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, 2020

☐ **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 check mark whether the registrant has filed a report on and attestation to its management's assessment of the e□ectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

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 $101,558,184.

The number of shares outstanding of the registrant's common stock on May 18, 2020 was 123,312,252.

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 2020 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. Such forward-looking statements within this report include, without limitation, statements regarding our drug candidates (including SM-88 and TYME- 18) and their clinical potential and non-toxic safety profiles, our drug development plans and strategies, ongoing and planned clinical trials, preliminary data results and the therapeutic design and mechanisms of our drug candidates. 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 effect of the novel coronavirus (COVID-19) pandemic and the associated economic downturn and impacts on the Company's ongoing clinical trials; the cost of development and potential commercialization of our lead drug candidate and of other new products; expected releases of interim or final data from our clinical trials; possible collaborations; and the timing, scope and objectives of our ongoing and planned clinical trials and other statements that are not historical. The forward-looking statements contained in this report are based on management's current expectations and projections which are subject to uncertainty, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. These statements involve known and unknown risks, uncertainties and other factors which may cause the Company's actual results, performance or achievements to be materially different from any historical results and future results, performance or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include but are not limited to: the severity, duration, and economic impact of the coronavirus pandemic; that the information is of a preliminary nature and may be subject to change; uncertainties inherent in the cost and outcomes of research and development, including the cost and availability of acceptable-quality clinical supply and the ability to achieve adequate clinical study design and start and completion dates; the possibility of unfavorable study results, including unfavorable new clinical data and additional analyses of existing data; risks associated with early, initial data, including the risk that the final data from any clinical trials may differ from prior or preliminary study data; final results of additional clinical trials that may be different from the preliminary data analysis and may not support further clinical development; that past reported data are not necessarily predictive of future patient or clinical data outcomes; whether and when any applications or other submissions for SM-88 may be filed with regulatory authorities; whether and when regulatory authorities may approve any applications or submissions; decisions by regulatory authorities regarding labeling and other matters that could affect commercial availability of SM-88; the ability of TYME and its collaborators to develop and realize collaborative synergies; competitive developments; and the factors described in the section captioned "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K, as well as subsequent reports we file from time to time with the U.S. Securities and Exchange Commission (available at www.sec.gov).

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. Moreover, we operate in a 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 any forward-looking statements we make. We cannot assure you that forward-looking statements in this report or therein will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us to any other person that we will achieve our objectives and plans in any specified time frame, or at all. 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.

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

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

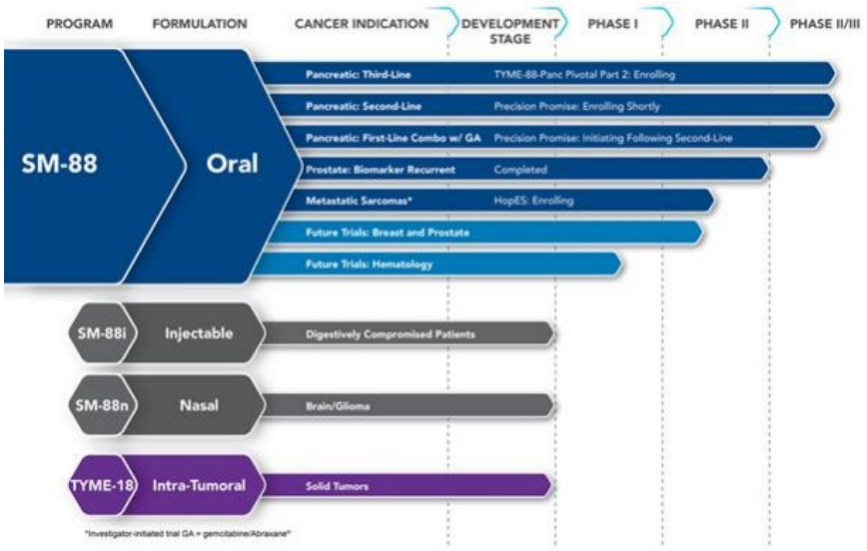
ITEM 1. BUSINESS

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 first-in-class CMBT compounds include SM-88 and TYME-18. These compounds are structurally and mechanistically different, and we believe they offer the potential for better and safer medicines. Early clinical results demonstrated by SM-88 in multiple advanced cancers, including pancreatic, prostate, sarcomas and breast, reinforce the potential of our emerging CMBT pipeline. Moreover, this pipeline offers hope to patients for a new future in long-term management of advanced cancers.

Our lead clinical CMBT compound, SM-88, is an oral investigational modified proprietary tyrosine derivative that is hypothesized to interrupt the metabolic processes of cancer cells by breaking down the cells' key defenses and leading to cell death through oxidative stress and exposure to the body's natural immune system. To date, clinical trial data have shown that SM-88 has achieved confirmed tumor responses across 15 different cancers, both solid and liquid tumors, including pancreatic, lung, breast, prostate, sarcoma and lymphoma cancers with minimal serious Grade 3 or higher adverse events, which we believe is rare for investigational compounds. Our lead compound SM-88 is now in a pivotal trial and an adaptive randomized Phase II/III clinical trial with registration intent for patients with second- and third-line pancreatic cancer. Patients are also being enrolled in a Phase II study evaluating SM-88 in high-risk sarcomas, and we presented final SM-88 Phase II clinical data at European Society for Medical Oncology's ESMO 2019 conference showing encouraging clinical benefit in patients with bio-marker recurrent prostate cancer.

Our Pipeline



TYME-18 is a CMBT compound under development that is delivered intratumorally. Like SM-88, TYME-18 leverages the unique metabolism of cancer to create a treatment for inoperable tumors. Preliminary observations of the local administration of TYME-18, an amphiphilic steroid acid, suggested its potential as an important regulator of energy metabolism that may impede the ability of tumors to increase in size which could prove useful in difficult-to-treat cancers. 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. We plan to continue with the development of TYME-18 in solid tumors and to provide details of an IND (Initial New Drug Application) enabling program this calendar year.

TYME has multiple cancer metabolism-based assets and other formulations for SM-88 in development, including injectable, intranasal, and transdermal, which are in pre-clinical stages.

TYME has an expanding patent portfolio broadly covering compositions, methods, manufacturing and use of its pipeline to 2032, and beyond. To date, TYME has 194 issued patents and patent applications worldwide, including 10 issued patents and an additional 12 patent applications in the United States.

Our Guiding Principles

TYME is committed to improving the lives of cancer patients worldwide through a workplace culture that empowers, engages, enriches and inspires employees who come to work every day to change the course of metastatic cancers through bold and creative pursuits in science, and a promise to put patients first. We are passionate about the people we serve - the patients. We are bold and courageous in our approach to turn the impossible into the possible. We hold trustworthiness in the highest regard. We aspire to always do better, and we work to exceed expectations through excellence in all we say and do.

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 tyrosine, 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 approximately 180 cancer patients treated with SM-88 to date, which includes patients of the Compassionate Use Program (discussed below) for whom we have safety results, but limited information regarding efficacy.

SM-88 is currently administered with the conditioning agents Methoxsalen, Phenytoin and Sirolimus (“MPS”). The conditioning agents are administered at doses between 5% and 25% of their U.S. Food and Drug Administration (“FDA”) approved doses in non-cancer indications. We believe, based on scientific literature of their respective biologic functions, the physiologic, but sub-therapeutic doses of these agents may augment either the uptake of SM-88 or destabilize cancer cells.

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 or disease 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 NYU Langone Health and could establish 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 approximately 180 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 approximately 180 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 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 extensive experience with 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 a favorable 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 65 issued patents and 129 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 as 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 advanced cancer patients' access to SM-88 through a compassionate use program under Institutional Review Board ("IRB") supervision (the "Compassionate Use Patients"). In early 2018, we performed a retrospective analysis on 53 Compassionate Use Patients who had available data and 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 confirmed responses 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 was initially designed as 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 ESMO World Congress on Gastrointestinal Cancer on July 4, 2019. Based on the encouraging efficacy data and the well tolerated safety profiles, the TYME-88-Panc protocol was amended in 2019 and is now intended as a pivotal registration trial. The amended protocol is a 1:1 randomized study of SM-88 versus an investigator's choice of three pre-determined single agent therapies.

Part 1 of TYME-88-Panc included 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, 38 patients were 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 6.4 months median OS of evaluable patients (n=38). The 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 at the start of treatment would be 2 to 2.5 months.

As a result of the encouraging results demonstrated in Part 1 of the TYME-88-Panc study of SM-88, TYME has launched Part 2 of TYME-88-Panc study designed as a multi-center randomized (1:1), controlled pivotal trial that will evaluate the efficacy and safety of SM-88 used with MPS in patients with metastatic adenocarcinoma of the pancreas whose disease has progressed or recurred and have received two lines of prior systemic therapy. Approximately 250 patients will be randomized to receive 920 mg of SM-88 with MPS (Arm A n=125) or one of three pre-defined single agent therapies (Arm B n=125). Patients will be treated until there is unacceptable toxicity or disease progression or if any treatment discontinuation criteria are met. The primary endpoint is OS. Key exploratory endpoints include PFS, clinical benefit response rate ("CBR"), defined as patients achieving SD or better, circulating tumor cells ("CTCs") and quality of life. The study will include leading pancreatic cancer research sites across the United States.

Based on information available on April 25, 2019, certain efficacy indicators correlated with greater OS, including the achievement of SD or better under RECIST and decreases in CTCs. Clinical benefit rates of SD or better under RECIST were achieved by 44% (11/25) of patients with available imaging as of April 25, 2019. Notably, patients achieving SD or better demonstrated a statistically significant (p=0.02) improvement in survival with a 92% reduction in risk of death (hazard ratio=0.08 (95% CI 0.01 – 0.63)). The CBR was durable, with a majority of these patients remaining in SD or better at more than seven months after receiving treatment with SM-88.

In TYME-88-Panc, based on information available as of April 25, 2019, a median reduction of 63% in CTC burden was observed in evaluable patients. Importantly, patients (10 of 24) with available results reaching an 80% reduction or greater in CTCs demonstrated a 60% decrease in risk of death (p=0.18, hazard ratio: 0.4 (95%CI (0.11 – 1.5)).

As of April 25, 2019, the study reported that SM-88 was well tolerated with only 4.0% of patients (2 of 49) who experienced serious adverse events ("SAEs") deemed at least possibly related to SM-88 (abdominal pain, arthralgia, and hypotension). One patient with reported SAEs continued on treatment.

The amended pivotal protocol for TYME-88-Panc ("Part 2") is enrolling and, in early January 2020 the Company announced the first patient was dosed.

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 randomized Phase II/III trial platform with registration intent sponsored by the Pancreatic Cancer Action Network ("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 initiated in January 2020.

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

Phase II Prostate Cancer Trial

We presented final data from our Phase II trial of SM-88 in patients with non-metastatic, biochemical-recurrent prostate cancer at the ESMO Congress 2019 on September 30, 2019. Twenty-three (23) patients were enrolled in the trial and entered with rising prostate-specific antigen levels, detectable CTCs and no radiographically detectable metastases. The study duration was six months, per the study protocol, although some patients were granted a waiver to remain on treatment for longer periods. Seventy-four percent (74%) of patients (17/23) had previously received androgen deprivation therapy as treatment for prostate cancer. All enrolled patients were given daily oral SM-88 with MPS for the duration of treatment.

Based on data as of September 2019, 100% of patients (23/23) on trial remained free of metastatic progression and 87% of patients (20/23) maintained radiographic progression-free survival ("rPFS") with a median duration of 6.5 months from the initial diagnoses of prostate specific antigen ("PSA") rise. All patients who maintained rPFS also exhibited meaningful reductions in CTCs.

All patients with available CTC results for at least 3 cycles (n=19) achieved a decrease from baseline, with a median decrease of 65.3% at the end of 3 cycles. The median baseline PSA for patients with radiographic progression was 13.4 compared to 5.6 for patients with no radiographic progression (p=0.02). 13% of patients experienced a PSA progression after commencing therapy and 52% of patients (12/23) experienced an improvement in median PSA doubling time, a positive prognostic indicator.

Patients without local progression (20/23) had slightly higher testosterone levels at baseline and throughout treatment on SM-88 as compared to those who experienced local radiographic progression (3/23), based on data as of September 2019. According to the European Organization for Research and Treatment of Cancer Quality of Life

Questionnaire, patients generally reported stable cognitive and sexual function domain measures, with no detectable worsening in any domain. Patient weight, EKG QT interval, glucose and hematocrit and other measures, which are often side effects of androgen deprivation therapy, did not appear affected while receiving SM-88.

The SM-88 therapy was well tolerated in all patients in the trial. There were no treatment-related SAEs. No adverse events resulted in dose delay, discontinuation, or reduction. The majority of Grade 1 adverse events deemed possibly or probably related to the SM-88 investigational therapy were gastrointestinal in nature.

Enrollment in our Phase II prostate cancer trial has been completed and final results are expected to be published in the second half of calendar year 2020.

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, began dosing patients in January 2020. 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

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. A subsequent study repeated the same efficacy results, with 11 of 12 TYME-18 treated mice showing complete resolution of targeted lesions. We plan to continue with the development of TYME-18 in solid tumors and to provide details of an IND-enabling program this calendar year.

Animal Health

Our co-founder, Steve Hoffman, holds substantially all 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 (the “Board”) 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 was 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.

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

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, development and regulatory plans in addition to proprietary scientific knowledge provide us with certain competitive advantages, we currently have limited financial resources and 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 and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing our products may depend on the extent to which we have rights under valid and enforceable licenses, patents or trade secrets that cover these activities. With respect to both our owned and licensed IP, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial products and methods of manufacturing such products, as well as being held valid if challenged.

Tyme maintains a broad intellectual property portfolio of 194 patent applications granted and/or pending worldwide. 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 or the facilities at which the drug is manufactured. The FDA will not approve the drug product unless it verifies that compliance with current good manufacturing practice ("cGMP") standards is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication(s) being studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional nonclinical or clinical testing or supplemental information 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, 2020, we have two active INDs with the FDA, both of which are associated with SM-88. The two INDs are active 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 addition, clinical investigators have previously and may in the future request their own INDs in order to use SM-88 or other products in Investigator Initiated Trials ("IITs"). For example, the HopES trial for sarcoma is an IIT where the IND for SM-88 use is held directly by the clinical trial site.

In February 2019 and July 2019, we participated in Type C meetings with the FDA. During those meetings we received guidance on our pivotal trial for SM-88 in third line pancreatic cancer. The trial is a randomized study comparing SM-88 to the control arm. The control arm consists of physician's choice of therapies. The primary end point is 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 substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If an investigational drug is designated as a breakthrough therapy, the drug will be eligible for all fast track designation features, including expedited development and review of such drug for trial and market approval. All requests for Breakthrough Therapy Designation are to 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 and accelerated approval 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 PIP.

International Conference on Harmonization (ICH)

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

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

Pharmaceutical Coverage, Pricing and Reimbursement

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

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

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

Manufacturing

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

We currently purchase all our drug substance and drug products from contract manufacturers and intend to continue to do so on an as-needed purchase order basis. We 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 comply with their in-house quality assurance programs and be available for inspections by regulatory agencies, including the FDA and European drug regulatory agencies. During the development of our drug candidates, we anticipate scaling the manufacturing process 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 administered 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, including 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 APIs. 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, 2020, we had a total of 18 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 18 employees, eight perform research and development activities and ten 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 us, 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.

Collaboration with Eagle

On January 7, 2020, TYME and Eagle Pharmaceuticals, Inc. ("Eagle") entered into a Securities Purchase Agreement (the "Eagle SPA"), pursuant to which the Company issued and sold to Eagle 10,000,000 shares of common stock, at a price of $2.00 per share. The Eagle SPA provides that Eagle will, subject to certain conditions, make an additional payment of $20 million upon the occurrence of a milestone event, which is defined as the earlier of (i) achievement of the primary endpoint of overall survival in the TYME-88-Panc pivotal trial; or (ii) achievement of the primary endpoint of overall survival in the PanCAN Precision Promise SM-88 registration arm; or (iii) FDA approval of SM-88 in any cancer indication. This payment would be split into a $10 million milestone cash payment and a $10 million investment in TYME at a 15% premium to the then prevailing market price. Eagle's shares will be restricted from sale until the earlier of three months following the milestone event or the three-year anniversary of the agreement.
Also, on January 7, 2020, we entered into a Co-Promotion Agreement with Eagle (the "Co-Promote"), whereby Eagle agreed to provide sales representatives to cover 25% of the Company's sales force requirements and will receive 15% of the net sales of all SM-88 products in the U.S. during the term of the Co-Promote. TYME will also be responsible for clinical development, regulatory approval, commercial strategy, marketing, reimbursement and manufacturing of SM-88. TYME retains the remaining 85% of net U.S. revenues and reserves the right to repurchase Eagle's rights under the Co-Promote for $200 million.

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 and related transactions, among other things, we (i) changed our jurisdiction of incorporation from Florida to Delaware; (ii) changed our name from Global Group Enterprises Corp. to Tyme Technologies, Inc., and (iii) acquired our current clinical-stage pharmaceutical business.

At-the-Market Sales of Common Stock

In November 2017, we entered into an equity distribution agreement with Canaccord Genuity Inc. ("Canaccord"), pursuant to which we were able to 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"). In total, we 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.

In October 2019, TYME terminated the equity distribution agreement with Canaccord and entered into an Open Market Sale Agreement℠ (the "Sale Agreement") with Jefferies LLC ("Jefferies") as sales agent, pursuant to which the Company may, from time to time, sell shares of Common Stock through Jefferies having an aggregate offering price of up to $30.0 million (the "Jefferies ATM"). Since initiation, we have raised approximately $1.5 million in net proceeds after commissions and other transaction expenses and have sold 1,361,315 shares of Common Stock.

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 ("Common Stock"), 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 "Existing Warrants"). The net proceeds to the Company, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company, were approximately $11 million.

Exchange Agreements

On May 20, 2020, the Company entered into exchange agreements with holders (the "Holders") of the Existing Warrants. The Existing Warrants were offered and issued pursuant to the Company's Registration Statement on Form S-3 (Registration No. 333-211489), which was declared effective by the Securities and Exchange Commission on August 16, 2017, a base prospectus dated August 16, 2017 and a prospectus supplement dated March 28, 2019.

Pursuant to exchange agreements (the "Share Exchange Agreements") with Holders of Existing Warrants to purchase 5,833,333 shares of Common Stock in the aggregate, the Company issued an aggregate of 2,406,250 shares of Common stock (the "Exchange Shares") in exchange for such Existing Warrants. Concurrently therewith, each such Holder executed and delivered to the Company a leak-out agreement (a "Share Leak-Out Agreement") that contains trading restrictions with respect to the Exchange Shares, which (i) for the first 90 days, prohibit any sales of Exchange Shares, (ii) for the subsequent 90 days, limit sales of Exchange Shares on any day to 2.5% of that day's trading volume of Common Stock, and (iii) prohibit new short positions or short sales on Common Stock for the combined 180 day period.

The Company also entered into an exchange agreement (the "Warrant Exchange Agreement") with another Holder of Existing Warrants to purchase 2,166,667 shares of Common Stock in the aggregate. Pursuant to the Warrant Exchange Agreement, the Company issued such Holder a new warrant (the "New Warrant") to purchase the same number of shares of Common Stock. The New Warrant has the same expiration date, April 2, 2024, as the Existing Warrants, but has an exercise price of $1.80 and does not include the price protection, anti-dilution provisions or other restrictions on Company action from the Existing Warrants. Concurrently therewith, such Holder executed and delivered to the Company a leak-out agreement that contains trading restrictions on sales of Common Stock issued upon exercise of the New Warrant that are substantially similar to the restrictions on Exchange Shares in the Share Leak-Out Agreement, provided that the leak-out restrictions will only apply to the first 893,750 shares of Common Stock issued pursuant to the New Warrant.

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 Annual Report on 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.

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.

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Risks Related to Owning Our Stock

Each of our co-founders holds a substantial ownership interest in our Company, which gives them the ability to influence certain decision making and these individuals have certain rights to our intellectual property that may allow them to use our IP in ways that could be inconsistent with our use.

Steve Hoffman, our Chief Executive Officer, Chief Science Officer and a director, owned more than 21.5% of our outstanding common stock as of March 31, 2020. Additionally, Michael Demurjian, our former Chief Operating Officer, also owned more than 19.4% of our outstanding common stock as of March 31, 2020. As such, Mr. Hoffman and Mr. Demurjian will each be positioned to exercise significant influence over our Company's affairs, including, but not limited to, electing members of our Board of directors and exercising influence and voting rights in connection with structural defenses and anti-takeover measures, and fundamental corporate transactions, and they may seek action that may not reflect the best interests of all of the stockholders of our Company.

Additionally, the Company has granted Mr. Hoffman perpetual, exclusive non-royalty bearing license rights with respect to certain patents and patent applications that the Company uses for SM-88 in all fields other than in connection with the treatment of cancer. Further, in their employment agreements, Mr. Hoffman and Mr. Demurjian agreed that all intellectual property ("IP") they develop or had developed during their employment with us is the property of the Company, but only with respect to the treatment of cancer in humans. We have been considering expanding into cancer therapeutics in certain animals and obtaining the relevant IP rights from them. We have had discussions with Mr. Hoffman and Mr. Demurjian about the financial and other terms to reach an agreement such that the Company would have the ability to pursue cancer therapeutics in dogs, cats and horses, but no assurance can be provided that we will obtain such rights.

This license to Mr. Hoffman may limit the Company's ability to profit from alternative uses of SM-88, were such uses to be discovered. Further, the use of the patents or patent applications that are used for SM-88 or that otherwise overlap with our IP could be associated with a negative event outside of the control of the Company and outside the treatment of cancer in humans, which, in either case, may have an adverse effect on our business.

Our share price is likely to be volatile due to factors beyond our control and may drop below prices paid by investors; investors could lose all of their investment in our Company.

All readers of this report should consider an investment in our common stock as speculative, involving a high degree of risk, 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. 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.

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, as a result of, among other reasons, the ongoing COVID-19 pandemic and related government and economic reactions, which are further described in this section. 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;
- limitations on the availability of acceptable-quality clinical supply or issues in manufacturing SM-88, the MPS components or any future drugs we may develop and receive governmental approval to market;
- regulatory developments or enforcement in the United States and non-U.S. countries with respect to our or our competitors' products;
- failure to achieve pricing and reimbursement levels expected by us or the market;
- competition from existing products or new products that may emerge;
- developments or disputes concerning patents or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- changes in estimates or recommendations by securities analysts, to the extent any cover our common stock;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- public concern over SM-88 or any future drugs we may develop and receive governmental approval to market;
- litigation or the threat of litigation;
- future issuances and sales of our common stock;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key personnel;

- changes in the structure of healthcare payment systems in the United States or overseas;
- the failure of SM-88, if approved, or any other approved drug product we may develop, to achieve commercial success;
- economic and other external factors or disasters or widespread health or other 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.

Due to these risks and the other risks described in this report, investors could lose their entire investment in our Company.

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 $0.86 to $2.04 between April 1, 2019 and March 31, 2020, 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, 2020, the average daily trading volume for our common stock was approximately 551,961 shares. In addition, the price of our common stock has been volatile. Our common stock had a closing price of $1.89 on April 1, 2019, and ended fiscal year 2020 at a closing price of $1.10. During the fiscal year 2020, our common stock had a low closing price of $0.90, which occurred on March 18, 2020, and had a high closing price of $1.95, which occurred on January 16, 2020.

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, impacts of public health crises, including the ongoing COVID-19 pandemic, 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.

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, in January 2020, we entered into a securities purchase agreement with Eagle Pharmaceuticals, Inc. ("Eagle"), pursuant to which Eagle would be required, upon the Company's achievement of certain milestone events, to purchase Series A Preferred Stock of the Company that is convertible

into common stock, which, upon conversion, if any, would result in additional dilution. 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. 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 product 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.

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. On January 7, 2020, the Board designated and reserved 10,000 shares as Series A Preferred in connection with the Eagle SPA (See Item 8. Note 9). Shares of Series A Preferred or other voting or convertible preferred stock could be issued or rights to purchase such shares could be issued, to create voting impediments or to frustrate persons seeking to affect a takeover or otherwise gain control of our Company. The ability of our Board to issue such additional shares of preferred stock, with rights and preferences it deems advisable, could discourage an attempt by a party to acquire control of our Company by tender offer or other means. Such issuances could therefore deprive stockholders of benefits that could result from such an attempt, such as the realization of a premium over the market price for their shares in a tender offer or the temporary increase in market price that such an attempt could cause. Moreover, the issuance of such additional shares of preferred stock to persons friendly to our Board could make it more difficult to remove incumbent managers and directors from office even if such change were to be favorable to stockholders generally.

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 collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates or future revenue streams or have to grant licenses on terms that are not favorable to us. For example, in January 2020, as part of a strategic investment in our Company, we entered into a co-promotion agreement with Eagle, whereby Eagle agreed to provide sales representatives to cover 25% of the Company's sales force requirements and will receive 15% of the net sales of all SM-88 products in the U.S. during the term of the agreement. The transactions with Eagle are further discussed under the heading "Collaboration with Eagle" in Item 1 of this Annual Report on Form 10-K. In addition, general market conditions, as well as market conditions for companies in our financial and business position, as well as the ongoing issues arising from the COVID-19 epidemic, may make it difficult for us to seek financing from the capital markets, and the terms of any financing may adversely affect the holdings or the rights of our stockholders. 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.

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, these 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 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. However, in connection with entering into a securities purchase agreement between the Company and Eagle in January 2020, the Board agreed to waive the provisions of Section 203 to the extent it is or could become applicable to Eagle.

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.

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

The outbreak of the novel coronavirus (COVID-19) and its impact on business and economic conditions could adversely affect our business, results of operations and financial condition, and the extent and duration of those effects will be uncertain.

The outbreak of the novel coronavirus (COVID-19) has evolved into a global pandemic. COVID-19 has spread to many regions of the world. The pandemic, including the fear of exposure to and the actual effects of the illness, together with the measures implemented to reduce its spread, which include restrictions on travel and large gatherings and requirements to shelter-in-place, have significantly impacted the global economy. It has disrupted global supply chains, lowered equity market valuations, created significant volatility and disruption in financial markets, and increased unemployment levels. The extent to which COVID-19 impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the virus and the actions to contain it or treat its impact, among others.

The spread of COVID-19 and efforts to contain the virus may have the following effects, which become more likely to occur or may be exacerbated the longer the crisis continues:

- Our clinical trials may be affected by the pandemic. Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. In general, the pandemic has made it very difficult to recruit subjects and

patients and to conduct clinical trials. The FDA issued guidance to be implemented without the normal prior public comment period as the FDA had concluded that public participation would not be feasible or appropriate. Guidance is not legally enforceable, but the FDA recommends the following of its guidance and guidance is particularly instructive during public health emergencies as the most efficient way for FDA to communicate broadly. Challenges are expected to arise from quarantines, site closures, travel limitations, interruptions to the supply chain for investigational products, or other considerations if site personnel or trial subjects become infected with or quarantined due to COVID-19. These challenges may lead to difficulties in meeting protocol requirements, including protocol-specified procedures. The FDA emphasized that safety of trial participants is critically important. Decisions to continue or discontinue individual patients or a trial are expected to be made by trial sponsors in consultation with clinical investigators and Institutional Review Boards. COVID-19 screening procedures may need to be implemented. As challenging as the clinical trial process is during normal times, the risks, strategic and operational challenges and the costs of conducting such trials has increased substantially during the pandemic. The full impact of COVID-19 on our clinical development and clinical trials is currently unknown.

- Infections and deaths related to the pandemic have disrupted the American and global healthcare and healthcare regulatory systems. Such disruptions may divert healthcare resources away from our clinical trials and have the potential to materially delay the review and/or approval of regulatory submissions and regulatory communications with the FDA and global regulators. It is unknown how long these disruptions could continue were they to occur. The elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

- Major international medical conferences have been disrupted, impacting the dissemination and review of scientific/medical information, including presentations, papers and abstracts that would have been presented about our products.

- While we have not had material disruptions in our operations to date, shelter-in-place orders or other mandated local travel restrictions could result in our employees or other personnel conducting research and development or manufacturing activities for the Company having no or limited access their laboratories or other facilities. A greater number of these personnel working remotely may also expose us to greater risks related to cybersecurity and cyber-liability.

Should COVID-19 continue to spread or government countermeasures become stricter, our business operations, results of operations and financial condition may further be affected as follows:

- Some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. Further, if the spread of the coronavirus pandemic continues and our operations are adversely impacted, we risk a delay, default and/or nonperformance under existing agreements, which may increase our costs. These cost increases may not be fully recoverable or adequately covered by insurance.

- We currently utilize third parties to, among other things, manufacture raw materials. If any third parties in the supply chain for materials used in the production of our product candidates are adversely impacted by restrictions resulting from the coronavirus outbreak, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our clinical trials and research and development operations.

- Our business may experience a material economic effect due to the additional work and resource demands for our employees and vendors, particularly those who continue to be involved in handling the current operational challenges of clinical trial administration and business disrupted by the pandemic.

- It may adversely impact our ability to file on a routine and timely basis our periodic reports or other filings under federal securities or other laws and regulations.
- Our business may experience a material economic effect. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. The extent to which the coronavirus further impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the coronavirus and the actions to contain the coronavirus or treat its impact, among others. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole. However, the likelihood of material impact on the Company and its operations increases the longer the virus impacts activity levels in the United States and across the world. Management will continue to monitor the situation closely and implement business continuity and emergency response plans as needed.

Our proprietary lead drug product, SM-88, is in clinical development in two principal areas. We are currently participating in the advancement of Phase II, Phase II/III and/or pivotal clinical trials for pancreatic cancer and sarcoma. We are considering additional clinical trials in other solid tumors and/or hematologic malignancies. Clinical drug development is expensive, time-consuming and uncertain, and we may ultimately not be able to obtain regulatory approval for the commercialization of our lead candidate.

