Company's lead clinical CMBT program, SM-88 (racemetyrosine), is a novel, oral, monotherapy investigational agent that has been studied in clinical trials for over five years within more than 150 cancer patients. TYME recently completed enrollment for two Phase II clinical trials in prostate and pancreatic cancer, and the Company is preparing for pivotal studies for SM-88 in pancreatic cancer during the second half of calendar year 2019. One of these pivotal trials is focused on patients with third-line pancreatic cancer and would be an amendment to the ongoing TYME-88-Panc trial (Part 2). The Company has also partnered with the Pancreatic Cancer Action Network ("PanCAN") to study SM-88 in an adaptive pivotal trial known as Precision Promise ℠ starting as second-line monotherapy and could expand to first-line combination therapy with standard of care. A Phase II investigator-initiated trial evaluating SM-88 monotherapy in late-stage sarcomas was launched in May 2019, under the direction of principal investigator Dr. Sant Chawla and in collaboration with the Joseph Ahmed Foundation ("JAF"). All of SM-88's current clinical programs study SM-88 in use with three low-dose conditioning agents: methoxsalen, phenytoin, and sirolimus (hereafter, referred to as "MPS"). The Company is actively evaluating the expansion of our clinical program to other cancers as SM-88 has demonstrated complete or partial responses in 15 different forms of cancer with a well-tolerated safety profile.

The accompanying consolidated financial statements include the results of operations of Tyme Tech and its wholly owned subsidiaries.

Liquidity

The consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has historically funded its operations primarily through equity offerings. During fiscal year 2019, the Company raised gross proceeds of approximately $5.8 million through the issuance of its common stock. Most recently in April 2019, the Company raised net proceeds of $11.3 million after underwriting discounts and before expenses through an underwritten registered offering. Previously on November 2, 2017, the Company entered into an equity distribution agreement ("Equity Distribution Agreement") with Canaccord Genuity Inc. ("Canaccord"), to commence an at-the-market offering (the "ATM Financing Facility") pursuant to which the Company may, from time to time, subject to certain rules and regulations, sell shares of the Company's common stock, par value $0.0001 per share, having an aggregate offering price up to $30.0 million, through Canaccord, as the Company's sales agent. In the year ended March 31, 2019, the Company raised approximately $5.8 million in aggregate gross proceeds before commissions and expenses through the ATM Financing Facility and paid Canaccord aggregate commissions of $0.2 million. At March 31, 2019, there remained approximately $17.9 million of availability to sell shares through the facility. The proceeds of those offerings are being used by the Company for continued clinical studies, drug commercialization and development activities and other general corporate and operating expenses.

For the year ended March 31, 2019, the Company had negative cash flow from operations of $20.1 million and net loss of $33.0 million, which included $10.2 million of non-cash expenses, primarily non-cash equity compensation and warrant modification expense. As of March 31, 2019, the Company had working capital of approximately $9.8 million.

Management has concluded that substantial doubt does not exist regarding the Company's ability to satisfy its obligations as they come due during the twelve-month period following the issuance of these financial

statemen ts. This conclusion is based on the Company's assessment of qualitative and quantitative conditions and events, considered in aggregate as of the date of issuance of these financial statements that are known and reasonably knowable. Among other relevant co nditions and events, the Company has considered its operational plans, liquidity sources, obligations due or expected, funds necessary to maintain the Company's operations, and potential adverse conditions or events as of the issuance date of these financi al statements.

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

Basis of Presentation

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

Significant Accounting Policies

Principles of Consolidation

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

Risks and Uncertainties

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

Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of expenses during the reporting period. Significant items subject to such estimation include the calculation of the 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. At March 31, 2019 and 2018, the Company did not have any cash equivalents. The Company's cash and cash equivalents consisted of $14.3 million at March 31, 2019 and $29.0 million at March 31, 2018.

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 $14.0 million at March 31, 2019 and $28.7 million at March 31, 2018. Although the Company has exceeded the federally insured limit, it has not incurred losses related to these deposits. Management monitors the Company's accounts with these institutions to minimize credit risk.

Fair Value of Financial Instruments

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

approximates the carrying value, which represents the present value of future severance payments. The fair value of the derivative liability is discussed below.

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

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

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

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

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

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

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

An adjustment to the pricing method used within either Level 1 or Level 2 inputs could generate a fair value measurement that effectively falls in a lower level in the hierarchy. The Company had no assets or liabilities classified as Level 1, Level 2, or Level 3 for the year ended March 31, 2019 and 2018. There were no transfers between Level 1, Level 2 and Level 3 in any of the periods reported.

The changes in the fair value of the derivative liabilities for the year ended March 31, 2018 are as follows:

Fair value at March 31, 2017	$	378,600
Fair value of liability-classified anti-dilution feature		11,785
Change in fair value of derivative liability		(390,385)
Fair value at March 31, 2018	$	—

Prepaid and Other Current Assets

Prepaid expenses 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. Prepaid and other current assets includes $0.6 million and $0.5 million of prepaid insurance as of March 31, 2019 and 2018, respectively.

Property and Equipment, Net

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

Impairment of Long-Lived Assets

The Company assesses the recoverability of its long-lived assets, which include fixed assets, whenever significant events or changes in circumstances indicate impairment may have occurred. If indicators of impairment exist, projected future undiscounted cash flows associated with the asset are compared to its carrying amount to determine whether the asset's value is recoverable. Any resulting impairment is recorded as a reduction in the carrying value of the related asset in excess of fair value and a charge to operating results. For the years ended March 31, 2019 and 2018, the Company determined that there were no triggering events requiring an impairment analysis.

Research and Development

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

Income Taxes

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

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

A valuation allowance is provided when, after consideration of available positive and negative evidence that it is not more likely than not that the benefit from deferred tax assets will be realizable. In recognition of this risk, we have provided a full valuation allowance against the net deferred tax assets. The assumptions about future taxable income require the use of significant judgment and are consistent with the plans and estimates we are using to manage the underlying businesses. In evaluating the objective evidence that historical results provide, we consider three years of cumulative operating income (loss).

The calculation of t ax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations in various jurisdictions. ASC 740 “Income Taxes” states that a tax benefit from an uncertain tax position may be recognized when it is more likely tha n 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.

When and if the Company were to recognize interest and penalties related to unrecognized tax benefits, they would be reported in tax expense.

Segment Information

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

Derivative Liabilities

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

Derivative Liability - PPO

The Company had recorded a derivative liability related to an anti-dilution provision as part of a 2014 financing agreement. That anti-dilution provision was determined to be a freestanding financial instrument that was carried as a liability at fair value of $0.4 million. During the year ended March 31, 2018 the anti-dilution provision expired without the triggering of any such protection. Accordingly, as of March 31, 2018 and thereafter, there was no fair value of the derivative liability .

Basic and Diluted Loss Per Share

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

Stock-based Compensation

The Company follows the authoritative guidance for accounting for stock-based compensation in ASC 718, Compensation-Stock Compensation. The guidance requires that stock-based payment transactions be recognized in the financial statements based on their fair value at the grant date and recognized as compensation expense over the vesting period as services are being provided. (See Note 11, 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. The Company accounts for forfeitures as they occur.

The Company accounted for stock-based awards issued to non-employees in accordance with ASC 505-50, "Equity-Based Payment to Non-Employees" and accordingly the fair value of the stock options granted to non-employees was remeasured each reporting period until the earlier of: a) the performance commitment date, or b) the date the services required under the arrangement have been completed and the resulting increase or decrease in value, if any, was recognized as expense or income, respecti vely, during the period the related services are rendered. Effective July 1, 2018, the Company adopted ASU 2018-07 and, as such, the fair value options granted to non-employees is estimated at the date of grant only.

Reclassification

Certain prior year amounts have been reclassified to conform to the current year presentation.

Recently Adopted Accounting Pronouncements

In June 2018, the FASB issued ASU 2018-07, which simplifies the accounting for share-based payments made to nonemployees so that the accounting for such payments is substantially the same as those made to employees, with certain exceptions. Under this ASU, equity-classified share based awards to nonemployees will be measured at fair value on the grant date of the awards, entities will need to assess the probability of satisfying performance conditions if any are present, and awards will continue to be classified according to ASC 718 upon vesting which eliminates the need to reassess classification upon vesting, consistent with awards granted to employees, unless the award is modified after the service has been rendered, any other conditions necessary to earn the right to benefit from the instruments have been satisfied, and the nonemployee is no longer providing services. The Company elected to early adopt ASU 2018-07 effective July 1, 2018.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718) - Scope of Modification Accounting* ("ASU 2017-09"), which amends the scope of modification accounting for share-based payment arrangements. The standard provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under ASC 718. Specifically, an entity would not apply modification accounting if the fair value, vesting conditions, and classification of the awards are the same immediately before and after the modification. The Company adopted ASU 2017-09 in its consolidated financial statements in the first quarter of fiscal year 2019. It did not have a material impact on the Company's financial statements.

In February 2017, the FASB issued Update No. 2017-05, *Other Income-Gains and Losses from the Derecognition of Nonfinancial Assets (Subtopic 610-20): Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets* ("ASU 2017-05"). This update is meant to clarify the scope of ASC Subtopic 610-20, Other Income-Gains and Losses from the Derecognition of Nonfinancial Assets and to add guidance for partial sales of nonfinancial assets. The Company adopted ASU 2017-05 in its consolidated financial statements in the first quarter of fiscal year 2019. It did not have a material impact on the Company's financial statements.

In January 2017, the FASB issued ASU 2017-01, amending *Business Combinations: Clarifying the Definition of a Business* ("ASU 2017-01"), to clarify the definition of a business with the objective of providing a more robust framework to assist management when evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The amendments are to be applied prospectively to business combinations that occur after the effective date. The Company adopted ASU 2017-01 in its consolidated financial statements in the first quarter of fiscal year 2019. It did not have a material impact on the Company's 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. The Company adopted ASU 2016-01 in its consolidated financial statements in the first quarter of fiscal year 2019. It did not have a material impact on the Company's financial statements.

Recent Accounting Pronouncements

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features* . These amendments simplify the accounting for certain financial instruments with down round features. The amendments require companies to disregard the down round feature when assessing whether the instrument is indexed to its own stock, for purposes of determining liability or equity classification. This ASU is effective for the Company beginning with the quarter ending June 30, 2020. The Company is evaluating the expected impact on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 is effective for annual periods beginning after December 15, 2018. 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 will adopt ASU 2016-02 in its consolidated financial statements in the first quarter of fiscal year 2020. The Company has performed an analysis for implementing this standard and has determined it will not have a material impact on the consolidated financial statements.

Note 3. Net Loss Per Common Share

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

	Year Ended March 31,	
	2019	**2018**
Basic and diluted net loss per common share calculation		
Net loss	$ (32,983,115)	$ (18,969,493)
Weighted average common shares outstanding — basic and diluted	102,354,050	90,567,476
Net loss per share of common stock — basic and diluted	$ (0.32)	$ (0.21)

The following outstanding securities at March 31, 2019 and 2018 have been excluded from the computation of diluted weighted average shares outstanding, as they would have been anti-dilutive:

	Year Ended March 31,	
	2019	**2018**
Stock options	8,953,527	5,438,072
Warrants	4,499,603	5,585,874
Total	13,453,130	11,023,946

Note 4. Property and Equipment, Net.

Property and equipment, net consisted of the following:

	March 31, 2019	March 31, 2018
Machinery and equipment	$ 37,007	$ 21,463
Less: accumulated depreciation	26,644	18,224
	$ 10,363	$ 3,239

Depreciation expense was $8,420 and $4,296 for the years ended March 31, 2019 and 2018, respectively.

Note 5. Accounts Payable and Other Current Liabilities.

Accounts payable and other current liabilities consisted of the following:

	March 31, 2019	March 31, 2018
Legal	$ 602,129	$ 421,261
Consultant and professional services	170,257	134,324
Accounting and auditing	331,119	81,652
Research and development	1,907,787	1,678,675
Board of Directors and Scientific Advisory Board Compensation	489,393	442,610
Other	191,623	58,568
	$ 3,692,308	$ 2,817,090

Note 6. Severance Payable

On March 15, 2019 the Company entered into a Release Agreement related to the separation of employment of their Chief Operating Officer. The Agreement provides for salary continuance for five years, reimbursement of health benefits for three years and a modification to his outstanding stock options to extend the post-termination exercise period for his vested options from three months to five years. The Company recorded severance expense at its present value of $2.5 million, (using a discount rate of 6%) for the year ended March 31, 2019, including $0.4 million relating to the stock option modification. The severance liability payable as of March 31, 2019 was $2.1 million.

Note 7. Debt.

Insurance Note Payable

During the years ended March 31, 2019 and 2018, the Company entered into a short-term financing arrangement with its insurance carrier related to payment of premium for its Director and Officer liability insurance coverage totaling $0.6 million and $0.5 million for the policy years ending on March 31, 2019 and 2018, respectively. As of March 31, 2019 and March 31, 2018, there remained a balance of $0.6 million and $0.5 million, respectively, recorded to Insurance note payable on the accompanying consolidated balance sheets.

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 ("Board") 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 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 designate d any class or series of Company preferred stock for use in the future.

Common Stock

Voting

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

Dividends

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

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.

March 2017 PPO

On March 10, 2017, the Company raised $9.2 million in gross proceeds through a private placement ("March 2017 Private Placement") of 3,588,620 shares of our common stock and 3,588,620 common stock purchase warrants (each, a "Warrant"). Each Warrant entitles its holder to purchase one share of common stock (each, a "Warrant Share") at an exercise price of $3.00 per Warrant Share, subject to adjustment. The warrants expire two years from the date of issuance and vest immediately. On March 15, 2019, the Board extended the expiration date of the 3,245,288 outstanding warrants through September 30, 2019.

April 2017 PPO

In April 2017, the Company raised $2.7 million in gross proceeds through a private placement ("April 2017 Private Placement") of 1,069,603 shares of common stock and 1,069,603 common stock purchase warrants (each, a "Warrant"). Each Warrant entitles its holder to purchase one share of common stock (each, a "Warrant Share") at an exercise price of $3.00 per Warrant Share. The warrants expire two years from the date of issuance and vest immediately. On March 15, 2019, the Board extended the expiration date of the 238,233 outstanding warrants through September 30, 2019.

The Company considers the extensions to be a modification of the March 2017 Private Placement and April 2017 Private Placement warrants. The Company recognized a warrant modification expense of $1.3 million for the year ended March 31, 2019, which represents the incremental value of the modified warrant as compared to the original warrant, both valued on the modification dates which is reflected in warrant modification expense in the consolidated statement of operations. The warrants were valued using the Black-Scholes option-pricing model on the date of the modification using the following assumptions: (a) fair value of common stock $2.31, (b) expected volatility of 87% and 84%, (c) dividend yield of 0%, (d) risk-free interest rate of 2.46% and 2.52%, (e) expected life of 1 and 6.5 months.

At March 31, 2019, 4,469,836 common stock purchase warrants relating to securities purchase agreements were outstanding and exercisable.

The fo llowing summarizes the common stock warrant activity for the years ended March 31, 2019 and March 31, 2018:

	Warrant Shares of Common Stock	Weighted Average Exercise Price
Outstanding at March 31, 2017	4,526,271	$ 3.42
Granted	1,069,603	3.00
Exercised	(10,000)	3.00
Cancelled	—	—
Outstanding at March 31, 2018	5,585,874	3.34
Granted	—	—
Exercised	(1,086,271)	3.00
Cancelled	—	—
Outstanding at March 31, 2019	4,499,603	$ 3.42

During the year ended March 31, 2019, 1,086,271 warrants were exercised on a cashless basis resulting in the issuance of 235,685 shares.

At-the-Market Financing Facility

On November 2, 2017, the Company entered into an equity distribution agreement ("Equity Distribution Agreement") with Canaccord Genuity Inc. ("Canaccord"), to commence an at-the-market offering (the "ATM Financing Facility") pursuant to which the Company may, from time to time, subject to certain rules and regulations, sell shares of the Company's common stock, par value $0.0001 per share, having an aggregate offering price up to $30 million, through Canaccord, as the Company's sales agent. In the year ended March 31, 2018, the Company raised approximately $6.2 million in gross proceeds through the ATM via sale of 1,543,364 of our common stock. The Company incurred $0.3 million of related costs which offset the proceeds. In the year ended March 31, 2019, the Company raised approximately $5.8 million in gross proceeds through the ATM via sale of 2,383,884 shares of our common stock. The Company incurred $0.2 million of related costs which offset the proceeds. At March 31, 2019, there remained approximately $17.9 million of availability to sell shares through the facility. Under the ATM Financing Facility, the Company is not required to issue the full available amount authorized and it may be cancelled at any time.

Public Offering

In March 2018, we raised approximately $23.3 million in gross proceeds through a public offering of 10,350,000 shares of our common stock. The Offering was made pursuant to the Company's registration statement on Form S-3 (Registration No. 333-211489), which was declared effective by the U.S. Securities and Exchange Commission on August 16, 2017, a base prospectus dated August 16, 2017 and a prospectus supplement dated March 1, 2018.

Note 9. 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.

Purchase Commitments

The Company has entered into three contracts with manufacturers to supply certain components used in SM-88 in order to achieve favorable pricing on supplied products. These contracts have non-cancellable elements related to the scheduled deliveries of these products in future periods. Payments are made by us to the manufacturer when the products are delivered and of acceptable quality. The contracts are structured to match clinical supply needs for our ongoing trials and we expect the timing of associated payments to predominately occur during fiscal year 2020. Total outstanding future obligations associated with the contracts were $2.0 million at March 31, 2019.

In May 2019, the Company increased the work scope of one of the contracts resulting in a commitment increase of $495,000.

Leases

The Company has a two-year lease for office space in New Jersey with a monthly rent of $2,289 for the first six months and $4,292 for the remaining term expiring February 2021. Future rent payments are $40,000 and $47,000 for fiscal years 2020 and 2021, respectively.

The Company has a two-year lease for office furniture in New Jersey with future rent payments of $19,000 and $17,000 for fiscal years 2020 and 2021, respectively.

The Company subleases office space in New York, the rent obligation has been prepaid through August 30, 2020. Rent expense, primarily for the New York office, including short term rentals was approximately $243,000 and $93,000 for the years ended March 31, 2019 and 2018 respectively.

Legal Proceedings

From time to time, the Company may be involved in litigation, claims or other contingencies arising in the ordinary course of business. The Company would accrue a liability when a loss is considered probable and the amount can be reasonably estimated. When a material loss contingency is reasonably possible but not probable, the Company would not record a liability, but instead would disclose the nature and the amount of the claim, and an estimate of the loss or range of loss, if such estimate can be made. Legal fees are expensed as incurred. The Company is 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.

Note 10. Related Party Transactions.

Legal

Drinker Biddle & Reath LLP ("DBR") has provided legal services to the Company. A partner of DBR was a member of the Board and had received, and was entitled to receive in the future, cash compensation payable to non-employee directors and equity compensation payable to non-employee directors generally under the 2016 Director Plan. See Note 11, Equity Incentive Plan. On September 10, 2018, the Company entered into an employment agreement with the partner and he was appointed as the Company's Chief Legal Officer and Secretary. He ceased to be a non-employee director on September 10, 2018 and he resigned as a member of the Board effective September 30, 2018. On September 1, 2018, the partner resigned from the partnership of DBR and he assumed a consulting role as "Of Counsel" with the firm. During the years ended March 31, 2019, and 2018, approximately $1.0 million and $1.8 million (of which $0.2 million was capitalized into equity), respectively, have been incurred as legal expenses associated with DBR, and the Company had approximately $325,000 and $384,000 in accounts payable and accrued expenses payable to DBR at March 31, 2019 and March 31, 2018, respectively.

Note 11. Equity Incentive Plan.

On March 5, 2015, the Company's Board adopted and the Company's stockholders approved, the Company's 2015 Equity Incentive Plan (the "2015 Plan"). No more than an aggregate of 3,333,333 shares of common stock may be awarded during the twelve month period starting March 5 of each succeeding year. Awards under the 2015 Plan may include, but need not be limited to, one or more of the following: options, stock appreciation rights, restricted stock, performance grants, stock bonuses, and any other type of award deemed by the administrator to be consistent with the purposes of the 2015 Plan. The exercise price of all options awarded under the 2015 Plan must be no less than 100% of the fair market value of the Company common stock as determined on the date of the grant and have a term of no greater than ten years from the date of grant. In February 2018, the 2015 Plan was amended making available 12.5% of shares of common stock issued and outstanding. As of March 31, 2019, there were 5,262,531 shares available for grant under the 2015 Plan.

On August 23, 2018 the stockholders approved the Amended and Restated 2016 Stock Option Plan for Non-Employee Directors (the "2016 Director Plan"), which: (i) increased the total number of shares of Common Stock authorized and reserved for issuance under the 2016 Director Plan by 2,000,000 shares to 2,750,000 shares: (ii) made "Initial Grants" upon a director's initial appointment to the Board consisting of an immediate stock option grant of 100,000 shares at fair market value; and (iii) made "Annual Grants" for members who continue in service as members of the Board subsequent to each annual meeting of stockholders occurring subsequent to an Initial Grant, an annual stock option grant of 50,000 shares at fair market value. The Initial Grants and Annual Grants have a ten year term, subject to applicable termination or forfeiture provisions, and vest in equal quarterly increments over a one-year period from the date of grant. As of March 31, 2019, there were 1,425,150 shares available for grant under the 2016 Director Plan.

Stock Options

As of March 31, 2019, and 2018, there was approximately $7.3 million and $9.6 million, respectively, of total unrecognized compensation related to non-vested stock options. The cost is expected to be recognized over the remaining weighted average remaining service period of 1.2 years.

During the years ended March 31, 2019 and 2018, the Company had stock compensation expense of $9.0 million and $7.7 million, respectively. For the year ended March 31, 2019, stock compensation expense is recognized as $5.7 million in general and administrative expense, $2.9 million in research and development expense, and $0.4 million in severance expense. For the year ended March 31, 2018, stock compensation expense has been recognized as $4.1 million in general and administrative expense and $3.6 million in research and development expense.

The Company uses the Black-Scholes option pricing model to determine the fair value of stock options granted. In accordance with ASC 718, the compensation expense for employees and non-employees is amortized on a straight-line basis over the requisite service period, which approximates the vesting period. The Company accounts for forfeitures as they occur, rather than estimating forfei tures as of an award's grant date.

The expected volatility of options granted has been determined using the method described under ASC 718 using the expected volatility of similar companies. The expected term of options granted to employees and directors in the current fiscal period has been based on the term by using the simplified "plain-vanilla" method as allowed under SAB No. 110. The expected term of options granted to non-employees and consultants is based on the grant's full contractual life.

The Company considered other methods to estimate expected term other than the simplified method. However, as noted above, there is no historical exercise data to provide a reasonable basis upon which to estimate expected term due to the limited period of time its equity shares have been publicly traded and no other refined estimate of expected life that is appropriate.

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

	Year Ended March 31,	
	2019	2018
Risk free interest rate	2.24%-3.10%	1.74%-2.70%
Expected volatility	71.86%-76.31%	65.95%-90.32%
Expected term	3-6.5 years	1-10 years
Dividend yield	0.0%	0.0%

The following is a summary of the activity of the Company's stock options under the 2015 Plan and 2016 Director Plan as of March 31, 2019:

	Number of Options	Weighted Average Exercise Price
Outstanding at March 31, 2018	5,438,072	$ 5.11
Granted	3,693,233	2.66
Exercised	(100,000)	2.70
Cancelled	(50,000)	2.33
Forfeited	(27,778)	8.75
Outstanding at March 31, 2019	8,953,527	4.13
Options exercisable at March 31, 2019	5,488,325	$ 4.79

Weighted-average grant date fair value of options granted during the years ended March 31, 2019 and 2018 was $1.76 and $2.72, respectively.

	Stock Options Outstanding				Stock Options Vested			
Range of Exercise Price	Number Outstanding at March 31, 2019	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value	Number Vested at March 31, 2019	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value
$2.06-$8.75	8,953,527	$ 4.13	7.89	$ —	5,488,325	$ 4.79	7.45	$ —

The intrinsic value calculated as the excess of the market value of as March 31, 2019 over the exercise price of the options, is zero. The market value as of March 31, 2019 was $1.76 as reported by the NASDAQ Cap ital Market. The total intrinsic value of options exercised during the year ended March 31, 2019 was zero.

	Options	Weighted Average Grant Date Fair Value Per Share
Non-vested options at March 31, 2018	$ 2,548,210	$ 3.93
Granted	3,693,233	1.76
Vested	(2,698,463)	3.08
Forfeited	(27,778)	7.57
Cancelled	(50,000)	1.52
Non-vested options at March 31, 2019	$ 3,465,202	$ 2.29

The fair value of options vested during the years ended March 31, 2019 and 2018 was $8,298,730 and $12,509,695, respectively.

Note 12. 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 $33.0 million and $19.0 million for the years ended March 31, 2019 and 2018, 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:

	March 31,	
	2019	2018
Net operating loss carryforward	$ 10,663,981	$ 5,736,229
Research and development credit carryforward	718,748	410,369
Stock options - NQSOs	4,518,506	2,759,122
Accruals and other temporary differences	864,789	757,567
Gross deferred tax assets	16,766,024	9,663,287
Deferred tax valuation allowance	(16,766,024)	(9,663,287)
Net deferred taxes	$ —	$ —

Based on the Company's history of operating losses since inception and consideration of available positive and negative evidence, the Company has concluded that it is not more likely than not that the benefit of its deferred tax assets will be realized. Accordingly, the Company continues to maintain a full valuation allowance against its net deferred tax assets as of March 31, 2019. The valuation allowance increased by $7.1 million for the year ended March 31, 2019 primarily due to the increase in the net operating loss carryforward and stock based compensation.

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

	Year Ended March 31,	
	2019	2018
U.S. statutory income tax rate	21.0%	31.5%
Stock options	—	(7.0)
Permanent differences	(0.8)	0.6
Tax rate change	—	(27.7)
R&D credit carryforwards	1.3	0.5
Valuation allowance	(21.5)	2.1
Effective tax rate	—%	—%

As of March 31, 2019, the Company had gross U.S. federal net operating loss carryforwards of approximately $50.8 million, which may be available to offset future income tax liabilities and will begin to expire at various dates starting in 2033. As of March 31, 2019, none of the Company's state net operating losses have value due to the apportionment rule in the states where state income tax returns are currently filed. As of March 31, 2019, the Company had gross federal research and development tax credit carryforwards of $0.8 million, available to reduce future tax liabilities which will begin to expire at various dates starting in 2030.

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

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

	Year Ended March 31,	
	2019	2018
Gross unrecognized tax benefits at beginning of year	$ 469,167	$ 617,233
Decreases for tax positions in prior period	(396,749)	(148,066)
Increase for tax positions in current period	54,420	—
Gross unrecognized tax benefits at end of year	$ 126,838	$ 469,167

As of March 31, 2019, the Company had $126,838 of unrecognized tax benefits, which were offset with the net operating loss and valuation allowance on the consolidated balance sheet. None of the gross unrecognized tax benefits would affect the effective tax rate at March 31, 2019, if recognized. In addition, the Company did not record any penalties or interest related to uncertain tax positions for the periods presented in these consolidated financial statements. The Company does not have any positions for which it is reasonably possible that there will be significant increase or decrease in the amounts of unrecognized tax benefits within twelve months of the reporting date.

The Company files income tax returns in the United States, and various state jurisdictions. The federal and state income tax returns are generally subject to tax examinations for the period January 1, 2015 through March 31, 2018. 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.

The Company has completed the accounting for the tax impact of the Tax Cuts and Jobs Act ("the Act") as of March 31, 2019 and has recorded no provisional amounts.