The risk of failure for drugs in clinical development is high and it is impossible to predict when our lead drug candidate for the treatment of cancer, SM-88, will prove effective or safe in humans or will receive regulatory approval. The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA, the European Medicines Agency (the "EMA"), national competent authorities in Europe and other non-U.S. regulatory authorities, which establish regulations that differ from country to country. We are not permitted to market SM-88 and any other drug product we may develop in the 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, and we may experience delays as an impact of COVID-19. 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 or 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, conducting our small-scale completed Phase I or Phase II clinical trials, and initiating or partnering to initiate pivotal 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 or unable 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, including fears or restrictions related to the COVID-19 pandemic, 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 manner. Patient enrollment is affected by factors including the design of clinical trial protocols, size of patient populations, eligibility criteria, proximity and availability of clinical trial sites, and other factors. If we have difficulty enrolling 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 conducted several Phase I or Phase II trials and have initiated our pivotal trial for SM-88 in pancreatic cancer. We have also partnered with PanCAN to study SM-88 in an adaptive randomized Phase II/III trial with registration intent known as Precision Promise. The successful completion of these trials will be 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 the following:

- 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 prospective 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-review, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by the FDA, the EMA, other regulatory authorities or the IRB/IEC overseeing the clinical trial, due to a number of factors, which include, but are not limited to:

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

Any failure or significant delay in clinical and regulatory development plans for SM-88 or any other product 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 clinical trials, and may differ from future clinical trials, no assurance can be given that our ongoing or future clinical 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. Adverse changes 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 Human 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 transient pain (13%). Many of these patients who were treated with SM-88 were late-stage cancer patients with one or more previous treatments or existing medical

conditions, which can cause AEs unrelated to SM-88. Patients may also report additional AEs that have not yet been 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 materially 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 if it does not achieve its primary endpoints in its Phase II/III pancreatic clinical trials, and other factors, such as product safety or nonclinical registration requirements, may prevent SM-88 from gaining regulatory approval even if it achieves its primary endpoints. The FDA, the EMA or other global 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.

Preclinical development programs and preclinical mechanism research activities are uncertain. Our preclinical programs and activities 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.

We are conducting a range of preclinical experiments with external CROs and academic partners to more fully illustrate the mechanism of action of SM-88 in oncology. However it is unknown if the impact of SM-88 on processes studied in cultured cells or animal models would be replicated in humans or provide a clinical benefit. The FDA is interested in understanding the general biologic properties of SM-88, and there is a risk that the results produced by our planned preclinical activities might not satisfy their requirements to support a regulatory approval. Therefore, additional activity may be required to address the FDA's questions, or we might not be able to effectively address these questions.
In addition to SM-88, we are researching other drug platforms, such as TYME-18. Before we can commence human 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, 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 product 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 product 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 product 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 product 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 product 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 product 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 product 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, difficulties and costs and may require additional nonclinical or clinical trials, which would be costly and time-consuming or even delay or prevent the introduction of SM-88 in those countries. In addition, our failure to obtain regulatory approval in one country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any drug candidates approved for sale in any jurisdiction, including international markets and we therefore do not have experience in obtaining regulatory approval. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to create stockholder value for SM-88 will be harmed.

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

The fast track program, a provision of the 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 an investigational 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 all fast track designation features.

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 is unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development. If SM-88 or any other drug candidate we may develop were to receive orphan drug designation, we still may not have market exclusivity in particular markets. There is no assurance we will be able to receive orphan drug designation for SM-88 or any other drug candidate we may develop. Further, the granting of a request for orphan drug designation does not alter the standard regulatory requirements and process for obtaining marketing approval.

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

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

SM-88 or any other drug product we may develop may have serious adverse, undesirable or unacceptable side effects, which may delay or prevent marketing approval. If such side effects are identified during the development of SM-88 or any other product candidate we may develop or following such candidate's approval, if any, we may need to abandon our development of SM-88 or such other candidate, 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 drug liability claims.

If SM-88 or any other product 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.

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval and commercialization of SM-88 or any other product candidate we may develop and may affect the prices we obtain. 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, the Prescription Drug Price Relief Act, introduced in the Senate in January 2019, would require the HHS Secretary to assure that Americans do not 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 Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the “Medicare Modernization Act”) established the Medicare Part D program and provided authority for limiting the number of drugs that will be covered in any therapeutic class thereunder. The Medicare Modernization Act, including its cost reduction initiatives, could limit the coverage and reimbursement rate that we receive for any of our approved products. Private payors may follow Medicare coverage policies and payment limitations in setting their own reimbursement rates resulting in similar limits in payments from private payors.

Further, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, adopted in March 2010 (together, 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 law has continued the downward pressure on the pricing of medical items and services, especially under the Medicare program, and increased the industry’s regulatory burdens and operating costs. Since its enactment, there have been

executive, judicial and Congressional challenges to certain aspects of the Health Care Reform Law, which are further described in this section, and we expect there will be additional challenges and amendments to the Health Care Reform Law in the future.

Other legislative changes have been proposed and adopted since the Health Care Reform Law was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011 (the "BBA"), which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2% per fiscal year through 2025. These reductions were extended through 2027 under the BBA. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers (including hospitals and cancer treatment centers), and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. Although a number of these, and other proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. On December 18, 2019, the FDA issued a notice of proposed rulemaking that, if finalized, would allow for the importation of certain prescription drugs from Canada. The FDA also issued a draft guidance document outlining a potential pathway for manufacturers to obtain an additional National Drug Code, or NDC, for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. The regulatory and market implications of the notice of proposed rulemaking and draft guidance are unknown at this time. We cannot be sure whether additional legislative changes will be enacted or what the impact of such changes on the marketing approvals of SM-88 or any other drug product we may develop, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent labeling and post-marketing testing and other requirements.

The Health Care Reform Law and other healthcare reform measures adopted in the future may result in more rigorous coverage criteria new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints,

discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products to purchase and which suppliers will be included in their prescription drug and other healthcare programs. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices. These reforms could also reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

Recently, several 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 pharmaceutical 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.

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. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to new requirements or policies, or if we are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

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. For example, in January 2020, we entered into a co-promotion agreement with Eagle, whereby Eagle agreed to provide sales representatives to cover 25% of the Company's sales force requirements and will receive 15% of the net sales of all SM-88 products in the U.S. during the term of the agreement. 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.

Even if SM-88 obtains regulatory approval, it will remain subject to ongoing regulatory requirements and oversight.

If marketing authorization is obtained for our lead drug candidate, SM-88, it will continue to be under review by regulatory authorities and be subject to regulatory requirements. 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.

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 product 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 product 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 product 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.
- An unforeseen production shortage resulting from any events, including interruptions to business operations as a result of widespread health crises, such as the COVID-19 pandemic, affecting raw material and or intermediate supply or manufacturing capabilities abroad and domestic.
- The manufacturing facilities in which SM-88 is made could be adversely affected by equipment failures, labor shortages, labor strikes, natural disasters, widespread disease and other public health crises, including COVID-19, 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 marketing applications for SM-88. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for SM-88, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we and/or our manufacturing partners are not able to maintain regulatory compliance, we may not be permitted to market SM-88 and/or may be subject to drug recalls, seizures, injunctions or criminal prosecution.
- Any adverse developments affecting manufacturing operations for SM-88, if approved for marketing by the FDA, may result in shipment delays, inventory shortages, lot inspection failures, drug withdrawals or recalls or other interruptions in the supply of SM-88. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet regulator-approved manufacturing specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.
- 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.
- Third parties may hold IP rights that impact, restrict or inhibit manufacturing or sale of a commercial version of SM-88.

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

The anticancer treatment industry is highly competitive and subject to rapid and significant technological changes. We are currently developing SM-88 to compete with other drugs that currently exist or are being developed. Drugs we may develop in the future are also likely to face competition from other drugs, some of which we may not be currently be aware of. In marketing our products, we will have domestic and international competitors, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical

companies, universities and other research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, patient recruitment and manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in more advanced stages of development or collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies also may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make SM-88 and any other drug product we may develop obsolete. Some or all of these factors may contribute to our competitors succeeding in obtaining patent protection and/or marketing approval or developing and commercializing products in our field before we do.

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

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

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.

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.

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 product 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 product 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 judgments exceed any insurance coverage we may have, could decrease our cash resources and adversely affect our business, financial condition and results of operations and could possibly cause us to cease our operations in their entirety.

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

Although 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, 2020, our accumulated deficit was $107,815,252. 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 product 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.

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

- completing research and clinical development of SM-88, including successful completion of required clinical trials;
- obtaining marketing approval for SM-88;
- developing a sustainable and scalable manufacturing process for SM-88 and maintaining supply and manufacturing relationships with third parties that can conduct the process and provide adequate (in amount and quality) drugs to support clinical development and the market demand for SM-88, if approved;
- launching and commercializing SM-88, either directly or with a collaborator or distributor;
- establishing sales, marketing and distribution capabilities in the United States and in other markets, such as the EU;
- obtaining market acceptance of SM-88 as a viable treatment option;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and/or developing new product 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 product candidate we may develop. Even if SM-88 or another product 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 and when or if we will be able to achieve profitability. For example, our expenses could increase if the 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. 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 product 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.

To achieve on our long-term business objectives, we will require substantial additional funding, which may require us to agree to restrictions on our operations or 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 product candidates through our research and clinical development process. The completion of the development, regulatory approval and the potential commercialization of SM-88 or any other product 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 product 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 product candidates, and establishing sales, marketing and distribution capabilities, including in collaboration with others;
- 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 increase our overall capacity and 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 product candidates we may develop;
- the amount and timing of revenues, if any, we receive from commercial sales of SM-88 or any other product candidates for which we receive marketing approval in the future, which is expected to be offset by revenues we must share with collaborators; and
- 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 achieve, we expect to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, royalty agreements and other marketing and distribution arrangements. The demand for the equity and debt of biotechnology 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. 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, royalty rights or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product 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.

While we regularly consider options and opportunities to raise additional capital and obtain financing and 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. Additionally, 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 product 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 product 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 product 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 currently rely on, and will likely continue to rely on, third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators to study our product candidates in clinical trials. We may independently conduct future clinical trials for any drug product we may develop, including SM-88, but will continue to collaborate with such parties to study SM-88 in their clinical trials of SM-88 or other drug candidates. For example, we partnered with PanCAN to study SM-88 in its adaptive randomized Phase II/III trial with registration intent known as Precision Promise. Also, HopES is a Phase II investigator-initiated trial evaluating SM-88 monotherapy in late-stage sarcomas, under the direction of principal investigator Dr. Sant Chawla and in collaboration with The Joseph Ahmed Foundation. Our reliance on these third parties for clinical development activities reduces our control over these activities, relieves us of certain rights we otherwise would have and puts us at risk for the acts or omissions of these third parties, but it 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 and 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, including as a result of restrictions put in place because of the COVID-19 pandemic, 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 product 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 components of MPS used with SM-88. Supplies are obtained through limited term supply agreements under individual purchase orders. At this time, no supply agreements in place exceed 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 qualifications under applicable regulatory requirements and ensuring non-infringement of third-party IP rights could result in a significant interruption of supplies and could require the new manufacturer(s) to bear significant additional costs which may be passed on to us.

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

Because we rely on third parties to assist in the research, development and manufacture of SM-88 and may do so with any other product 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 have entered into a co-promotion agreement and may enter into additional license or collaboration agreements with third parties with respect to SM-88 and any other product candidates we may develop that may place the development or promotion of our product 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 such collaborations are not successful, SM-88 and any other product candidates we may choose to develop may not reach their full market potential.

In January 2020, we entered into a co-promotion agreement with Eagle Pharmaceuticals, Inc. ("Eagle"), whereby Eagle agreed to provide sales representatives to cover 25% of the Company's sales force requirements and will receive 15% of the net sales of all SM-88 products in the U.S. during the term of the agreement. TYME remains responsible for the remaining promotional effort. The co-promotion of SM-88 in the United States will be supervised by a joint sales operations committee composed of representatives from the Company and Eagle. Under the agreement, the Company will remain responsible for clinical development and commercial strategy and for the costs of seeking regulatory approval, manufacturing and distribution of SM-88. TYME has the ability to purchase back the Eagle 15% share of the net U.S. sales for $200 million.

The co-promotion agreement provides parameters and sales requirements, but certain specific requirements related to promotional activities and requirements will be defined in more detail and finalized as any product nears commercialization. If we and Eagle disagree on these matters, it could lead to disputes or be disruptive to sales efforts. Additionally, Eagle may change its strategic focus or pursue alternative technologies or treatments in a manner that results in reduced or delayed revenue to us. If Eagle fails to effectively promote and assist in the commercialization of our SM-88 products, our business, financial condition, results of operations and prospects could be harmed. In addition, any material alteration of the collaboration agreements, or dispute or litigation proceedings we may have with Eagle in the future could delay development programs, distract management from other business activities and generate substantial expense.

We may in the future enter into additional license or collaboration arrangements with other third parties with respect to SM-88 and any other product candidates we may develop that may place the development or promotion of our product candidates partially or entirely outside of our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us, and could be subject to similar types of risks as described above. In addition, any collaborations are and will be 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 product 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 product candidate, repeat or conduct new clinical trials or require a new formulation of SM-88 or other product 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;

- 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;

- 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; and

- 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 product candidate we may develop or results in costly litigation or arbitration that diverts management attention and resources.

If our collaborations are not successful, or we are unable to reach agreement with a collaboration partner or disputes arise under collaboration arrangements, SM-88 and any other product candidates we may choose to develop may not reach their full market potential, and our business, financial condition, results of operations and prospects could be harmed.

Risks Related to the Operation of our Company

Our future operational success depends on our ability to retain our key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on our chief executive officer, chief operating officer, chief financial officer and the other members of our executive and scientific teams. Our executives may terminate their employment with us at any time.

The loss of the services of any of these people could impede the achievement of our research, development and commercialization objectives.

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

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

We are highly reliant on our executives, but certain of them, including our chief executive and science officer, Steven Hoffman, our president and chief financial officer, Ben Taylor, 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, 2020, we had 18 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, acts of foreign enemies, war, nationalization, government sanction, blockage, embargo, widespread public health crises, 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. For example, our corporate headquarters is located in New York, New York, and we have another office in Bedminster, New Jersey. Both of these states are currently under shelter-in-place order because of the ongoing COVID-19 pandemic.

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, widespread public health crises or pandemics, such as COVID-19, and related government responses, or natural disasters including earthquakes, typhoons, floods and fires.

We may seek approvals of our product 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. Following the formation of a majority Conservative government in December 2019, the United Kingdom approved the withdrawal agreement and left the EU on January 31, 2020. The terms of the United Kingdom's final withdrawal remain subject to ongoing negotiation until December 31, 2020, during which current EU regulations will continue to apply in the United Kingdom. The United Kingdom Parliament banned extensions to the transition period, so the United Kingdom must finalize new trading agreements with the EU by December 31, 2020. Trade negotiations are expected to begin in early March 2020, but the nature of the economic relationship between the EU and United Kingdom remains uncertain, and there is no guarantee that both parties will be able to reach an agreement before the transition period expires. 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 (the "Exchange Act"). 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.

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. Any lawsuit brought against us by one or more of our stockholders, could result in substantial costs to defend the lawsuit, divert the time and attention of our management, result in substantial monetary judgments or settlement costs and harm our reputation, any of which could seriously harm our business.

Further, as we continue to seek to expand, raise capital, and develop and commercialize products, we have entered into, and expect to enter into in the future, agreements and instruments, such as our outstanding warrants and co-promotion agreement, which are subject to interpretation and the potential for dispute. If we and the counterparty to any such agreements or holders of such instruments are unable to resolve our disagreements, such disagreements may result in lawsuits, other legal proceedings and/or protracted negotiations, including those whereby we seek to enforce our rights. Even if successful, litigation, other legal proceedings or protracted negotiations could be expensive and time consuming and could divert management's attention from managing our business and could result in significant adverse judgments or costs of settlement, amendments to agreements or adjustments to instruments, any of which may have a material adverse effect on our liquidity, financial position, business, reputation or prospects.

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.

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 or ability 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 become aware of any 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 or the protection afforded by those patents 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 partes* 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 and may cost significant time and resources to defend. 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 product 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 or their manufacture may also materially harm our business, financial condition and results of operations. Furthermore, we would be exposed to a threat of litigation.

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

- we or our collaborators may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our drugs or processes do not infringe those third parties' patents;
- if our competitors file patent applications that claim technology also claimed by us or our licensors or collaborators, we or our licensors or collaborators may be required to participate in interference or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third-party with a dominant patent position;

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

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

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

- patent litigation and other proceedings initiated by or against us may also absorb significant management time;
- if proceedings are initiated by or against the Company to determine the priority of invention, they 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, unregisterable 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 or trademark dilution. 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 and Agencies

Health care reform measures could hinder or prevent the commercial success of SM-88 any other 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. Among the provisions of the Health Care Reform Law of importance to our current and potential product candidates are the following:

- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand 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;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, which include, among other things, new government investigative powers and enhanced penalties for non-compliance;
- expansion of eligibility criteria for Medicaid programs in certain states;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- an independent payment advisory board that will submit recommendations to Congress to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

Additionally, various initiatives continue to increase pathways for patients to seek treatment of investigational products outside of clinical trials, including the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, state right to try laws, and the FDA's Expanded Access program. These initiatives could potentially impact patient enrollment in clinical trials. These pathways do not currently include any obligations for a manufacturer to make its investigational products available to patients. The future direction and impact of these initiatives is unknown.

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, including initiatives designed to control or influence product pricing. 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 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.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the Health Care Reform Law.

On January 20, 2017, President Trump signed an executive order directing federal agencies with authorities and responsibilities under the Health Care Reform Law to exercise all available authority and discretion to waive, defer, grant exemptions from or delay the implementation of any provision of the Health Care Reform Law that would impose a fiscal burden on any U.S. state or a cost, fee, tax, penalty or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance or makers of medical devices, products or medications (the "January 2017 Executive Order"). The January 2017 Executive Order does not describe specific federal rules that it applies to but 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 of 2017 (the "Tax 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"). On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the Health Care Reform Law, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Health Care Reform Law are invalid as well. While the Trump administration and CMS have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts to repeal and replace the Health Care Reform Law will impact the Health Care Reform Law and our business. On March 2, 2020 the Supreme Court of the United States announced that it would hear an appeal brought by Democratic-led states seeking to affirm the constitutionality of the Health Care Reform Law.

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 so-called "Cadillac" 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 2017 and October 2017 Executive Orders, the Tax 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 the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of or payment for, healthcare benefits, items or services relating to healthcare matters;
- the federal physician self-referral law, commonly known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services reimbursed by Medicare or Medicaid if the physician or a member of the physician's family has a financial relationship with the entity and which also prohibits the submission of any claims for reimbursement for designated health services furnished pursuant to a prohibited referral;
- the federal transparency requirements under the Health Care Reform Law, 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 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; for example, California has recently passed the California Consumer Privacy Act (the "CCPA"), which we may become subject to in the future. The CCPA introduces strict compliance regulations on organizations doing business in California that collect personal information about California residents. The CCPA defines personal information broadly and allows for fines as well as a private right of action from individuals in relation to certain security breaches involving personal information. The CCPA is also prompting similar legislative developments in other U.S. states , which could lead to a series of overlapping but varying laws. These developments, as we become subject to such laws, are likely to increase our compliance burden and our risk, including risks of regulatory fines, litigation and associated reputational harm. Further, 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.

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

The Tax Act 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.

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

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

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. FDA review time and communications with the FDA may be delayed, prolonged and otherwise negatively impacted by the FDA's response to the COVID-19 pandemic. With many FDA staff working on COVID-19 activities, it is possible the FDA may need to reprioritize work in order to appropriately address the ongoing pandemic. 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.

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

If approved, the marketing for SM-88, will be limited to the specific approved 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.

In addition to other areas of regulatory oversight, we will also need to comply with a variety of laws and regulations concerning the advertising and promotion of our products. For instance, the FDA closely regulates the post-approval

labeling, marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, product-specific risk evaluation mitigation strategies (REMS), industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. If we desire to market additional indications for SM-88, we will need to seek additional regulatory approvals requiring additional clinical trials to support the new indications, 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 our products for off-label uses after FDA approval for the applicable indication(s) or to have engaged in inappropriate pre-approval promotion of SM-88, we may receive warning letters and become subject to significant liability, which would materially harm our business. The federal government and states' attorneys general have 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 or engage in improper pre-approval promotion, 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.

Adverse results, side effects or injuries may happen and may lead to product liability claims. Liability claims could divert management's attention from our core business, be expensive to defend, result in sizable damage awards against us that may not be covered by liability insurance, and 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 oncology products, the FDA will likely 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 of 1933, as amended (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, quarterly and current reports, 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. Premiums for director and officer insurance can vary substantially from year-to-year and have recently been increasing due to the growth in threatened and actual suits across public companies, which is even more pronounced in biotechnology. 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.

′e will continue to incur relatively outsized costs as a result of recently becoming a public company and in the administration of our organizational structure, including compliance with changing regulations of corporate governance and public disclosure, which will pose challenges for our management.

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 federal securities law, SOX, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and other laws and related rules and regulations promulgated thereunder. 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, as changing laws and regulations and standards relating to corporate governance and public disclosure have created uncertainty and increased the costs and risks of accessing the U.S. public markets. 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. 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 operations and normal business activities.

Additionally, there continues to be public interest and increased legislative pressure related to environmental, social and governance (“ESG”) activities of public companies. We risk negative stockholder reaction, including from proxy advisory services, as well as damage to our brand and reputation, if we do not act responsibly in a number of key areas, including diversity and inclusion, environmental stewardship, support for local communities, corporate governance and transparency and considering ESG factors in our operations. There is a growing number of states requiring organizations to report their board composition as well or mandating gender diversity, including New York and California.

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. For example, Nasdaq’s quantitative listing standards require, among other things, that listed companies maintain a minimum closing bid price of $1.00 per share. Given the increased volatility and market reaction to the COVID-19 pandemic, we may be unable to maintain such a bid price and could face delisting proceedings.

ITEM 1B. UNRESOLVED STAFF COMMENTS

We are a smaller reporting company as defined in Regulation S-K of the Securities Act, and are not required to provide the information under this item.

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 approximately 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.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ADDITIONAL ITEM. EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers and their positions as of May 22, 2020 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.	57
Ben R. Taylor	Mr. Taylor has served as President and Chief Financial Officer since April 2017.	43
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.	57
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.	46
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.	48
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.	56
Barbara C. Galaini	Ms. Galaini has served as our Principal Accounting Officer since August 2018 and our Corporate Controller since April 2018.	62

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 market, 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 May 18, 2020 was $1.70.

Holders; Shares Outstanding

We had a total of 123,312,252 shares of our common stock outstanding on May 18, 2020, held by approximately 180 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, 2020," which is incorporated herein by this reference.

Share Repurchases

During the twelve months ended March 31, 2020, we did not repurchase any shares of common stock.

ITEM 6. SELECTED FINANCIAL DATA

We are a smaller reporting company as defined in Regulation S-K 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 first-in-class CMBT compounds include SM-88 and TYME-18. These compounds are structurally and mechanistically different, and we believe they offer the potential for better and safer medicines. Early clinical results demonstrated by SM-88 in multiple advanced cancers, including pancreatic, prostate, sarcomas and breast, reinforce the potential of our emerging CMBT pipeline. Moreover, we believe our pipeline offers hope to patients for a new future in long-term management of advanced cancers.

Our lead clinical CMBT compound, SM-88, is an oral investigational modified proprietary tyrosine derivative that is hypothesized to interrupt the metabolic processes of cancer cells by breaking down the cells' key defenses and leading to cell death through oxidative stress and exposure to the body's natural immune system. To date, clinical trial data have shown that SM-88 has achieved confirmed tumor responses across 15 different cancers, both solid and liquid tumors, including pancreatic, lung, breast, prostate, sarcoma and lymphoma cancers with minimal serious Grade 3 or higher adverse events, which we believe is rare for investigational compounds. Our lead compound SM-88 is now in a pivotal trial and a Phase II/III adaptive randomized trial with registration intent for patients with second- and third-line pancreatic cancer. In fiscal year 2020, we launched our pivotal study for SM-88 in the third-line treatment of pancreatic cancer through an amendment to our ongoing TYME-88-Panc trial (Part 2); with the first patient dosed in the third quarter of the fiscal year. We anticipate the trial to be fully enrolled by the end of calendar year 2020 or early calendar year 2021. We currently estimate the cost of the TYME-88-Panc trial (Part 2) to be approximately $15 million, with such costs anticipated to extend through calendar year 2021. We have partnered with the Pancreatic Cancer Action Network ("PanCAN") to study SM-88 in an adaptive randomized Phase II/III trial with registration intent known as Precision Promise℠. In Precision Promise, SM-88 is initially being studied as second-line monotherapy and the study of SM-88 could expand to first-line combination therapy with standard of care. The remaining estimated cost for Precision Promise Stage 1 is approximately $7.5 million. Patients are also being enrolled in a Phase II study evaluating SM-88 in high-risk sarcomas and we presented final SM-88 Phase II clinical data at the European Society for Medical Oncology's ESMO 2019 conference showing encouraging clinical benefit in patients with bio-marker recurrent prostate cancer. The Company is actively evaluating the expansion of our clinical program to hematological, breast, prostate and other cancers.

TYME-18 is a CMBT compound under development that is delivered intratumorally. Like SM-88, TYME-18 leverages the unique metabolism of cancer to create a treatment for inoperable tumors. Preliminary observations of the local administration of TYME-18, an amphiphilic steroid acid, suggested its potential as an important regulator of energy metabolism that may impede the ability of tumors to increase in size which could prove useful in difficult-to-treat cancers. 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. The Company plans to continue with the development of TYME-18 in solid tumors and to provide details of an IND-enabling program this calendar year.

COVID-19 Update

In March 2020, the World Health Organization categorized the novel coronavirus (COVID-19) as a pandemic and the President of the United States declared the COVID-19 outbreak a national emergency. The COVID-19 pandemic, and actions taken by governments and others in response thereto, has negatively impacted the global economy, financial markets, and the industries in which we operate and has disrupted day-to-day life. We are
closely monitoring the impact of COVID-19 on all aspects of our business, our clinical trials, and the safety of
patients. We have worked closely with our clinical trial sites during the pandemic. At this time, all trials for SM-88 are still actively enrolling patients and we believe we have sufficient clinical supply to complete all of our trials. We are targeting full enrollment for the TYME-88-Panc pivotal trial by late-2020 to early 2021. We are committed to working with the clinical trial sites to assure appropriate access for patients who are seeking clinical trial options for these advanced cancers for which the patients have limited or no other treatment options. However, the extent to which COVID-19 impacts our product candidates and business, including our access to capital markets and financing sources, depends on numerous evolving factors that that are highly uncertain and cannot be accurately predicted, including those identified under "Risk Factors" in this Annual Report on Form 10-K, many of which are beyond our control. Management continues to monitor the situation closely and intends to implement business continuity and emergency response plans as needed.

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 Annual Report on 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.

As of March 31, 2020, the Company had gross U.S. federal net operating loss carryforwards of approximately $69.3 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, 2020, the Company had gross federal research and development tax credit carryforwards of $2.1 million available to reduce future tax liabilities which will begin to expire at various dates starting in 2030. As of March 31, 2020, 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. We had unrecognized tax benefits of $318,000 and $127,000 at March 31, 2020 and 2019, respectively. Increases or decreases would not have an effect on the effective tax rate.

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, 2016 through March 31, 2019. 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. 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.

The Company adopted ASU 2018-07 and, as such, the fair value of options granted to non-employees is estimated at the date of grant only, and the expected term is determined using the simplified method for options granted to non-employees and consultants.

Derivative Warrant Liability

Certain freestanding common stock warrants that are related to the issuance of common stock are classified as liabilities and recorded at fair value due to characteristics that require liability accounting, primarily the obligation to issue registered shares of common stock upon notification of exercise and certain price protection provisions. Warrants of this type are subject to re-measurement at each balance sheet date and any change in fair value is recognized as a component of other income (expense) in the consolidated statement of operations.

As noted in Note 9, Stockholders’ Equity, the Company classifies a warrant to purchase shares of its Common Stock as a liability on its consolidated balance sheet if the warrant is a free-standing financial instrument that contains

certain price protection features that cause the warrants to be treated as derivatives. Each warrant of this type is initially recorded at fair value on date of grant using the Monte Carlo simulation model and is subsequently re-measured to fair value at each subsequent balance sheet date. Changes in fair value of the warrant are recognized as a component of other income (expense) in the consolidated statement of operations. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrant. The Company utilizes Level 3 fair value criteria to measure the fair value of the warrants.

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

Results of Operations

Year ended March 31, 2020 Compared to Year Ended March 31, 2019

Net loss for the year ended March 31, 2020 was $22,001,000 compared to $32,983,000 for the year ended March 31, 2019. The decrease in the net loss compared to the prior year is due to decreased operating costs and expenses and income from change in fair value of warrant liability in 2020, as highlighted below.

Cash used in operating activities for the year ended March 31, 2020 was $19,560,000 compared to $20,116,000 for the year ended March 31, 2019. See “Cash Flows” section below for further details.

Revenue

During the years ended March 31, 2020 and March 31, 2019, 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, 2020, operating costs and expenses totaled $25,760,000, compared to $31,777,000 for the year ended March 31, 2019, representing a decrease of $6,017,000, of which $2,471,000 relates to severance expense recorded in the year ended March 31, 2019. Operating costs and expenses by function were comprised of the following:

- Research and development expenses were $12,956,000 for the year ended March 31, 2020, compared to $14,719,000 for the year ended March 31, 2019, representing a decrease of $1,763,000. 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 $7,713,000 for the year ended March 31, 2020, compared to $9,554,000 for the year ended March 31, 2019, representing a decrease of $1,841,000 between the comparable periods. The decrease is mainly attributable to the timing of activity related to Part 1 of our Tyme-88-Panc Phase II trial and our recently completed Phase II prostate clinical trial that was completed in fiscal year 2020. 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 $2,697,000 for the year ended March 31, 2020, compared to $2,307,000 for the year ended March 31, 2019, representing an increase of $390,000 between comparable periods, primarily due to costs associated with an increased employee base.
    - Included in research and development expense for the year ended March 31, 2020 is $2,537,000 of stock based compensation related to stock options granted to research and development personnel compared to $2,844,000 for the year ended March 31, 2019, representing a decrease of $307,000 between the comparable periods, primarily due to reduction in expense for grants that fully amortized partially offset by the amortization of expense related to options granted to employees during fiscal year 2020.

- General and administrative expenses were $12,804,000 for the year ended March 31, 2020, compared to $14,587,000 for the year ended March 31, 2019, representing a decrease of $1,783,000. The general and administrative expenses include:
    - Stock based compensation related to stock options granted was $3,549,000 for the year ended March 31, 2020, compared to $5,719,000 for the year ended March 31, 2019, representing a decrease of $2,170,000, primarily attributable to grants that fully amortized, partially offset by amortization of grants granted to employees, board members and consultants during fiscal year 2020.
    - Legal, professional services, accounting and auditing expenses for the year ended March 31, 2020, was $3,205,000, compared to $3,834,000 for the year ended March 31, 2019, representing a decrease of $629,000, primarily related to decreases in legal and accounting fees, partially offset by increases in investor relations and communications activity in fiscal year 2020.
    - Salary and salary related expenses for non-research and development personnel was $3,741,000 for the year ended March 31, 2020, compared to $3,245,000 for the year ended March 31, 2019, representing an increase of $496,000 between the comparable periods due to costs associated with an increased employee base.
    - Other general and administrative expenses for the year ended March 31, 2020 was $2,309,000, compared to $1,789,000 for the year ended March 31, 2019, representing an increase of $520,000 between the comparable periods due to higher costs in fiscal year 2020 related to warrant issuances, insurance and other administrative costs.
- There was no severance expense for the year ended March 31, 2020. For the year ended March 31, 2019, severance expense was $2,471,000. On March 15, 2019, we entered into a Release Agreement related to the separation of employment of our former Chief Operating Officer. The Release 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 value and included $0.4 million relating to stock option modification.

Other Income/Expenses

For the year ended March 31, 2020, the Company had $3,645,000 of income related to the change in fair value of warrant liability. The warrant liability was established in connection with the issuance of warrants from the underwritten registered offering that closed on April 2, 2019.

For the year ended March 31, 2020, the Company incurred $114,000 of interest expense as compared to $7,000 in the year ended March 31, 2019 related to the severance and insurance note payables.

Interest income for the year ended March 31, 2020 was $229,000 as compared to $90,000 in the year ended March 31, 2019, which represents interest income earned on bank deposits.

Warrant Modification

There was no warrant modification expense for the year ended March 31, 2020. 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 (see Note 9 to the Consolidated Financial Statements) 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.

Income Tax

Our effective income tax rate for the years ended March 31, 2020 and 2019 was zero percent.

Adjusted Net Loss and Adjusted Net Loss per Share

Adjusted net loss for the year ended March 31, 2020, was $19,560,000 or $0.17 per share compared to $22,743,000 or $0.23 per share for the year ended March 31, 2019 after adjusting for change in fair value of warrant liability, warrant modification expense, severance stock based compensation and amortization of employees, directors and consultants stock options. Adjusted net loss and adjusted net loss per share are non-GAAP measures. See "Use of Non-GAAP Measures" below for a reconciliation to the comparable GAAP measures.

Use of Non-GAAP Measures

Adjusted net loss and adjusted net loss per share as presented in this report are non-GAAP measures. The adjustments relate to the change in fair value of warrant liability, warrant modification expenses, severance stock based compensation and amortization of employees, directors and consultants stock options. These financial measures are presented on a basis other than in accordance with U.S. generally accepted accounting principles ("Non-GAAP Measures"). In the reconciliation tables that follow, we present adjusted net loss and adjusted net loss per share, reconciled to their comparable GAAP measures, net loss and net loss per share. These items are adjusted because they are not operational or because they are significant noncash charges and management believes these adjustments are meaningful to understanding the Company's performance during the periods presented. These Non-GAAP Measures should be considered a supplement to, not a substitute for, or superior to, the corresponding financial measures calculated in accordance with GAAP. Our definitions of adjusted net loss and adjusted loss per share may not be comparable to similar measures reported by other companies.

Reconciliation of Net Loss to Adjusted Net Loss

	For the Year Ended March 31,	
	2020	**2019**
Net loss (GAAP)	$ (22,001,000)	$ (32,983,000)
Adjustments:		
Change in fair value of warrant liability	(3,645,000)	—
Warrant modification expense	—	1,289,000
Severance stock based compensation	—	388,000
Amortization of employees, directors and consultants stock options	6,086,000	8,563,000
Adjusted net loss (non-GAAP)	$ (19,560,000)	$ (22,743,000)

Reconciliation of Net Loss Per Share to Adjusted Basic and Diluted Net Loss Per Share

	For the Year Ended March 31,	
	2020	**2019**
Net loss per share (GAAP)	$ (0.19)	$ (0.32)
Adjustments:		
Change in fair value of warrant liability	(0.03)	—
Warrant modification expense	—	0.01
Severance stock based compensation	—	*
Amortization of employees, directors and consultants stock options	0.05	0.08
Adjusted basic and diluted net loss per share (non-GAAP)	$ (0.17)	$ (0.23)

* The effect of the change was negligible to the adjusted basic and diluted net loss per share.

The Non-GAAP Measures for the year ended March 31, 2020 and 2019 provide management with additional insight into the Company's results of operations from period to period by excluding certain non-operational and non-cash charges, and are calculated using the following adjustments to net loss:

a) The warrants issued as part of an equity offering on April 2, 2019 are measured at fair value using a Monte Carlo model which takes into account, as of the valuation date, factors including the current exercise price, the remaining contractual term of the warrant, the current price of the underlying stock, its expected volatility, the risk-free interest rate for the term of the warrant and the estimates of the probability of fundamental transactions occurring. The warrant liability is revalued at each reporting period or upon exercise. Changes in fair value are recognized in the consolidated statements of operations and are excluded from adjusted net loss and adjusted net loss per share.

b) The Company uses the Black-Scholes option pricing model to determine fair value of stock options granted. For employees and non-employees, the compensation expense is amortized over the requisite service period which approximates the vesting period. The expense is excluded from adjusted net loss and adjusted net loss per share.

c) The Company uses the Black-Scholes option pricing model to determine the expense associated with the modification of warrants and stock based compensation grants.

Adjusted basic net loss per share is computed by dividing adjusted net loss by the weighted average number of shares of Company common stock outstanding for the period, and adjusted diluted loss per share is computed by also 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.

Liquidity and Capital Resources

Liquidity and Capital Requirements Outlook

We anticipate requiring additional capital to further fund the development of our product candidates, as well as to engage in potential partnerships or collaborations. The most significant funding needs are in connection with (i) conducting Part 2 of TYME-88-Panc, our pivotal trial, and participating in Precision Promise, an adaptive randomized Phase II/III trial with registration intent, which examine our lead compound SM-88 for patients with second- and third-line pancreatic cancer, (ii) participating in an investigator-initiated clinical trial of SM-88 in sarcoma, and (iii) 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 greater scale of these trials is expected to lead to increased costs, including providing SM-88 for patient use. If we determine to move beyond the pre-clinical stage for any of our pre-clinical trials or if we pursue studies in other cancer types, our liquidity requirements will be increased. As discussed elsewhere in this Annual Report on Form 10-K, we are actively evaluating the expansion of our clinical program to hematological, breast, prostate and other cancers.

Primarily as a result of its active clinical trials, as well as other business developments, the Company currently anticipates that its quarterly cash usage, or “cash burn rate”, will increase in fiscal 2021 compared to fiscal 2020 and is expected to approximate $7.0 million to $8.0 million per quarter.

As of March 31, 2020, the Company had cash on hand of approximately $26.7 million and a working capital of approximately $22.5 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 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, including the ongoing COVID-19 pandemic and related government and economic reactions, 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.

The Company has historically funded its operations primarily through equity offerings of its common stock. 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.

From time to time, we may also restructure our outstanding securities or seek to repurchase or redeem them if we
believe doing so would provide us with additional flexibility to raise capital or is otherwise in the best interests of the Company.

Historical Financings

On January 7, 2020, the Company and Eagle Pharmaceuticals, Inc. ("Eagle") entered into a Securities Purchase Agreement (the "Eagle SPA"), pursuant to which the Company issued and sold to Eagle 10,000,000 shares of common stock, at a price of $2.00 per share. The Eagle SPA provides that Eagle will, subject to certain conditions, make an additional payment of $20 million upon the occurrence of a milestone event, which is defined as the earlier of (i) achievement of the primary endpoint of overall survival in the TYME-88-Panc pivotal trial; (ii) achievement of the primary endpoint of overall survival in the PanCAN Precision Promise℠ SM-88 registration arm; or (iii) U.S. Food and Drug Administration ("FDA") approval of SM-88 in any cancer indication. This payment would be split into a $10 million milestone cash payment and a $10 million investment in TYME at a 15% premium to the then prevailing market price. Eagle's shares will be restricted from sale until the earlier of three months following the milestone event or the three-year anniversary of the agreement.

On October 18, 2019, the Company entered into an Open Market Sale Agreement℠ (the "Sale Agreement") with Jefferies LLC ("Jefferies"), pursuant to which the Company may, from time to time, sell shares of Common Stock, having an aggregate offering price of up to $30,000,000 through Jefferies, as the Company's sales agent (the "Jefferies ATM"). The shares will be offered and sold by the Company pursuant to its previously filed and currently effective Registration Statement on Form S-3, as amended (Reg. No. 333-211489). Any sales of Common Stock pursuant to the Sales Agreement will be made by methods deemed to be an "at-the-market offering" as defined in Rule 415 promulgated under the Securities Act. Jefferies will use commercially reasonable efforts to sell the shares from time to time, based on the instructions of the Company. The Company will pay Jefferies a commission rate of three percent (3%) of the gross proceeds from the sales of shares of Common Stock sold pursuant to the Sale Agreement. Under the Sale Agreement, the Company is not required to use the full available amount authorized and it may, by giving notice as specified in the Sale Agreement, terminate the Sale Agreement at any time. During the year ended March 31, 2020, the Company raised approximately $1.7 million in gross proceeds via the sale of 1,361,315 shares of common stock under the Jefferies ATM. The Company incurred $0.2 million of related costs which offset such proceeds. As of March 31, 2020, there remained approximately $28.3 million of availability in the Jefferies ATM.

Prior to the Jefferies ATM, the Company had a similar facility with Canaccord Genuity Inc. ("Canaccord") that was closed shortly prior the opening of the Jefferies ATM. On November 2, 2017, the Company had entered into an equity distribution agreement with Canaccord to commence an at-the-market offering that had an aggregate potential offering price up to $30,000,000 (the "Canaccord ATM"). The Company did not sell any shares through the

Canaccord ATM during the year ended March 31, 2020. During the fiscal year ending March 31, 2019, the Company raised approximately $5,844,000 in gross proceeds from the facility. On October 2, 2019, the Company sent notice terminating the Canaccord ATM effective October 12, 2019, having raised a total of $12.1 million through the facility between November 2, 2017 and October 2, 2019.

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 ("Common Stock"), and warrants to purchase up to 8,000,000 shares of its common stock with an exercise price of $2.00 per share (the "Existing Warrants") 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. However, as further described under the subheading "Exchange Agreements" below, on May 20, 2020, the Company exchanged the Existing Warrants with their respective holders for shares of the Company's Common Stock or new warrants in reliance upon the exemption from registration provided by Section 3(a)(9) of the Securities Act of 1933, as amended. After such exchanges, the Existing Warrants no longer remained outstanding.

Cash Flows

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

	2020	2019
Net cash used in operating activities	$ (19,560,000)	$ (20,116,000)
Net cash used in investing activities	$ —	$ (16,000)
Net cash provided by financing activities	$ 31,958,000	$ 5,458,000

Operating Activities

Our cash used in operating activities in the year ended March 31, 2020 totaled $19.6 million which is the sum of (i) our net loss of $22.0 million, adjusted for non-cash expenses totaling $2.4 million (which includes equity-based compensation, change in fair value of warrant liability and depreciation and amortization), and (ii) changes in operating assets and liabilities which netted to a negligible amount.

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.

Investing Activities

There were no investing activities in the year ended March 31, 2020. 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, 2020, our finance activities mainly consisted of the following:

- In April 2019, the Company raised $11.3 million after underwriting discounts and before offering expenses through an underwritten registered offering of 8,000,000 shares of our Common Stock, and 8,000,000 common stock purchase warrants. Each Existing Warrant entitles its holder to purchase one share of Common Stock (each, a "Warrant Share") at an exercise price of $2.00 per Warrant Share. The Warrants expire five years from the date of issuance and vest immediately. The warrants are recorded as a derivative liability on the statement of balance sheet and will be subject to remeasurement.
- The Company raised approximately $1.7 million in gross proceeds via sale of 1,361,315 shares of Common Stock through the Jefferies ATM. The Company incurred $0.2 million of related costs which offset the

proceeds. At March 31, 2020 there remained approximately $28.3 million of availability to sell shares through the Jefferies ATM.

- In January 2020, the Company raised $20 million before offering expenses through the Eagle SPA, pursuant to which the Company issued and sold to Eagle 10,000,000 shares of common stock, at a price of $2.00 per share.
- The Company made payments of $597,000 on the insurance note payable related to premiums for its Director and Officer liability insurance coverage.

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

- The Company raised approximately $5.7 million in net proceeds after sales commissions and expenses of the offering through the Canaccord ATM via the sale of 2,383,884 shares of our common stock.
- The Company made payments of $480,000 on the insurance note payable related to premiums for its Director and Officer liability insurance coverage.

Subsequent Events

Exchange Agreements

On May 20, 2020, the Company entered into exchange agreements with holders (the "Holders") of the Existing Warrants. The Existing Warrants were offered and issued pursuant to the Company's Registration Statement on Form S-3 (Registration No. 333-211489), which was declared effective by the Securities and Exchange Commission on August 16, 2017, a base prospectus dated August 16, 2017 and a prospectus supplement dated March 28, 2019.

Pursuant to exchange agreements (the "Share Exchange Agreements") with Holders of Existing Warrants to purchase 5,833,333 shares of Common Stock in the aggregate, the Company issued an aggregate of 2,406,250 shares of Common stock (the "Exchange Shares") in exchange for such Existing Warrants. Concurrently therewith, each such Holder executed and delivered to the Company a leak-out agreement (a "Share Leak-Out Agreement") that contains trading restrictions with respect to the Exchange Shares, which (i) for the first 90 days, prohibit any sales of Exchange Shares, (ii) for the subsequent 90 days, limit sales of Exchange Shares on any day to 2.5% of that day's trading volume of Common Stock, and (iii) prohibit new short positions or short sales on Common Stock for the combined 180 day period.

The Company also entered into an exchange agreement (the "Warrant Exchange Agreement") with another Holder of Existing Warrants to purchase 2,166,667 shares of Common Stock in the aggregate. Pursuant to the Warrant Exchange Agreement, the Company issued such Holder a new warrant (the "New Warrant") to purchase the same number of shares of Common Stock. The New Warrant has the same expiration date, April 2, 2024, as the Existing Warrants, but has an exercise price of $1.80 and does not include the price protection, anti-dilution provisions or other restrictions on Company action from the Existing Warrants. Concurrently therewith, such Holder executed and delivered to the Company a leak-out agreement that contains trading restrictions on sales of Common Stock issued upon exercise of the New Warrant that are substantially similar to the restrictions on Exchange Shares in the Share Leak-Out Agreement, provided that the leak-out restrictions will only apply to the first 893,750 shares of Common Stock issued pursuant to the New Warrant.

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.

Contract Service Providers

On April 1, 2020, the Company amended the Clinical Research Funding and Drug Supply Agreement dated October 9, 2018, with PanCAN, to enroll individuals diagnosed with pancreatic cancer in a platform style clinical research study. Stage 1 of the study was initiated in the fourth quarter of fiscal year 2020. After taking into consideration amounts already paid, the remaining estimated cost to the Company, which primarily consists of patient treatment costs, for Stage 1 is approximately $7.5 million, subject to enrollment adjustments, and is expected to be incurred over the next two and a half years.

Purchase Commitments

The Company has entered into 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 2021. Total outstanding future obligations associated with the contracts were $1.6 million at March 31, 2020.

Leases

The Company leases office space in New York and office space and furniture in New Jersey. The New York rent obligation has been prepaid through August 30, 2020, the end of the lease. The New Jersey leases expire in February 2021. The Company's future minimum lease payments for the New Jersey leases are approximately $56,000 due in fiscal 2021.

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 in Regulation S-K 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 REGISTERED 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, 2020 and 2019, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended March 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended March 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

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 Public Company Accounting Oversight Board (United States) ("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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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 regarding 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, New York
May 22, 2020

Tyme Technologies, Inc. and Subsidiaries
Consolidated Balance Sheets

	March 31, 2020	March 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 26,700,416	$ 14,302,328
Prepaid rent	-	242,755
Prepaid clinical costs	396,962	592,134
Prepaid expenses and other current assets	981,949	1,001,898
Total current assets	28,079,327	16,139,115
Property and equipment, net	5,181	10,363
Prepaid rent, net of current portion	-	101,148
Prepaid clinical costs, net of current portion	1,266,025	1,266,025
Operating lease right-of-use asset	150,301	—
Total assets	$ 29,500,834	$ 17,516,651
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and other current liabilities (including $73,000 and $325,000 of related party accounts payable, respectively)	$ 2,827,302	$ 3,692,308
Severance payable	380,722	428,240
Accrued bonuses	1,800,979	1,495,248
Insurance note payable	518,124	597,339
Operating lease liability	54,661	—
Total current liabilities	5,581,788	6,213,135
Long-term liabilities		
Severance payable	1,254,910	1,635,634
Warrant liability	3,639,000	—
Total liabilities	10,475,698	7,848,769
Commitments and contingencies (See Note 10)		
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, 123,312,252 issued and outstanding at March 31, 2020, and 300,000,000 authorized, 103,946,048 issued and outstanding at March 31, 2019	12,333	10,397
Additional paid in capital	126,828,055	95,472,181
Accumulated deficit	(107,815,252)	(85,814,696)
Total stockholders' equity	19,025,136	9,667,882
Total liabilities and stockholders' equity	$ 29,500,834	$ 17,516,651

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,	
	2020	2019
Operating expenses:		
Research and development	$ 12,955,879	$ 14,719,481
General and administrative (including $447,000 and $977,000 of related party legal expenses, respectively)	12,804,493	14,586,165
Severance expense	—	2,470,906
Total operating expenses	25,760,372	31,776,552
Loss from operations	(25,760,372)	(31,776,552)
Other income (expense):		
Warrant modification expense	—	(1,289,125)
Change in fair value of warrant liability	3,644,601	—
Interest income	229,458	89,977
Interest expense	(114,243)	(7,415)
Total other income (expenses)	3,759,816	(1,206,563)
Loss before income taxes	(22,000,556)	(32,983,115)
Net loss	$ (22,000,556)	$ (32,983,115)
Basic and diluted loss per common share	$ (0.19)	$ (0.32)
Basic and diluted weighted average shares outstanding	114,533,102	102,354,050

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, 2020 and 2019

	Common Stock		Additional Paid-in capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
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
Issuance of common stock from underwritten registered offering, net of associated expenses of $111,227 and warrants of $7,283,601	8,000,000	800	3,884,372	—	3,885,172
Cashless exercise of warrants	4,889	—	—	—	—
Issuance of common stock from at-the-market financing facility, net of associated expenses of $221,103	1,361,315	136	1,529,110	—	1,529,246
Issuance of common stock from securities purchase agreement, net of associated expenses of $142,281	10,000,000	1,000	19,856,719	—	19,857,719
Stock based compensation	—	—	6,085,673	—	6,085,673
Net loss	—	—	—	(22,000,556)	(22,000,556)
Balance, March 31, 2020	123,312,252	$ 12,333	$ 126,828,055	$ (107,815,252)	$ 19,025,136

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	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (22,000,556)	$ (32,983,115)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	5,182	8,420
Amortization of employees, directors and consultants stock options	6,085,673	8,563,379
Warrant modification expense	—	1,289,125
Severance stock based compensation	—	388,282
Change in fair value of warrant liability	(3,644,601)	—
Change in operating assets and liabilities:		
Prepaid rent	—	(337,453)
Prepaid clinical costs	195,172	(442,734)
Prepaid expenses and other assets	538,073	433,334
Operating lease right-of-use asset	297,596	—
Accounts payable and other current liabilities	(865,006)	654,229
Severance payable	(428,242)	2,063,874
Accrued bonuses	305,731	246,558
Operating lease liability	(49,333)	—
Net cash used in operating activities	(19,560,311)	(20,116,101)
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	(597,339)	(480,093)
Proceeds from registered offerings, net of issuance costs	32,555,738	5,668,244
Proceeds from exercise of stock options	—	270,000
Net cash provided by financing activities	31,958,399	5,458,151
Net increase (decrease) in cash	12,398,088	(14,673,494)
Cash and cash equivalents — beginning of year	14,302,328	28,975,822
Cash and cash equivalents — end of year	$ 26,700,416	$ 14,302,328
Supplemental Cash Flow Information:		
Cash paid for interest and income taxes are as follows:		
Interest	$ 114,243	$ 7,415
Income taxes	$ —	$ —
Noncash investing and financing activities:		
Financing of insurance premiums	$ 518,124	$ 597,339
Deferred expenses related to post year end financing	$ —	$ 220,988
Cashless exercise of 78,431 warrants for 4,889 shares in 2020 and 1,086,271 warrants for 235,685 shares of common stock in 2019	$ —	$ —

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. 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 patients' 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 compound, SM-88, is an oral investigational modified proprietary tyrosine derivative that is hypothesized to interrupt the metabolic processes of cancer cells by breaking down the cells' key defenses and leading to cell death through oxidative stress and exposure to the body's natural immune system. Clinical trial data have shown that SM-88 has achieved confirmed tumor responses across 15 different cancers, both solid and liquid tumors, including pancreatic, lung, breast, prostate, sarcoma and lymphoma cancers with minimal serious Grade 3 or higher adverse events, which the Company believes is rare for investigational compounds. The Company's lead compound SM-88 is now in a pivotal trial and an adaptive randomized Phase II/III trial with registration intent for patients with second- and third-line pancreatic cancer. In fiscal year 2020, we launched our pivotal study for SM-88 in the third-line treatment of pancreatic cancer through an amendment to our ongoing TYME-88-Panc trial ("Part 2"); with the first patient dosed in the third quarter of the fiscal year. We anticipate the trial to be fully enrolled by the end of calendar year 2020 or early calendar year 2021. We have also partnered with PanCAN to study SM-88 in an adaptive randomized Phase II/III trial with registration intent known as Precision Promise. Patients are being enrolled in a Phase II study evaluating SM-88 in high-risk sarcomas as well. The Company is actively evaluating the expansion of our clinical program to hematological, breast, prostate and other cancers.

TYME-18 is a CMBT compound under development that is delivered intratumorally. Like SM-88, TYME-18 leverages the unique metabolism of cancer to create a treatment for inoperable tumors. Preliminary observations of the local administration of TYME-18, an amphiphilic steroid acid, suggested its potential as an important regulator of energy metabolism that may impede the ability of tumors to increase in size which could prove useful in difficult-to-treat cancers. 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. The Company plans to continue with the development of TYME-18 in solid tumors and to provide details of an IND-enabling program this calendar year.

The accompanying consolidated financial statements include the results of operations of Tyme Technologies, Inc. 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.

In April 2019, the Company raised net proceeds of $11.3 million after underwriting discounts and before expenses through an underwritten registered offering.

On October 18, 2019, TYME entered into an Open Market Sale Agreement℠ (the "Sale Agreement") with Jefferies LLC ("Jefferies") as sales agent, pursuant to which the Company may, from time to time, sell shares of Common Stock through Jefferies having an aggregate offering price of up to $30.0 million (the "Jefferies ATM"). In the year ended March 31, 2020, the Company raised approximately $1.7 million in aggregate gross proceeds before commissions and expenses through the Sale Agreement and paid commissions and expenses of $0.2 million. At March 31, 2020, there remained approximately $28.3 million of availability to sell shares through the Jefferies ATM.

On January 7, 2020, the Company entered into a Securities Purchase Agreement with Eagle Pharmaceuticals, ("Eagle"), pursuant to which the Company raised $20,000,000 through the issuance and sale to Eagle of 10,000,000 shares of Common Stock, at a price of $2.00 per share. The proceeds of the aforementioned 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, 2020, the Company had negative cash flow from operations of $19.6 million and net loss of $22.0 million, which included $2.4 million of net non-cash charges, primarily non-cash equity compensation expense partially offset by income from change in fair value of warrant liability. As of March 31, 2020, the Company had working capital of approximately $22.5 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 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.

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 Technologies, Inc. and its subsidiaries, Tyme, Inc. and Luminant. All intercompany transactions and balances have been eliminated in consolidation.

Reclassifications

Certain prior year amounts have been reclassified to conform to the current year presentation. These reclassifications have no effect on the previously reported net loss or cash flows.

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.

Current Economic Conditions

In March 2020, the World Health Organization categorized the novel coronavirus (COVID-19) as a pandemic and the President of the United States declared the COVID-19 outbreak a national emergency. The COVID-19 pandemic, and actions taken by governments and others in response thereto, has negatively impacted the global economy, financial markets, and the industries in which the Company operates and has disrupted day-to-day life. The Company believes that the current economic conditions may continue to have a negative impact for the foreseeable future, and the extent to which it may impact liquidity and financial conditions is uncertain and may be significant.

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 and warrant valuation. 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, 2020 and 2019, the Company did not have any cash equivalents. The Company's cash and cash equivalents consisted of $26.7 million at March 31, 2020 and $14.3 million at March 31, 2019.

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 $26.4 million at March 31, 2020 and $14.0 million at March 31, 2019. 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 Company records certain financial assets and liabilities at fair value in accordance with the provisions of ASC Topic 820, Fair Value Measurements and Disclosures. 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 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 warrant liability is discussed in Note 7.

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 $0.8 million and $0.6 million of prepaid insurance as of March 31, 2020 and 2019, 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 and operating lease right of use 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, 2020 and 2019, 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 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. 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 Warrant Liability

Certain freestanding common stock warrants that are related to the issuance of common stock are classified as liabilities and recorded at fair value due to characteristics that require liability accounting, primarily the obligation to issue registered shares of common stock upon notification of exercise and certain price protection provisions. Warrants of this type are subject to re-measurement at each balance sheet date and any change in fair value is recognized as a component of other income (expense) in the consolidated statement of operations.

As noted in Note 9, Stockholders' Equity, the Company classifies a warrant to purchase shares of its Common Stock as a liability on its consolidated balance sheet if the warrant is a free-standing financial instrument that contains certain price protection features that cause the warrants to be treated as derivatives. Each warrant of this type is initially recorded at fair value on date of grant using the Monte Carlo simulation model and is subsequently re-measured to fair value at each subsequent balance sheet date. Changes in fair value of the warrant are recognized as a component of other income (expense) in the consolidated statement of operations. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrant. The Company utilizes Level 3 fair value criteria to measure the fair value of the warrants.

Basic and Diluted Loss Per Share

The Company calculates net loss per share in accordance with *Earning per Share (Topic 260)*. 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 13, 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 adopted ASU 2018-07 and, as such, the fair value options granted to non-employees is estimated at the date of grant only.

Recently Adopted Accounting Pronouncements

Leases

The Company adopted ASU 2016-02, *Leases (Topic 842)* on April 1, 2019. For its long-term operating leases, the Company recognized an operating lease right-of-use asset and an operating lease liability on its consolidated balance sheets. The Company elected the optional practical expedients to forgo applying guidance in Topic 842 to short-term leases (leases 12 or fewer months at commencement and no purchase option). The package of expedients allows an entity to forgo reassessing (1) whether a contract contains a lease, (2) classification of leases, and (3) whether capitalized costs associated with a lease meet the definition of "initial direct costs" in Topic 842. The Company elected to use the optional transition method and therefore prior period amounts continue to be reported in accordance with the historic accounting under the previous lease guidance, ASC 840, *Leases (Topic 840)*.

The lease liability is determined as the present value of future lease payments using an estimated rate of interest that the Company would pay to borrow equivalent funds on a collateralized basis at the lease commencement date. The right-of-use asset is based on the liability adjusted for any prepaid or deferred rent. The Company determines the lease term at the commencement date by considering whether renewal options and termination options are reasonably assured of exercise.

Fixed rent expense for the Company's operating leases is recognized on a straight-line basis over the term of a lease and is included in operating expenses on the consolidated statements of operations. Variable lease payments including lease operating expenses are recorded as incurred.