Note 13. Quarterly Information (unaudited)

	June 30, 2018	September 30, 2018	December 31, 2018	March 31, 2019
Fiscal Year Ended March 31, 2019				
Operating expenses:				
Research and development	$ 3,010,688	$ 3,443,516	$ 4,525,228	$ 3,740,049
General and administrative	3,708,481	3,569,174	3,550,223	3,758,287
Severance expense	—	—	—	2,470,906
Total operating expenses	6,719,169	7,012,690	8,075,451	9,969,242
Loss from operations	(6,719,169)	(7,012,690)	(8,075,451)	(9,969,242)
Warrant modification expense	—	—	—	(1,289,125)
Other income (expense), net	(3,627)	(2,430)	27,497	61,122
Loss before income taxes	(6,722,796)	(7,015,120)	(8,047,954)	(11,197,245)
Income tax expense	—	—	—	—
Net loss	$ (6,722,796)	$ (7,015,120)	$ (8,047,954)	$ (11,197,245)
Basic and diluted loss per common share	$ (0.07)	$ (0.07)	$ (0.08)	$ (0.10)
Basic and diluted weighted average shares outstanding	101,226,479	101,647,555	103,009,449	103,546,379

	June 30, 2017	September 30, 2017	December 31, 2017	March 31, 2018
Fiscal Year Ended March 31, 2018				
Operating expenses:				
Research and development	$ 1,264,358	$ 2,551,920	$ 2,585,991	$ 2,437,392
General and administrative	1,924,204	2,744,998	2,975,274	2,875,741
Total operating expenses	3,188,562	5,296,918	5,561,265	5,313,133
Loss from operations	(3,188,562)	(5,296,918)	(5,561,265)	(5,313,133)
Other income	315,624	74,761	—	—
Loss before income taxes	(2,872,938)	(5,222,157)	(5,561,265)	(5,313,133)
Income tax expense	—	—	—	—
Net loss	$ (2,872,938)	$ (5,222,157)	$ (5,561,265)	$ (5,313,133)
Basic and diluted loss per common share	$ (0.03)	$ (0.06)	$ (0.06)	$ (0.06)
Basic and diluted weighted average shares outstanding	89,258,377	89,321,067	89,929,161	93,829,568

Note 14. Subsequent Events.

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

On April 2, 2019, the Company closed on an underwritten registered offering of 8,000,000 shares of its common stock, par value $0.0001 per share, and warrants to purchase up to 8,000,000 shares of its common stock with an exercise price of $2.00 per share at a combined purchase price of $1.50 per share of common stock and accompanying warrant. The net proceeds to the Company, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company, was approximately $11 million.

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

There were no disagreements with Grant Thornton LLP.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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 the Company that are designed to ensure that information required to be disclosed by the Company in the reports that the Company 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. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed the Company in the reports that the Company files or submits under the Exchange Act is accumulated and communicated to the Company's management, including our principal executive and principal financial officer, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this Annual Report on Form 10-K. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of March 31, 2019, our disclosure controls and procedures were effective.

Remediation of Previous Material Weakness in Internal Control Over Financial Reporting

In connection with the preparation of our consolidated financial statements as of and for the year ended March 31, 2018, the following matters involving internal controls and procedures that our management considered to be material weaknesses and were remediated as follows:

- Ineffective information technology general controls ("ITGC") and application controls within the Company's general ledger system, disbursement solution and payroll solution, including:
    - Insufficient segregation of duties;
    - Lack of review controls over activity by administrative users;
    - Validation of information and reports used by management.
- Ineffective controls over period end financial disclosure and reporting processes, including:
    - Lack of a formal closing process;
    - Lack of communication with non-finance business personnel and sufficient review of business activities, including significant transactions, to determine proper accounting and reporting;
    - Insufficient management oversight of outside accounting and financial reporting advisory firm.
- Lack of sufficient and timely review over account balances, including:
    - Inadequate support and description of reconciling items;
    - Inadequate journal entry review and supporting documentation.

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

During the year ended March 31, 2019, the Company has executed on its remediation plan for the above material weaknesses and the material weaknesses have been remediated as discussed below.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined under Rule 13a-15(f) under the Securities and Exchange Act of 1934, as amended. Management assessed the effectiveness of our internal control over financial reporting as of March 31, 2019. 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 internal control over financial reporting as of March 31, 2019, our Chief Executive Officer and Chief Financial Officer concluded that as of such date, our internal control over financial reporting was effective.

Changes in Internal Control Over Financial Reporting

During fiscal year ended March 31, 2019, the Company executed on its remediation plan with respect to the material weaknesses identified as of March 31, 2018. Management has implemented certain practices and procedures addressing the foregoing material weaknesses. Such remediation efforts are disclosed below.

Management's Remediation of Material Weaknesses

Management believes that the underlying causes of the material weaknesses in internal control over financial reporting has been remediated through the following steps:

- Ineffective information technology general controls ("ITGC") and application controls within the Company's general ledger system, disbursement solution and payroll solution.
    - We added resources to the finance function and continue to establish processes that segregate duties consistent with control objectives.
    - We evaluated the control functionality within the disbursement, general ledger, and human resources systems that provide key control functionality. Within these systems, we modified and improved security administration and other access level and application controls. Where the systems controls are inherently limited, we designed compensating controls outside such system.
    - We formalized processes and policies, including processes and policies for IT general controls. Where necessary, we have implemented relevant key controls, including modified access rights, password settings, and access level review.
- Ineffective controls over period end financial disclosure and reporting processes.
    - We enhanced and formalized our financial close process including more and improved analytical reviews.
    - We increased the frequency of our periodic meetings with our outside accounting and financial reporting advisory firm and enhanced the discussion of operating results, significant transactions, internal controls, conclusions reached regarding technical accounting matters and financial reporting disclosures.

- We established a disclosure committee that includes both finance and non-finance representatives responsible for ensuring the accuracy, completeness, timeliness and consistency of public disclosure.

- Lack of sufficient and timely review over account balances.
  - We established a periodic review by financial management of account balance detail, journal entry posting activity and account reconciling items.
  - We created improved reports and analysis that are relied upon in making financial and business decisions.
  - We improved processes that allow for proactive review of significant transactions, including the creation of a centralized repository for significant agreements and additional controls at time of vendor set up.

The material weaknesses were not considered remediated until the applicable remedial controls operated for a sufficient period. Management has concluded, through testing, that the controls operate effectively at March 31, 2019.

Other than as described above under "Management Remediation of Material Weaknesses", there have been no changes in our internal control over financial reporting during the year ended March 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Our independent registered public accounting firm, Grant Thornton LLP, has issued an audit report with respect to our internal control over financial reporting, which appears in Part II, Item 9a of this Annual Report on Form 10-K.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Tyme Technologies, Inc.

Opinion on internal control over financial reporting
We have audited the internal control over financial reporting of Tyme Technologies, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of March 31, 2019 based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of March 31, 2019, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated financial statements of the Company as of and for the year ended March 31, 2019, and our report dated June 12, 2019 expressed an unqualified opinion on those financial statements.

Basis for opinion
The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and limitations of internal control over financial reporting
A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ GRANT THORNTON LLP

New York, New York
June 12, 2019

ITEM 9B. OTHE R INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

Directors

Set forth below are the names of and certain information as of May 30, 2018 regarding our Board of Directors:

Name	Age	Position(s) with the Company/Principal Occupation	Date Elected to Our Board of Directors
Steve Hoffman	56	Director, Chief Executive Officer and Chief Science Officer of the Company	March 5, 2015*
Dr. Gerald Sokol	76	Director/Chief of Radiation Oncology, University of South Florida's Tampa General Hospital	March 10, 2015
Timothy C. Tyson	67	Director/Former Chairman and Chief Executive Officer, Avara Pharmaceutical Services	March 10, 2015
Paul Sturman	58	Director/Chief Executive Officer, Nature's Bounty Co.	March 2, 2017
David Carberry	66	Director/Former Chief Financial Officer of Excellis Health Solutions, LLC (Retired)	March 30, 2017
Tommy G. Thompson	77	Director/Chairman and Chief Executive Officer, Thompson Holdings	August 28, 2017**
Donald W. DeGolyer	58	Director/Chief Executive Officer, Vertice Pharma LLC	May 24, 2018
Douglas A. Michels	62	Director/Former President and CEO OraSure Technologies	October 1, 2018

* Mr. Hoffman served as director of Tyme, Inc. (or Tyme, our subsidiary) since its formation on July 26, 2013 and served as director of the Company since the completion of the Merger on March 5, 2015.

** Mr. Thompson previously served as a special advisor to our Board and before that served as a member of our Board.

Executive Officers

See Part I, Additional Item of this Form 10-K under the heading "Executive Officers of the Registrant."

Other Information

Other information required by this Item 10 is incorporated by reference to, and will be contained in, our definitive proxy statement, which will be filed within 120 days after March 31, 2019.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 is incorporated by reference to, and will be contained in, our definitive proxy statement, which will be filed within 120 days after March 31, 2019.

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, and will be contained in, our definitive proxy statement, which will be filed within 120 days after March 31, 2019.

The following table provides cer tain information with respect to all of our equity compensation plans in effect as of March 31, 2019:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights		Weighted Average Exercise Price	Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (3)
Equity compensation plans approved by stockholders prior to March 31, 2019	8,953,527	(1)	$ 4.13	6,687,681
Equity compensation plans not approved by stockholders prior to March 31, 2019	29,767	(2)	$ 5.00	—
Total Equity	8,983,294		$ 4.14	6,687,681

(1) Includes 8,953,527 shares of our common stock issuable under option awards made prior to March 31, 2019 under our 2015 Equity Incentive Plan and our 2016 Director Plan, each approved by stockholders; these option awards carry a weighted average exercise price of $4.13 per share. For a description of the terms of the 2015 Equity Incentive Plan and 2016 Director Plan, please see Note 11 to the consolidated financial statements presented elsewhere herein.

(2) Includes 29,767 shares of our common stock issuable upon the exercise of certain warrants to purchase common stock as of March 31, 2019 at a weighted average exercise price $5.00 per share; the warrants described in this sentence are limited to warrants issued in return for goods or services provided and do not include warrants issued in connection with capital raising transactions, consistent with applicable SEC disclosure obligations.

(3) Includes 6,687,681 shares of our common stock issuable under awards eligible to be made (and not outstanding) as of March 31, 2019 under our 2015 Equity Incentive Plan and 2016 Director Plan.

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

The information required by this Item 13 is incorporated by reference to, and will be contained in, our definitive proxy statement, which will be filed within 120 days after March 31, 2019.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item 13 is incorporated by reference to, and will be contained in, our definitive proxy statement, which will be filed within 120 days after March 31, 2019.

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 filed in this Annual Report on Form 10-K under Item 8 of Part II hereof:

1. FINANCIAL STATEMENTS AND SUPPLEMENTAL DATA

(b) EXHIBITS

See Exhibit Index.

ITEM 16. FORM 10-K SUMMARY

Omitted at the company's option.

Exhibit Number	Description
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, filed with the SEC on September 19, 2014.)
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Tyme Technologies, Inc., effective April 2, 2018 (Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K, filed with the SEC on April 2, 2018.)
3.3	Amended and Restated By-Laws of Tyme Technologies, Inc., effective April 2, 2018. (Incorporated by reference to Exhibit 3.2 to our Current Report on Form 8-K, filed with the SEC on April 2, 2018.)
4.1	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, filed with the SEC on February 8, 2016.)
4.2	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, filed with the SEC on December 30, 2015.)
4.3	Form of Warrant. (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on March 22, 2017.)
4.4	Form of Notice to Warrant Holders. (Incorporated by referenced to Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on March 18, 2019.)
4.5	Form of Warrant. (Incorporated by referenced to Exhibit 4.1 to our Current Report on Form 8-K, filed with the SEC on April 2, 2019.)
4.6 *	Description of Common Stock, dated as of June 12, 2019.
10.1	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, filed with the SEC on March 11, 2015.)
10.2	Equity Distribution Agreement, dated as of November 2, 2017, by and between Tyme Technologies, Inc. and Canaccord Genuity, Inc. (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on November 6, 2017.)
10.3†	2015 Equity Incentive Plan of Tyme Technologies, Inc. (Incorporated by reference to Exhibit 10.8 to our Current Report on Form 8-K, filed with the SEC on March 11, 2015.)
10.4†	Amendment No. 1 to the Tyme Technologies, Inc. 2015 Incentive Plan, effective May 6, 2016. (Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q, filed with the SEC on August 9, 2016.)
10.5†	Amendment No. 2 to the Tyme Technologies, Inc. 2015 Incentive Plan, effective February 5, 2018. (Incorporated by reference to Exhibit 99.1 to our Current Report on Form 8-K, filed with the SEC on April 2, 2018.)
10.6†	Form of Nonqualified Stock Option Agreement under the Tyme Technologies, Inc. 2015 Equity Incentive Plan. (Incorporated by reference to Exhibit 99.3 to our Current Report on Form 8-K, filed with the SEC on April 2, 2018.)

10.7†	Form of Amendment to Nonqualified Stock Option Agreement under the Tyme Technologies, Inc. 2015 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.6 to our Quarterly Report on Form 10-Q, filed with the SEC on July 31, 2018.)
10.8†	Form of Stock Option Agreement under the Tyme Technologies, Inc. 2015 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.7 to our Quarterly Report on Form 10-Q, filed with the SEC on July 31, 2018.)
10.9†	Amended and Restated 2016 Stock Option Plan for Non-Employee Directors, effective May 24, 2018. (Incorporated by reference to Exhibit 99.1 to our Current Report on Form 8-K, filed with the SEC on May 29, 2018.)
10.10†	Form of Contingent Nonqualified Stock Option Agreement under the Tyme Technologies, Inc. 2016 Stock Option Plan for Non-Employee Directors. (Incorporated by reference to Exhibit 99.2 to our Current Report on Form 8-K, filed with the SEC on May 29, 2018.)
10.11†*	Form of Nonqualified Stock Option Agreement under the Tyme Technologies, Inc. 2016 Stock Option Plan for Non-Employee Directors.
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, 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, filed with the SEC on March 11, 2015.)
10.14†*	Release Agreement, dated as of March 15, 2019, between Tyme Technologies, Inc. and Michael Demurjian.
10.15†	Amended Letter Agreement, dated as of July 30, 2018, by and between Ben R. Taylor and Tyme Technologies, Inc. (Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q filed with the SEC on July 31, 2018.)
10.16†	Amended and Restated Nonqualified Stock Option Agreement, dated as of July 30, 2018, between Tyme Technologies, Inc. and Ben R. Taylor. (Incorporated by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q filed with the SEC on July 31, 2018.)
10.17†	Amended Letter Agreement, dated as of July 30, 2018, by and between Jonathan Eckard and Tyme Technologies, Inc. (Incorporated by reference to Exhibit 10.4 to our Quarterly Report on Form 10-Q filed with the SEC on July 31, 2018.)
10.18†	Amended and Restated Nonqualified Stock Option Agreement, dated as of July 30, 2018, between Tyme Technologies, Inc. and Jonathan Eckard. (Incorporated by reference to Exhibit 10.5 to our Quarterly Report on Form 10-Q filed with the SEC on July 31, 2018.)
10.19†*	Letter Agreement, dated as of September 10, 2018, between Tyme Technologies, Inc. and James Biehl .
21.1*	List of Subsidiaries.
23.1*	Consent of Independent Public Accounting Firm.
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 Certifications.
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

SIGNA TURES

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

Dated: June 12, 2019

TYME TECHNOLOGIES, INC.

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

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

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

Signature	Title	Date
/s/ Steve Hoffman Steve Hoffman	Chief Executive Officer and Director (Principal Executive Officer)	June 12, 2019
/s/ Barbara C. Galaini Barbara C. Galaini	Corporate Controller (Principal Accounting Officer)	June 12, 2019
/s/ Ben R. Taylor Ben R. Taylor	Chief Financial Officer and President (Principal Financial Officer)	June 12, 2019
/s/ Gerald Sokol Gerald Sokol	Director	June 12, 2019
/s/ Paul L. Sturman Paul L. Sturman	Director	June 12, 2019
/s/ David Carberry David Carberry	Director	June 12, 2019
/s/ Timothy C. Tyson Timothy C. Tyson	Director	June 12, 2019
/s/ Douglas A. Michels Douglas A. Michels	Director	June 12, 2019
/s/ Tommy G. Thompson Tommy G. Thompson	Director	June 12, 2019
/s/ Donald W. DeGolyer Donald W. DeGolyer	Director	June 12, 2019

Exhibit 4.6

DESCRIPTION OF COMMON STOCK

We are authorized to issue up to 300,000,000 shares of common stock, $0.0001 par value per share.

Voting

Each holder of common stock is entitled to one vote per share on all matters requiring a vote of the security holders, including the election of directors. We do not have cumulative voting rights.

Dividends

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

Rights Upon Liquidation

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

Rights and Preferences

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

Fully Paid and Nonassessable.

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

Anti-Takeover Provisions

Statutory Provisions

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

This prohibition is effective unless:

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

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

Certificate of Incorporation and By-Law Provisions

Our certificate of incorporation and by-laws contain certain provisions that may have the effect of delaying, deferring or preventing a future takeover or change in control of the Company, including transactions in which stockholders might otherwise receive a premium for their shares, unless such takeover or change in control is approved by the board of directors. 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.

These provisions include, among other items:

- *Classified Board.* Our certificate of incorporation provides that our board of directors is divided three classes of directors with a three-year term of office that expires as to one class each year, commonly referred to as a "staggered board". The classification of directors has the effect of making it more difficult for stockholders to change the composition of our board.
- *Removal of Directors* . Our certificate of incorporation provides that our directors (other than those elected by the holders of any series of preferred stock) may be removed only for cause and only by the affirmative vote of at least a majority of the total voting power of the outstanding shares of the capital stock of the corporation entitled to vote in any annual election of directors or class of directors, voting together as a single class. The limitations on the removal of directors would have the effect of making it more difficult for a third party to acquire control of us, or of discouraging a third party from acquiring control of us.
- *Vacancies; Number of Directors.* Vacant directorships, including newly created seats, may only be filled by (1) a majority of the directors then in office, although less than a quorum, or (2) by a sole remaining director, if applicable, or (3) only in the case where there are no directors then in office, by the stockholders. In addition, our certificate of incorporation also provides that the number of directors will be fixed from time to time by the board of directors in its sole and absolute discretion. These provisions would prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management.
- *Special Meetings of Stockholders* . Our certificate of incorporation also provides that the annual meetings and, subject to the rights of any preferred stockholders, the special meetings of the stockholders can be called only by a resolution of the board of directors in its sole and absolute discretion.
- *Advance Notice Procedures* . Our by-laws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder who was a stockholder of record, entitled to vote at the meeting, and who has given our secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. These provisions may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the Company.
- *Amendment of the By-laws* . Our by-laws provide that our by-laws may be altered, amended or repealed by the affirmative vote of a majority of our stockholders entitled to vote or a majority of our directors then in office without prior notice to or approval by our stockholders. Accordingly, our board of directors could take action to amend our by-laws in a manner that could have the effect of delaying, deferring or discouraging another party from acquiring control of the Company.

- *Issuance of Undesignated Preferred Stock* . The board of directors has the authority, without further action by the stockholders, to issue shares of preferred stock with rights and preferences, including voting rights, designated from time to time by the board. The enables the board to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise.

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

Exhibit 10.11

TYME TECHNOLOGIES, INC. 2016 STOCK OPTION PLAN FOR NON-EMPLOYEE DIRECTORS

NONQUALIFIED STOCK OPTION AWARD AGREEMENT

THIS AGREEMENT is made on _____ (the "Date of Grant"), by and between Tyme Technologies, Inc., a Delaware corporation (the "Company"), and _____ (the "Participant").

WHEREAS, the Company has adopted the Tyme Technologies, Inc. 2016 Stock Option Plan for Non-Employee Directors (the "Plan"); and

WHEREAS, the Company desires to grant to the Participant options under the Plan to acquire an aggregate of _____ shares of common stock of the Company ("Common Stock"), on the terms set forth herein.

NOW, THEREFORE, the parties hereby agree as follows:

1. Definitions . Capitalized terms not otherwise defined herein shall have the meanings set forth in the Plan.

2. Grant of Options . The Participant is hereby granted an option (the "Option") to purchase an aggregate of _____ (____) shares of Common Stock, pursuant to the terms of this Agreement and the provisions of the Plan. This Option is intended to constitute a nonqualified stock option.

3. Option Price . The initial exercise price per share of Common Stock subject to this Option shall be $_____, subject to equitable adjustment in accordance with the Plan.

4. Conditions to Exercisability . Except as otherwise provided herein, the Option shall become exercisable according to the following schedule, provided that the Optionee is serving as a director of the Company on such dates:

Date	Number of Shares

[Notwithstanding the foregoing, (i) the Option shall become immediately vested and exercisable in the event of the Participant's death, and (ii) if the Participant's service on the Board terminates by reason of Retirement, Permanent Disability or Partial Disability, the Option shall become immediately vested and exercisable.]

5. Period of Option . [This Option shall remain outstanding for a term of [___] years from the Date of Grant. Upon the cessation of a Participant's membership on the Board for any reason, vested Options granted to the Participant shall expire upon the earliest to occur of (i) [_____] years from the date of such cessation of Board membership, (ii) the tenth anniversary of the date of grant of the Option, or (iii) the [_____] anniversary of the Participant's death, provided that the periods set forth in clauses (i) and (iii) may be extended upon Board approval. Any portion of an Option that is not vested on the Participant's cessation of Board membership for any reason (or does not become vested by reason of such cessation of membership) shall be permanently forfeited on the date such membership ceases.] **[** This Option shall remain outstanding for a term of [five] [two] years from the Date of Grant.]

6. Exercise of Option . This Option may be exercised in whole or part, to the extent then exercisable, in the following manner: the Participant shall deliver to the Company written notice specifying the number of shares of Common Stock that the Participant elects to purchase. The Participant must include with such notice full payment of the exercise price for the Common Stock being purchased pursuant to such notice. The exercise price shall be paid in full at the time of exercise. The exercise price may be paid in cash or by check; by tendering shares of Common Stock previously acquired by the Participant; or in a combination of any of the foregoing, in an amount having a combined value equal to such exercise price. The value of any Common Stock tendered pursuant to the preceding sentence shall be the Fair Market Value of such Common Stock as of the last trading day prior to the date of exercise. The Committee, in its discretion, may require that any previously-owned shares of Common Stock tendered by the Participant in payment of the exercise price have been held by the Participant for at least six months prior to such tender. Upon the delivery of shares of Common Stock acquired pursuant to the exercise of Options, the Company shall have the right to require the payment of the amount of any taxes that are required by law to be withheld with respect to such delivery. The Participant shall not be deemed to be a holder of any shares of Common Stock pursuant to exercise of this Option until the date of the issuance of a stock certificate to him or her for such shares and until such shares are paid for in full, including any applicable withholding taxes. If permitted by the Committee at the time of exercise, this Option may also be exercised pursuant to a cashless exercise program.

7. Investment Representation and Legend of Certificates . The Company shall have the right to place upon the face and/or reverse side of any stock certificate or certificates evidencing the shares of Common Stock such legend as the Committee may prescribe for the purpose of preventing disposition of such shares of Common Stock in violation of the Securities Act.

8. Non Transferability . The Option shall not be transferable by Participant, other than by will, the laws of descent and distribution or pursuant to a domestic relations order, and is exercisable during the lifetime of Participant only by Participant, except as otherwise specifically provided in this Agreement or the Plan. The terms of this Agreement shall be binding upon the executors, administrators, heirs, successors and assigns of Participant.

9. Continued Directorship **.** Nothing herein shall confer upon the Participant the right to continue to serve as a director of the Company or to be entitled to any remuneration or benefits not set forth in the Agreement.

10. Clawback or Recoupment Policy . This Option, Common Stock delivered pursuant to this Option, and any gains or profits on the sale of such Common Stock shall be subject to any "clawback" or recoupment policy adopted by the Company.

11. Applicable Law . This Agreement shall be governed by and construed and enforced in accordance with the internal laws of the State of Delaware without regard to principles of conflict of laws.

12. Limitations Applicable to Section 16 Persons . The grant of the Option pursuant to this Agreement is intended to qualify for an exemption from Section 16 of the Exchange Act pursuant to Rule 16b-3(d)(1) promulgated thereunder. To the extent such exemption is not available, n otwithstanding any other provision of the Plan or this Agreement, the Option and this Agreement shall be subject to any additional limitations set for th in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3 of the Exchange Act) that are requirements for the application of such exemption. To the extent permitted by applicable law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

13. Counterparts . This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

Tyme Technologies, Inc.

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

By:_____
Name:_____

Exhibit 10.14

RELEASE AGREEMENT

This Release Agreement (this " Release Agreement ") is made by and between Tyme Technologies, Inc. and Michael Demurjian on this 15th day of March, 2019.

DEFINITIONS

1. As used herein, unless otherwise specified, the term "Company" shall mean Tyme Technologies, Inc., and all of its affiliates, successors, predecessors, assigns, parents, subsidiaries and divisions (whether incorporated or unincorporated).

2. As used herein, unless otherwise specified, the term "Employee" shall mean Michael Demurjian.

RECITALS

WHEREAS, Employee and the Company entered into an employment agreement dated as of March 5, 2015 (the " Employment Agreement ");

WHEREAS, pursuant to this Release Agreement, the Company and Employee have mutually agreed that Employee will resign as an officer and director of the Company, effective as of the date hereof (the " Separation Date "), and that, subject to Employee's compliance with this Release Agreement, Employee will receive the post-employment payments and benefits that he would otherwise receive in the event of a termination of Employee's employment without "Cause" (as defined in the Employment Agreement) pursuant to Section 5(a) of the Employment Agreement and the other payments and benefits set forth herein;

WHEREAS, it is a condition to Employee's receipt of such post-employment payments and benefits that Employee execute and remain in continued compliance with this Release Agreement; and

WHEREAS, capitalized terms used but not defined in this Release Agreement shall have the meanings given to such terms in the Employment Agreement.

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

1. Termination of Employment; Resignation from Board Service . Employee and the Company hereby mutually agree that Employee's employment with the Company under the Employment Agreement shall terminate, effective as of the Separation Date. As of the Separation Date, Employee shall cease to be the Executive Vice President, Chief Operating Officer of the Company. Effective as of the Separation Date, Employee hereby unconditionally and irrevocably resigns as a member of the Board of Directors of the Company (the " Board ") and resigns from all other offices, titles, positions and appointments at the Company and any of

its subsidiaries and affiliates, including as a director, manager, officer, employee, committee member or trustee.

2. Severance; Stock Options . The Company shall provide Employee with the following payments and benefits in full satisfaction of the Company's obligations (a) under the Employment Agreement, (b) with respect to his outstanding stock options and (c) otherwise, subject to Employee's continued compliance with his obligations under this Release Agreement, including compliance with the obligations and restrictions set forth in Sections 4 through 11 of this Release Agreement:

(i) Continued payment of Base Salary, at a rate of $450,000 per annum (*i.e.* , the rate in effect as of the date hereof) from the Separation Date through March 5, 2024, paid in installments at the same times and in the same manner as his base salary was paid prior to the Separation Date.

(ii) Provided that Employee timely elects to continue his (and, to the extent applicable, his spouse and dependents) participation in the health and, to the extent eligible following the Separation Date, other welfare plans in which Employee currently participates pursuant to the Consolidated Omnibus Budget Reconciliation Act (" COBRA Coverage "), the Company will, for the 18-month period of COBRA Coverage, continue to pay the portion of Employee's premium cost for health and such other welfare benefits at the same rate as for active employees of the Company (such monthly Company premium contribution amount, the " Company Contribution Amount "). Following the end of the COBRA Coverage, Employee shall have no further rights to any continued participation in the Company's health or other welfare plans; provided , however , that the Company shall pay Employee the Company Contribution Amount (subject to applicable tax withholding) for 18 months following the end of the COBRA Coverage. Notwithstanding the foregoing, in the event that Employee becomes covered under another employer's group health plan following the end of the COBRA Coverage, the Company shall have no obligation to pay the Company Contribution Amount during the period that Employee is covered under such plan.

(iii) With respect to Employee's 500,000 outstanding stock options to acquire shares of capital stock in or issued by the Company (" Capital Stock ") at an exercise price of $8.75 per share (such stock options, " Options ") , Employee acknowledges and agrees that the terms of the award agreement by and between Employee and the Company, dated May 6, 2015 (the " Award Agreement "), and the Company's 2015 Equity Incentive Plan (the " Equity Plan ") shall govern the treatment of such Options; provided , however , Options that are fully vested as of the Separation Date shall remain exercisable until March 5, 2024, subject to Employee's continued compliance with his obligations under this Release Agreement. For the avoidance of doubt, any Options that are

unvested as of the Separation Date shall be immediately forfeited as of the Separation Date and Employee's rights in such unvested Options shall thereupon lapse and expire.

Employee acknowledges that the payments and benefits described in clauses (i), (ii) and (iii) above are in excess of any earned wages or benefits due and owing Employee, and would not be paid or provided unless Employee executed this Release Agreement. Employee further acknowledges and agrees that such payments and benefits are adequate and independent consideration for Employee executing this Release Agreement and releasing any and all claims against the Company.