Upon adoption, the Company recognized an operating right-of-use asset and operating lease liability in its consolidated balance sheet of approximately $0.4 million and $0.1 million, respectively. The Company also classified prepaid rent of $0.3 million as an operating right-of-use asset upon adoption. There were no adjustments to the Company's opening accumulated deficit upon adoption. The impact of the adoption of Topic 842 on the consolidated balance sheets as of April 1, 2019 was as follows:

	April 1, 2019 Prior to Adoption of ASC Topic 842	ASC Topic 842 Adjustment	April 1, 2019 As Adjusted
Prepaid rent	$ 343,903	$ (343,903)	$ —
Deferred rent	$ —	$ —	$ —
Operating right-of-use assets	$ —	$ 447,897	$ 447,897
Operating lease liability	$ —	$ 103,994	$ 103,994

Derivatives and Hedging

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 has adopted this ASU effective April 1, 2019 and there was no impact on the consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which modifies the disclosure requirements on fair value in Topic 820. Under this ASU, certain disclosure requirements for fair value measurements are eliminated, amended or added. The guidance is effective for the Company fiscal year and interim periods within those fiscal years, beginning after December 15. 2019. The Company does not expect the adoption of ASU 2018-13 to have a material impact on its consolidated financial statements and disclosures.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808)* ("ASU 2018-18') which amends Topic 808 to clarify when transactions between participants in a collaborative arrangement under Topic 808 are within the scope of the new revenue standard, ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. Because Topic 808 does not provide comprehensive recognition or measurement guidance for collaborative arrangements, the accounting for those arrangements is often based on an analogy to other accounting literature or on an entity's accounting policy election. The amendment added the unit-of account guidance in Topic 808 to align with the guidance in Topic 606 and clarifies that when the collaborative arrangement participants is a customer in the context of a unit of account, the transaction should be accounted as revenue under Topic 606. The amendment also precludes presenting transactions with revenue under Topic 606 if the collaborative arrangement participant is not a customer. The amendment is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The Company is assessing the impact on its consolidated financial statements and disclosures.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), as part as part of its overall simplification initiative to reduce costs and complexity of applying accounting standards while maintaining or improving the usefulness of the information provided to users of financial statements. Amendments include removal of certain exceptions to the general principles of ASC 740, *Income Taxes* and simplification in several other areas such as accounting for a franchise tax (or similar tax) that is partially based on income. ASU 2019-12 is effective for public business entities for annual reporting periods beginning after December 15, 2020, and interim periods within those reporting periods. The Company is assessing the impact on its consolidated financial statements and disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), which requires that a financial asset (or a group of financial assets) measured at amortized cost be presented at the net amount expected to be collected. Currently, U.S. GAAP delays recognition of the full amount of credit losses until the loss is probable of occurring. Under this ASU, the income statement will reflect an entity's current estimate of all expected credit losses. The measurement of expected credit losses will be based upon historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down of the security.

In November 2018, the FASB issued ASU 2018-19, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses* ("ASU 2018-19"), which clarifies that receivables from operating leases are not within the scope of Subtopic 326-20. Instead impairment of receivables arising from operating leases should be accounted for in accordance with Topic 842, Leases.

In May 2019, the FASB issued ASU 2019-05, *Financial Instruments-Credit Losses (Topic 326): Targeted Transition Relief* ("ASU 2019-05"), which provides transition relief for entities adopting ASU 2016-13. ASU 2019-05 amends ASU 2016-13 to allow companies to irrevocably elect, upon adoption of ASU 2016-13, the fair value option on financial instruments that (1) were previously recorded at amortized cost and (2) are within the scope of ASC 326-20 if the instruments are eligible for the fair value option under ASC 825-10. The fair value option election does not apply to held-to-maturity debt securities. Entities are required to make this election on an instrument by-instrument basis.

In November 2019, the FASB issued ASU 2019-11, *Codification Improvements to Topic 326, Financial Instruments-Credit Losses,* which amends and clarifies aspects of the guidance in ASC 326.

The guidance in ASU 2016-13, ASU 2018-19, ASU 2019-05 and ASU 2019-11 as amended in November 2019 by ASU 2019-10, *Financial Instruments-Credit Losses (Topic 326), Derivatives and Hedging (Topic 815, and Leases (Topic 842): Effective dates*, is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company is assessing the impact on its consolidated financial statements and disclosures.

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,	
	2020	2019
Basic and diluted net loss per common share calculation		
Net loss	$ (22,000,556)	$ (32,983,115)
Weighted average common shares outstanding — basic and diluted	114,533,102	102,354,050
Net loss per share of common stock — basic and diluted	$ (0.19)	$ (0.32)

The Company calculates net loss per share in accordance with *Earnings per Share ("EPS") (Topic 260)*. 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.

Warrants issued in April 2019, discussed further in Note 7, participate on a one-for-one basis with common stock in the distribution of dividends, if and when declared by the Board of Directors (the "Board") on the Company's Common Stock. For purposes of computing EPS, these warrants are considered to participate with common stock in the earnings of the Company and, therefore, the Company calculates basic and diluted EPS using the two-class method. Under the two-class method, net income for the period is allocated between common stockholders and participating securities according to dividends declared and participation rights in undistributed earnings. No income

was allocated to the warrants for the year ended March 31, 2020 as results of operations was a loss for the period. In May 2020, these warrants were all exchanged for Common Stock or new warrants without such participation rights and are no longer outstanding (See Note 15).

The following outstanding securities at March 31, 2020 and 2019 have been excluded from the computation of diluted weighted average shares outstanding, as they would have been anti-dilutive:

	Year Ended March 31,	
	2020	2019
Stock options	11,815,982	8,953,527
Warrants	8,937,651	4,499,603
Total	20,753,633	13,453,130

Note 4. Property and Equipment, Net.

Property and equipment, net consisted of the following:

	March 31, 2020	March 31, 2019
Machinery and equipment	$ 37,007	$ 37,007
Less: accumulated depreciation	31,826	26,644
	$ 5,181	$ 10,363

Depreciation expense was $5,182 and $8,420 for the years ended March 31, 2020 and 2019, respectively.

Note 5. Accounts Payable and Other Current Liabilities.

Accounts payable (including accounts payable to a related party – see Note 12) and other current liabilities consisted of the following:

	March 31, 2020	March 31, 2019
Legal	$ 199,671	$ 602,129
Consultant and professional services	109,504	170,257
Accounting and auditing	118,837	331,119
Research and development	1,863,355	1,907,787
Board of Directors and Scientific Advisory Board Compensation	484,750	489,393
Other	51,185	191,623
	$ 2,827,302	$ 3,692,308

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, 2020 and March 31, 2019 was $1.6 million and $2.1 million, respectively.

Note 7. Fair Value Measurements.

The carrying amounts reported in the Company's consolidated financial statements for cash, accounts payable, and other current liabilities approximate their respective fair values because of the short-term nature of these accounts. 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 warrant liability is discussed below.
The Company had no material re-measurements of fair value with respect to financial assets and liabilities, during the periods presented, other than those assets and liabilities that are measured at fair value on a recurring basis.

The Company has segregated all financial assets and liabilities that are measured at fair value on a recurring basis into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date in the table below. Other than the warrants issued in connection with the issuance of Common Stock from the underwritten registered offering that closed on April 2, 2019 (the "April 2019 Warrants"), the Company had no assets or liabilities classified as Level 3 as of March 31, 2020 or March 31, 2019. Transfers are calculated on values as of the transfer date. There were no transfers between Levels 1, 2 and 3 during the years ended March 31, 2020 and March 31, 2019.

The fair value of the April 2019 Warrants is considered a Level 3 valuation and was determined using a Monte Carlo simulation model. This model incorporated several assumptions at each valuation date including: the price of the Company's Common Stock on the date of valuation, its expected volatility, the remaining contractual term of the warrant, the risk free interest rate over the term and estimates of the probability of fundamental transactions occurring (See Note 9 for further discussion of the issuance of Common Stock from an underwritten registered offering).

The Company's financial instruments measured at fair value on a recurring basis are as follows:

Description	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
March 31, 2020				
Warrant liability	$ 3,639,000	—	—	$ 3,639,000
March 31, 2019				
Warrant liability	—	—	—	—

The following table summarizes activity for liabilities measured at fair value using Level 3 significant unobservable inputs:

	March 31, 2020
Beginning balance, March 31, 2019	$ —
Fair value of liability-classified warrants issued with common stock	7,283,601
Change in fair value of warrant liability	(3,644,601)
Ending balance	$ 3,639,000

Note 8. Debt.

Insurance Note Payable

During the years ended March 31, 2020 and 2019, 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 $0.5 million and $0.6 million for the policy years ending on March 18, 2021 and 2020, respectively. As of March 31, 2020 and March 31, 2019, there remained a balance of $0.5 million and $0.6 million, respectively, recorded to Insurance note payable on the accompanying consolidated balance sheets.

Note 9. 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 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. In connection with the Securities Purchase Agreement, dated January 7, 2020, between the Company and Eagle (the "Eagle SPA"), the Company designated and reserved 10,000 shares as Series A Preferred Stock. The Series A Preferred Stock shares rank senior to the Company's common stock and have no voting rights. The shares, if issued, would be convertible into common stock and will have a conversion ratio equal to the quotient of $1,000 divided by an amount equal to 1.15 times the average of the volume weighted average price of the Company's Common Stock for the seven trading days immediately following announcement of the Milestone Event (as defined in the SPA).

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 entitled 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 were set to expire two years from the date of issuance and vested immediately. On March 15, 2019, the Board extended the expiration date of the 3,245,288 outstanding warrants through September 30, 2019. On September 30, 2019, the outstanding warrants expired without being exercised.

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 entitled 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 were set to expire two years from the date of issuance and vested immediately. On March 15, 2019, the Board extended the expiration date of the 238,233 outstanding warrants through September 30, 2019. On September 30, 2019, the outstanding warrants expired without being exercised.

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.

April 2019 - Registered Offering

In April 2019, the Company completed an underwritten registered offering of 8,000,000 shares of its common stock, par value $0.0001 per share (the "Common Stock"), at a price of $1.50 per share. The total net proceeds of the offering were $11.3 million after deducting underwriter's discounts and before expenses related to the offering.

As part of the offering, the investors received warrants to purchase up to 8,000,000 shares of the Company's Common Stock at an exercise price of $2.00 per share (the "Warrants").

The Warrants participate with Common Stock on a one-for-one basis for distribution dividends or other assets of the Company.

The exercise price of the Warrants is subject to adjustment upon the occurrence of specific events, including stock dividends, stock splits, combinations and reclassifications of the Company's Common Stock. Subject to certain exceptions, if the Company issues or sells Common Stock or other securities convertible into Common Stock during the term of the Warrants at a per share price less than the exercise price of the Warrants, or if the Company subsequently reduces the exercise price of equity-linked instruments that were outstanding on April 2, 2019, then the exercise price of the Warrants will be reduced to such lower sale or exercise price.

The Company determined that the Warrants should be recorded as a derivative liability on the consolidated balance sheet due to the Warrants' contractual provisions requiring issuance of registered common shares upon exercise and certain price protection rights. At the issuance date, the Warrants were recorded at the fair value of $7.3 million as determined using the Monte Carlo pricing simulation. The Warrants were re-measured at March 31, 2020 and the change in fair value for the year ended March 31, 2020 of approximately $3.6 million, was recorded as a component of other income (expense) within the consolidated statement of operations. As further described under Note 15, "Subsequent Events," on May 20, 2020, the Company exchanged these Warrants with their respective holders for shares of the Company's Common Stock or new warrants in reliance upon the exemption from registration provided by Section 3(a)(9) of the Securities Act of 1933, as amended. After such exchanges, the Warrants no longer remained outstanding.

The following table details key inputs and assumptions used in the Monte Carlo simulation models used to estimate the fair value of the warrant liability as of March 31, 2020 and April 2, 2019, respectively:

	March 31, 2020	April 2, 2019
Stock price	$ 1.10	$ 1.85
Volatility	60%	48%
Remaining term (years)	4.01	5.00
Expected dividend yield	—	—
Risk-free rate	0.33%	2.28%

The following summarizes the common stock warrant activity for the years ended March 31, 2020 and March 31, 2019:

	Warrant Shares of Common Stock	Weighted Average Exercise Price
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
Granted	8,000,000	2.00
Exercised	(78,431)	3.00
Expired	(3,483,521)	3.00
Outstanding at March 31, 2020	8,937,651	$ 2.31

During the year ended March 31, 2020 78,431 warrants were exercised on a cashless basis resulting in the issuance of 4,889 shares. 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 March 31, 2020, 8,907,884 common stock purchase warrants relating to securities purchase agreements were outstanding and exercisable.

Issued	Classification	Warrants Outstanding	Exercise Price	Expiration
December 2015	Equity	446,500	$ 5.00	December 2025
February 2016	Equity	461,384	$ 5.00	February 2026
July 2016	Equity	29,767	$ 5.00	June 2026
April 2019	Liability	8,000,000	$ 2.00	April 2024

At-the-Market Financing Facility

On October 18, 2019, the Company entered into the Sale Agreement with Jefferies, pursuant to which the Company may, from time to time, sell shares of Common Stock, having an aggregate offering price of up to $30,000,000 through Jefferies, as the Company's sales agent. The shares will be offered and sold by the Company pursuant to its previously filed and currently effective Registration Statement on Form S-3, as amended (Reg. No. 333-211489). Any sales of Common Stock pursuant to the Sales Agreement will be made by methods deemed to be an "at-the-market offering" as defined in Rule 415 promulgated under the Securities Act. Jefferies will use commercially reasonable efforts to sell the shares from time to time, based on the instructions of the Company. The Company will pay Jefferies a commission rate of three percent (3%) of the gross proceeds from the sales of shares of Common Stock sold pursuant to the Sale Agreement. Under the Sale Agreement, the Company is not required to use the full available amount authorized and it may, by giving notice as specified in the Sale Agreement, terminate the Sale Agreement at any time.

On October 18, 2019, the Company commenced the Jefferies ATM and during the year ended March 31, 2020, the Company raised approximately $1.7 million in gross proceeds via sale of 1,361,315 shares of Common Stock. The Company incurred $0.2 million of related costs which offset the proceeds. At March 31, 2020, there remained approximately $28.3 million of availability to sell shares through the Jefferies ATM.

On November 2, 2017, the Company had entered into an equity distribution agreement with Canaccord Genuity Inc. ("Canaccord") to commence an at-the-market offering that had an aggregate potential offering price up to $30,000,000 (the "Canaccord ATM"). The Company did not sell any shares through the Canaccord ATM during the year ended March 31, 2020. During the fiscal year ending March 31, 2019, the Company raised approximately $5,844,000 in gross proceeds from the facility. On October 2, 2019, the Company sent notice terminating the equity distribution agreement effective October 12, 2019, having raised a total of $12.1 million through the facility between November 2, 2017 and October 2, 2019.

Securities Purchase Agreement

On January 7, 2020, the Company and Eagle entered into the Eagle SPA, pursuant to which the Company issued and sold to Eagle 10,000,000 shares of common stock, at a price of $2.00 per share. The Eagle SPA provides that Eagle will, subject to certain conditions, make an additional payment of $20 million upon the occurrence of a milestone event, which is defined as the earlier of (i) achievement of the primary endpoint of overall survival in the TYME-88-Panc pivotal trial; (ii) achievement of the primary endpoint of overall survival in the PanCAN Precision Promise SM-88 registration arm; or (iii) FDA approval of SM-88 in any cancer indication. This payment would be split into a $10 million milestone cash payment and a $10 million investment in TYME at a 15% premium to the then prevailing market price. Eagle's shares will be restricted from sale until the earlier of three months following the milestone event or the three-year anniversary of the agreement.

Note 10. Commitments and Contingencies.

Contract Service Providers

In the course of the Company's normal business operations, it enters into agreements and arrangements with contract service providers to assist in the performance of its research and development and clinical research activities.

On April 1, 2020, the Company amended the Clinical Research Funding and Drug Supply Agreement, dated October 9, 2018, with PanCAN, to enroll individuals diagnosed with pancreatic cancer in a platform style clinical research study. Stage 1 of the study was initiated in the fourth quarter of fiscal year 2020. After taking into consideration amounts already paid, the remaining estimated cost to the Company, which primarily consists of patient treatment costs, for Stage 1 is approximately $7.5 million, subject to enrollment adjustments, and is expected to be incurred over the next two and a half years.

Purchase Commitments

The Company has entered into 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 $1.6 million at March 31, 2020.

Legal Proceedings

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. 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.

Note 11. Leases.

The Company leases office space in New York and office space and furniture in New Jersey. The New York rent obligation has been prepaid through August 30, 2020, the end of the lease. The New Jersey leases expire in February 2021.

Total Company rent expense, including short term rentals, was approximately $313,000 and $243,000 for years ended March 31, 2020 and 2019, respectively.

Operating lease right-of-use ("ROU") assets and liabilities on the consolidated balance sheet represents the present value of the remaining lease payments over the remaining lease terms. ROU assets also include any initial direct costs incurred and any lease payments made at or before the lease commencement date, less lease incentives received. Payments for additional monthly fees to cover the Company's share of certain facility expenses are not included in operating lease ROU assets and liabilities. The Company uses its estimated incremental borrowing rate of 6.0% to calculate the present value of its lease payments, as the implicit rates in the leases are not readily determinable.

As of March 31, 2020, the future minimum lease payments under non-cancellable operating lease agreements for which the Company has recognized operating lease ROU assets and lease liabilities were as follows:

	March 31, 2020
Fiscal year 2021	$ 56,000
Total remaining lease payments	56,000
Less: present value adjustment	(1,000)
Total operating lease liabilities	55,000
Less: current portion	(55,000)
Operating lease liabilities, net of current portion	$ -

Note 12. Related Party Transactions.

Legal

Faegre Drinker Biddle & Reath ("Faegre Drinker"), formerly 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 13, 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, 2020 and 2019, approximately $0.9 million and $1.0 million (of which $0.5 million and $0.2 million was capitalized into equity), respectively, have been incurred as legal expenses associated with Faegre Drinker, and the Company had approximately $73,000 and $325,000 in accounts payable and accrued expenses payable to Faegre Drinker at March 31, 2020 and March 31, 2019, respectively.

Note 13. 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"). 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, 2020, there were 4,896,006 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, 2020, there were 1,279,167 shares available for grant under the 2016 Director Plan.

Stock Options

As of March 31, 2020, and 2019, there was approximately $4.2 million and $7.3 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 amortization period of 1.5 years. During the years ended March 31, 2020 and 2019, the Company had stock compensation expense of $6.1 million and $9.0 million, respectively. For the year ended March 31, 2020, stock compensation expense is recognized as $3.6 million in general and administrative expense, $2.5 million in research and development expense. For the year ended March 31, 2019, stock compensation expense recognized was $5.7 million in general and administrative expense and $2.9 million in research and development expense and $0.4 million in severance 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 forfeitures 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,	
	2020	**2019**
Risk free interest rate	0.304% - 2.38%	2.24% - 3.10%
Expected volatility	71.65% - 78.95%	71.86% - 76.31%
Expected term	2.5 - 6 years	3 - 6.5 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, 2020:

	Number of Options	Weighted Average Exercise Price
Outstanding at March 31, 2019	8,953,527	$ 4.13
Granted	3,167,280	1.47
Exercised	-	-
Cancelled/Forfeited	(42,500)	1.67
Expired	(262,325)	4.10
Outstanding at March 31, 2020	11,815,982	3.43
Options exercisable at March 31, 2020	8,224,475	$ 4.05

Weighted-average grant date fair value of options granted during the years ended March 31, 2020 and 2019 was $0.96 and $1.76, respectively.

	Stock Options Outstanding				Stock Options Vested			
Range of Exercise Price	Number Outstanding at March 31, 2020	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value	Number Vested at March 31, 2020	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value
$0.98 - $8.75	11,815,982	$ 3.43	7.53	$ 8,400	8,224,475	$ 4.05	7.15	$ 400

The intrinsic value calculated as the excess of the market value of as March 31, 2020 over the exercise price of the options, is $8,400. The market value as of March 31, 2020 was $1.10 as reported by the NASDAQ Capital Market. The total intrinsic value of options exercised during the year ended March 31, 2020 was zero.

	Options	Weighted Average Grant Date Fair Value Per Share
Non-vested options at March 31, 2019	3,465,202	$ 2.29
Granted	3,167,280	0.96
Vested	(2,998,475)	2.01
Forfeited	(42,500)	0.96
Non-vested options at March 31, 2020	3,591,507	$ 1.36

The fair value of options vested during the years ended March 31, 2020 and 2019 was $6,035,672 and $8,298,730, respectively.

Note 14. 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 $22.0 million and $33.0 million for the years ended March 31, 2020 and 2019, 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,	
	2020	2019
Net operating loss carryforward	$ 14,562,024	$ 10,663,981
Research and development credit carryforward	1,804,233	718,748
Stock options - NQSOs	5,877,971	4,518,506
Accruals and other temporary differences	825,696	864,789
Gross deferred tax assets	23,069,924	16,766,024
Deferred tax valuation allowance	(23,069,924)	(16,766,024)
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, 2020. The valuation allowance increased by $6.3 million for the year ended March 31, 2020 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,	
	2020	2019
U.S. statutory income tax rate	21.0%	21.0%
Permanent differences	3.3	(0.8)
R&D credit carryforwards	4.4	1.3
Valuation allowance	(28.7)	(21.5)
Effective tax rate	—%	—%

As of March 31, 2020, the Company had gross U.S. federal net operating loss carryforwards of approximately $69.3 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, 2020, 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 permitted under the Protecting Americans Against Tax Hikes Act, which allows the Research and Development tax credit to be applied to Form 941 quarterly payroll tax returns, the Company reduced payroll taxes by $170 thousand and $33 thousand for the years ended March 31, 2020 and March 31, 2019, respectively. As of March 31, 2020, the Company had gross federal research and development tax credit carryforwards of $2.1 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,	
	2020	2019
Gross unrecognized tax benefits at beginning of year	$ 126,838	$ 469,167
Increases (decreases) for tax positions in prior period	70,293	(396,749)
Increase for tax positions in current period	121,263	54,420
Gross unrecognized tax benefits at end of year	$ 318,394	$ 126,838

As of March 31, 2020, the Company had $318,394 of unrecognized tax benefits, which were offset with the net operating loss and valuation allowance on the consolidated balance sheets. None of the gross unrecognized tax benefits would affect the effective tax rate at March 31, 2020, 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, 2016 through March 31, 2019. 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 15. 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.

Exchange Agreements

On May 20, 2020, the Company entered into exchange agreements with holders (the "Holders") of warrants to purchase shares of the Company's Common Stock, which warrants were issued on April 2, 2019 (the "Existing Warrants"). The Existing Warrants were offered and issued pursuant to the Company's Registration Statement on Form S-3 (Registration No. 333-211489), which was declared effective by the Securities and Exchange Commission on August 16, 2017, a base prospectus dated August 16, 2017 and a prospectus supplement dated March 28, 2019.

Pursuant to exchange agreements (the "Share Exchange Agreements") with Holders of Existing Warrants to purchase 5,833,333 shares of Common Stock in the aggregate, the Company issued an aggregate of 2,406,250 shares of Common stock (the "Exchange Shares") in exchange for such Existing Warrants. Concurrently therewith, each such Holder executed and delivered to the Company a leak-out agreement (a "Share Leak-Out Agreement") that contains trading restrictions with respect to the Exchange Shares, which (i) for the first 90 days, prohibit any sales of Exchange Shares, (ii) for the subsequent 90 days, limit sales of Exchange Shares on any day to 2.5% of that day's trading volume of Common Stock, and (iii) prohibit new short positions or short sales on Common Stock for the combined 180 day period.

The Company also entered into an exchange agreement (the "Warrant Exchange Agreement") with another Holder of Existing Warrants to purchase 2,166,667 shares of Common Stock in the aggregate. Pursuant to the Warrant Exchange Agreement, the Company issued such Holder a new warrant (the "New Warrant") to purchase the same number of shares of Common Stock. The New Warrant has the same expiration date, April 2, 2024, as the Existing Warrants, but has an exercise price of $1.80 and does not include the price protection, anti-dilution provisions or

other restrictions on Company action from the Existing Warrants. Concurrently therewith, such Holder executed and delivered to the Company a leak-out agreement that contains trading restrictions on sales of Common Stock issued upon exercise of the New Warrant that are substantially similar to the restrictions on Exchange Shares in the Share Leak-Out Agreement, provided that the leak-out restrictions will only apply to the first 893,750 shares of Common Stock issued pursuant to the New Warrant.

ITEM 9. CHANGES IN AND DISAGREEMENTS 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 Securities Exchange Act of 1934, as amended (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 by 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 Exchange Act, 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, 2020, our disclosure controls and procedures were effective.

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 Exchange Act.

Our 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 and includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- 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 the board of directors of the Company; and
- 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 because of declines in the degree of compliance with policies or procedures.

Management assessed the effectiveness of our internal control over financial reporting as of March 31, 2020. 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, 2020, our Chief Executive Officer and Chief Financial Officer concluded that as of such date, our internal control over financial reporting was effective.

This Annual Report on Form 10-K does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to the rules of the SEC that permit the Company to provide only management's report in this Annual Report on Form 10-K.

Changes in Internal Control Over Financial Reporting

There have been no changes in the Company's internal control over financial reporting that occurred during the quarter ended March 31, 2020 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B. OTHER 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 18, 2020 regarding our Board of Directors:

Name	Age	Position(s) with the Company/Principal Occupation	Date Elected to Our Board of Directors
Steve Hoffman	57	Director, Chief Executive Officer and Chief Science Officer of the Company	March 5, 2015*
Dr. Gerald Sokol	77	Director/Chief of Radiation Oncology, University of South Florida's Tampa General Hospital	March 10, 2015
Timothy C. Tyson	68	Director/Former Chairman and Chief Executive Officer, Avara Pharmaceutical Services	March 10, 2015
Paul Sturman	59	Director/Chief Executive Officer, Nature's Bounty Co.	March 2, 2017
David Carberry	67	Director/Former Chief Financial Officer of Excellis Health Solutions, LLC (Retired)	March 30, 2017
Donald W. DeGolyer	59	Director/Chief Executive Officer, Vertice Pharma LLC	May 24, 2018
Douglas A. Michels	63	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 a merger on March 5, 2015 whereby we acquired our current clinical-stage pharmaceutical business.

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, 2020.

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, 2020.

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, 2020.

The following table provides certain information with respect to all of our equity compensation plans in effect as of March 31, 2020:

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, 2020	11,815,982	(1)	$ 3.43	6,175,173
Equity compensation plans not approved by stockholders prior to March 31, 2020	29,767	(2)	$ 5.00	—
Total Equity	11,845,749		$ 3.43	6,175,173

(1) Includes 11,815,982 shares of our common stock issuable under option awards made prior to March 31, 2020 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 $3.43 per share. For a description of the terms of the 2015 Equity Incentive Plan and 2016 Director Plan, please see Note 13 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, 2020 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 6,175,173 shares of our common stock issuable under awards eligible to be made (and not outstanding) as of March 31, 2020 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, 2020.

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, 2020.

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

Report of Independent Registered Public Accounting Firm 85

Consolidated Balance Sheets as of March 31, 2020 and March 31, 2019 86

Consolidated Statements of Operations for the years ended March 31, 2020 and 2019 87

Consolidated Statements of Stockholders' Equity for the years ended March 31, 2020 and 2019 88

Consolidated Statements of Cash Flows for the years ended March 31, 2020 and 2019 89

Notes to Consolidated Financial Statements as of March 31, 2020 and 2019 90

(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	Certificate of Designation of Series A Convertible Preferred Stock, dated January 7, 2020. (Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K, filed with the SEC on January 8, 2020.)
3.4	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	Registration Rights Agreement, dated January 7, 2020, between the Company and Eagle. (Incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K, filed with the SEC on January 8, 2020.)
4.7	Form of New Warrant, dated May 20, 2020. (Incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K, filed with the SEC on May 20, 2020.)
4.8	Description of Common Stock, dated as of June 12, 2019. (Incorporated by reference to Exhibit 4.6 to our Annual Report on Form 10-K, filed with the SEC on 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	Open Market Sale Agreement, dated as of October 18, 2019, by and between Tyme Technologies, Inc. and Jefferies LLC. (Incorporated by reference to Exhibit 1.1 to our Current Report on Form 8-K, filed with the SEC on October 18, 2019.)

10.4†	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.)
10.5†	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.)
10.6†	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.)
10.7†	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.)
10.8†	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.)
10.9†	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.)
10.10†	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.)
10.11†	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.)
10.12†	Form of Nonqualified Stock Option Agreement under the Tyme Technologies, Inc. 2016 Stock Option Plan for Non-Employee Directors. (Incorporated by reference to Exhibit 10.11 to our Annual Report on Form 10-K, filed with the SEC on June 12, 2019.)
10.13†	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.)
10.14†	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.)
10.15†	Release Agreement, dated as of March 15, 2019, between Tyme Technologies, Inc. and Michael Demurjian. (Incorporated by reference to Exhibit 10.14 to our Annual Report on Form 10-K, filed with the SEC on June 12, 2019.)
10.16†	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.)
10.17†	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.)
10.18†*	Employment Agreement, dated as of October 9, 2018, by and between Michele Korfin and Tyme Technologies, Inc.

10.19†	Securities Purchase Agreement, dated January 7, 2020, between the Company and Eagle Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on January 8, 2020.)***
10.20†*	Co-Promotion Agreement with Eagle Pharmaceuticals, Inc., dated January 7, 2020.****
10.21	Form of Share Exchange Agreement, dated May 20, 2020. (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on May 20, 2020.)
10.22	Form of Warrant Exchange Agreement, dated May 20, 2020. (Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K, filed with the SEC on May 20, 2020.)
10.23	Form of Share Leak-Out Agreement, dated May 20, 2020. (Incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K, filed with the SEC on May 20, 2020.)
10.24	Form of Warrant Leak-Out Agreement, dated May 20, 2020. (Incorporated by reference to Exhibit 10.4 to our Current Report on Form 8-K, filed with the SEC on May 20, 2020.)
21.1*	List of Subsidiaries.
23.1*	Consent of Independent Registered 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
** Furnished herewith
*** Certain exhibits have been omitted and the Company agrees to furnish supplementally to the SEC a copy of any omitted exhibits upon request.
**** Certain confidential information contained in the document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful to the Company if publicly disclosed.