3. Release of All Claims. (a) In consideration of the above, and the other promises set forth in this Release Agreement, Employee, with the intention of binding himself, his heirs, family members, executors, administrators, representatives and assigns, fully and forever waives, releases, acquits and discharges the Company and its current and former owners, directors, officers, trustees, shareholders, managers, employees and agents (collectively, the " Released Parties ") from and for all manner of claims, actions, suits, charges, grievances and/or causes of action, in law or in equity, existing by reason of and/or based upon any fact or set of facts, known or unknown, existing from the beginning of time through the Separation Date which Employee now has, owns or holds, or has at any time heretofore had, owned or held against the Released Parties (collectively, the " Released Claims "), including, but not limited to, all claims, actions, suits, charges, grievances and/or causes of action arising under the Employment Agreement and Options granted under the Award Agreement and the Equity Plan, all claims, actions, suits, charges, grievances and/or causes of action for wages, compensation, liquidated damages, commissions, bonuses, benefits, sums of money, damages of every type, costs, attorneys' fees, judgments, executions, wrongful discharge, breach of contract, breach of implied contract, breach of the covenant of good faith and fair dealing, tortious interference with contract or business relationships, assault, battery, invasion of privacy, misappropriation of trade secrets, promissory estoppel, unjust enrichment, loss of consortium, violation of the penal statutes, negligent or intentional infliction of emotional distress, negligence, defamation, retaliation and/or discrimination and/or harassment on account of age, sex, sexual orientation, creed, religion, race, color, national origin, sensory disability, mental disability, physical disability, veteran or military status, marital status, or any other classification recognized under all applicable discrimination laws, or any other claim or cause of action, which has or could have been alleged under the common law, civil rights statutes, Title VII of the Civil Rights Act of 1964, the Family and Medical Leave Act, the Employee Retirement Income Security Act, the Rehabilitation Act of 1973, the Americans with Disabilities Act, COBRA, the Workers Adjustment Retraining Notification Act, the Equal Pay Act, the Uniformed Services Employment and Reemployment Rights Act, the National Labor Relations Act, any and all federal, state or local statutes, ordinances and laws, and every type of relief (legal, equitable and otherwise) available to Employee. Nothing in this Release Agreement shall be construed as releasing the Released Parties from (i) any claims arising after Employee signs this Release Agreement; (ii) any claims related to the enforcement of this Release Agreement; (iii) any rights or claims to any Base Salary accrued, but unpaid as of the Separation Date; (iv) any rights or claims to any benefits earned or vested pursuant to the Company's benefit plans as of the Separation Date; (v) any rights arising out of Employee's ownership of shares of Capital Stock; (vi) any rights or claims Employee may have to workers' compensation or unemployment

benefits; (vii) cla ims for indemnification in accordance with the Company's by-laws and certificate of incorporation; and/or (viii) any claims that cannot be waived by law.

(b) Employee agrees and acknowledges that he has no further right to receive any compensation, payments or benefits from the Company, other than (i) as set forth in this Release Agreement and (ii) with respect to any matters that are excluded from the Release pursuant to the last sentence of Section 3(a). Employee further agrees and acknowledges that, except as otherwise specified in this Release Agreement, the Company has no further obligations under the Employment Agreement.

4. Covenant Not To Sue . Employee represents that he has not filed any action, charge, suit or claim against any Released Party with any federal, state or local agency or court relating to any Released Claim. Employee covenants and agrees that he will not pursue or allege any claim, matter or cause of action in violation of, and/or released under, this Release Agreement. Employee further agrees that should any claims, charges, complaints, suits or other actions be filed hereafter on his behalf by any federal, state or local agency or by any other person or entity with respect to a Released Claim, he will immediately withdraw with prejudice, or cause to be withdrawn with prejudice, and/or dismiss with prejudice, or cause to be dismissed with prejudice, any such claims, charges, complaints, suits or other actions filed against any of the Released Parties. Employee further agrees that, to the fullest extent permitted by law, Employee shall receive no relief of any type (monetary, equitable or otherwise) with respect to, relating to and/or on account of any such claims, matters or actions. Employee agrees to opt out of any class action or collective action filed against any of the Released Parties to the extent related to a Released Claim.

5. Restrictive Covenants . Employee acknowledges and agrees that he will continue to adhere to those restrictions set forth in Sections 6, 7 and 8(a)-(d) of the Employment Agreement which survive the termination of his employment; provided , however , the "Restricted Period" within the meaning of the Employment Agreement shall end on March 5, 2024; and provided , further , however , that, with respect to clause 8(a)(A) of the Employment Agreement, such clause shall only apply to a business that is competitive with the business of the Company as of the Separation Date.

6. Lock-Up . Without the prior written consent of the Company, prior to the end of the first full calendar week following the Company's filing of its Annual Report on Form 10-K for the fiscal year ending March 31, 2019 (the " Initial Period "), Employee shall not, directly or indirectly (including through any affiliates or otherwise), (a) sell, transfer, assign, pledge, encumber, hypothecate or similarly dispose of (by operation of law or otherwise), directly or indirectly, any shares, interests or other equivalents (however designated, whether voting or non-voting) of Capital Stock or securities convertible into, or exchangeable, exercisable or settled for Capital Stock (such securities, " Convertible Securities "); (b) enter into any contract, option or other arrangement or understanding with respect to the sale, transfer, assignment, pledge, encumbrance, hypothecation or similar disposition of (by operation of law or otherwise), any Capital Stock or Convertible Securities, including any option, right or warrant to purchase Capital Stock or Convertible Securities; (c) enter into a transaction which would have the same effect; or (d) enter into any swap, hedge or other arrangement that transfers, in whole or in part, any of the economic consequences of ownership of the Capital Stock or Convertible Securities

(clauses (a), (b), (c) and (d), the " Restricted Actions "). Following the Initial Period, the Restricted Actions shall continue to apply until the Fall Away Date (as defined below), provided that the Restricted Actions shall not apply to sales or transactions of (i) 50,000 shares of Capital Stock or Convertible Securities in the aggregate per week for six consecutive weekly periods beginning at the end of the Initial Period and (ii) 20,000 shares of Capital Stock or Convertible Securities in the aggregate in any weekly period thereafter until March 5, 2024 (the " Fall Away Date "). In addition to the foregoing restrictions, during any calendar week, Employee shall not , directly or indirectly (including through any affiliates or otherwise), sell, transfer, assign, pledge, encumber, hypothecate or similarly dispose of any Capital Stock or Convertible Securities at prices less than 95% of the closing price on the last trading day of the immediately preceding calendar week, and any sale, transfer, assignment, pledge, encumbrance, hypothecation or similar disposition by Employee , directly or indirectly (including through any affiliates or otherwise), shall comply, at all times, with applicable law. The Company shall cooperate with Employee in connection with any such sales or trades, including allowing the removal of al l restrictive legends and stop transfer instructions with respect to any Capital Stock that is deemed "restricted securities" for the purposes of Rule 144 promulgated under the Securities Act of 1933, as amended (the " Securities Act "), and, in connection t herewith, accepting opinions of counsel with respect to the availability of the exemption from registration under Section 5 of the Securities Act under said Rule 144 similar in nature to opinions of counsel the Company has accepted for other stockholders o f the Company with respect to Capital Stock constituting restricted securities under Rule 144.

7. Financial Cooperation . In connection with any offering of Capital Stock by the Company or its shareholders, Employee shall take all actions reasonably necessary to permit the consummation of any such offering, including (a) providing such information regarding Employee as shall be required in connection with any such offering and (b) if requested by the Company or the managing underwriter or underwriters of such offering, agreeing to a lock-up agreement in the form requested by such underwriters and for such period of time as such underwriters may specify.

8. Confidentiality . To the fullest extent permitted by law, Employee agrees to keep confidential all facts, opinions, and information which relate in any way to Employee's employment or cessation of employment with the Company or Employee's membership on or resignation from the Board, as well as the terms of this Release Agreement; provided , however , Employee may discuss the terms of this Release Agreement (x) with his spouse, legal representative and/or tax preparer, each of whom must also agree to maintain confidentiality and comply with this Section 8, (y) with the U.S. Equal Employment Opportunity Commission or (z) if otherwise compelled to do so by a court of competent jurisdiction or government agency. Notwithstanding anything in this Release Agreement to the contrary, nothing contained in this Release Agreement or the surviving provisions of the Employment Agreement identified in Section 5 is intended to prohibit or restrict Employee in any way from: (a) making any disclosure of any information about the Company, Employee's employment or membership on the Board or this Release Agreement as required by law, or to a government agency in connection with any charge or investigation; (b) providing information to, filing a charge with, or testifying or otherwise assisting in any investigation or proceeding brought by any federal, state or local regulatory or law enforcement agency (including without limitation the U.S. Equal Employment Opportunity Commission) or legislative body, any self-regulatory organization, or

the Comp any's legal, compliance or human resources officers; (c) cooperating, participating or assisting in an investigation or proceeding brought by the Securities Exchange Commission (" SEC ") without notifying the Company; or (d) making other disclosures that are protected under the whistleblower provisions of federal or state law or regulation. However, Employee acknowledges and agrees that Employee cannot recover any monetary damages or equitable relief in connection with a charge or proceeding brought by Emplo yee or through any action brought by a third party with respect to the Released Claims. This Release Agreement does not, however, waive or release Employee's right to receive a monetary award from the SEC.

9. Nondisparagement; Communications . (a) Employee shall not, at any time or by any means whatsoever, either directly or indirectly, disparage or encourage or induce others to disparage the Company or its subsidiaries or affiliates, any of their clients, customers or businesses, or any of their current or former officers, directors, employees or shareholders. For purposes of this Section 9, the term "disparage" includes any statement to any third party (whether through non-public communication with any person, social media or in any public communication to the media).

(b) Employee agrees that, during the period commencing on the Separation Date and ending on March 5, 2024, prior to making any public statement with respect to the Company or its subsidiaries or affiliates, any of their clients, customers or businesses, or any of their current or former officers, directors, employees or shareholders (whether verbally or in writing, on or off the record, to the press, through social media or otherwise), Employee shall first obtain the written approval of the Chief Executive Officer of the Company. Employee further agrees that Employee shall not, during such period, engage in any Prohibited Communications (as defined on Schedule A attached hereto) without the prior written approval of the Chief Executive Officer of the Company.

(c) The Company agrees that, during the period commencing on the Separation Date and ending on March 5, 2024, the members of the Board and the executive officers of the Company shall not make any public statement that disparages Employee. Employee and the Company shall mutually agree upon the language in any press release or public announcement regarding Employee's termination of employment with the Company or resignation from the Board. Notwithstanding the foregoing, nothing in this Section 9(c) shall preclude the members of the Board or the executive officers of the Company from responding truthfully to a valid subpoena, cooperating with a governmental agency in connection with any investigation it is conducting, or taking any action otherwise required or permitted by law.

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

11. Cooperation . (a) To the fullest extent permitted by law, Employee will not cooperate with, or assist in, any claim, charge, lawsuit or arbitration against the Company with respect to a Released Claim, unless required to do so by a lawfully issued subpoena, by court order or as expressly provided by regulation or statute. In the event Employee is served with a

subpoena or is required by court order or otherwise to testify in any type of proceeding involving the Company and related to a Released Claim, Employee shall immediately advise the Company in writing of the same.

(b) During the period commencing on the Separation Date and ending on March 5, 2024, Employee shall cooperate with the Company in any internal investigation, administrative, regulatory or judicial proceeding or any dispute with a third party. Employee's cooperation may include being available to the Company upon reasonable notice for interviews and factual investigations, appearing at the Company's request to give testimony without requiring service of a subpoena or other legal process, volunteering to the Company pertinent information, and turning over to the Company all relevant documents which are or may come into Employee's possession. Employee understands that in the event the Company asks for Employee's cooperation in accordance with this provision, the Company will reimburse him for reasonable travel expenses (including lodging and meals) upon submission of receipts acceptable to the Company.

12. Non-Admission of Liability . It is expressly understood and agreed that this Release Agreement shall not be deemed or construed as an admission of fault or liability by any party hereto and that no party is admitting that it has committed any wrong. The Company and Employee each agree that this Release Agreement is inadmissible by Employee as evidence in any proceeding, legal or otherwise, except to the extent necessary to enforce its provisions.

13. Entire Agreement . This Release Agreement, the surviving provisions of the Employment Agreement identified in Section 5 and the surviving provisions of the Award Agreement contain all the agreements between the parties hereto relating to the Employee's employment and termination thereof. Except as specifically set forth herein, this Release Agreement supersedes any prior agreements or representations, whether oral or written, between the parties hereto as to the subject matter contained herein. This Release Agreement may be modified, supplemented or superseded only in a written document signed by both parties hereto. Employee represents and acknowledges that in executing this Release Agreement, Employee is not relying upon any representation or statement made by the Company with regard to the subject matter, basis or effect of this Release Agreement.

14. Withholding . Any payments made under this Release Agreement shall be subject to applicable federal, state and local tax reporting and withholding requirements.

15. Governing Law; Arbitration; Enforcement .

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

(b) Except as provided in Section 15(c), any dispute or controversy arising with respect to this Release Agreement and Employee's employment or termination thereof shall, at the election of either Employee or the Company, be submitted to JAMS for

resolution in arbitration in accordance with the rules and procedures of JAMS. Either party shall make such election by delivering written notice thereof to the other party at any time (but not la ter than 45 days after such party receives notice of the commencement of any administrative or regulatory proceeding or the filing of any lawsuit relating to any such dispute or controversy) and thereupon any such dispute or controversy shall be resolved o nly in accordance with the provisions of this Section 15(b). Any such proceedings shall take place in New York City before a single arbitrator (rather than a panel of arbitrators), pursuant to any streamlined or expedited (rather than a comprehensive) arb itration process, before a non-judicial (rather than a judicial) arbitrator, and in accordance with an arbitration process which, in the judgment of such arbitrator, shall have the effect of reasonably limiting or reducing the cost of such arbitration. Th e resolution of any such dispute or controversy by the arbitrator appointed in accordance with the procedures of JAMS shall be final and binding. Judgment upon the award rendered by such arbitrator may be entered in any court having jurisdiction thereof, and the parties consent to the jurisdiction of the New York courts for this purpose. The prevailing party shall be entitled to recover the costs of arbitration (including reasonable attorneys' fees and the fees of experts) from the losing party. If at th e time any dispute or controversy arises with respect to this Release Agreement, JAMS is not in business or is no longer providing arbitration services, then the American Arbitration Association shall be substituted for JAMS for the purposes of the foregoi ng provisions of this Section 15(b).