SIGNATURES

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

Dated: May 22, 2020

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)	May 22, 2020
/s/ Barbara C. Galaini Barbara C. Galaini	Corporate Controller (Principal Accounting Officer)	May 22, 2020
/s/ Ben R. Taylor Ben R. Taylor	Chief Financial Officer and President (Principal Financial Officer)	May 22, 2020
/s/ Gerald Sokol Gerald Sokol	Director	May 22, 2020
/s/ Paul L. Sturman Paul L. Sturman	Director	May 22, 2020
/s/ David Carberry David Carberry	Director	May 22, 2020
/s/ Timothy C. Tyson Timothy C. Tyson	Director	May 22, 2020
/s/ Douglas A. Michels Douglas A. Michels	Director	May 22, 2020
/s/ Donald W. DeGolyer Donald W. DeGolyer	Director	May 22, 2020

EXHIBIT 10.18

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

October 9, 2018

Ms. Michele Korfin
202 Meadow View Lane Glen Garner. NJ 08826

Dear Michele:

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

1. Employment. Your employment with the Company will be upon the terms and conditions set forth in this letter agreement beginning on the first business day immediately following the date that you sign this letter agreement (the "**Effective Date**") and ending as provided in Section 4 (the "**Employment Period**").

2. Position and Duties. During the Employment Period, you will serve as Chief Commercial 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**") and/or the President of the Company ("**President**") which are consistent with your position. You will report directly to the CEO. 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**"). Except for travel for business purposes, you will be employed and your primary offices will be located at the Company offices located at 17 State Street – 7th Floor – New York, New York 10004 (the "**Company Office**") or the office expected to be located near Bridgewater, New Jersey (the "**New Jersey Office**"). You will divide your working time between the Company Office and the New Jersey Office as the Company reasonably determines is necessary for the performance of your duties hereunder.

3. Compensation.

(a) During the Employment Period, your base salary will be $390,000 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 the first anniversary date of this letter agreement) by the Board and may be increased by the Board in its sole discretion (for the avoidance of doubt, such increased amount shall be considered your "Base

Salary" for all purposes of this letter agreement). Unless agreed by you in writing, your Base Salary may not be decreased by the Board or otherwise.

(b) 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.

(c) In connection with your entering into this letter agreement, we shall grant to you, on October 9, 2018 (the "**Grant Date**"), under the Company's 2015 Equity Incentive Plan (the "**2015 Plan**"), an option (the "Option") to purchase up to 500,000 shares (each, an "Option Share") of the common stock, par value $0.0001 per share (the "**Common Stock**"), of the Company, at a per Option Share purchase (exercise) price equal to the Fair Market Value (as defined in the 2015 Plan) of the Common Stock on the Grant Date. The Option shall have a term of ten years and, except as provided in Section 5(a)(v) below, shall vest as follows: 50,000 shares on the date hereof and 450,000 shares in twelve equal quarterly installments of 37,500 shares beginning on January 1, 2019 (each, a "**Vesting Date**"), provided that you are employed by the Company on the relevant Vesting Date, and otherwise subject to the provisions of the 2015 Plan. For the avoidance of doubt, except as provided in Section 5(a)(v) below, in the event you terminate employment with the Company prior to full vesting of the Option, the unvested portion of the Option will expire and terminate in full as of such termination and you will not have any right to exercise the unvested portion of the Option. The number of Option Shares and purchase price shall be adjusted in the event of any stock splits, mergers, consolidations or similar transactions. The Option shall be evidenced by a Stock Option Agreement in the form attached as **Exhibit A** to this letter agreement (the "**Stock Option**"). In the event of any conflict between the provisions of this paragraph 3(c) and the provisions of the 2015 Plan and Stock Option, the provisions of the 2015 Plan and Stock Option shall govern.

(d) During the Employment Period, you will be entitled to participate in all employee benefit programs, including without limitation health/medical insurance, for which senior executive employees of the Company are generally eligible, subject to applicable 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. For the avoidance of doubt, time devoted to satisfy minimum continuing medical education shall be considered travel for work.

(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**").

(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.

4. Termination. The Employment Period will end on the date which is 12 months (*i.e.*, one year) following the Effective Date, unless it is sooner terminated or is extended as provided below. Unless the Employment Period has been terminated in accordance with the following sentence of this Section 4 or one party has given at least 60 days' advance, written notice (the "**Renewal Notice**") that you or the Company seek to terminate the employment arrangement at the expiration of the then current Employment Period, commencing with the one year anniversary of the Effective Date, and on each subsequent anniversary of the Effective Date, the Employment Period shall automatically be extended by an additional 12 months. 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. For the avoidance of doubt, if the Company gives you a Nonrenewal Notice at any time after the Effective Date, the giving of such Nonrenewal Notice shall be deemed to be a termination of your employment by the Company without Cause for purposes of Section 5(a) below.

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 one year of your Base Salary, less applicable withholdings, 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; provided, however, if the Employment Period is terminated by the Company or by you with or without Good Reason within 30 days after the Effective Date, you will not be entitled to the payments and benefits set forth in Section 5(a)(ii), (iii), (iv) and (v). 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 B**; 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), with 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), the Company's Directors and Officers Liability Insurance coverage, 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 Company (other than termination upon your death) or by you must be communicated by written notice (in either case, a "**Notice of Termination**") to you, 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 Employment Period by you must be communicated to the Company no less than 30 days prior to the intended Termination Date; provided, however, you may provide Notice of Termination to the Company at any time within 30 days after the Effective Date and, unless otherwise specified, the Termination Date shall be the date of such Notice of Termination.

(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 CEO or President 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 Company Affiliates pursuant to this letter agreement 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 you to waive or diminish any of your rights hereunder), but only to the extent that such circumstances are reasonably curable, and (c) you elect to terminate the Employment 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 the 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 additional 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 you 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 President, (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 under 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 the 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 the 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 Confidential 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 continued 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 President and perform all actions reasonably requested by the CEO and President (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 have and will continue to 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, you agree that, during the Restriction Period (as defined in Section 9(b) below), and for a period of eighteen (18) months following such Restriction Period, 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 resources in connection with expanding its business, directly or indirectly, either on your own behalf or on behalf of any other person, firm or entity:

(i) own, manage, operate, 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 engaged in the business of manufacturing, marketing, sale, research or development of pharmaceuticals for cancer utilizing a methodology or mechanism that is similar to methodologies or mechanisms used by the Company (collectively, "**Specified Therapies**"); provided, however, that this Section 9(a)(i) shall not prohibit you from working, after the Restriction Period for an entity that engages in the manufacture, sale, marketing or distribution of pharmaceutical products so long as neither you nor such employer is involved in the manufacturing, marketing, sale or research or development of therapeutics or pharmaceuticals for any of the Specified Therapies; 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 (i) the Employment Period and any other period during which you are employed by the Company or any of its Affiliates, whether pursuant to this Agreement or otherwise, and (ii) a period of six months following your separation from employment, regardless of the reason for your separation and whether caused by you or the Company.

(c) Nothing in Section 9(a) will prohibit you from being a passive owner of not more than 2% of the outstanding stock of a publicly-traded corporation, so long as you have no active participation in the business of such corporation.

(d) During the Restriction Period and for a period of eighteen (18) months following the Restriction Period, you also will not:

(i) induce or attempt to induce any customer, supplier or other business relation of the Company or any of 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;

(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, if she or she has been in such a role at any time within the immediately prior three months; or

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

(e) The Company, on behalf of itself and all 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.

(f) Notwithstanding anything herein to the contrary, Section 9(a) shall not apply if this Agreement is terminated within 30 days after the Effective Date by the Company without cause or by you with or without Good Reason.

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:

Ben Taylor, President Tyme Technologies,
Inc. 17 State Street - 7th Floor
New York, New York 10004

and with a copy (which shall not constitute notice) to: Attn: Jim Biehl, Esq.
Tyme Technologies, Inc. 17 State Street - 7th
Floor
New York, New York 10004

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 able to perform the 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 does not and will not conflict with, breach, violate or cause a default under any agreement, contract or instrument to which it is a party or any judgment, order or decree to which it is subject and (ii) upon the execution and delivery of this letter agreement by the Company and you, such agreements will be valid and binding obligations of the Company.

13. Lock-Up Agreement. In connection with a registration with the United States Securities and Exchange Commission under the Securities Act of the public sale of shares of Common Stock, you shall not to sell, make any short sale of, loan, grant any option for the purchase of, or otherwise dispose of any securities of the Company (other than those included in the registration) without the prior written consent of the Company or such underwriters, as the case may be, for such period of time prior to the effective date of such registration and continuing through and following the effective date of such registration (not to exceed 180 days) as the Company or the underwriters, as the case may be, shall specify. You agree that the Company may

instruct its transfer agent to place stop-transfer notations in its records to enforce the provisions of this Section. You shall execute a form of agreement reflecting the foregoing restrictions as requested by the underwriters managing such offering.

14. 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 York, 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 New York, New York.

(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) "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.

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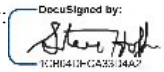
If this letter agreement correctly expresses our mutual understanding, please sign and date a copy of this letter agreement and return it to the Company.

Very truly yours,

Tyme Technologies, Inc.

5004308-94986By: DocuSigned by: 

Name: Steve Hoffman

Title:
Executive Officer

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

Michele Korfin

10/9/2018 | 11:48:12 EDT
Date

EXHIBIT A

Tyme Technologies, Inc.
Nonqualified Stock Option Agreement

EXHIBIT B

Form of Release RELEASE

This Release ("**Release**") is delivered by Michele Korfin 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 Michele Korfin and all of her 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 October 9, 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 of consortium, violation of the penal statutes, negligent or intentional infliction of emotional distress, negligence, defamation, retaliation and/or discrimination and/or harassment on account of age, sex, sexual orientation, creed, religion, race, color, national origin, sensory disability, mental disability, physical disability, veteran or military status, marital status, or any other classification recognized under all applicable discrimination laws, or any other claim or cause of action, which has or could have been alleged under the common law, civil rights statutes, Title VII of the Civil Rights Act of 1964 ("**Title VII**"), the Age Discrimination in Employment Act ("**ADEA**"), the Family and Medical Leave Act ("**FMLA**"), the Employee Retirement Income Security Act ("**ERISA**"), the Rehabilitation Act of 1973, the Older Workers Benefits Protection Act ("**OWBPA**"), the Americans with Disabilities Act ("**ADA**"), The Consolidated Omnibus Budget Reconciliation Act ("**COBRA**"), the Workers Adjustment Retraining Notification Act ("**WARN**"), the Equal Pay Act ("**EPA**"), the Uniformed Services Employment and Reemployment Rights Act ("**USERRA**"), the National Labor Relations Act ("**NLRA**"), the New York State Human Rights Law, the New York City Human Rights Law, the New York Labor Law, and any and all other federal, state, local statutes, ordinances, and laws, and every type of relief (legal, equitable and otherwise), available to Employee. Employee covenants and agrees that she 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 releasing 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 terms of the Employment Agreement that survive the termination of the Employment Period (as defined in the Employment Agreement) or Employment Agreement; (c) Employee's rights described in Section 5(d) of the Employment Agreement; (d) Employee's non-forfeitable rights to accrued benefits (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 (including without limitation any such rights under Employer's Certificate of Incorporation, By-laws and Directors and Officers Liability Insurance coverage); (f) any claims 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 proceeding 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 her ability to obtain relief of any kind from Employer to the extent permitted by law.

3. Covenant Not to Sue. Employee represents that she 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 her behalf by any federal, state or local agency or by any other person or entity with respect to a Released Claim, she 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 employment with Employer, as well as the terms of this Release; provided however, Employee may discuss the terms of this Release with her 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 she 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 she 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 her for reasonable travel expenses (including lodging and meals) upon submission of receipts acceptable to Employer.

7. ADEA Notice and Acknowledgement. Employee acknowledges that she 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 her 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 45 days to review and consider this Release. Employee may voluntarily and knowingly waive this 45-day period, or any part thereof, if she signs this Release prior to the expiration of 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 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 she is waiving and releasing any and all rights she may have to pursue the Released Claims against Employer, from the beginning of time up to the effective date of this Release, including, without limitation, all ADEA claims.

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

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 she 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:

Michele Korfin

EXHIBIT 10.20

EXECUTION VERSION

CO-PROMOTION AGREEMENT

by and between

TYME TECHNOLOGIES, INC.
And

EAGLE PHARMACEUTICALS, INC.

January 7, 2020

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CO-PROMOTION AGREEMENT

This Co-Promotion Agreement (this "**Agreement**") is entered into and dated as of January 7, 2020 (the "**Effective Date**") by and between Tyme Technologies, Inc., a Delaware corporation ("**TYME**"), and Eagle Pharmaceuticals, Inc., a Delaware corporation ("**Eagle**"). TYME and Eagle are each referred to individually as a "**Party**" and together as the "**Parties**".

RECITALS

WHEREAS, TYME is an emerging biotechnology company developing cancer metabolism-based therapies and owns or otherwise controls certain intellectual property rights, clinical data and regulatory filings related to the compound SM-88 (racemetyrosine) (defined below), which is the subject of clinical development;

WHEREAS, Eagle is in the business of developing and commercializing drugs, primarily in the critical care and oncology areas, including through collaboration agreements;

WHEREAS, the Parties believe that it would be mutually beneficial to collaborate on promotional activities for the Product (defined below) and, accordingly, TYME desires that Eagle conduct certain promotional activities, and Eagle desires to conduct such activities, for the Product in the Territory;

WHEREAS, simultaneously with the execution and delivery of this Agreement, the Parties have entered into that certain Securities Purchase Agreement, providing for, among other things, the issuance and sale by TYME of shares of TYME common stock to Eagle in return for Eagle's upfront payment of $20 million in cash and TYME's right to receive additional milestone payments upon the achievement of certain milestones as provided therein;

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1 DEFINITIONS

Unless otherwise defined in this Agreement, the following terms shall have the meanings provided hereunder:

1.1 "**Act**" shall mean the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., as it may be amended from time to time, and the regulations promulgated thereunder.

1.2 "**Adverse Event**" shall mean any untoward medical occurrence in a patient or clinical investigation subject who is administered the Product, but which does not necessarily have a causal relationship with the treatment for which the Product is used. An "Adverse Event" can include any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of the Product, whether or not related to the Product. A pre- existing condition that worsened in severity after administration of the Product would be considered an "Adverse Event".

1.3 "**Affiliate**" shall mean, with respect to any Person, any other Person that directly or indirectly controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses the power to direct or cause the direction of the management, business and policies of such Person, whether through the ownership of fifty percent (50%) or more (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting securities of such Person, by contract or otherwise.

1.4 "**Agreement**" shall have the meaning set forth in the preamble to this Agreement.

1.5 "**Alliance Managers**" shall have the meaning set forth in Section 4.1.5.

1.6 "**Applicable Laws**" shall mean all applicable statutes, ordinances, regulations, codes, rules, or orders of any kind whatsoever of any Governmental Authority in the Territory pertaining to any of the activities and obligations contemplated by this Agreement, including, as applicable, the Act, the Generic Drug Enforcement Act of 1992 (21 U.S.C. § 335a et seq.), the Anti-Kickback Statute (42 U.S.C. § 1320a-7b et seq.), the Health Insurance Portability and Accountability Act of 1996, the Federal False Claims Act (31 U.S.C. §§ 3729-3733) (and applicable state false claims acts), the Physician Payments Sunshine

Act, the Code, the Department of Health and Human Services Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, released April 2003, the Antifraud and Abuse Amendment to the Social Security Act, the American Medical Association guidelines on gifts to physicians, generally accepted standards of good clinical practices adopted by current FDA regulations, as well as any state laws and regulations (i) impacting the promotion of pharmaceutical products,
(ii) governing the provision of meals and other gifts to medical professionals, including pharmacists, or (iii) governing consumer protection and deceptive trade practices, including any state anti-kickback/fraud and abuse related laws, all as amended from time to time.

1.7 "**Business Day**" means each day of the week, excluding Saturday, Sunday or a day on which banking institutions in New York, New York, USA are closed.

1.8 "**Buyout Amount**" means $200 million.

1.9 "**Claims**" shall mean all charges, complaints, actions, suits, proceedings, hearings, investigations, claims, demands, judgments, orders, decrees, stipulations or injunctions, in each case of a Third Party (including any Governmental Authority).

1.10 "**Code**" shall mean the Code on Interactions with Healthcare Professionals promulgated by the Pharmaceutical Research and Manufacturers of America (PhRMA)/BIO, as it may be amended.

1.11 "**Commercialize**," "**Commercializing**," and "**Commercialization**" means activities directed to manufacturing, obtaining pricing and reimbursement approvals for, marketing, promoting, distributing, importing, and/or selling the Product.

1.12 "**Commercially Reasonable Efforts**" means, with respect to a Party's obligations under this Agreement, a measure of effort and resources consistent with the exercise of prudent scientific and business judgment and the reasonable practices that would typically be exerted by a similarly situated pharmaceutical or biotechnology company of comparable size and capabilities as such company for the Development or Commercialization of a pharmaceutical product with similar characteristics owned by such company at a similar stage of development or commercialization as the Product, taking into account efficacy and safety considerations, and other relevant scientific, technical, and commercial factors, including product profile, the regulatory environment, competitiveness of the marketplace and market potential, and price and reimbursement status.

1.13 "**Compensation Report**" shall have the meaning set forth in Section 4.2.2(b).

1.14 "**Compliance Manager**" shall have the meaning set forth in Section 4.3.10.

1.15 "**Compliance Report**" shall have the meaning set forth in Section 4.2.2(c).

1.16 "**Confidential Information**" shall mean all secret, confidential, non-public or proprietary Know-How, whether provided in written, oral, graphic, video, computer or other form, provided by or on behalf of one Party to the other Party pursuant to this Agreement, including information relating to the disclosing Party's existing or proposed research, development efforts, promotional efforts, regulatory matters, patent applications or business and any other materials that have not been made available by the disclosing Party to the general public. All such information related to this Agreement disclosed by or on behalf of a Party (or its Affiliate) to the other Party (or its Affiliate) pursuant to the Confidentiality Agreement shall be deemed to be such Party's Confidential Information disclosed hereunder. For purposes of clarity, (i) TYME's Confidential Information shall include all Product Materials unless and until made available by TYME to the general public (including through Eagle) and (ii) the terms of this Agreement shall be considered Confidential Information of both Parties.

1.17 "**Confidentiality Agreement**" shall have the meaning set forth in Section 8.1.1.

1.18 "**Detail(s)**" shall mean the Product presentation during a face-to-face sales call between a Target Professional and a Sales Representative, during which a presentation of the Product's attributes, benefits, prescribing information and safety information are orally presented, for use in the Field in the Territory. Neither e-details, nor presentations made at conventions, exhibit booths, a sample drop, educational programs or speaker meetings, or similar gatherings, shall constitute a Detail.

1.19 "**Detail Report**" shall have the meaning set forth in Section 4.2.2.

1.20 "**Development**" shall mean non-clinical, pre-clinical and clinical drug discovery, research, and/or development activities, including without limitation quality assurance and quality control development, and any other activities reasonably related to or leading to the development and submission of information to a Regulatory Authority. When used as a verb, "**Develop**" means to engage in Development.

1.21 "**Dispute**" shall have the meaning set forth in Section 12.6.

1.22 "**Dollar**" or "**$**" shall mean United States dollar.

1.23 "**Eagle Activities**" shall mean any and all promotional activities (including Detailing) conducted by Eagle with respect to the Product in the Territory, as set forth in the Sales Plan or otherwise mutually agreed upon by the Parties in writing, in each case, in accordance with the terms of this Agreement.

1.24 "**Eagle Property**" shall have the meaning set forth in Section 7.1.1.

1.25 "**Eagle Quarterly Minimum Details**" for an applicable Fiscal Quarter shall mean the number established by the Operating Parameters Schedule as in effect from time to time.

1.26 "**Effective Date**" shall have the meaning set forth in the preamble to this Agreement.

1.27 "**Exclusive Detail**" shall mean a Detail for which the Product is the sole product detailed on the call.

1.28 "**Exhibit**" shall mean an exhibit attached to this Agreement.

1.29 "**FDA**" shall mean the United States Food and Drug Administration or any successor agency performing comparable functions.

1.30 "**Field**" shall mean the treatment of any and all indications for which the Product is approved in humans in the Territory.

1.31 "**Field Force Personnel**" shall mean collectively, the Sales Representatives, and any other employees of Eagle engaged in the Eagle Activities.

1.32 "**First Commercial Sale**" shall mean the first commercial sale of the Product for monetary value by TYME, one or more of its Affiliates or one or more of its licensees in an arm's length transaction to a Third Party that is not a licensee, including without limitation any final sale to a distributor or wholesaler under any non-conditional sale arrangement, of the Product in the Field in the Territory after Regulatory Approval of the Product has been granted in the Field in the Territory. For the avoidance of doubt, sales or transfers of the Product for clinical and non-clinical research and trials (including studies reasonably necessary to comply with Applicable Law or requests by a Regulatory Authority), early access programs or for compassionate or similar use, shall not be considered a First Commercial Sale.

1.33 "**Fiscal Quarter**" shall mean each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1.

1.34 "**Fiscal Year**" shall mean each successive period of (12) twelve months commencing on April 1 and ending on March 31st.

1.35 "**GAAP**" shall mean United States generally accepted accounting principles.

1.36 "**Governmental Authority**" shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member, which has competent and binding authority to decide, mandate, regulate, enforce, or otherwise control the activities of the Parties contemplated by this Agreement.

1.37 "**Indemnified Party**" shall have the meaning set forth in Section 10.3.

1.38 "**Indemnifying Party**" shall have the meaning set forth in Section 10.3.

1.39 "**Intellectual Property**" shall have the meaning set forth in Section 7.1.2.

1.40 "**Inventions**" shall have the meaning set forth in Section 7.1.2.

1.41 "**Know-How**" shall mean information, whether or not in written form, including biological, chemical, pharmacological, toxicological, medical or clinical, analytical, quality, manufacturing, research, or sales and marketing information, including processes, methods, procedures, techniques, plans, programs and data.

1.42 "**License**" shall mean any agreement pursuant to which TYME grants to a Third Party (a "**Licensee**") a license, sublicense, or other right to any TYME Patent Rights or Regulatory Filings or Regulatory Approvals relating to the Product; *provided, however*, that a License shall not include (a) any agreement with any distributor or wholesaler that obtains solely the right to distribute the Product after purchase from TYME and (i) serves as a logistics services provider or (ii) otherwise distributes the Product to pharmacies, group purchasing organizations or similar entities, but in each case of (i) and (ii), without the right to co-market or co-promote the Product, or (b) any agreement pursuant to which TYME or any of its Affiliates grants a license or sublicense of any of its intellectual property rights (i) solely to conduct research, (ii) solely to manufacture the Product, or (iii) otherwise to service providers solely on a non-exclusive basis in the ordinary course of Development or Commercialization of the Product (e.g., material transfer agreements, distribution agreements, and consulting agreements).

1.43 "**Licensee**" has the meaning set forth in the definition of License.

1.44 "**Losses**" shall mean any and all amounts paid or payable to Third Parties with respect to a Claim (including any and all losses, damages, obligations, liabilities, fines, fees, penalties, awards, judgments, interest), together with all documented out-of-pocket costs and expenses, including attorney's fees, reasonably incurred.

1.45 "**Minimum Sales Representatives Requirement**" has the meaning set forth in the definition of Operating Parameters Schedule.

1.46 "**Multidisciplinary Detail**" shall mean a Detail call to a sales account with a multidisciplinary oncology practice, as determined by TYME.

1.47 "**Net Sales**" shall mean, for an applicable period, with respect to the Product, commencing with the First Commercial Sale, net sales as determined in accordance with GAAP, which, for the avoidance of doubt, shall comprise the gross amounts received by TYME, its Affiliates and Licensees for arm's length sales of the Product in the Field in the Territory to a Third Party (excluding any sales among TYME, its Affiliates and any Licensee), less the following deductions solely to the extent incurred or allowed with respect to such sales, and solely to the extent such deductions are in accordance with GAAP, and which are not already reflected as a deduction from the invoiced price: (a) discounts (to the extent not previously applied to such amounts received), charge-back payments, and rebates; (b) credits or allowances for damaged goods, rejections, recalls or returns of the Product; (c) freight, insurance, postage, and shipping charges for delivery of the Product, to the extent separately billed on the invoice as well as any bona fide service fee specifically incurred for the distribution of the Product; (d) taxes, customs, or duties levied on, absorbed, or otherwise imposed on the sale of the Product, as adjusted for rebates and refunds, to the extent not paid by the Third Party and only to the extent such taxes, customs, or duties are not reimbursed to the paying party, but excluding all income taxes; (e) allowances for doubtful or uncollectible amounts (provided that, such amounts shall be included in the computation of "Net Sales" to the extent subsequently collected or earned) and (f) that portion of the annual fees due under Section 9008 of the United States Patient Protection and Affordable Care Act of 2010 (Pub. L. No. 111-48) and any other fees imposed by Applicable Law. If the Product is sold by TYME, its Affiliates or Licensees through intermediaries such as agents, consignees or co-promoters who do not purchase and take title to the Product, the promotion fee will be due only on sales to those Third Parties who actually purchase and take title to the Product through such intermediaries.

If the Product is transferred to Third Parties in connection with clinical and non-clinical research and trials (including studies reasonably necessary to comply with Applicable Law), Product samples, charitable purposes, promotional purposes, early access programs, compassionate sales or use, or an indigent program or similar *bona fide* arrangements for which TYME or

any of its Affiliates or Licensees for good faith business reasons receives consideration in respect thereof that is less than the average cost of goods for this Product, such consideration shall not be included in Net Sales.

1.48 "**NDA**" means a New Drug Application filed with the FDA that is required for approval for the Product in the United States, or its foreign equivalent in the Territory.

1.49 "**Operating Parameters Schedule**" means the requirements set forth in Schedule 4.1 to this Agreement, as such may, subject to the provisions of Section 3.4.2, be revised from time to time by TYME in consultation with the SOC. The Operating Parameters Schedule shall be updated no less than annually with the minimum required number of Sales Representatives (the "**Minimum Sales Representatives Requirement**") and the Eagle Quarterly Minimum Details.

1.50 "**Party**" shall have the meaning set forth in the preamble to this Agreement.

1.51 "**Patent Rights**" means (a) patents and patent applications, and any foreign counterparts thereof, (b) all divisionals, continuations, continuations-in-part of any of the foregoing, and any foreign counterparts thereof, and (c) all patents issuing on any of the foregoing, and any foreign counterparts thereof, together with all registrations, reissues, re-examinations, supplemental protection certificates, substitutions or extensions thereof, and any foreign counterparts thereof.

1.52 "**Person**" shall mean any individual, corporation, partnership, limited liability company, association, joint- stock company, trust, unincorporated organization or other entity, or government or political subdivision thereof.

1.53 "**Pivotal Clinical Study**" shall mean a human clinical study of the Product in any country on a sufficient number of subjects that is designed to establish that the Product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with the Product in the dosage range to be prescribed, which trial is intended to support Regulatory Approval of the Product, as described in 21 C.F.R. § 312.21(c), or equivalent clinical study in a country other than the United States.

1.54 "**Primary Multidisciplinary Detail**" shall mean a Multidisciplinary Detail call where the Product (i) is the first product Detailed, (ii) is emphasized more than any other product and (iii) is the primary focus of such Detail, primary focus meaning greater than 50% of the total call time during the Detail is spent on promoting the Product.

1.55 "**Product**" shall mean any product that contains SM-88 (racemetyrosine).

1.56 "**Product Labeling**" shall mean the labels and other written, printed or graphic matter upon (a) any container or wrapper utilized with the Product or (b) any written material accompanying the Product, including Product package inserts, in each case as approved by the FDA.

1.57 "**Product Materials**" shall have the meaning set forth in Section 4.4.1(a).

1.58 "**Product Training Materials**" shall have the meaning set forth in Section 4.4.1(a).

1.59 "**Professionals**" shall mean health care practitioners, consisting of physicians, nurse practitioners, physician assistants, pharmacists and any other medical professionals in the Territory with prescribing, formulary or dispensing authority (as authorized under Applicable Law) in the Territory for the Product.

1.60 "**Promotional Materials**" shall have the meaning set forth in Section 4.4.1(a).

1.61 "**Promotional Program**" shall mean an educational program regarding the Product conducted by a Third Party healthcare provider within TYME's approved speakers bureau for SM-88 (racemetyrosine), located in a healthcare provider office or an outside venue, all in accordance with TYME speakers bureau guidelines.

1.62 "**Quarterly Average Sales Force Size**" shall have the meaning set forth in Section 4.2.2.

1.63 "**Regulatory Approval**" shall mean any and all necessary approvals, licenses, registrations or authorizations from any Governmental Authority, in each case, necessary to Commercialize the Product in the Territory.

1.64 "**Regulatory Authority**" means any national or supranational Governmental Authority, including without limitation the FDA, that has responsibility for granting any licenses or approvals or granting pricing and/or reimbursement approvals necessary for the development, marketing, and sale of the Product in any country.

1.65 "**Regulatory Exclusivity**" means any exclusive marketing rights or data exclusivity rights conferred by any Governmental Authority under Applicable Law with respect to the Product in a country or jurisdiction in the Territory to prevent Third Parties from Commercializing the Product in such country or jurisdiction, other than a Patent Right, including without limitation orphan drug exclusivity, pediatric exclusivity and rights conferred in the U.S. under the Hatch-Waxman Act or the FDA Modernization Act of 1997.

1.66 "**Regulatory Filings**" means any and all regulatory applications, filings, modifications, amendments, supplements, revisions, reports, submissions, authorizations, and Regulatory Approvals, and associated correspondence required to Develop and Commercialize the Product in the Territory, including without limitation any reports or amendments necessary to maintain Regulatory Approvals.

1.67 "**Restricted Period**" shall have the meaning set forth in Section 2.3.1.

1.68 "**Schedule**" shall mean a schedule attached to this Agreement.

1.69 "**Sales Forecast**" shall have the meaning set forth in Section 4.1.3.

1.70 "**Sales Plan**" shall mean the written sales plan relating to promotion and Detailing of the Product in the Field in the Territory by the Sales Representatives, which shall include, without limitation, the Eagle Quarterly Minimum Details and other commercial activities geared towards achieving the Sales Forecast, that is prepared by the SOC and approved by TYME as provided in Section 3.

1.71 "**Sales Representative**" shall mean an individual employed and compensated by Eagle as a full-time employee as part of its sales forces and who engages in Detailing of the Product in the Territory, and who is also trained with respect to the Product in accordance with this Agreement (including the Product Labeling and the use of the Promotional Materials) to deliver Details for the Product in the Field in the Territory.

1.72 "**Senior Officer**" shall mean, with respect to TYME, its Chief Executive Officer and Chief Operating Officer (or such officer's designee), and with respect to Eagle, its President and Chief Operating Officer (or such officer's designee). From time to time, each Party may change its Senior Officer by giving written notice to the other Party.

1.73 "**SM-88 (racemetyrosine)**" means TYME's SM-88 (racemetyrosine) novel oral therapy. SM-88 (D,L-alpha- metyrosine; racemetyrosine [USAN]) is a proprietary modified dysfunctional tyrosine derivative.

1.74 "**Specialty**" means a sales account's primary oncology specialty designation, as reasonably determined by TYME.

1.75 "**SOC**" shall have the meaning set forth in Section 3.1.

1.76 "**Target Launch Date**" shall mean the date selected by TYME, in its sole discretion, and of which TYME has provided notice to Eagle in writing at least nine (9) months in advance thereof, for the initial Commercialization of the Product in the Territory.

1.77 "**Target Professionals**" shall mean, with respect to the Product, one of the specifically identified community and/or hospital-based Professionals to be called upon by a Sales Representative based upon the Sales Plan. "Target Professionals" shall exclude key thought leaders as identified on Schedule 1.77 to this Agreement, which Schedule shall be prepared and provided by TYME prior to the Target Launch Date.

1.78 "**Term**" shall have the meaning set forth in Section 11.1.

1.79 "**Territory**" shall mean the United States of America and its territories and possessions.

1.80 "**Third Party(ies)**" shall mean any person or entity other than TYME and Eagle and their respective Affiliates.

1.81 "**TYME Trademarks and Copyrights**" shall mean the logos, trade dress, slogans, domain names and housemarks of TYME or any of its Affiliates as may appear on any Product Materials or Product Labeling, in each case, as may be updated from time to time by TYME.

ARTICLE 2 RIGHTS AND OBLIGATIONS

2.1 **Engagement; Grant of Rights**. During the Term, subject to the terms and conditions of this Agreement, TYME hereby grants to Eagle the non-exclusive right to Detail and promote the Product in the Territory in the Field, and to conduct the Eagle Activities in accordance with the terms and conditions of this Agreement. Notwithstanding the foregoing, TYME retains and reserves the right for TYME and its Affiliates to promote the Product in the Territory and to grant the non- exclusive right to Detail and/or promote the Product in the Territory to any other Third Party in its sole discretion. Eagle shall have no other rights relating to the Product, except as specifically set forth in this Agreement. Eagle's rights and obligations under this Section 2.1 are non-transferable, non-assignable, and non-delegable. Eagle shall not subcontract the Eagle Activities with any Third Party (including any contract sales force). For clarity, Eagle shall not have any other license rights hereunder except as expressly set forth in this Section 2.1, nor any rights to sublicense any rights hereunder.

2.2 **Retention of Rights**. Except with respect to the limited rights granted to Eagle to conduct the Eagle Activities for the Product in the Territory in the Field pursuant to Section 2.1, TYME retains all rights in and to the Product. TYME shall have the sole right, as between the Parties, to Develop and Commercialize the Product, including without limitation, determining the marketing and regulatory strategies for seeking (if and when appropriate) Regulatory Approvals and Regulatory Exclusivity in the Territory for Product in the Field, filing for such Regulatory Approvals and Regulatory Exclusivity for Product in the Territory, preparing, submitting, and maintaining any and all Regulatory Filings and Regulatory Approvals for Product in the Field in the Territory, and seeking any necessary Regulatory Approvals of Regulatory Authorities for Product Labeling and Promotional Materials to be used in connection with Commercializing Product in the Field in the Territory. TYME shall solely own and control any and all Regulatory Approvals and any and all other Regulatory Filings submitted in connection with seeking and maintaining Regulatory Approvals for the Product in the Field in the Territory. As between the Parties, TYME shall be responsible for all costs and expenses incurred by TYME in connection with the foregoing activities. Without limiting the generality of the foregoing (and without limiting TYME's retained rights set forth in Section 2.1), TYME specifically retains the following rights (and Eagle and its Affiliates shall have no rights to the following, except as set forth below in this Section 2.2):

2.2.1 responsibility for all decisions regarding regulatory submissions and for all communications that relate to any Regulatory Approvals or other Regulatory Filings prior to and after any Regulatory Approval with respect to the Product in the Field in the Territory;

2.2.2 responsibility for the manufacture and distribution of the Product, and any future development of the Product;

2.2.3 responsibility, except as expressly set forth herein, for interactions with any Governmental Authority, including but not limited to FDA, with respect to the Product (provided that, Eagle shall retain the right to respond to communications or inquiries from Governmental Authorities in connection with the conduct of any Eagle Activities);

2.2.4 responsibility for creation and final approval of all Product Materials content (including submission of Promotional Materials to FDA's Office of Prescription Drug Promotion) with respect to the conduct of the Eagle Activities for the Product, except as expressly set forth herein;

2.2.5 selling and booking all sales of the Product;

2.2.6 responsibility for the Product's overall commercial strategy, including marketing, payer strategy, pricing, regulatory and other government affairs; and

2.2.7 responsibility for handling all safety related activities related to the Product as set forth in ARTICLE 5 (including submitting all safety reports and interacting with Governmental Authorities with respect thereto) and initiating and managing any Product recalls.

For clarity, except as provided in Sections 2.1 or 2.4, Eagle shall not acquire any license or other intellectual property interest, by implication or otherwise, in any technology, Know-How or other Intellectual Property owned or controlled by TYME or any of its Affiliates, and TYME is not providing any such technology, Know-How or other Intellectual Property, or any assistance related thereto, to Eagle for any use other than for the mutual benefit of the Parties as expressly contemplated hereby.

2.3 **Non-Competition; Non-Solicitation**.

2.3.1 **Non-Competition**. During the Term of this Agreement and through and including the first anniversary of the date of Termination of this Agreement (the "**Restricted Period**"), neither Eagle nor its Affiliates shall, directly or indirectly, market, detail, offer for sale, sell, or promote any oncology product in the Territory that is targeting an indication for which SM-88 (racemetyrosine) is approved other than the sales of the Product in accordance with the terms and conditions of this Agreement without TYME's prior written consent, which shall be given or withheld within its sole discretion.

2.3.2 **Non-Solicitation**. During Restricted Period, neither Eagle nor TYME (nor any of their respective Affiliates) shall directly or indirectly solicit for hire or employ as an employee, consultant or otherwise, any employee, consultant or other professional personnel of the other Party who has had direct involvement with the SOC, Eagle Activities under this Agreement or TYME's Commercialization activities for the Product, without the other Party's prior written consent, which shall not be unreasonably withheld; provided, however, that this restriction shall not apply to: (a) conducting any general solicitation not specifically targeted at any such employee; or (b) hiring any employee who responds to such general advertising or who approaches such Party or its Affiliates without any solicitation or inducement to leave the employ of such other Party or its Affiliates.

2.4 **TYME Trademarks and Copyrights**.

2.4.1 Eagle shall have the non-exclusive right to use the TYME Trademarks and Copyrights solely on Product Materials in order to perform the Eagle Activities and solely in accordance with the terms and conditions of this Agreement. TYME shall promptly notify Eagle of any updates or changes to the TYME Trademarks and Copyrights on the Product Materials, and Eagle shall thereafter solely use such updated Product Materials in performing its obligations under this Agreement. Eagle shall promptly notify TYME upon becoming aware of any violation of this Section 2.4.1.

2.4.2 Eagle shall follow all instructions and guidelines of TYME (of which TYME shall provide Eagle copies) in connection with the use of any TYME Trademarks and Copyrights, and, if TYME reasonably objects to the manner in which any such TYME Trademarks and Copyrights are being used, Eagle shall immediately cease the use of any such TYME Trademarks and Copyrights in such manner upon written notice from TYME thereof. Without limiting the foregoing, Eagle shall also adhere to at least the same quality control provisions as companies in the pharmaceutical industry adhere to for their own trademarks and copyrights. In all cases, Eagle shall use the TYME Trademarks and Copyrights with the necessary trademark (and copyright, as applicable) designations, and shall use the TYME Trademarks and Copyrights in a manner that does not derogate from TYME's rights in the TYME Trademarks and Copyrights. Eagle shall not at any time during the Term knowingly do or allow to be done any act or thing which will in any way impair or diminish the rights of TYME in or to the TYME Trademarks and Copyrights. All goodwill and improved reputation generated by Eagle's use of the TYME Trademarks and Copyrights shall inure to the benefit of TYME, and any use of the TYME Trademarks and Copyrights by Eagle shall cease at the end of the Term. Eagle shall have no rights under this Agreement in or to the TYME Trademarks and Copyrights except as specifically provided herein. During the Term, Eagle shall not contest the ownership of the TYME Trademarks and Copyrights, their validity, or the validity of any registration therefor. During the Term, Eagle shall not knowingly register and/or use any marks (including in connection with any domain names) that are confusingly similar to the TYME Trademarks and Copyrights.

ARTICLE 3 JOINT SALES OPERATIONS COMMITTEE

3.1 **Formation of the Joint Sales Operations Committee**. As soon as practicable, but no later than nine (9) months prior to the Target Launch Date, the Parties shall form a joint sales operations committee ("**SOC**") whose responsibilities during the Term shall be to oversee the activities set forth in Section 3.3. The SOC shall consist of no more

than seven (7) members, with four (4) members designated by TYME and three (3) members designated by Eagle, each with suitable seniority and relevant experience and expertise to enable such person to address matters falling within the purview of the SOC; provided, that each Party may also have up to three (3) observers present at any SOC meeting. All meetings of the SOC shall be chaired by one of the four representatives from TYME. From time to time, each Party may change any of its representatives on the SOC by giving written notice to the other Party. The SOC shall determine a meeting schedule; provided that in any event, meetings shall be conducted no less frequently than quarterly by teleconference or in person, or as otherwise agreed by the Parties. In person meetings shall occur at such places as mutually agreed by the Parties. Employees or consultants of either Party that are not representatives of the Parties on the SOC may attend meetings of the SOC as one of a Party's designated observers; provided that, such attendees (i) shall not participate in the decision-making process of the SOC, and (ii) are bound by obligations of confidentiality and non-disclosure equivalent to those set forth in ARTICLE 8.

3.2 **Meetings and Minutes**. Meetings of the SOC may be called by either Party on no less than thirty (30) days' prior notice during the Term. Each Party shall make all proposals for agenda items and shall provide all appropriate information with respect to such proposed items at least ten (10) days in advance to the applicable meeting; provided that under exigent circumstances requiring input by the SOC, a Party may provide its agenda items to the other Party within a shorter period of time in advance of the meeting, or may propose that there not be a specific agenda for that particular meeting, so long as the other Party consents to such later addition of such agenda items or the absence of a specific agenda for such meeting, such consent not to be unreasonably withheld. Members may participate in a meeting of the SOC by means of a conference telephone or other communications equipment allowing all persons participating in the meeting to hear each other. Participation by such means shall constitute presence in person at the meeting. The chairperson shall prepare and circulate for review and approval of the Parties minutes of each meeting within thirty (30) days after the meeting. Each Party shall bear its own costs for its members to attend such meetings.

3.3 **Purpose of the SOC**. The purposes of the SOC shall be to, subject to Section 3.4:

3.3.1 provide a forum to discuss and coordinate the Parties' activities under this Agreement, in particular sales performance and metrics, and, subject to Section 3.4.2, develop, update, amend and approve the Sales Plan, including the identification of sales accounts;

3.3.2 provide a forum to discuss and coordinate the promotion of the Product in the Territory;

3.3.3 provide a forum to discuss Product Materials (it being understood that the SOC shall not have the right to approve such Product Materials);

3.3.4 provide a forum for discussing the annual Sales Forecast and revisions thereto (it being understood that TYME retains the right to update the Sales Forecast as described in Section 4.1.3);

3.3.5 provide a forum for reviewing, updating and agreeing on revisions to the Operating Parameters Schedule, including without limitation, to update the Eagle Quarterly Minimum Details and the Minimum Sales Representatives Requirement;

3.3.6 facilitate the flow of information and otherwise promote the communications and collaboration within and among the Parties relating to this Agreement and the promotion of the Product;

3.3.7 discuss planning and implementation of all Eagle Activities, including but not limited to training of Sales Representatives and development and implementation of policies and procedures for conduct of Promotional Programs and Details and Sales Representatives' interactions with sales accounts;

3.3.8 decide on the acceptable form of and review and discuss the Detail Reports and reports of Net Sales;

3.3.9 review and discuss the Compensation Reports and the incentive compensation matters described in Section 4.1.4, including any applicable adjustments to Product-related sales goals and targets of the Sales Representatives proposed by TYME (it being understood that Eagle shall retain final decision-making authority with respect to such matters but shall give good faith consideration to TYME's feedback with respect thereto);

3.3.10 review and discuss any matters brought to its attention by either Party's Alliance Manager;

3.3.11 discuss the Promotional Materials matters described in Section 4.4.1(a);

3.3.12 discuss supply or distribution issues relating to the Product;

3.3.13 act as a first level escalation to address disagreements or disputes between the Parties;

3.3.14 form and oversee any sub-committee or working group in furtherance of the activities contemplated by this Agreement;

3.3.15 decide on the acceptable form of and review and discuss the Compliance Reports; and

3.3.16 perform such other responsibilities as may be mutually agreed upon by the Parties in writing from time to time; provided, however, for clarity the SOC shall have no authority to amend or modify any provisions of this Agreement and no authority to waive or definitively interpret the provisions of this Agreement.

In connection with the SOC meetings contemplated under Section 3.2 (but in any event, no less frequently than each Fiscal Quarter), Tyme shall provide Eagle with a written summary of its material Development and Commercialization strategies and activities with respect to the Product in the Territory since the last SOC meeting or Fiscal Quarter, as applicable, including the results of such activities, and a description of its then-current marketing plans, marketing campaigns and Product-related messaging with key opinion leaders, except and to the extent such information is subject to confidentiality or similar restrictions on disclosure imposed by contractual, regulatory or similar requirements.

3.4 **Decision Making**.

3.4.1 **Quorum; Voting**. Meetings of the SOC shall occur only if at least one (1) representative of each Party is present at the meeting. Each Party shall have one (1) vote. The SOC shall use good faith efforts to reach consensus on all matters properly brought before it. If the SOC does not reach unanimous consensus on an issue at a meeting, or within a period of 30 days thereafter, then the SOC shall submit in writing the respective positions of the Parties to the Senior Officers of the Parties. Such Senior Officers shall use good faith efforts to resolve promptly such matter, which good faith efforts shall include at least one (1) teleconference between such Senior Officers within 30 days after the SOC's submission of such matter to them. Any final decision mutually agreed to in writing by the Senior Officers shall be conclusive and binding on the Parties. If the Senior Officers are not able to agree on the resolution of any such issue within 30 days after such issue was first referred to them, then, except with respect to those disputes that are expressly subject to arbitration pursuant to Section 12.6: (i) Eagle shall have the right to conclusively determine all matters related to the incentive compensation of the Sales Representatives and (ii) subject to Section 3.4.2, TYME shall have the right to conclusively determine all other matters; provided, however, for clarity, that such determination and any related activities comply with the terms and conditions of this Agreement. Notwithstanding anything to the contrary in the foregoing, for the avoidance of doubt, any such determination shall not amend, modify or waive any provisions of this Agreement or definitively interpret the provisions of this Agreement.

3.4.2 **Eagle Approvals**. Any proposed change or amendment to the (a) Operating Parameters Schedule or (b) Sales Plan that would (i) increase Eagle's percentage of the sales force requirements above the percentage provided in the Operating Parameters Schedule (as may be subsequently amended by mutual agreement of the Parties), (ii) increase the number of Eagle Quarterly Minimum Requirements (as such requirements may be updated by mutual agreement of the Parties),
(iii) increase the number of Sales Representatives from the number agreed to prior to the Target Launch Date (or as otherwise agreed by mutual agreement of the Parties) or (iv) without duplication of items (i) – (iii) hereof, materially increase Eagle's costs associated with conducting any Eagle Activities other than Detailing shall, in each case of (a) and (b), require the written approval of Eagle (which approval shall not be unreasonably withheld). The initial Sales Plan developed by the SOC to be in effect at the Target Launch Date, which shall set forth the commercial activities geared towards achieving the Sales Forecast, including, without limitation the Eagle Quarterly Minimum Details and the target number of Promotional Programs, shall be developed by the SOC, approved by TYME and require the written approval of Eagle (which Eagle approval shall not be unreasonably withheld).

ARTICLE 4 EAGLE ACTIVITIES FOR THE PRODUCT

4.1 **Eagle Activities**.

4.1.1 **General**. Eagle shall conduct the Eagle Activities for the Product in the Field in the Territory in accordance with this Agreement, including, without limitation, in accordance with the then-current Sales Plan.

4.1.2 **Sales Representatives**. Without limiting the generality of the foregoing, Eagle shall hire, and continuing throughout the remainder of the Term, shall maintain, a sales force with responsibility to Detail the Product in the Territory in accordance with the terms of the Operating Parameters Schedule. Eagle shall have such sales force in place by such time specified in the Operating Parameters Schedule in order to appropriately train on the Product prior to Target Launch Date. The Sales Representatives and their managers shall have the qualifications and meet the criteria set forth in Schedule
4.1.2 hereto, which schedule shall be jointly developed and mutually agreed by TYME and Eagle within 180 days of the execution and delivery of this Agreement.

4.1.3 **Sales Forecast**.

(a) No later than three (3) months prior to the Target Launch Date, TYME shall develop a forecast of reasonably expected Net Sales of the Product in the Territory in the Field for a one (1) year period, including projected quarterly Net Sales (the "**Sales Forecast**"). Thereafter, each Fiscal Year of the Term, TYME shall prepare an annual Sales Forecast for such period. The Sales Forecast shall be updated by TYME from time to time as appropriate, discussed at the SOC, and comprise part of the Sales Plan.

(b) On a quarterly basis, the SOC shall review actual Fiscal Year-to-date Net Sales performance compared to the Sales Forecast.

4.1.4 **Target Incentive Compensation**. Prior to the Target Launch Date, Eagle shall develop an incentive compensation package for each Sales Representative that derives an appropriate portion of target incentive compensation from achieving target sales of the Product, subject to TYME's review and comment prior to implementation of the incentive plan. On at least a quarterly basis, the Parties shall meet, through the SOC, to review the target incentive compensation and the actual incentive compensation paid out to the Sales Representatives to discuss, in good faith, any appropriate adjustments to the sales targets and goals related to the Product.

4.1.5 **Alliance Managers**. Each Party shall appoint a person who shall oversee interactions between the Parties for all matters related to this Agreement, and any related agreements between the Parties (each an "**Alliance Manager**"). The Alliance Managers shall endeavor to ensure clear and responsive communication between the Parties and the effective exchange of information, and shall serve as a single point of contact for all matters arising under this Agreement. The Alliance Managers shall have the right to attend all SOC meetings and, if applicable, subcommittee meetings as non-voting participants and may bring to the attention of the SOC or, if applicable, the subcommittee, any matters or issues either of them reasonably believes should be discussed, and shall have such other responsibilities as the Parties may mutually agree in writing. Each Party may designate different Alliance Managers by notice in writing to the other Party.

4.2 **Detailing**.

4.2.1 **Detail Requirements**. Commencing promptly upon completion of training of the Field Force Personnel that are engaged in Detailing the Product as described in Section 4.4.1 (but on the condition that Promotional Materials have been approved and delivered), Eagle shall deploy its Field Force Personnel that are engaged in Detailing to Detail the Product in accordance with the terms of this Agreement, including without limitation, the requirements for reach, frequency and position of the Product in the Detail provided in the Operating Parameters Schedule and the requirements of the then-current Sales Plan as updated from time to time. From time to time, Field Force Personnel shall organize and coordinate on the presentation of Promotional Programs as developed by the SOC and included in the then-current Sales Plan; however, except as set forth in this Agreement, without the prior written consent of TYME (not to be unreasonably withheld, delayed or conditioned), Eagle shall not conduct any Eagle Activities, other than Detailing, with respect to any Product. The Promotional Program requirements, guidelines and TYME approved speaker bureau will be provided to Eagle prior to initiation of the Promotional Programs.

4.2.2 **Records and Reports**.

(a) Eagle shall keep accurate and complete records, consistent with pharmaceutical industry standards, of each Detail and its obligations hereunder in connection therewith. Such records shall be kept for the longer of (i) five (5) years after the end of the Fiscal Year to which they relate and (ii) such period of time as required by Applicable Laws. Within 15 days following the end of each Fiscal Quarter during the Term, Eagle shall provide TYME with a written report (each a "**Detail Report**"), setting out (1) the quarterly average number of Sales Representatives during such Fiscal Quarter (calculated by taking the sum of the number of Sales Representatives employed by Eagle (or its affiliates) that have incentive compensation packages that comply with the terms of Section 4.1.4 on each Business Day of the Fiscal Quarter divided by the number of Business Days in such Fiscal Quarter) (the "**Quarterly Average Sales Force Size**"), (2) the aggregate actual number of Details for the Product made by its Sales Representatives during such Fiscal Quarter, (3) the aggregate number of Exclusive Details, (4) the aggregate number of Multidisciplinary Details, (5) the number of Primary Multidisciplinary Details, and (6) the number of Details broken down by the name of the Target Professionals and such professional's Specialty. Through the SOC, the Parties shall agree on a mutually acceptable form of Detail Report.

(b) Within 30 days following the end of each Fiscal Quarter during the Term, Eagle shall provide TYME with a written report (each a "**Compensation Report**"), which describes (i) the details of the incentive compensation package of each Sales Representative as it relates to the Product and (ii) the actual incentive compensation payouts for each Sales Representatives as described in Section 4.1.4. Through the SOC, the Parties shall agree on a mutually acceptable form of Compensation Report.

(c) Within 30 days following the end of each Fiscal Quarter during the Term, Eagle shall provide TYME with a written report (each a "**Compliance Report**"), which sets out a summary of any compliance-related disciplinary actions relating to any Field Force Personnel that are engaged in Detailing and any associated remedial actions. Through the SOC, the Parties shall agree on a mutually acceptable form of Compliance Report.

(d) TYME shall have the right, at its own expense, during normal business hours and upon reasonable prior notice, through an independent third party, reasonably acceptable to Eagle, and upon execution of a confidentiality agreement reasonably satisfactory to Eagle in form and substance, to inspect the applicable records and books maintained by Eagle relating to the Eagle Activities solely for purposes of verifying Eagle's compliance with the terms of this Agreement. For purposes of clarity, any such inspection right described in this Section 4.2.2(d) shall be limited to only those books and records of Eagle that are applicable to Eagle's performance of its obligations under this Agreement and may be conducted no more than once per calendar year. Where necessary, on reasonable request, TYME's inspection rights shall include interviewing Sales Representatives and other employees of Eagle. Eagle shall reasonably cooperate in any such inspection conducted by TYME. TYME shall treat all information subject to review under this Section 4.2.2(d) in accordance with the confidentiality provisions of this Agreement.

4.3 **Compliance with Applicable Law**.

4.3.1 In conducting the Eagle Activities hereunder, Eagle shall, and shall require all Field Force Personnel to, comply in all respects with Applicable Laws. In addition, TYME shall, and shall require all of its sales representatives to, comply in all respects with Applicable Laws in connection with its Development or Commercialization (including promotion and Detailing) of the Product in the Territory.

4.3.2 Neither Eagle or Field Force Personnel, nor TYME, its Affiliates or their respective licensees, shall offer, pay, solicit or receive any remuneration to or from any Professionals (including Target Professionals), in order to induce referrals of or purchase of the Product.

4.3.3 In performing the activities contemplated by this Agreement, neither Eagle or Field Force Personnel, nor TYME, its Affiliates or their respective licensees, shall make any payment, either directly or indirectly, of money or other assets to government or political party officials, officials of international public organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing where such payment would constitute violation of any Applicable Law. In addition, neither Eagle nor TYME shall make any payment, either directly or indirectly, to officials if such payment is for the purpose of unlawfully influencing decisions or actions with respect to the subject matter of this Agreement.

4.3.4 No employee of Eagle or its Affiliates shall have authority to give any direction, either written or oral, relating to the making of any commitment by TYME or its agents to any Third Party in violation of terms of this or any other provision of this Agreement

4.3.5 Neither Eagle nor TYME shall undertake any activity under or in connection with this Agreement which violates any Applicable Law.

4.3.6 TYME shall ensure that any patient assistance program used in connection with the Product (and the services performed thereby in connection with the Product) shall be operated in accordance with Applicable Law. Notwithstanding the immediately preceding sentence, TYME shall have no liability with respect to any breach or non-compliance with Applicable Law relating to any patient assistance program used in connection with the Product to the extent caused by the act or omission of any Field Force Personnel, which act or omission is not in compliance with the terms of this Agreement, Applicable Law or instructions of TYME.

4.3.7 TYME shall ensure that government-insured patients do not receive co-pay support from TYME with respect to the Product.

4.3.8 TYME shall ensure that its donations to, and interactions with, any 501(c)(3) charitable foundation that provides co-pay assistance to government-insured patients with respect to the Product are in full compliance with all Applicable Laws.

4.3.9 If, during the Term, Eagle becomes aware of a material violation or failure to comply with Applicable Law or the terms of this Agreement by a member of the Field Force Personnel that are engaged in Detailing, it shall promptly, but no later than two (2) Business Days after it becomes aware, notify TYME of such violation and, as promptly as possible thereafter, shall notify the steps it has taken or intends to take to remediate such violation.

4.3.10 As soon as practicable, but no later than six (6) months prior to the Target Launch Date, each Party shall appoint a representative to act as its compliance manager under this Agreement, each of which shall be routinely responsible for advising such Party on compliance matters and has suitable seniority and other relevant experience and expertise (each, a "**Compliance Manager**"). From time to time, each Party may change its Compliance Manager by giving written notice to the other Party. The Compliance Managers shall serve as a key point of contact between the Parties for compliance-related matters. Each Compliance Manager shall facilitate the resolution of any compliance issue with the Compliance Manager of the other Party. The Compliance Managers shall use good faith efforts to reach consensus on all compliance matters. If the Compliance Managers do not reach consensus on an issue promptly, then such issue shall be submitted to dispute resolution process described in Section 12.6. Upon the reasonable request of TYME from time to time, Eagle shall deliver to TYME copies of Eagle's compliance program policies and compliance training materials which are applicable to the Field Force Personnel's promotion of the Product. Other than as expressly stated herein, Eagle shall not be required to modify its compliance policies or practices in connection with the compliance-related provisions herein.

4.4 **Field Force Personnel Training; Product Materials**.

4.4.1 **Training, Training Materials and Promotional Materials**.

(a) Subject to the terms of this Section 4.4.1, TYME shall prepare and control the content of (i) all Product training materials for Field Force Personnel (the "**Product Training Materials**") and (ii) all Product marketing and educational materials (the "**Promotional Materials**") (the Product Training Materials and the Promotional Materials, collectively, the "**Product Materials**"). TYME shall be solely responsible for ensuring that the Product Materials prepared and approved by it are in compliance with the Regulatory Approval for the Product, the Product Labeling and Applicable Law. Once approved by TYME, the content of the Product Materials shall be provided by TYME to Eagle in advance of the Eagle Activities to allow for Eagle to review such content and provide verbal feedback to TYME in advance of use of the Product Materials. Within 15 days of receipt of such Product Materials, Eagle shall verbally provide to TYME any comments and/or proposed revisions to such Product Materials, which comments and revisions TYME shall reasonably consider so long as TYME deems such suggestions are acceptable in the promotion of the Product; provided that in any event, to the extent that TYME reasonably believes that such changes are not in compliance with Applicable Law, the Regulatory Approval for the Product or the applicable Product Labeling, then TYME shall not be required to incorporate any such suggestions from Eagle in the Product Materials. In the event of any disagreement between the Parties regarding any feedback received from Eagle

with respect to the Product Materials, TYME shall have the right to conclusively determine such matter; provided that, Eagle shall not be required to use any Product Materials that it reasonably believes violate Applicable Law. If Eagle has provided comments to TYME on the Product Materials and TYME accepts some or all of such comments, then, once revised, TYME shall provide to Eagle the revised versions of such Product Materials for further review by Eagle, in accordance with the terms and timelines of this Section 4.4.1(a) above. Eagle shall use only Product Materials approved by TYME in the performance of Eagle Activities under this Agreement. The content of Product Materials shall not be modified or changed by Eagle or Field Force Personnel at any time without the prior written approval of TYME in each instance. TYME shall be responsible for the costs and expenses of creation and development of the Product Materials and Eagle shall be responsible for the costs and expense of reproduction, printing and delivery of the Product Materials to and for Eagle. The information regarding the Product that is provided by Eagle or Field Force Personnel as part of the Eagle Activities shall not deviate from the Product Materials. The Parties shall coordinate the production and delivery of Product Materials to allow sufficient internal and field force review time to accommodate scheduled training meetings and distribution to Field Force Personnel that are engaged in Detailing. In the event that TYME incurs costs and expenses for which Eagle is responsible under this Section 4.4.1, TYME may deduct such amounts from the payments due under Section 6.1 and shall include a description thereof in the applicable report under Section 6.2. The Parties shall collaborate to finalize the Product Materials in accordance with this Section 4.4.1(a) in advance of the Target Launch Date.