(c) In the event Employee violates or breaches any covenant set forth in this Release Agreement, including the covenants referenced in Sections 4 through 11 of this Release Agreement, in any manner, the Company's obligation to provide the payments and benefits provided for in Section 2 and all other obligations of the Company under this Release Agreement will terminate immediately and the Company shall have the right to pursue further damages, as provided for under applicable law and the Employment Agreement. In the event of Employee's actual or threatened breach of any of the covenants referenced in Sections 4 through 11 of this Release Agreement, the Company shall have the right and remedy to have such provisions specifically enforced by any court having equity jurisdiction, it being acknowledged and agreed that any such breach or threatened breach will cause irreparable injury to the Company.

16. Successors and Assigns . This Release Agreement shall be inure to the benefit of the successors and assigns of the Company.

17. Severability . (a) If any portion of this Release Agreement is ruled unenforceable, all remaining portions of this Release Agreement shall remain valid and shall not affect the validity of the releases in this Release Agreement. Furthermore, an award of any damages for breach of this Release Agreement will not affect the validity of the releases in this Release Agreement.

(b) If any provision of this Release Agreement is adjudged by any court of law to be void or unenforceable in its entirety, the Company and Employee agree to cooperate to come up with a mutually acceptable alternative provision(s) to adequately protect the intent of the parties to provide Employee with the consideration set forth in Section 2 in

exchange for Employee's execution of a release of claims against the Company and the Employee's covenants set forth herein.

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

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

20. Notice . All documents, notices, requests, demands and other communications that are required or permitted to be delivered or given under this Release Agreement shall be in writing and shall be deemed to be given: (x) upon delivery, if delivered in person; (y) upon delivery, if sent by facsimile, provided that notice is also sent by first class mail (registered or certified), return receipt requested, with proper postage prepaid; or (z) five business days after being sent by first class mail (registered or certified), return receipt requested, with proper postage prepaid, and in each case, addressed as follows

(a) If to Employee:

Mr. Michael Demurjian
1400 Winesap Drive
Manasquan, New Jersey 08736

(b) If to Employer:

Tyme Technologies, Inc.
17 State Street, 7th Floor
New York, New York 10004
Attention: Chief Executive Officer
Chief Counsel

21. Section 409A . This Release Agreement is intended to comply with Section 409A of the Code and will be interpreted in a manner intended to comply with Section 409A of the Code. To the extent any reimbursements or in-kind benefits due to the Employee under this Release Agreement constitutes "deferred compensation" under Section 409A of the Code, any such reimbursements or in-kind benefits shall be paid to Employee in a manner consistent with Treas. Reg. Section 1.409A-3(i)(1)(iv). Each payment made under this Release Agreement shall be designated as a "separate payment" within the meaning of Section 409A of the Code.

EMPLOYEE WITHOUT ANY DURESS OR COERCION FREELY, KNOWINGLY AND VOLU NTARILY ENTERS INTO AND GIVES THIS RELEASE AGREEMENT. EMPLOYEE UNDERSTANDS AND AGREES WITH ALL OF THE PROVISIONS AND THE TERMS STATED IN THIS RELEASE AGREEMENT AND HAS BEEN AFFORDED SUFFICIENT AND REASONABLE TIME TO CONSIDER WHETHER TO ENTER INTO THIS REL EASE AGREEMENT. EMPLOYEE HAD ADEQUATE OPPORTUNITY TO CONSULT WITH AN ATTORNEY OF EMPLOYEE'S CHOOSING PRIOR TO EXECUTING THIS RELEASE AGREEMENT WHICH CONTAINS A RELEASE AND WAIVER. THIS RELEASE AGREEMENT SHALL BE IMMEDIATELY EFFECTIVE AND IRREVOCABLE UPON EXECUTION BY EMPLOYEE AND THE COMPANY.

/s/ Michael Demurjian
Michael Demurjian

March 15, 2019
Date

/s/ Steven Hoffman
Steven Hoffman
Chief Executive Officer
Tyme Technologies, Inc.

March 15, 2019
Date

EXHIBIT 10.19

TYME TECHNOLOGIES, INC.
17 State Street – 7 th Floor
New York, New York 10004

September 10, 2018

Mr. James Biehl

Dear Jim:

This letter (this " **letter agreement** ") sets forth our agreement with respect to your employment with Tyme Technologies, Inc., a Delaware corporation (the " **Company** ").

1. Employment . You will be employed by the Company upon the terms and conditions set forth in this letter agreement for the period effective as of the date hereof (the " **Effective Date** ") and ending as provided in Section 4 (the " **Employment Period** "). Prior to the Effective Date, you shall provide consulting services to the Company on an "as needed" basis, subject to your other personal and business obligations.

2. Position and Duties . During the Employment Period, you will serve as Chief Legal Officer of the Company and will have the usual and customary duties, responsibilities and authorities of a person in such positions and such other duties assigned to you by the Chief Executive Officer of the Company (the " **CEO** ") which are consistent with your positions. You will report directly to the CEO and the Board of Directors of the Company (the " **Board** "). You will devote your full working time, efforts and attention to, and diligently and conscientiously perform the duties of, such positions. In addition to performing such duties for the Company, you may be required to perform similar duties for the Company's existing subsidiaries or affiliates, and/or any subsidiaries and/or affiliates which may be formed or acquired from time to time in the future, including without limitation Tyme Inc., a Delaware corporation, and Luminant Biosciences, LLC (collectively, all such subsidiaries and/or affiliates shall be referred to as the " **Company Affiliates** "). Notwithstanding anything to the contrary contained in this letter agreement, you may provide outside counsel services to third parties (the " **Third Party Services** "); provided that (x) the time and efforts extended by you in providing the Third Party Services do not interfere with your work, efforts and attention to your duties to the Company and (y) in connection with your providing the Third Party Services, you do not in any way or manner note your position with the Company, use your Company provided URL address, telephone number, stationery, computer or other equipment, nor hold meetings at the Company's facilities. Except for travel for business purposes, you will be employed and your primary office will be located at the Company office anticipated to be located in or near Princeton, New Jersey (the " **Company Office** ").

3. Compensation .

(a) During the Employment Period, your base salary will be $450,000.00 per annum (your " **Base Salary** "). Your Base Salary will be payable in regular installments in accordance with the Company's general payroll practices and subject to withholding and other

payroll taxes. Your Base Salary may be reviewed annually (beginning on or about April 1, 2019) by the Board and may be increased by t he Board in its sole discretion. Unless agreed by you in writing, your Base Salary may not be decreased by the Board or otherwise.

(b) In addition to your Base Salary, you shall receive a signing bonus of $100,000.00, payable in full on the next regular payroll payment date following the Effective Date.

(c) You will also be entitled, conditioned upon your continued employment with the Company or one of the Company Affiliates through and including the applicable date of payment, to receive one or more special bonuses (each, a " **Performance Bonus** "), in such amount(s), for such period(s) and based on such criteria as determined from time to time, and if ever, by the Board in the Board's sole discretion.

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

(e) The Company shall reimburse you for all reasonable out-of-pocket business expenses incurred by you on behalf of the Company during the Employment Period; provided that you properly account to the Company for all such expenses in accordance with the policies of the Company and the rules, regulations and interpretations of the U.S. Internal Revenue Service relating to reimbursement of business expenses (" **Expenses** "). In addition, the Company shall reimburse you for all reasonable costs and expenses charged by the third parties in connection with the relocation of your office furniture and business files from their present location to the Company Office.

(f) During the Employment Period, the Company will maintain Directors and Officers Liability Insurance coverage that includes coverage of you, subject to the terms and conditions of such policy and with limits customary for similarly situated companies.

(g) In addition to the other compensation to which you are entitled under this letter agreement, effective as of the Effective Date, the Company shall grant you a ten-year option (the " **Option** ") to purchase up to 500,000 shares of the common stock, par value $0.0001 per share (the " **Common Stock** "), of the Company under the Company's 2015 Equity Incentive Plan (the " **2015 Plan** "), at an exercise price per share equal to the closing per share price of the Common Stock on the Effective Date, as reported by the Nasdaq Stock Market, such option shares to vest over a three-year period in equal quarterly installments of 41,666 shares (41,674 shares, in the case of the final installment). The Option will be evidenced by a Nonqualified Option Agreement (the " **Option Agreement** ") in the form attached as **Exhibit A** to this letter agreement. In the event of any conflict between the description and terms of the Option contained in this letter agreement and the description and terms contained in the Option Agreement (including without limitation

refe rences in the Option Agreement to the terms and conditions of the 2015 Plan), the description and terms contained in the Option Agreement shall govern.

(h) The Company shall reimburse you for all (x) registration and other fees and occupational taxes charged by state authorities to maintain your license to practice law in the State of New Jersey and Commonwealth of Pennsylvania and (y) fees and other reasonable Expenses incurred in connection with your attendance at and participation in continuing legal education courses and classes in order to maintain your license to practice law under the laws of the State of New Jersey and Commonwealth of Pennsylvania and regulations, promulgated under such laws.

4. Termination . The Employment Period will end on the date which is 30 months (*i.e.* , 2-½ years) following the Effective Date (the " **Expiration Date** "), unless sooner terminated as provided below. Unless the Employment Period has been terminated in accordance with the following sentence of this Section 4, commencing with the six-month anniversary of the Effective Date, and on each subsequent six-month anniversary thereafter, the Expiration Date shall automatically be extended by an additional six months, such that, on any given day during the Employment Period, the remaining Employment Period shall never be less than two years and one day. Notwithstanding the foregoing, the Employment Period (i) will terminate upon your death, (ii) may be terminated by the Company upon Notice of Termination (as defined in Section 5(e) below) delivered to you as a result of your Disability (as defined in Section 5(g) below), (iii) may be terminated by the Company at any time for Cause (as defined in Section 5(f) below), (iv) may be terminated by you for Good Reason (as defined in Section 5 (h) below) and (v) may be terminated by the Company without Cause or by you without Good Reason.

5. Severance .

(a) If the Employment Period is terminated by the Company without Cause or by you for Good Reason, you will be entitled to receive (i) your Base Salary as in effect at the time of such termination to the extent such amount has accrued through the Termination Date (as defined in Section 5(e) below) and remains unpaid, (ii) any fully earned and declared but unpaid Performance Bonus as of the Termination Date, (iii) an amount equal to the sum of your Base Salary that you would have received from the Termination Date through the then applicable Expiration Date , which shall be payable in the same amounts and at the same intervals as if the Employment Period had not ended, (iv) except as set forth in the final sentence of this Section 5(a), immediate and full vesting of all your equity awards, (v) if you timely elect continued coverage pursuant to COBRA, payment of your share of the premium cost at the same rate as for active employees of the Company for the 18-month period following the Termination Date and (vi) any unpaid Expenses as of the Termination Date. Except as set forth in Section 5(d), upon delivery of the payments and benefits described in this Section 5(a), the Company shall have no further obligation to you under this letter agreement or otherwise with respect to your employment with the Company; provided , however , the Company's obligation to make the payments to you described in clauses (iii), (iv) and (v) of this Section 5(a) is conditioned upon your executing and delivering, no later than 45 days following the Termination Date (and not revoking), a release relating to your employment by the Company in favor of the Company, the Company Affiliates and their respective stockholders, officers, members, managers, directors, employees, subsidiaries and affiliates substantially in the form attached as **Exhibit A** ; provided , further , that until the period to revoke such release has expired, the Company shall retain any Base Salary installment payment

that would otherwise be made pursuant to clause (iii) of this Section 5(a), wi th such payment being made on the next regularly scheduled payroll date after such revocation period expires. In the event that the Company's delivers written notice to you that the Board, in its good faith and reasonable judgment, has determined that you have been negligent in the performance of your duties, provided that you have been given an opportunity of no less than 30 days after receipt of such notice to cure any such instances of negligence, if the Company terminates your employment without Cause following the Board's good faith, reasonable determination that you have failed to cure, any unvested equity awards that you hold will be forfeited.

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

(c) If the Employment Period is terminated due to your Disability (as defined in Section 5(g) below) or death, the Company will pay you or your estate, whichever is applicable, (i) your Base Salary as in effect at the time of such termination to the extent such amount has accrued through the Termination Date and remains unpaid, (ii) any fully earned and declared but unpaid Performance Bonus as of the Termination Date, and (iii) any unpaid Expenses as of the Termination Date. Except as set forth in Section 5(d), upon delivery of the payments described in this Section 5(c), the Company will have no further obligation to you under this letter agreement or otherwise with respect to your employment with the Company.

(d) Except as otherwise required by law or as specifically provided herein, all of your rights to salary, severance, fringe benefits, bonuses and any other amounts hereunder (if any) accruing after the termination of the Employment Period will cease upon the earlier of the Termination Date and your last day of active service. In the event the Employment Period is terminated, your sole remedy, and the sole remedy of your successors, assigns, heirs, representatives and estate, will be to receive the payments described in this letter agreement. Notwithstanding the foregoing, the following rights will survive any termination of the Employment Period: (i) your rights to accrued and vested benefits under any benefit plan of the Company or any of the Company Affiliates, or as set forth in any other agreement between you and the Company or any of the Company Affiliates, (ii) your right to continued participation in the Company's health and welfare plans, except as otherwise provided in Section 5(a)(v), at your own expense pursuant to COBRA, (iii) your right to indemnification in respect of your service as a director or officer of the Company or any of the Company Affiliates, to the maximum extent provided under applicable law, the Company's Certificate of Incorporation and By-laws (each, as they may be amended from time-to-time), and any other agreement between you and the Company, (iv) your rights in respect of shares of Common Stock that you hold and (v) your rights in respect of any equity-based awards that remain outstanding following the Employment Period (subject to the provisions of this Agreement and any equity plan or award agreement that governs the terms of such equity-based awards).

(e) Any termination of the Employment Period by the Comp any (other than termination upon your death) or by you must be communicated by written notice (in either case, a " **Notice of Termination** ") to you, if the Company is the terminating party, or to the Company, if you are the terminating party. For purposes of this letter agreement, " **Termination Date** " means (i) if the Employment Period is terminated due to your death, the date of your death and (ii) if the Employment Period is terminated due to your Disability, by the Company (for Cause or without Cause) or by you (for Good Reason or without Good Reason), the date specified in the Notice of Termination (which may not be earlier than the date of such Notice of Termination). Notwithstanding anything contained herein to the contrary, any termination of the Employm ent Period by you must be communicated to the Company no less than 30 days prior to the intended Termination Date.