(b) By no later than six (6) months prior to the Target Launch Date, the Parties shall collaborate to plan and schedule training for the Sales Representatives at a mutually acceptable time(s) and date(s), including a launch meeting for the Sales Representatives at a mutually acceptable location. TYME shall lead such initial training and Eagle shall cooperate with any reasonable requests of TYME in order to support such training. The costs and expenses of such launch meeting shall be the responsibility of Eagle. All other training costs and expenses shall be the responsibility of Eagle. After the initial training, the Parties shall collaborate to provide additional training at such frequency, times and places as the circumstances warrant and the Parties mutually agree, but no less frequently than quarterly with at least three (3) live, in-person training sessions annually. Eagle shall have the right, but not the obligation, to conduct such additional training itself, provided that the Eagle trainers have been trained by TYME, and provided further that TYME shall have the right to attend such training upon reasonable notice by TYME to Eagle. Eagle shall certify in writing to TYME that all Field Force Personnel have completed the training described in this Section 4.4.1(b).

(c) Eagle and all Field Force Personnel that are engaged in Eagle Activities shall comply with the applicable provisions of the Code, and shall be trained on Eagle's compliance policies, including those that are consistent with the applicable provisions of Sec. 1128B(b) of the Social Security Act and the American Medical Association Ethical Guidelines for Gifts to Physicians from Industry (which such training may have been accomplished prior to the Term), prior to commencing any Eagle Activities. Eagle agrees that it shall train any employee or agent of Eagle who is involved in performing the activities contemplated by this Agreement on anti-corruption and anti-bribery at its own expense.

(d) Field Force Personnel that are engaged in Detailing shall conduct the Eagle Activities only after having undergone the training described in this Section 4.4 and, without limiting the foregoing, no Field Force Personnel member shall Detail the Product without having undergone such training. Subject to the foregoing, Eagle shall have the responsibility for on-going training of its Field Force Personnel that are engaged in Detailing in accordance with customary practice in the pharmaceutical industry, provided that TYME shall be entitled to approve all such training objectives and content.

4.4.2 **Ownership of Product Materials**. As between the Parties, TYME shall own all right, title and interest in and to any Product Materials (and all content contained therein) and any Product Labeling (and all content contained therein), including applicable copyrights and trademarks (other than any name, trademark, trade name or logo of Eagle or its Affiliates that may appear on such Product materials or Product Labeling), and to the extent Eagle (or any of its Affiliates) obtains or otherwise has a claim to any of the foregoing, Eagle hereby assigns (and shall cause any applicable Affiliate to assign) all of its right, title and interest in and to such Product Materials (and content) and Product Labeling (and content) (other than any name, trademark, trade name or logo of Eagle or its Affiliates that may appear on such Product materials or Product Labeling) to TYME and Eagle agrees to (and shall cause its applicable Affiliate to) execute all documents and take all actions as are reasonably requested by TYME to vest title to such Product Materials (and content) and Product Labeling (and content) in TYME (or its designated Affiliate).

4.5 **Provisions Related to Field Force Personnel**.

4.5.1 **Activities of Field Force Personnel**. Eagle hereby agrees and acknowledges that the following shall apply with respect to itself and the Field Force Personnel that are engaged in Detailing:

(a) Eagle shall instruct and cause the Field Force Personnel that are engaged in Detailing to use only the Product Labeling and, subject to the terms of Section 4.4, Product Materials approved by TYME for the conduct of the Eagle Activities for the Product and consistent with Applicable Laws. Eagle shall instruct the Field Force Personnel that are engaged in Detailing to, and shall monitor (in accordance with Eagle's standard practice) the Field Force Personnel that are engaged in Detailing, in order to ensure that such Field Force Personnel limit their claims of efficacy and safety for such Product to those claims which are consistent with and do not exceed the Product Labeling and any Promotional Materials.

(b) Eagle shall instruct the Field Force Personnel that are engaged in Detailing to conduct the Eagle Activities for the Product, and shall monitor and audit (in accordance with Eagle's standard practice) the Field Force Personnel that are engaged in Detailing so that such personnel conduct the Eagle Activities for such Product in adherence in all respects with Applicable Laws.

(c) Eagle shall instruct the Field Force Personnel that are engaged in Detailing regarding provisions of this Agreement applicable to Details of the Product, including Section 4.2 and this Section 4.5.1.

(d) Eagle acknowledges and agrees that TYME will not maintain or procure any worker's compensation, healthcare, or other insurance for or on behalf of the Field Force Personnel, all of which shall be Eagle's sole responsibility.

(e) Eagle acknowledges and agrees that all Field Force Personnel are employees of Eagle and are not, and are not intended to be treated as, employees of TYME or any of its Affiliates, and that such individuals are not, and are not intended to be, eligible to participate in any benefits programs or in any "employee benefit plans" (as such term is defined in section 3(3) of the Employee Retirement Income Security Act of 1974, as amended) that are sponsored by TYME or any of its Affiliates or that are offered from time to time by TYME or its Affiliates to their own employees. All matters of compensation, benefits and other terms of employment for any such Field Force Personnel shall be solely a matter between Eagle and such individual. TYME shall not be responsible to Eagle, or to the Field Force Personnel, for any compensation, expense reimbursements or benefits (including vacation and holiday remuneration, healthcare coverage or insurance, life insurance, severance or termination of employment benefits, pension or profit-sharing benefits and disability benefits), payroll- related taxes or withholdings, or any governmental charges or benefits (including unemployment and disability insurance contributions or benefits and workmen's compensation contributions or benefits) that may be imposed upon or be related to the performance by Eagle or such individuals of this Agreement, all of which shall be the sole responsibility of Eagle, even if it is subsequently determined by any Governmental Authority that any such individual may be an employee or a common law employee of TYME or any of its Affiliates or is otherwise entitled to such payments and benefits.

(f) Eagle shall be solely responsible for the acts or omissions of the Field Force Personnel that are not in compliance with Applicable Law and the terms of this Agreement while performing any of the activities under this Agreement. Eagle shall be solely responsible and liable for all probationary and termination actions taken by it, as well as for the formulation, content and dissemination (including content) of all employment policies and rules (including written probationary and termination policies) applicable to its employees.

4.5.2 **Termination of Employment; Cessation of Eagle Activities**. If any Field Force Personnel leaves the employ of Eagle (or any of its Affiliates), or otherwise ceases to conduct the Eagle Activities for the Product, Eagle shall, to the extent consistent with, and in a manner similar to, its practices with respect to departures of the sales representatives or other field force personnel, as applicable, promoting, marketing or detailing other products for Eagle, account for, and shall cause such departing Field Force Personnel to return to Eagle and delete from his/her computer files (to the extent such materials or information have been provided in, or converted into, electronic form) all materials relating to the Product that have been provided to such individual, including the Product Materials and account level information, including all copies of the foregoing.

4.5.3 **Discipline**. If TYME has a reasonable basis for believing any member of the Field Force Personnel that are engaged in Detailing has violated any Applicable Laws, or failed to comply with this Agreement, then TYME shall

notify Eagle of the alleged violation and Eagle shall promptly investigate the matter and, if the allegation turns out to be true, shall take the appropriate remedial action. Subject to the foregoing, Eagle shall be solely responsible for taking any disciplinary actions in connection with its Field Force Personnel that are engaged in Detailing. If, at any time, TYME has any other compliance-related concerns regarding any Field Force Personnel Detailing, TYME's Compliance Manager shall notify Eagle's Compliance Manager of such concerns in writing and the Compliance Managers shall discuss and resolve such matters pursuant to Section 4.3.10.

4.6 **Responsibility for Eagle Activity Costs and Expenses**. Other than as expressly set out herein, Eagle shall be solely responsible for any and all costs and expenses incurred by Eagle or any of its Affiliates in connection with the conduct of the Eagle Activities for the Product hereunder, including all costs and expenses in connection with Sales Representatives, including salaries, bonuses, employment benefits, travel expenses and other expenses, credentialing, licensing, providing benefits, deducting federal, state and local payroll taxes, and paying workers' compensation premiums, unemployment insurance contributions and any other payments required by Applicable Laws to be made on behalf of employees.

4.7 **Data Sharing**. Without limiting the information that Eagle shall provide to TYME hereunder, including, without limitation, the reports deliverable under Section 4.2 hereof, TYME shall provide to Eagle certain information relating to the sale, Commercialization, marketing and promotion of the Product, as may be mutually agreed by the Parties from time to time, for use by Eagle and the Field Force Personnel in connection with the Eagle Activities. The timing of the delivery of such information shall be mutually agreed upon by the Parties, acting reasonably.

4.8 **Material Changes**. Eagle acknowledges no Product is available for Commercialization as of the date hereof and that the service levels and requirements of Eagle and its personnel under this Article IV and the accompanying Schedules are based on the Parties' current expectations regarding SM-88 (racemetyrosine)'s approval pathway in pancreatic cancer. Should SM-88 (racemetyrosine) be approved in additional or different indications, a new Product or class of Product becomes available for Commercialization, or there is otherwise a material change in TYME's requirements hereunder, the Parties agree to amend the Operating Parameters Schedule in good faith to address such development. For the avoidance of doubt, the Parties agree that any such amendment will be made in good faith to preserve the spirit and service levels established hereunder for such new indications or changes. Any disputes arising from this Section 4.8 or amendments to the Operating Parameters Schedule incident thereto that are not resolved by the Senior Officers pursuant to Section 3.4.1 shall be governed by Section 12.6.

ARTICLE 5 REGULATORY, SAFETY AND SURVEILLANCE, COMMERCIAL MATTERS

5.1 **TYME Responsibility**. As between the Parties, except as expressly set out herein, all regulatory matters regarding the Product shall be the responsibility of TYME, including responsibility for all communications with Governmental Authorities, including but not limited to the FDA, related to the Product, and TYME shall have sole responsibility to seek and/or obtain any necessary approvals of any Product Labeling and the Promotional Materials used in connection with the Product, and for determining whether the same requires approval. As between the Parties, TYME shall be responsible for any reporting of matters regarding the manufacture, sale or promotion of the Product (including Adverse Events) to or with the FDA and other relevant Regulatory Authorities, in accordance with Applicable Laws. TYME shall maintain, at its cost, the Regulatory Approvals for the Product and shall comply with all Applicable Law relevant to the conduct of TYME's business with respect to the Product or pursuant to this Agreement, including, without limitation, all applicable requirements under the Act.

5.2 **Eagle Involvement**. Except as expressly permitted herein, Eagle shall not, without TYME's prior written consent, correspond or communicate with the FDA or with any other Governmental Authority concerning the Product, or otherwise take any action concerning any Regulatory Approval or other authorization under which the Product is marketed or sold. If not prohibited by any Government Authority or Applicable Law, Eagle shall provide to TYME, promptly upon receipt, copies of any communication from the FDA or other Governmental Authority related to the Product. If not prohibited by any Government Authority or Applicable Law, TYME has the right to review and comment on Eagle's draft responses to any Governmental Authorities relevant to Detail of the Product prior to Eagle's issuance of such response; and Eagle agrees to consider any comments or suggestions from TYME in good faith.

5.3 **Inspections**.

5.3.1 If not prohibited by any Government Authority or Applicable Law, Eagle shall notify TYME immediately upon receipt of any notice of inspection or investigation by any Governmental Authority related to or that Eagle

reasonably believes may impact any aspect of the Eagle Activities. If not prohibited by any Government Authority or Applicable Law, TYME shall have the right to have a representative present at any such portion of the inspection involving any Eagle Activities. In such cases, Eagle shall (i) keep TYME fully informed of the progress and status of any such inspection or investigation, (ii) prior to undertaking any action pursuant to this Section 5.3.1, notify TYME of the inspection or investigation, and disclose to TYME in writing the Governmental Authorities' assertions, findings and related results of such inspection or investigation pertaining to the Eagle Activities, and (iii) provide full disclosure to TYME with respect to any action undertaken or proposed to be undertaken pursuant to this Section 5.3.1 prior to acting as it pertains to the Eagle Activities. In addition, if such findings or the Governmental Authority requests or suggests that Eagle should change any aspect of the Eagle Activities, the Parties shall work together to make any such modification; provided, however, that notwithstanding anything to the contrary herein, Eagle shall not be required to engage in any Eagle Activities to the extent any finding or Government Authority has requested or suggested that Eagle may not engage in such activity.

5.3.2 If not prohibited by any Government Authority or Applicable Law, TYME shall notify Eagle immediately upon receipt of any notice of inspection or investigation by any Governmental Authority related to or that TYME reasonably believes may impact any aspect of the Eagle Activities. In such cases, TYME shall (i) keep Eagle fully informed of the progress and status of any such inspection or investigation, (ii) disclose to Eagle in writing the Governmental Authorities' assertions, findings and related results of such inspection or investigation pertaining to the Product or its promotion, and (iii) provide full disclosure to Eagle with respect to any action undertaken or proposed to be undertaken pursuant to this Section 5.3.2 prior to acting as it pertains to the Eagle Activities. In addition, if such findings or the Governmental Authority requests or suggests that Eagle should change any aspect of the Eagle Activities, the Parties shall work together to make any such modification; provided, however, that notwithstanding anything to the contrary herein, Eagle shall not be required to engage in any Eagle Activities to the extent any finding or Government Authority has requested or suggested that Eagle may not engage in such activity.

5.4 **Pharmacovigilance**. Subject to the terms of this Agreement, no later than six (6) months prior to the Target Launch Date, TYME and Eagle (under the guidance of their respective pharmacovigilance departments, or equivalent thereof) shall identify and finalize the responsibilities the Parties shall employ to protect patients and promote their well-being in a separate safety data exchange agreement ("**Pharmacovigilance Agreement**"). These responsibilities shall include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication and exchange (as between the Parties) of safety information, such as Adverse Events, lack of efficacy, misuse/abuse, and any other information concerning the safety of the Product. Such guidelines and procedures will be in accordance with, and enable the Parties and their Affiliates to fulfill, regulatory reporting obligations to Governmental Authorities. For the avoidance of doubt, such guidelines and procedures shall provide that any Eagle Sales Representative, Field Force Personnel or Eagle Affiliate that becomes aware of an Adverse Event shall follow all TYME policies and procedures regarding Adverse Event reporting, including TYME's Adverse Event Reporting standard operating procedure, which shall be provided to Eagle for training prior to the Target Launch Date. The Pharmacovigilance Agreement shall provide that: (i) TYME shall be responsible for all pharmacovigilance activities regarding the Product, including signal detection, medical surveillance, risk management, medical literature review and monitoring, Adverse Event reporting and responses to Governmental Authority requests or enquiries, and shall provide information related thereto to Eagle, and (ii) in the event Eagle receives safety information regarding the Product, or information regarding any safety-related regulatory request or inquiry, Eagle shall notify TYME as soon as practicable, but, in any event, within the timelines set forth in the Pharmacovigilance Agreement.

5.5 **Unsolicited Requests for Medical Information**. Eagle shall direct to TYME any unsolicited requests for off-label medical information from health care professionals with respect to the Product promptly following receipt by Eagle (but in no event later than two (2) days after receipt). TYME shall, within two (2) days following receipt of any such request from Eagle, address any such requests directly.

5.6 **Recalls and Market Withdrawals**. As between the Parties, TYME shall have the sole right to determine whether to implement, and to implement, a recall, field alert, withdrawal or other corrective action related to the Product. TYME shall bear the cost and expense of any such recall, field alert, withdrawal or other corrective action. Each Party shall promptly (but in any case, not later than one (1) day after) notify the other Party in writing of any order, request or directive of a court or other Governmental Authority to recall or withdraw the Product.

5.7 **Certain Reporting Responsibilities**. Notwithstanding the foregoing provisions of this ARTICLE 5, each Party shall be responsible for its own federal, state and local government pricing reporting and payment transparency reporting in the Territory arising from its Product promotional activities and related expenditures pursuant to Applicable Law. It is the intention of the Parties that any payments or transfer of value by a Party as it relates to the Product shall constitute transfers of

value by that Party and such Party shall be responsible for the reporting described in the immediately preceding sentence. However, if a Party is deemed to have provided any payments or transfers of value to a Third Party on behalf of the other Party as it relates to the Product, then such Party shall provide to the other Party, in a format reasonably acceptable to such other Party, the data and other information on a timely basis (i.e., in the case of manual reporting of such data and other information, within 30 days following the end of each Fiscal Quarter, and, in the case of automated reporting of such data and other information, on a periodic basis during each Fiscal Quarter as reasonably requested by such other Party) for such other Party's reporting under the Physician Payments Sunshine Act and other Applicable Laws.

5.8 **Booking of Sales Revenues**. TYME shall retain ownership of the rights to the Product and record on its books all revenues from sales of the Product. TYME shall be exclusively responsible for accepting and filling purchase orders, billing, and returns with respect to the Product. If Eagle receives an order for the Product, it shall promptly transmit such order to TYME (or its designee) for acceptance or rejection. TYME shall have sole responsibility for shipping, distribution and warehousing of the Product, and for the invoicing and billing of purchasers of the Product and for the collection of receivables resulting from the sales of the Product in the Territory.

5.9 **Returns**. Eagle is not authorized to accept any Product returns. Eagle shall advise any customer who attempts to return any Product to Eagle (or its Affiliates) that such Product must be shipped by the customer to the facility designated by TYME from time to time (and in accordance with other instructions provided by TYME). TYME shall provide to Eagle written instructions as to how Eagle should handle any Product that is actually physically returned to Eagle. Eagle shall take no other actions with respect to such return without the prior written consent of TYME.

5.10 **Development; Manufacturing; Distribution**; **Marketing**. TYME shall have the sole authority to Develop, Commercialize, manufacture, package, label, warehouse, sell and distribute the Product in the Territory. TYME shall use Commercially Reasonable Efforts to Develop and Commercialize at least one (1) Product in the Field in the Territory. Following the acceptance of the NDA for SM-88 (racemetyrosine) by the FDA and no later than 90 days prior to the Target Launch Date, TYME shall use Commercially Reasonable Efforts to cause sufficient quantities of Product to be available in inventory to promptly fill orders throughout the Territory and otherwise meet the forecasted demand for Product in the Territory. If, despite such efforts, there is insufficient supply of Product to meet demand, then TYME shall use Commercially Reasonable Efforts to promptly address such insufficiency. TYME shall contractually require (and shall use commercially reasonable efforts to enforce such contractual provisions) that all Product is manufactured, shipped, sold and distributed in accordance with all Product specifications and all Applicable Law and that its contract manufacturers and/or suppliers of Product operate their facilities in accordance with Applicable Law. TYME shall ensure that all Product Labeling complies with the applicable Regulatory Approval for the Product and Applicable Law. Other than as set forth in this Agreement, TYME shall be responsible for all marketing of the Product in the Territory.

ARTICLE 6 FINANCIAL PROVISIONS

6.1 **Promotion Fee**.

6.1.1 **Calculation of Promotion Fee**.

(a) Subject to Section 6.1.2, commencing with the Fiscal Quarter following the First Commercial Sale, as consideration for the Eagle Activities performed by Eagle, TYME shall pay Eagle a promotion fee based on Net Sales during the Term, calculated by multiplying fifteen percent (15%) by Net Sales of all Product in the Territory in each Fiscal Quarter.

(b) At any time after the date hereof, TYME shall have the right to terminate Eagle's right to Detail and Promote the Product in the Territory in the Field upon a payment to Eagle of all accrued, earned but unpaid promotion fee amounts plus the Buyout Amount.

6.1.2 **Adjustment of Promotion Fee**. In the event that Eagle fails to satisfy the Eagle Quarterly Minimum Details for the Product or fails to demonstrate Commercially Reasonable Efforts to execute on other aspects of the Sales Plan then in effect for a period of two (2) consecutive Fiscal Quarters, the promotion fee payable by TYME pursuant to Section 6.1.1(a) shall be reduced to twelve percent (12%) for subsequent Fiscal Quarters and Eagle shall continue to receive such reduced promotion fee until such Fiscal Quarter in which Eagle satisfies the Eagle Quarterly Minimum Details for the Product or demonstrates Commercially Reasonable Efforts to execute on other aspects of the Sales Plan, as the case may be.

Eagle's failure to meet the Eagle Quarterly Minimum Details or to demonstrate Commercially Reasonable Efforts to execute on other aspects of the Sales Plan then in effect for the Product for a period of four (4) consecutive Fiscal Quarters shall be deemed a material breach of this Agreement (it being understood that a failure to meet the Eagle Quarterly Minimum Details or to demonstrate Commercially Reasonable Efforts to execute on other aspects of the Sales Plan then in effect for the Product for any period less than four consecutive Fiscal Quarters shall not alone be deemed a material breach of this Agreement). For the avoidance of doubt, notwithstanding anything to the contrary herein, such material breach of this Agreement shall give rise to TYME's immediate ability to terminate the Agreement pursuant to Section 11.2.2 and shall not be subject to any cure period.

6.2 **Reports; Payments**.

6.2.1 **Quarterly Reports and Payments**. Within fifteen (15) Business Days after the end of each Fiscal Quarter during the Term, TYME shall provide to Eagle a written report setting forth in reasonable detail the calculation of the Net Sales for such Fiscal Quarter and the promotion fee payable in respect of such Net Sales in accordance with Section 6.1, including the number of units of the Product shipped to patients in the Territory during such Fiscal Quarter, together with an itemized list of such units by Target Professional writing the applicable prescription. Within sixty (60) days after the end of each Fiscal Quarter during the Term, TYME shall pay to Eagle the undisputed portion of the promotion fee payable in respect of such Net Sales in accordance with Section 6.1. If this Agreement terminates or expires during a Fiscal Quarter, the promotion fee payable to Eagle under Section 6.1 shall be calculated only on the Net Sales that occurred during prior to the effective date of such termination or expiration in such Fiscal Quarter.

6.2.2 **Monthly Estimate Reports**. Within fifteen (15) Business Days of the end of each month within each Fiscal Quarter, TYME shall provide to Eagle a written report setting forth TYME's good faith estimate of the Net Sales and the estimated promotion fee payable in respect of such Net Sales for each of such calendar month and the Fiscal Quarter- to-date period, together with its good faith estimates of each of the items described in Section 6.2.1 above. The Parties acknowledge and agree that the monthly reports shall only set forth TYME's good faith estimates of the items contained therein and are being provided to Eagle for information purposes only and shall not be determinative of the any amounts due hereunder.

6.2.3 **Payment Adjustments**. If new information becomes available after the close of a Fiscal Quarter under the process described in Section 6.2.1 that would adjust the amount of recognized Net Sales or payments under this Agreement, such adjustments shall be made in the Fiscal Quarter they become available. Additions or deductions in payments resulting from any adjustments shall be applied to the next regularly scheduled quarterly payment.

6.2.4 **Disputes**. Promptly upon receipt of the quarterly or monthly reports described in this Section 6.2, Eagle shall review such reports and, in the event that Eagle disputes any of the items described in such report, Eagle shall promptly notify TYME of any such disputes. The Parties shall meet promptly thereafter to attempt to resolve such disputes.

6.2.5 **Manner of Payment**. All payments under this Agreement shall be made in US Dollars by wire transfer or Automated Clearing House to a bank account designated in writing by Eagle or TYME, as applicable, which shall be designated at least five (5) Business Days before such payment is due.

6.2.6 **Late Payments**. If Eagle does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due to Eagle from the due date until the date of payment at the prime rate published in the Wall Street Journal on the due date plus two percent (2.0%) per annum or the maximum rate allowable by Applicable Law, whichever is less. Notwithstanding the foregoing, if the reason for any late payment is resulting from or arising out of any act or omission on the part of Eagle, including, but not limited to, any delay providing the payment instructions pursuant to Section 6.2.5, such interest shall not accrue. For clarity, any payments due from adjustments under Section 6.2.3 shall not be considered late payments.

6.3 **Taxes**. To the extent TYME is required to deduct and withhold taxes from any payment to Eagle, TYME shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Eagle an official tax receipt or other evidence of timely payment sufficient to enable Eagle to claim the payment of such taxes as a deduction or tax credit. Eagle may provide to TYME any tax forms that may be reasonably necessary in order for TYME to not withhold tax and TYME shall dispense with withholding, as applicable. TYME shall provide Eagle with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes.

6.4 **Recordkeeping**. Each Party shall maintain complete and accurate books and records in sufficient detail, in accordance with GAAP (to the extent applicable and in accordance with the Agreement) and all Applicable Law, to enable verification of the performance of such Party's obligations under this Agreement and any payments due to a Party under this Agreement. Unless otherwise specified herein, the books and records for a given Fiscal Year of the Term shall be maintained for a period of three (3) years after the end of such Fiscal Year or longer if required by Applicable Law.

6.5 **Eagle Rights**. Eagle shall have the right, at its own expense, during normal business hours and upon reasonable prior notice, through an independent certified public accountant reasonably acceptable to Tyme, and upon execution of a confidentiality agreement reasonably satisfactory to TYME in form and substance, to inspect the applicable records and books maintained by TYME solely for purposes of verifying the accuracy of Net Sales amounts reported by TYME pursuant to Section 6.2.1 hereof and the fees payable by TYME to Eagle under this Agreement in respect of such amounts. For clarity, such inspection right described in this Section 6.5 shall be limited to only those books and records of payment reports and amounts owed to Eagle as a result of Tyme's achievement of Net Sales of the Product in the Territory under this Agreement and (i) may be conducted no more than once per calendar year, (ii) may only cover the most recently completed Fiscal Year and the two (2) years prior to such Fiscal Year, and (iii) may not be conducted in March through June of any given Fiscal Year. Disputes, if any, must be submitted to TYME within sixty (60) days after the completion of such inspection. TYME shall reasonably cooperate in any such inspection or audit conducted by Eagle. Eagle shall treat all information subject to review under this Section 6.5 in accordance with the confidentiality provisions of this Agreement.

ARTICLE 7 INTELLECTUAL PROPERTY

7.1 **Ownership of Intellectual Property**.

7.1.1 **Eagle Property**. TYME acknowledges that Eagle owns or is licensed to use certain Know-How relating to proprietary sales and marketing information, methods and plans that has been independently developed or licensed by Eagle (such Know-How, the "**Eagle Property**"). The Parties agree that any improvement, enhancement or modification made, discovered, conceived, or reduced to practice by Eagle to any Eagle Property in performing its activities pursuant to this Agreement which is not primarily related to the Product, or which is not otherwise derived from the Confidential Information of TYME, shall be deemed Eagle Property. Eagle hereby grants to TYME a fully paid-up, royalty free, non-transferable, non- exclusive perpetual license (with a limited right to sub-license to its Affiliates) to any Eagle Property that appears on, embodied on or contained in Product Materials or Product Labeling solely for use in connection with TYME's promotion or other Commercialization of the Product in the Territory.

7.1.2 **TYME Property**. Subject to the terms of Section 7.1.1, TYME shall have and retain sole and exclusive right, title and interest in and to all inventions, developments, discoveries, writings, trade secrets, Know-How, methods, practices, procedures, designs, improvements and other technology, whether or not patentable or copyrightable, and any patent applications, patents, or copyrights based thereon (collectively, "**Intellectual Property**") relating to the Product that are (i) owned or controlled by TYME as of the Effective Date, (ii) made, discovered, conceived, reduced to practice or generated by TYME (or its employees or representatives) during the Term, or (iii) made, discovered, conceived, reduced to practice or generated by Eagle (or its employees or representatives) in performing its activities pursuant to this Agreement to the extent primarily related to the Product or which is otherwise derived from the Confidential Information of TYME ("**Inventions**"). Eagle agrees to assign, and hereby does assign, to TYME (and shall cause its Affiliates and its and their respective employees and other representatives to assign to TYME) any and all right, title and interest that Eagle (or any such Affiliates, employees or other representatives) may have in or to any Invention. For clarity, any and all Inventions and any information contained therein or related thereto shall constitute Confidential Information of TYME.

7.2 **Title to Trademarks and Copyrights**. The ownership, and all goodwill from the use, of any TYME Trademarks and Copyrights shall at all times vest in and inure to the benefit of TYME, and Eagle shall assign, and hereby does assign, any rights it may have in the foregoing to TYME. Eagle shall not, directly or indirectly, adopt, apply for or acquire any trademarks, trade names, or domain names that include or are confusingly similar to any of the TYME Trademarks and Copyrights.

7.3 **Protection of Trademarks and Copyrights**. As between the Parties, TYME shall have the sole right (but not the obligation), as determined by TYME in its sole discretion, to (i) maintain the TYME Trademarks and Copyrights and/or
(ii) protect, enforce and defend the TYME Trademarks and Copyrights. Eagle shall give notice to TYME of any infringement of, or challenge to, the validity or enforceability of the TYME Trademarks and Copyrights promptly after learning of such

infringement or challenge. If TYME institutes an action against Third Party infringers or takes action to defend the TYME Trademarks and Copyrights, Eagle shall reasonably cooperate with TYME, at TYME's cost and expense. Any recovery obtained by TYME as a result of such proceeding or other actions, whether obtained by settlement or otherwise, shall be retained by TYME. Eagle shall not have any right to institute any action to defend or enforce the TYME Trademarks and Copyrights.