(f) For purposes of this letter agreement, " **Cause** " means any one of the following: (i) a material breach by you of this letter agreement, (ii) your conviction of, guilty plea to, or confession of guilt of, a felony involving the Company, (iii) materially fraudulent, dishonest or illegal conduct by you in the performance of services for or on behalf of the Company or any of the Company Affiliates, (iv) any repeated conduct by you in material violation of Company policy, (v) any conduct by you that is materially detrimental to the reputation of the Company or any of the Company Affiliates, (vi) your misappropriation of funds of the Company or any of the Company Affiliates, (vii) your gross negligence or wilful misconduct or wilful failure to comply with written directions of the Board which directions are within the scope of your duties hereunder, or (viii) your engaging in conduct involving an act of moral turpitude. A purported termination of your employment for Cause shall not be effective unless (A) the Company provides written notice to you of the facts alleged by the Company to constitute Cause and such notice is delivered to you no more than 90 days after the Company has actual knowledge of such facts and (B) you have been given an opportunity of no less than ten days after receipt of such notice to cure the circumstances alleged to give rise to Cause and the Company, has cooperated in good faith with your efforts to cure such condition or circumstance, but only to the extent that such circumstances are reasonably curable.

(g) For purposes of this letter agreement " **Disability** " means any accident, sickness, incapacity or other physical or mental disability which prevents you from performing substantially all of the duties you have been assigned by the Company or any of its subsidiaries for either (i) 90 consecutive days or (ii) 180 days during any period of 365 consecutive days, in each case as determined in good faith by the Board. During the time periods specified above, the Company will continue to provide you with the compensation stated in Section 3 above.

(h) For purposes of this letter agreement, " **Good Reason** " means (i) a material diminution in your authority, title, duties or responsibilities, (ii) the failure of the Company to make all payments due to you under this letter agreement or otherwise or (iii) the relocation of your primary office to a location more than 25 miles from the Company Office. A purported termination of your employment for Good Reason shall not be effective unless (A) you provide written notice to the Company of the facts alleged by you to constitute Good Reason and such notice is delivered to the Board no more than 90 days after the occurrence of such event, (B) the Company has been given an opportunity of no less than 30 days after receipt of such notice to cure the circumstances alleged to give rise to Good Reason and you have cooperated in good faith with the Company's efforts to cure such condition or circumstance (which cooperation will not require

Executive to waive or diminish any of his rights hereunder), but only to the extent that such circumstances are reasonably curable, and (c) you elect to terminate the Employmen t Period within 30 days following the end of the Company's cure period due to the Company's failure to cure.

6. Change of Control .

(a) In the event of a Change of Control (as defined in the 2015 Plan or a successor plan), all equity awards you hold shall, to the extent unvested, fully vest as of immediately prior to such Change of Control.

(b) Notwithstanding any other provision of this letter agreement:

(i) In the event it is determined by an independent nationally recognized public accounting firm that is reasonably acceptable to you, which is engaged and paid for by the Company prior to the consummation of any transaction constituting a 280G Change of Control (which for purposes of this Section 6(b) shall mean a change in ownership or control as determined in accordance with the regulations promulgated under Section 280G of the Internal Revenue Code of 1986, as amended (the " **Code** "), which accounting firm shall in no event be the accounting firm for the entity seeking to effectuate the 280G Change of Control (the " **Accountant** "), which determination shall be certified by the Accountant and set forth in a certificate delivered to you not less than ten business days prior to the 280G Change of Control setting forth in reasonable detail the basis of the Accountant's calculations (including any assumptions that the Accountant made in performing the calculations), that part or all of the consideration, compensation or benefits to be paid to you under this letter agreement constitute "parachute payments" under Section 280G(b)(2) of the Code, then, if the aggregate present value of such parachute payments, singularly or together with the aggregate present value of any consideration, compensation or benefits to be paid to you under any other plan, arrangement or agreement which constitute "parachute payments" (collectively, the " **Parachute Amount** ") exceeds the maximum amount that would not give rise to any liability under Section 4999 of the Code, the amounts constituting "parachute payments" which would otherwise be payable to you or for your benefit shall be reduced to the maximum amount that would not give rise to any liability under Section 4999 of the Code (the " **Reduced Amount** "); provided that such amounts shall not be so reduced if the Accountant determines that without such reduction you would be entitled to receive and retain, on a net after-tax basis (including, without limitation, any excise taxes payable under Section 4999 of the Code), an amount which is greater than the amount, on a net after-tax basis, that you would be entitled to retain upon receipt of the Reduced Amount. In connection with making determinations under this Section 6(b), the Accountant shall take into account any positions to mitigate any excise taxes payable under Section 4999 of the Code, such as the value of any reasonable compensation for services to be rendered by you before or after the 280G Change of Control.

(ii) If the determination made pursuant to Section 6(b) results in a reduction of the payments that would otherwise be paid to you except for the

application of Section 6(b), the Company shall promptly give you notice of such determination. Such reduction in payments shall be first applied to reduce any cash payments that you would otherwise be entitled to receive (whether pursuant to this letter agreement or otherwise) and shall thereafter be applied to reduce other payments and benefits, in each case, in reverse order beginning with the payments or benefits that are to be paid the furthest in time from the date of such determination, unless, to t he extent permitted by Section 409A (as defined in Section 13(h)), you elect to have the reduction in payments applied in a different order; provided that, in no event may such payments be reduced in a manner that would result in subjecting you to addition al taxation under Section 409A. Within ten business days following such determination, the Company shall pay or distribute to you or for your benefit such amounts as are then due to you under this letter agreement and shall promptly pay or distribute to y ou or for your benefit in the future such amounts as become due to you under this letter agreement.

(iii) As a result of the uncertainty in the application of Sections 280G and 4999 of the Code at the time of a determination hereunder, it is possible that amounts will have been paid or distributed by the Company to or for your benefit pursuant to this letter agreement which should not have been so paid or distributed (each, an " **Overpayment** ") or that additional amounts which will have not been paid or distributed by the Company to or for your benefit pursuant to this letter agreement could have been so paid or distributed (each, an " **Underpayment** "), in each case, consistent with the calculation of the Reduced Amount hereunder. In the event that the Accountant, based upon the assertion of a deficiency by the Internal Revenue Service against either the Company or you which the Accountant believes has a high probability of success, determines that an Overpayment has been made, any such Overpayment paid or distributed by the Company to or for your benefit shall be repaid by you to the Company together with interest at the applicable federal rate provided for in Section 7872(f)(2)(A) of the Code; provided , however , that no such repayment shall be required if and to the extent such deemed repayment would not either reduce the amount on which you are subject to tax under Sections 1 and 4999 of the Code or generate a refund of such taxes. In the event that the Accountant, based on controlling precedent or substantial authority, determines that an Underpayment has occurred, any such Underpayment shall be promptly paid by the Company to or for your benefit together with interest at the applicable federal rate provided for in Section 7872(f)(2)(A) of the Code.

(iv) In the event of any dispute with the Internal Revenue Service (or other taxing authority) with respect to the application of this Section 6(b), you shall control the issues involved in such dispute and make all final determinations with regard to such issues. Notwithstanding anything herein to the contrary, the Company shall promptly pay, upon demand by you, all legal fees, court costs, fees of experts and other costs and expenses which you incur no later than ten years following your death in any actual, threatened or contemplated contest of your interpretation of, or determination under, the provisions of this Section 6(b).

7. Confidential Information .

(a) You will not disclose or use at any time any Confidential Information (as defined below in Section 7(c)), whether or not such information is developed by you, except to the extent that such disclosure or use is required in the performance or exercise by you in good faith of (i) duties assigned to you under this letter agreement or otherwise by the CEO or Board, (ii) rights as an employee, officer, director or shareholder of the Company or any of the Company Affiliates or (iii) rights under any agreement with the Company or any of the Company Affiliates.

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

(c) As used in this letter agreement, the term " **Confidential Information** " means information that is not generally known or available to the public and that is used, developed or obtained by the Company or any of the Company Affiliates in connection with its or their businesses, including without limitation (i) information, observations and data concerning its and their business and affairs, (ii) products or services, (iii) fees, costs and pricing structures, (iv) designs, (v) analyses, (vi) drawings, designs, photographs, artwork and reports, (vii) computer software, including operating systems, applications and program listings, (viii) flow charts, manuals and documentation, (ix) data bases, (x) accounting and business methods, (xi) inventions, devices, new developments, methods and processes, whether patentable or unpatentable and whether or not reduced to practice, (xii) other copyrightable works, (xiii) all production methods, processes, technology and trade secrets, (xiv) product and product candidate formulae and any trade secrets with respect to such products and product candidates and (xv) all similar and related information in whatever form.

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

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

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

(e) Notwithstanding the foregoing, nothing in or about this letter agreement prohibits you from (i) filing and, as provided for u nder Section 21F of the Securities Exchange Act of 1934, as amended (the " **Exchange Act** "), maintaining the confidentiality of a claim with the Securities and Exchange Commission (the " **SEC** "); (ii) providing Confidential Information to the SEC, or providing t he SEC with information that would otherwise violate this Section 7, to the extent permitted by Section 21F of the Exchange Act; (iii) cooperating, participating or assisting in an SEC investigation or proceeding concerning the Company without notifying th e Company; or (iv) receiving a monetary award as set forth in Section 21F of the Exchange Act. Furthermore, you are advised that you shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of any Confi dential Information that constitutes a trade secret to which the Defend Trade Secrets Act (18 U.S.C. Section 1833(b)) applies that is made (A) in confidence to a federal, state or local government official, either directly or indirectly, or to an attorney, in each case, solely for the purpose of reporting or investigating a suspected violation of law or (B) in a complaint or other document filed in a lawsuit or proceeding, if such filings are made under seal.

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

9. Non-Competition; Non-Solicitation; Non-Disparagement .

(a) You acknowledge that, in the course of your employment with the Company, you will become familiar with the Company's and the Company Affiliates' trade secrets

and with other Confidential Information concerning the Company and the Company Affiliates and that your services will be of special, unique and extraordinary value to the Company and the Company Affiliates. Therefore, y ou agree that, during the Restriction Period (as defined in Section 9(b) below), you will not (x) anywhere the Company or any of the Company Affiliates conducts business or (y) anywhere the Company or any of the Company Affiliates has spent time and resour ces in connection with expanding its business, directly or indirectly, either on your own behalf or on behalf of any other person, firm or entity:

(i) own, manage, operate, consult with, provide financing to, or join, control or participate in the ownership, management, operation or control of, any business wherever located (whether in corporate, proprietorship or partnership form or otherwise), if such business is competitive with the business of the Company; or

(ii) except as permitted by Section 7(e), say anything which is harmful to the reputation of the Company or any of the Company Affiliates or which could be reasonably expected to lead any person to cease to deal with the Company or any of the Company Affiliates on substantially equivalent terms to those previously offered or at all.

(b) For purposes of this letter agreement, " **Restriction Period** " means during the Employment Period, and for a period of one year following your receipt of the final payment described in Section 5, as applicable.

(c) Nothing in Section 9(a) will (x) prohibit you from being a passive owner of not more than 2% of the outstanding stock of a publicly-traded corporation, so long as you have no active participation in the business of such corporation or (y) prohibit you, following the termination of your employment by the Company, from acting as a legal counsel, consultant, employee, officer or director of a business that is in competition with the business of the Company; provided that the provisions of Section 7 shall continue to govern the disclosure or use of Confidential Information.

(d) During the Restriction Period, you will not:

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

(ii) engage, employ, solicit or contact with a view to the engagement or employment of, any employee, officer or manager of, or full-time consultant to, the Company or any of the Company Affiliates or any person who has been an employee, officer or manager of, or consultant to, the Company or any of the Company Affiliates at any time during the two-year period ending on the date of such determination.

(e) Nothing in clause (ii) of Section 9(d) shall prohibit you, following the termination of your employment by the Company, in connection with yo ur work for a future employer, from making or initiating a solicitation of employment distributed to the general public and engaging a current or former Company employee, officer, manager or consultant who responded to such general public solicitation.

(f) The Company, on behalf of itself and all of the Company Affiliates, agrees that during the Restriction Period they and their executive officers (or other persons acting on their behalf) will not say anything which is harmful to your reputation or which could be reasonably expected to lead any person to cease to deal with you or engage you in any consulting or employment position.

10. Enforcement .

(a) Because the employment relationship between you and the Company is unique and because you have access to Confidential Information and Work Product, you agree that money damages would be an inadequate remedy for any breach of Section 7, 8 or 9. Therefore, in the event of a breach or threatened breach of Section 7, 8 or 9, the Company may, in addition to its other rights and remedies, apply to any court of competent jurisdiction for specific performance and/or injunctive or other relief in order to enforce, or prevent any violations of, such provisions (without posting a bond or other security).

(b) Sections 5, 6, 7, 8 and 9 will expressly survive termination of this letter agreement. The existence of any claim or cause of action by you against the Company and/or any of the Company Affiliates shall not constitute a defense to the enforcement by the Company of the covenants contained in Section 6(b), 7, 8 or 9, but such claim or cause of action shall be litigated separately.

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

If to the Company, to:

Steve Hoffman, Chief Executive Officer
Tyme Technologies, Inc.
17 State Street - 7 th Floor
New York, New York 10004

and with a copy (which shall not constitute notice) to:

Keith S. Braun, Esq.
Moritt Hock & Hamroff LLP
400 Garden City Plaza
Garden City, New York 11530

If to you, to the address appearing in the Company's records.

Any party hereto may send any notice, request, demand, claim or other communication hereunder to the intended recipient at the address set forth above using any other means, but no such notice, request, demand, claim or other communication will be deemed to have been duly given unless and until it actually is received and acknowledged by the intended recipient. Any party hereto may change the address (or add new parties and their addresses) to which notices, requests, demands, claims, and other communications hereunder are to be delivered by giving the other parties hereto notice in the manner set forth in this Section 11.

12. Representations and Warranties . You hereby represent and warrant to the Company that (a) the execution, delivery and performance of this letter agreement by you does not and will not conflict with, breach, violate or cause a default under any agreement, contract or instrument to which you are a party or any judgment, order or decree to which you are subject, (b) you are not a party to or bound by any employment agreement, consulting agreement, non-compete agreement, confidentiality agreement or similar agreement with any other person or entity that is inconsistent with the provisions of this letter agreement, (c) upon the execution and delivery of this letter agreement by the Company and you, this letter agreement will be a valid and binding obligation of you and (d) you are in good health and are not suffering from, and have never suffered from, any serious illness, disease or other physical or mental condition that has prevented or materially interfered with, or might reasonably be expected in the future to prevent or materially interfere with, your ability to perform those services described in this letter agreement. The Company hereby represents and warrants to you that (i) the execution, delivery and performance of this letter agreement and the Option Agreement by the Company does not and will not conflict with, breach, violate or cause a default under any agreement, contract or instrument to which it is a party or any judgment, order or decree to which it is subject and (ii) upon the execution and delivery of this letter agreement and the Option Agreement by the Company and you, such agreements will be valid and binding obligations of the Company.

13. General Provisions .

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

(b) Complete Agreement . This letter agreement and any schedules or exhibits expressly constitute the entire agreement among the parties hereto with respect to the subject

matter hereof and supersedes and pre-empts any prior understandings, agreements or representations by or among the parties, written or oral, which may have related to the subject matter hereof in any way.

(c) Successors and Assigns . Except as otherwise provided herein, this letter agreement will be binding upon and inure to the benefit of you and the Company and our respective successors, permitted assigns, personal representatives, heirs and estates, as the case may be; provided , however , that your rights and obligations under this letter agreement will not be assigned without the prior written consent of the Company.

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

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

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

(g) Counterparts . This letter agreement may be executed in counterparts, each of which will be deemed an original and all of which together will constitute one and the same instrument. The signatures of any of the persons executing this letter agreement may be transmitted via facsimile or other electronic means and shall be sufficient evidence of the execution of this letter agreement.

(h) 409A Provision . (i) For purposes of this letter agreement the term " **termination of employment** " and similar terms relating to your termination of employment mean a " **separation from service** " as that term is defined under Section 409A of the Internal Revenue Code of 1986, as amended, and the final regulations issued thereunder (" **Section 409A** "). The Company and you intend that this letter agreement comply in form and operation with the requirements of Section 409A, and all provisions of this letter agreement shall be construed and interpreted in a manner consistent with the requirements for avoiding taxes or penalties under Section 409A. To the extent permitted by applicable Department of Treasury/Internal Revenue Service guidance, or law or regulation, the Company and you will take reasonable actions to reform this letter agreement or any actions taken pursuant to their operation of this letter agreement in order to comply with Section 409A.

(ii) For purposes of Section 409A, each of the payments that may be made hereunder is designated as a separate payment. To the extent that the Company determines that any payment or benefit pursuant to this letter agreement constitutes deferred compensation (within the meaning of Section 409A), such

payment or benefit shall be made at such times and in such forms as the Company determines are required to comply with Section 409A (including, without limitation, in the case of a "specified employee" within the meaning of Section 409A, the six-month delay for amounts payable upon a separation from service) and the Treasury Regulations and any applicable guidance thereunder.

(iii) Except as specifically permitted by Section 409A or as otherwise specifically set forth in this letter agreement, the benefits and reimbursements provided to you under this letter agreement and any Company plan or policy during any calendar year shall not affect the benefits and reimbursements to be provided to you under the relevant section of this letter agreement or any Company plan or policy in any other calendar year, and the right to such benefits and reimbursements cannot be liquidated or exchanged for any other benefit and shall be provided in accordance with Treas. Reg. Section 1.409A-3(i)(1)(iv) or any successor thereto. Further, in the case of reimbursement payments, reimbursement payments shall be made to you as soon as practicable following the date that the applicable expense is incurred and proper documentation is provided to the Company, but in no event later than the last day of the calendar year following the calendar year in which the underlying expense is incurred.

(i) Reimbursement of Legal Review Expenses . Upon execution of this letter agreement by you, the Company shall reimburse you for your reasonable legal costs and expenses that you have incurred in the negotiation and execution of this letter agreement, such reimbursement amount not to exceed $5,000.00 in total. Reimbursement will be made promptly after the Company's receipt of an invoice for such costs and expenses and, in any event, in accordance with Section 13(h)(iii).

(j) "Business Day" Defined . For purposes of this letter agreement, the capitalized term " **Business Day** " shall mean any calendar day other than a Saturday, Sunday or other day on which banks in New York, New York are authorized or required to be closed.

[THE REMAINDER OF THIS PAGE HAS INTENTIONALLY BEEN LEFT BLANK]

If this letter agreement correctly expresses our mutual understanding, please sign and date a copy of this letter agreement and return it to the Company.

Very truly yours,

Tyme Technologies, Inc.

By :/s/ Steve Hoffman

Name: Steve Hoffman
Title: Chief Executive Officer

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

/s/ James Biehl
James Biehl

EXHIBIT A
Form of Nonqualified Option Agreement

EXHIBIT B
Form of Release

RELEASE

This Release (" **Release** ") is delivered by James Biehl on this __ day of _____, 20__.

DEFINITIONS

A. As used herein, unless otherwise specified, the term " **Employer** " shall mean Tyme Technologies, Inc., and all of its affiliates, successors, predecessors, assigns, parents, subsidiaries, divisions (whether incorporated or unincorporated), and all of its and their past and present owners, directors, officers, trustees, shareholders, managers, employees and agents (in their individual and representative capacities).

B. As used herein, unless otherwise specified, the term " **Employee** " shall mean James Biehl and all of his heirs, family members, executors, accountants, administrators, attorneys, agents, assigns, successors and representatives.

RECITALS

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

WHEREAS, it is a condition to Employee's receipt of certain post-employment benefits (" **Conditional Benefits** ") under Sections 5(a)(iii), (iv) and (v) of the letter agreement, dated September 10, 2018 (the " **Employment Agreement** "), between Employee and Employer that Employee execute this Release.

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

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

2. Release of All Claims . In consideration of the above, and the other promises set forth in this Release, Employee fully and forever waives, releases, acquits and discharges Employer from and for all manner of claims, actions, suits, charges, grievances and/or causes of action, in law or in equity, existing by reason of and/or based upon any fact or set of facts, known or unknown, existing from the beginning of time through the effective date of this Release relating to and/or arising out of the Employment Agreement, Employee's employment with Employer and/or the cessation of Employee's employment with Employer (collectively, the " **Released Claims** "), including, but not limited to, all claims, actions, suits, charges, grievances and/or causes of action for wages, compensation, liquidated damages, commissions, bonuses, benefits, sums of money, damages of every type, costs, attorney fees, judgments, executions, wrongful discharge,

breach of contract, breach of implied contract, breach of the covenant of good faith and fair dealing, tortious interference with contract or business relationships, assault, battery, invasion of privacy, misappropriation of trade secrets, promissory estoppel, unjust enrichment, loss o f consortium, violation of the penal statutes, negligent or intentional infliction of emotional distress, negligence, defamation, retaliation and/or discrimination and/or harassment on account of age, sex, sexual orientation, creed, religion, race, color, national origin, sensory disability, mental disability, physical disability, veteran or military status, marital status, or any other classification recognized under all applicable discrimination laws, or any other claim or cause of action, which has or co uld have been alleged under the common law, civil rights statutes, Title VII of the Civil Rights Act of 1964 (" **Title VII** "), the Age Discrimination in Employment Act (" **ADEA** "), the Family and Medical Leave Act (" **FMLA** "), the Employee Retirement Income Securit y Act (" **ERISA** "), the Rehabilitation Act of 1973, the Older Workers Benefits Protection Act (" **OWBPA** "), the Americans with Disabilities Act (" **ADA** "), The Consolidated Omnibus Budget Reconciliation Act (" **COBRA** "), the Workers Adjustment Retraining Notification Act (" **WARN** "), the Equal Pay Act (" **EPA** "), the Uniformed Services Employment and Reemployment Rights Act (" **USERRA** "), the National Labor Relations Act (" **NLRA** "), any and all federal, state, local statutes, ordinances, and laws, and every type of relief (legal, equitable and otherwise), available to Employee. Employee covenants and agrees that he will not pursue or allege any claim, matter or cause of action in violation of, and/or released under, this Release. Nothing in this Release shall be construed as rel easing Employer from, and the Released Claims shall not include: (a) any obligation to pay those amounts due to Employee under Section 5(a) of the Employment Agreement, subject to the terms and conditions thereof; (b) Employee's rights to enforce the term s of the Employment Agreement that survive the termination of the Employment Period (as defined in the Employment Agreement); (c) Employee's rights described in Section 5(d) of the Employment Agreement; (d) Employee's non-forfeitable rights to accrued bene fits (within the meaning of Sections 203 and 204 of ERISA), (e) Employee's right to indemnification or exculpation under the Employment Agreement, Employer's policies or law with respect to Employee's service as a director or officer of Employer; (f) any c laims for wages that are due and owing to Employee; (g) any claims that by law cannot be waived by private agreement without judicial or governmental supervision; or (h) Employee's right to file a charge with or participate in any investigation or proceedi ng conducted by the U.S. Equal Employment Opportunity Commission (" **EEOC** ") or similar government agency; provided that even though Employee can file a charge or participate in an investigation or proceeding conducted by the EEOC or similar government agency, by executing this Release, Employee is waiving his ability to obtain relief of any kind from Employer to the e xtent permitted by law.

3. Covenant Not to Sue . Employee represents that he has not filed any action, charge, suit, or claim against Employer with any federal, state or local agency or court relating to any Released Claim. Employee further agrees that should any claims, charges, complaints, suits or other actions be filed hereafter on his behalf by any federal, state or local agency or by any other person or entity with respect to a Released Claim, he will immediately withdraw with prejudice, or cause to be withdrawn with prejudice, and/or dismiss with prejudice, or cause to be dismissed with prejudice, any such claims, charges, complaints, suits or other actions filed against Employer. Employee further agrees that, to the fullest extent permitted by law, Employee shall receive no relief of any type (monetary, equitable, or otherwise) with respect to, relating to and/or on account of any such claims, matters or actions. Employee agrees to opt-out of any class action or collective action filed against Employer to the extent related to a Released Claim.

4. Confidentiality . To the fullest extent permitted by law, Employee agrees to keep confidential all facts, opinions, and information which relate in any way to Employee's employment and/or cessation of employ ment with Employer, as well as the terms of this Release; provided however , Employee may discuss the terms of this Release with his spouse, legal representative, and/or tax preparer, each of whom must also agree to maintain confidentiality and comply with this Section 4. Notwithstanding anything herein to the contrary, Section 7(e) of the Employment Agreement will apply to this Release.

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

6. Cooperation .

(a) To the fullest extent permitted by law, Employee will not cooperate with, or assist in, any claim, charge, lawsuit, or arbitration against Employer with respect to a Released Claim, unless required to do so by a lawfully issued subpoena, by court order or as expressly provided by regulation or statute. In the event Employee is served with a subpoena or is required by court order or otherwise to testify in any type of proceeding involving Employer and related to a Released Claim, Employee shall immediately advise Employer in writing of same.

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

7. ADEA Notice and Acknowledgement . Employee acknowledges that he has carefully read this Release and fully understands its contents. Prior to signing this Release, Employee has been advised in writing hereby and has had an opportunity to consult with his attorney of choice concerning the terms and conditions of this Release with regard to any claim or right Employee may have under the ADEA or otherwise. Employee has been offered at least [21][45] days to review and consider this Release. Employee may voluntarily and knowingly waive this [21/45]-day period, or any part thereof, if he signs this Release prior to the expiration of [21/45] days. After signing this Release, Employee shall have seven days from the signing date to revoke this Release. This Release shall not be effective (including for purposes under the Employment Agreement) until after the seven-day revocation period has expired. Any revocation must be made in writing and delivered to the Chief Executive Officer or Chief Financial Officer of Employer. Until all applicable periods set forth in this Section 7 have expired, Employer shall not be required to make any payment to Employee which payment is, under Section 5(a)(iii) or (iv) of the Employment Agreement, contingent upon the signing and delivery to the Company of this Release. By signing this Release, Employee agrees and understands that he is waiving and

releasing any and all rights he may have to pursue claims against Employer, from the beginning of time up to the effective date of th is Release, including, without limitation, all ADEA claims.

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

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

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

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

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

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

Dated:

James Biehl

EXHIBIT 21.1

List of Subsidiaries

Tyme, Inc., a Delaware Corporation ("Tyme")

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

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our reports dated June 12, 2019, with respect to the consolidated financial statements and internal control over financial reporting included in the Annual Report of Tyme Technologies, Inc. on Form 10-K for the year ended March 31, 2019. We consent to the incorporation by reference of said reports in the Registration Statements of Tyme Technologies, Inc. on Forms S-3 (File No. 333-211489 and No. 333-229104) and on Forms S-8 (File No. 333-219856 and No. 333-227077).

/s/ Grant Thornton LLP
New York, New York

June 12, 2019

EXHIBIT 31.1

RULE 13a-14(a)/15d-14(a) CERTIFICATION

I, Steve Hoffman, certify that:

1. I have reviewed this Annual Report on Form 10-K of Tyme Technologies, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: June 12, 2019

/s/ Steve Hoffman

Steve Hoffman
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

RULE 13a-14(a)/15d-14(a) CERTIFICATION

I, Ben R. Taylor, certify that:

1. I have reviewed this Annual Report on Form 10-K of Tyme Technologies, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: June 12, 2019

/s/ Ben R. Taylor

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

EXHIBIT 32.1

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

In connection with the Annual Report on Form 10-K of Tyme Technologies, Inc. (the "Company") for the twelve-month period ended March 31, 2019, to which this certification is being filed as of the date hereof as an exhibit thereto (the "Report"), I, Steve Hoffman, Chief Executive Officer of the Company, and I, Ben R. Taylor, President and Chief Financial Officer of the Company, each 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, as amended (15 U.S.C. 78m or 78 *o* (d)); and

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

Date: June 12, 2019

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

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

THIS CERTIFICATION WILL NOT BE DEEMED "FILED" FOR PURPOSES OF SECTION 18 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, OR OTHERWISE SUBJECT TO THE LIABILITY OF THAT SECTION. SUCH CERTIFICATION WILL NOT BE DEEMED TO BE INCORPORATED BY REFERENCE INTO ANY FILING UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, EXCEPT TO THE EXTENT THAT OUR COMPANY SPECIFICALLY INCORPORATES IT BY REFERENCE. A SIGNED ORIGINAL OF THIS CERTIFICATION HAS BEEN PROVIDED TO THE COMPANY AND WILL BE RETAINED BY THE COMPANY AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.