7.4 **Protection of Patent Rights**. As between the Parties, TYME shall have the sole right (but not the obligation), as determined by TYME in its sole discretion, to (i) prosecute and maintain the TYME Patent Rights and/or (ii) protect, enforce and defend the TYME Patent Rights. Eagle shall give notice to TYME of any misappropriation or infringement of, or challenge to, the validity or enforceability of the TYME Patent Rights promptly after learning of such misappropriation or infringement or challenge. If TYME institutes an action against Third Party infringers or takes action to stop the misappropriation or infringement of the TYME Patent Rights, Eagle shall reasonably cooperate with TYME, at TYME's cost and expense. Any recovery obtained by TYME as a result of such proceeding or other actions, whether obtained by settlement or otherwise, shall be retained by TYME. Eagle shall not have any right to institute any action to defend or enforce the TYME Patent Rights.

7.5 **Disclosure of Know-How**. For clarity, the Parties hereby agree and acknowledge that to the extent that either Party hereto has disclosed, or in the future discloses, to the other Party any Know-How or other Intellectual Property of such Party or its Affiliates pursuant to this Agreement, the other Party shall not acquire any ownership rights in such Know-How or other Intellectual Property by virtue of this Agreement or otherwise, and as between the Parties, all ownership rights therein shall remain with the disclosing Party (or its Affiliate).

ARTICLE 8 CONFIDENTIALITY

8.1 **Confidential Information**.

8.1.1 **Confidentiality and Non-Use**. Each Party agrees that, during the Term and for a period of five (5) years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of its rights or performance of any obligations hereunder) any Confidential Information furnished to it by or on behalf of the other Party pursuant to this Agreement, except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties. Without limiting the foregoing, each Party shall use at least the same standard of care as it uses to protect its own Confidential Information to ensure that its employees, agents, consultants and contractors do not disclose or make any unauthorized use of such Confidential Information. Each Party shall promptly notify the other upon discovery of any unauthorized use or disclosure of the other's Confidential Information. Any and all information and materials disclosed by a Party pursuant to the Confidentiality Agreement between the Parties dated June 25, 2019 (the "**Confidentiality Agreement**") shall be deemed Confidential Information disclosed pursuant to this Agreement. The foregoing confidentiality and non-use obligations shall not apply to any portion of the other Party's Confidential Information that the receiving Party can demonstrate by competent tangible evidence:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure to the receiving Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party or its Affiliates in breach of this Agreement;

(d) was disclosed to the receiving Party or its Affiliate by a Third Party who has a legal right to make such disclosure and who did not obtain such information directly or indirectly from the other Party (or its Affiliate); or

(e) was independently discovered or developed by the receiving Party or its Affiliate without access to or aid, application, use of the other Party's Confidential Information, as evidenced by a contemporaneous writing.

8.1.2 **Authorized Disclosure**. Notwithstanding the obligations set forth in Section 8.1.1, a Party may disclose the other Party's Confidential Information and the terms of this Agreement to the extent:

(a) such disclosure is reasonably necessary (x) to comply with the requirements of Governmental Authorities; or (y) for the prosecuting or defending litigation as contemplated by this Agreement;

(b) such disclosure is reasonably necessary to its Affiliates, employees, agents, consultants and contractors on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights under this Agreement; provided that in each case, the disclosees are bound by obligations of confidentiality and non-use consistent with those contained in this Agreement and the disclosing Party shall be liable for any failures of such disclosees to abide by such obligations of confidentiality and non-use; or

(c) such disclosure is reasonably necessary to comply with Applicable Laws, including regulations promulgated by applicable securities exchanges, court order, administrative subpoena or order.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 8.1.2(a) or 8.1.2(c), such Party shall, if permitted, promptly notify the other Party of such required disclosure and shall use reasonable efforts to assist the other Party (at the other Party's cost) in obtaining, a protective order preventing or limiting the required disclosure.

8.2 **Public Announcements**. No public announcement or statements (including presentations to investor meetings and customer updates) concerning the existence of or terms of this Agreement or incorporating the marks of the other Party or their respective Affiliates shall be made, either directly or indirectly, by either Party or a Party's Affiliates, without first obtaining the written approval of the other Party and agreement upon the nature, text and timing of such announcement or disclosure. Either Party shall have the right to make any such public announcement or other disclosure required by Applicable Law after such Party has provided to the other Party a copy of such announcement or disclosure and an opportunity to comment thereon and the disclosing Party shall reasonably consider the other Party's comments. Each Party agrees that it shall cooperate fully with the other with respect to all disclosures regarding this Agreement to the Securities Exchange Commission and any other Governmental Authorities, including requests for confidential treatment of proprietary information of either Party included in any such disclosure. Once any written statement is approved for disclosure by the Parties or information is otherwise made public in accordance with this Section 8.2, either Party may make a subsequent public disclosure of the same contents of such statement in the same context as such statement without further approval of the other Party. Notwithstanding anything to the contrary contained herein, in no event shall either Party disclose any financial information of the other without the prior written consent of such other Party, unless such financial information already has been publicly disclosed by the Party owning the financial information or otherwise has been made part of the public domain by no breach of a Party of its obligations under this ARTICLE 8.

ARTICLE 9 REPRESENTATIONS AND WARRANTIES; ADDITIONAL COVENANTS

9.1 **Representations and Warranties of TYME**. TYME represents and warrants to Eagle as of the Effective Date that:

9.1.1 it is a corporation duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation;

9.1.2 the execution, delivery and performance of this Agreement by it has been duly authorized by all requisite corporate action;

9.1.3 it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

9.1.4 this Agreement constitutes a legal, valid and binding obligation enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity);

9.1.5 the execution, delivery and performance of this Agreement by TYME does not require the consent of any Person (including under any agreement with a Third Party) or the authorization of (by notice or otherwise) any Governmental Authority including the FDA;

9.1.6 there is no action, suit or proceeding pending or, to the knowledge of TYME, threatened, against TYME or any of its Affiliates, or to the knowledge of TYME, any Third Party acting on their behalf, which would be reasonably expected to impair, restrict or prohibit the ability of TYME or Eagle to perform its obligations and enjoy the benefits of this Agreement;

9.1.7 it has no knowledge of any information relating to the safety or efficacy of the Product or any communications with any Governmental Authority, which would reasonably be expected to materially impair, restrict, prohibit or affect TYME's ability to perform its obligations and enjoy the benefits of this Agreement;

9.1.8 it is in compliance in all material respects with all Applicable Laws applicable to the subject matter of this Agreement;

9.1.9 it is not a party to any agreement or arrangement with any Third Party or under any obligation or restriction agreement (including any outstanding order, judgment or decree of any court or administrative agency) which in any way limits or conflicts with its ability to execute and deliver this Agreement and to fulfill any of its obligations under this Agreement;

9.1.10 it is currently conducting a Pivotal Clinical Study for SM-88 (racemetyrosine) though its TYME- 88-Panc trial and SM-88 (racemetyrosine) is also being studied in the Pancreatic Cancer Action Network adaptive Phase II/III trial known as Precision Promise$_{SM}$, which TYME believes can serve as a Pivotal Clinical Study; however, TYME does not currently have an NDA for SM-88 (racemetyrosine) accepted by the FDA;

9.1.11 neither TYME nor any of its personnel (i) have been debarred under the 21 U.S.C. § 335a, (ii) are excluded, debarred, suspended, or otherwise ineligible to participate in the federal health care programs or in federal procurement or nonprocurement programs, (iii) are convicted of a criminal offense that falls within the ambit of the federal statute providing for mandatory exclusion from participation in federal health care programs but has not yet been excluded, debarred, suspended, or otherwise declared ineligible to participate in those programs, (iv) are listed on the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov) or (v) are listed on the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at hhtp://epls.arnet.gov). If, during the Term, TYME or any of its personnel becomes or is the subject of a proceeding that could lead to, as applicable, (i) debarment under 21 U.S.C. § 335a, (ii) exclusion, debarment, suspension or ineligibility to participate in the federal health care programs or in federal procurement or nonprocurement programs, (iii) convicted (or conviction) of a criminal offense that falls within the ambit of the federal statute providing for mandatory exclusion from participation in federal healthcare programs,
(iv) listed (or listing) on the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov) or (v) listed (or listing) on the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at hhtp://epls.arnet.gov), TYME shall immediately notify Eagle, and Eagle shall have the option to prohibit such Person from performing work relating to this Agreement or the Product; and

9.1.12 the Product Materials provided by TYME to Eagle for the conduct of Eagle Activities are, and shall be, compliant with the Regulatory Approval for the Product, the Product Labeling and Applicable Law.

9.2 **Representations and Warranties of Eagle**. Eagle represents and warrants to TYME as of the Effective Date that:

9.2.1 it is a corporation duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation;

9.2.2 the execution, delivery and performance of this Agreement by it has been duly authorized by all requisite corporate action;

9.2.3 it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

9.2.4 this Agreement constitutes a legal, valid and binding obligation enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement

of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity);

9.2.5 the execution, delivery and performance of this Agreement by Eagle does not require the consent of any Person or the authorization of (by notice or otherwise) any Governmental Authority or the FDA;

9.2.6 there is no action, suit or proceeding pending or, to the knowledge of Eagle, threatened, against Eagle or any of its Affiliates, or to the knowledge of Eagle, any Third Party acting on their behalf, which would be reasonably expected to impair, restrict or prohibit the ability of TYME or Eagle to perform its obligations and enjoy the benefits of this Agreement;

9.2.7 it is in compliance in all material respects with all Applicable Laws applicable to the subject matter of this Agreement;

9.2.8 it is not a party to any agreement or arrangement with any Third Party or under any obligation or restriction agreement (including any outstanding order, judgment or decree of any court or administrative agency) which in any way limits or conflicts with its ability to execute and deliver this Agreement and to fulfill any of its obligations under this Agreement;

9.2.9 it has no knowledge of any information relating to any communications with any Governmental Authority, which would reasonably be expected to materially impair, restrict, prohibit or affect Eagle's ability to perform its obligations and enjoy the benefits of this Agreement;

9.2.10 neither Eagle nor any of its personnel (i) have been debarred under the 21 U.S.C. § 335a, (ii) are excluded, debarred, suspended, or otherwise ineligible to participate in the federal health care programs or in Federal procurement or nonprocurement programs, (iii) are convicted of a criminal offense that falls within the ambit of the federal statute providing for mandatory exclusion from participation in federal health care programs but has not yet been excluded, debarred, suspended, or otherwise declared ineligible to participate in those programs, (iv) are listed on the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov) or (v) are listed on the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at hhtp://epls.arnet.gov). If, during the Term, Eagle or any of its personnel become or are the subject of a proceeding that could lead to, as applicable, (i) debarment under 21 U.S.C. § 335a, (ii) exclusion, debarment, suspension or ineligibility to participate in the federal health care programs or in Federal procurement or nonprocurement programs, (iii) convicted (or conviction) of a criminal offense that falls within the ambit of the federal statute providing for mandatory exclusion from participation in federal healthcare programs, (iv) listed (or listing) on the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov) or (v) listed (or listing) on the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at hhtp://epls.arnet.gov), Eagle shall immediately notify TYME, and TYME shall have the option to prohibit such Person from performing work under this Agreement; and

9.2.11 all Field Force Personnel that are engaged in Detailing are, and shall be, licensed to the extent required and in accordance with all Applicable Laws.

9.3 **Disclaimer of Warranty**. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN THIS AGREEMENT, TYME (AND ITS AFFILIATES) AND EAGLE (AND ITS AFFILIATES) MAKE NO REPRESENTATIONS AND NO WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND TYME (AND ITS AFFILIATES) AND EAGLE (AND ITS AFFILIATES) EACH SPECIFICALLY DISCLAIM ANY OTHER REPRESENTATIONS AND WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS, STATUTORY OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY INTELLECTUAL PROPERTY OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE 10 INDEMNIFICATION; LIMITATIONS ON LIABILITY

10.1 **Indemnification by TYME**. TYME shall defend, indemnify and hold harmless Eagle and its Affiliates and its and their respective officers, directors, employees, agents, representatives, successors and assigns from and against all

Claims, and all associated Losses, to the extent incurred or suffered by any of them to the extent resulting from or arising out of (a) any misrepresentation or breach of any representations, warranties, agreements or covenants of TYME under this Agreement, (b) the negligence, willful misconduct or violation of Applicable Laws by TYME (or any of its Affiliates or its or their respective officers, directors, employees, agents or representatives), (c) the misappropriation or infringement of the intellectual property rights of any Third Party in connection with the Product, including from the use of the TYME Trademarks and Copyrights on Product Labeling or Product Materials in accordance with this Agreement, or (d) the Development and Commercialization of the Product by or on behalf of TYME, its Affiliates and any of their respective licensees, including the death or personal injury to any person related to use of the Product; except in each case to the extent any such Claims, and all associated Losses, are caused by an item for which Eagle is obligated to indemnify TYME pursuant to Section 10.2.

10.2 **Indemnification by Eagle**. Eagle shall defend, indemnify and hold harmless TYME and its Affiliates and its and their respective officers, directors, employees, agents, representatives, successors and assigns from and against all Claims and all associated Losses, to the extent incurred or suffered by any of them to the extent resulting from or arising out of (a) any misrepresentation or breach of any representations, warranties, agreements or covenants of Eagle under this Agreement, (b) the negligence, willful misconduct, or violation of Applicable Laws by Eagle (or any of its Affiliates or its and their respective officers, directors, employees, agents or representatives) or (c) labor disputes, Equal Employment Opportunity Commission charges or employment-related claims arising from or related to Eagle's employees; except in each case to the extent any such Claims, and all associated Losses, are caused by an item for which TYME is obligated to indemnify Eagle pursuant to Section 10.1.

10.3 **Indemnification Procedures**. The Party seeking indemnification under Section 10.1 or 10.2, as applicable (the "**Indemnified Party**") shall give prompt notice to the Party against whom indemnity is sought (the "**Indemnifying Party**") of the assertion or commencement of any Claim in respect of which indemnity may be sought under Section 10.1 or 10.2, as applicable, and shall provide the Indemnifying Party such information with respect thereto that the Indemnifying Party may reasonably request. The failure to give such notice shall relieve the Indemnifying Party of any liability hereunder only to the extent that the Indemnifying Party has suffered actual prejudice thereby. The Indemnifying Party shall assume and control the defense and settlement of any such action, suit or proceeding at its own expense; provided, however, if the Indemnified Party is TYME, it shall assume and control the defense and settlement of any such action, suit or proceeding. The Indemnified Party shall, if requested by the Indemnifying Party, cooperate in all reasonable respects in such defense, at the Indemnifying Party's expense. The Indemnified Party shall be entitled at its own expense to participate in such defense and to employ separate counsel for such purpose. For so long as the Indemnifying Party is diligently defending any proceeding pursuant to this Section 10.3, the Indemnifying Party shall not be liable under Section 10.1 or 10.2, as applicable, for any settlement effected without its consent. No Party shall enter into any compromise or settlement which commits the other Party to take, or to forbear to take, any action without the other Party's prior written consent (unless such compromise or settlement includes no payments by the Indemnified Party, an unconditional release of, and no admission of liability by, the Indemnified Party from all liability in respect of such Claim).

10.4 **Limitation of Liability**. NOTWITHSTANDING ANY OTHER PROVISION CONTAINED HEREIN (OTHER THAN AS SET FORTH IN THE SECOND SENTENCE OF THIS SECTION 10.4), IN NO EVENT SHALL TYME (OR ITS AFFILIATES) OR EAGLE (OR ITS AFFILIATES) BE LIABLE TO THE OTHER OR ANY OF THE OTHER PARTY'S AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING LOST PROFITS) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES THAT ARISE OUT OF OR RELATE TO THIS AGREEMENT OR IN CONNECTION WITH A BREACH OR ALLEGED BREACH OF THIS AGREEMENT, WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, AND REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. THE FOREGOING SENTENCE SHALL NOT LIMIT (1) THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY FROM AND AGAINST THIRD PARTY CLAIMS UNDER SECTION 10.1 OR 10.2, AS APPLICABLE, OR (2) DAMAGES AVAILABLE FOR A PARTY'S BREACH OF THE NON-COMPETE AND NON-SOLICIT OBLIGATIONS IN SECTION 2.3 AND THE CONFIDENTIALITY AND NON-USE OBLIGATIONS IN ARTICLE 8.

10.5 **Insurance**. Each Party acknowledges and agrees that during the Term, it shall maintain, through purchase or self-insurance, adequate insurance, including products liability coverage and comprehensive general liability insurance, adequate to cover its obligations under this Agreement and which are consistent with normal business practices of prudent companies similarly situated. Each Party shall provide reasonable written proof of the existence of such insurance to the other Party upon request. TYME does not and will not maintain or procure any worker's compensation, healthcare, or other insurance for or on behalf of any Field Force Personnel, all of which shall be Eagle's sole responsibility. For clarity, the insurance

requirements of this Section 10.5 shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this ARTICLE 10.

ARTICLE 11 TERM AND TERMINATION

11.1 **Term**. This Agreement shall become effective as of the Effective Date and, unless earlier terminated as provided in this ARTICLE 11, will continue for ten (10) years (the "**Term**").

11.2 **Early Termination** . A Party shall have the right to terminate this Agreement before the end of the Termas follows:

11.2.1 by Eagle at its sole discretion and for any reason or no reason, upon twelve (12) months written notice to TYME given any time after the second (2nd) anniversary of the First Commercial Sale of the Product in the Territory;

11.2.2 by a Party upon written notice to the other Party in the event of a material breach of this Agreement by such other Party where such breach is not cured (if able to be cured) within 60 days following such other Party's receipt of written notice of such breach (and any such termination shall become effective at the end of such 60-day period unless the breaching Party has cured such breach prior to the expiration of such 60-day period), provided, however, for the avoidance of doubt such 60-day period shall not apply for termination relating to a material breach arising under Section 6.1.2 of this Agreement;

11.2.3 by either Party upon 90 days' written notice to the other Party following the withdrawal of the Product from the market by TYME (or the decision by TYME to withdraw the Product from the market) due to (i) any decision, judgment, ruling or other requirement of the FDA, or (ii) material safety concern;

11.2.4 by TYME pursuant to Section 6.1.1(b); and

11.2.5 by a Party immediately upon written notice to the other Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings with respect to such other Party, or upon an assignment of a substantial portion of the assets for the benefit of creditors by such other Party, or in the event a receiver or custodian is appointed for such other Party's business or a substantial portion of such other Party's business is subject to attachment or similar process; provided, however, in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within ninety (90) days after the filing thereof.

11.3 **Effects of Termination**. Upon the expiration or effective date of termination of this Agreement, (i) all rights and obligations of both Parties hereunder shall immediately terminate, subject to any survival as set forth in Section 11.4, (ii) Eagle, at TYME's direction, shall immediately return to TYME or destroy in accordance with all Applicable Laws all Product Materials, reports and other tangible items provided by or on behalf of TYME to Eagle or otherwise developed or obtained by Eagle pursuant to the terms of this Agreement (other than Eagle Property) (and at the request of TYME, Eagle shall certify destruction of such materials if Eagle does not to return such materials to TYME), (iii) Eagle shall immediately cease all Eagle Activities with respect to the Product, and (iv) each of TYME and Eagle shall, at the other Party's direction, either return to such other Party or destroy all Confidential Information of such other Party. Notwithstanding the foregoing, each Party may retain archival copies of any Confidential Information to the extent required by law, regulation or professional standards or copies of Confidential Information created pursuant to the automatic backing-up of electronic files where the delivery or destruction of such files would cause undue hardship to the receiving Party, so long as any such archival or electronic file back- up copies are accessible only to its legal or IT personnel, provided that such Confidential Information shall continue to be subject to the terms of this Agreement.

11.4 **Survival**. Termination or expiration of this Agreement shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination or expiration. Notwithstanding any expiration or termination of this Agreement, such expiration or termination shall not relieve any Party from obligations which are expressly or by implication intended to survive expiration or termination, including Sections 2.3, 4.4.2, 5.7, 5.9, 6.2.4, 6.2.5, 10.1, 10.2, 10.3, 10.4, 11.3 and 11.4, Articles 7, 8 and 12 (to the extent applicable to implementation of the survival of the preceding Sections and Articles) and, solely as it relates to the last Fiscal Quarter, Sections 6.1, 6.2 and 6.3, which shall survive and be in full force and effect.

ARTICLE 12 MISCELLANEOUS

12.1 **Force Majeure**. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement (other than any failure to make payments owed under this Agreement) to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, potentially including, embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any Governmental Authority. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practicable, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances and re-commence its performance hereunder as soon as practicable.

12.2 **Assignment**. Except as provided in this Section 12.2, this Agreement may not be assigned or otherwise transferred, nor may any rights or obligations hereunder be assigned or transferred, by either Party, without the written consent of the other Party (such consent not to be unreasonably withheld); provided that a merger, sale of stock or comparable transaction shall not constitute an assignment. In the event either Party desires to make such an assignment or other transfer of this Agreement or any rights or obligations hereunder, such Party shall deliver a written notice to the other Party requesting the other Party's written consent in accordance with this Section 12.2, and the other Party shall provide such Party written notice of its determination whether to provide such written consent within 30 days following its receipt of such written notice from such Party. Notwithstanding the foregoing, (a) either Party may, without the other Party's consent, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate; and (b) either Party may assign this Agreement to a successor in interest in connection with the sale or other transfer of all or substantially all of such Party's assets or rights relating to the Product; provided that such assignee shall remain subject to all of the terms and conditions hereof in all respects and shall assume all obligations of such Party hereunder whether accruing before or after such assignment. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement. Any attempted assignment not in accordance with this Section 12.2 shall be void. This Agreement shall be binding on, and inure to the benefit of, each Party, and its permitted successors and assigns.

12.3 **Severability**. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use reasonable efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

12.4 **Notices**. All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by e-mail (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier, or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to TYME, to:

Tyme Technologies, Inc. 17 State Street –
7th Floor New York, NY 10004
Attention: Chief Executive Officer
E-Mail: steve.hoffman@tymeinc.com

With a copy to:
Tyme Technologies, Inc. 17 State Street –
7th Floor New York, NY 10004
Attention: Chief Legal Officer
E-Mail: jim.biehl@tymeinc.com

if to Eagle, to:

Eagle Pharmaceuticals, Inc.
50 Tice Boulevard Woodcliff Lake, NJ
07677

Attention: Executive Vice President & General Counsel E-Mail: mcordera@eagleus.com

With a copy to:
Eagle Pharmaceuticals, Inc. 50 Tice
Boulevard Woodcliff Lake, NJ 07677
Attention: Chief Operating Officer & President E-Mail:
dpernock@eagleus.com

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered; (b) on the Business Day after dispatch if sent by nationally-recognized overnight courier; or (c) on the fifth (5th) Business Day following the date of mailing, if sent by mail.

12.5 **Governing Law**. This Agreement and any and all matters arising directly or indirectly herefrom shall be governed by and construed and enforced in accordance with the internal laws of the State of Delaware applicable to agreements made and to be performed entirely in such state, including its statutes of limitation but without giving effect to the conflict of law principles thereof.

12.6 **Dispute Resolution**. If a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith that (a) is expressly reserved for resolution pursuant to this Section 12.6 or (b) is outside of the decision-making authority of the SOC pursuant to Section 3.4 (a "**Dispute**"), then the Dispute shall be submitted to and finally settled by binding arbitration by JAMS under its Comprehensive Arbitration Rules and Procedures. A Dispute settled by an arbitrator shall be conducted by three arbitrators, each having ten years of experience in the pharmaceutical industry and also shall have served as an arbitrator at least three times prior to their service as an arbitrator in this arbitration. Within ten (10) days of commencement of an arbitration each Party shall select one (1) arbitrator and together select a third arbitrator who shall serve as a neutral arbitrator. The two designated arbitrators shall select a third neutral arbitrator within ten (10) days of their selection if the Parties cannot agree on the third arbitrator. If the two arbitrators cannot agree on selection of a third arbitrator within ten (10) days of their appointment, JAMS shall do so in accordance with its rules. The fees of the arbitrator(s) and JAMS shall be paid by the losing Party, which shall be designated by the arbitrator(s). If the arbitrator(s) is unable to designate a losing Party, it shall so state and the fees shall be split equally by the Parties. The arbitrator(s) is hereby empowered to award any remedy allowed by Law, including money damages, prejudgment interest and attorneys' fees, and to grant final, complete, interim or interlocutor relief, including injunctive relief. The Parties hereby submit to the exclusive jurisdiction of the federal and state courts located in Wilmington, Delaware for the purposes of an order to compel arbitration, for preliminary relief in aid of arbitration and for a preliminary injunction to maintain the status quo or prevent irreparable harm prior to the appointment of the arbitrators and to the non-exclusive jurisdiction of such courts for the enforcement of any ward issued hereunder.

12.7 **Waiver of Jury Trial**. EACH OF THE PARTIES HERETO IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

12.8 **Entire Agreement; Amendments**. This Agreement, together with the Schedules and Exhibits hereto, contains the entire understanding of the Parties with respect to the subject matter hereof. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the subject matter hereof (including the Confidentiality Agreement, but solely with respect to information which is deemed Confidential Information hereunder) are superseded by the terms of this Agreement. The Exhibits and Schedules to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties hereto.

12.9 **Headings**. The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.

12.10 **Independent Contractors**. It is expressly agreed that Eagle and TYME shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Eagle nor TYME shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

12.11 **Third Party Beneficiaries**. Except as set forth in ARTICLE 10, no Person other than TYME or Eagle (and their respective Affiliates and permitted successors and assignees hereunder) shall be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

12.12 **Waiver**. The waiver by either Party hereto of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise.

12.13 **Cumulative Remedies**. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

12.14 **Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

12.15 **Use of Names**. Except as otherwise provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name, trademark or logo of the other Party for any purpose in connection with the performance of this Agreement.

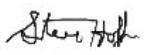
12.16 **Further Actions and Documents**. Each Party agrees to execute, acknowledge and deliver all such further instruments, and to do all such further acts, as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.

12.17 **Certain Conventions**. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, or Exhibit shall be deemed to be a reference to an Article, Section, subsection, paragraph, clause, or Exhibit, of or to, as the case may be, this Agreement, unless otherwise indicated. Unless the context of this Agreement otherwise requires, (a) words of any gender include each other gender, (b) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (c) words using the singular shall include the plural, and vice versa, (d) whenever any provision of this Agreement uses the term "including" (or "includes"), such term shall be deemed to mean "including without limitation" (or "includes without limitations"), and (e) references to any Articles or Sections include Sections and subsections that are part of the references' Article or Section (e.g., a section numbered "Section 2.2.1" would be part of "Section 2.2", and references to "ARTICLE 2" or "Section 2.2" would refer to material contained in the subsection described as "Section 2.2.1").

12.18 **Counterparts**. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile or electronic mail (including pdf) and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes and shall have the same force and effect as original signatures.

[signature page follows]

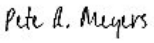
IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.



TYME TECHNOLOGIES, INC.

By:
Name: Steve Hoffman
Title: Chief Executive Officer

EAGLE PHARMACEUTICALS, INC.



By:
Name: Pete A. Meyers
Title: Chief Financial Officer

Schedule 1.77
Exclusions from "Target Professionals"

Key Thought Leaders:

[TO BE PROVIDED BY TYME PRIOR TO THE TARGET LAUNCH DATE]

Schedule 4.1 Operating Parameters

Schedule

(As in effect January 7, 2020)

Sales Force:

- Eagle shall provide an adequate sales force, as defined below under Sales Force Requirements, to call on community and hospital based health care providers. TYME will continue to be the exclusive contact with key opinion leaders and key academic researchers, who will be defined prior to the SM-88 launch.
- Sales Force Requirements:
  - Eagle will be responsible for having sufficient SM-88 representatives to cover 25% of the Sales Force Requirements
    - Eagle will have the sales representatives in place in time for appropriate training at least 90 days prior to the Target Launch Date
    - The Eagle SM-88 sales representatives will have separate accounts from the TYME representatives as identified in the Sales Plan (as such term is defined in the Agreement)
    - The Eagle SM-88 accounts will be identified prior to the acceptance of the NDA by the FDA
    - The percentage of the Sales Force Requirement covered by the Eagle SM-88 representatives will be reviewed with the Sale Operations Committee, as defined below, after the initial 6 months following launch and may be increased upon committee agreement, however coverage over 25% of the Sales Force Requirements shall require the consent of Eagle
  - The total sales force for SM-88 will be sized based on the following Sales Force Requirements:
    - Reach: The key assumption is that the sales representatives will be detailing SM-88 to at least 20 Target Professionals (as defined in the Agreement) per week per representative, with the accounts to be identified prior to acceptance of the NDA by the FDA
    - Frequency: The accounts will be tiered based on Pancreatic Cancer patient volume. Accounts and the tiering will be defined prior to the acceptance of the NDA by the FDA. The Sales Call frequency based on tiering will be:
      - Tier 1: Sales Call Frequency of at least 2 – 3 times/month
      - Tier 2: Sales Call Frequency of at least 1 time/month
      - Tier 3: Sales Call Frequency of at least 1 time/6 weeks
    - The Sales Force Size requirement may be modified if there is a shift in reach and/or account tiering, which will be reviewed by the Sales Operations Committee, as defined in the Agreement
  - TYME maintains the right to, on a reasonable basis, have its personnel accompany an Eagle sales representative during a detail, following appropriate advance notice
  - Position of SM-88 in the Eagle detail: SM-88 must be considered the first call position for at least 70% of the calls for a multi-disciplinary oncologist account. SM-88 will be the sole detail for all calls that are focused on a gastrointestinal oncologist
  - Minimum Sales Representatives Requirement: initial requirement and time period to which it will be applicable will be determined by TYME by reference to the Sales Force Requirements no later than three months prior to NDA filing
  - Eagle Quarterly Minimum Details: initial requirement and time period to which it will be applicable will be determined by TYME by reference to the Sales Force Requirements no later than three months prior to NDA filing

Training:

- TYME will be responsible for training the Eagle sales force and for the creation of all sales training materials used by the Eagle team. As this material will be regulatory compliant, no changes can be made by Eagle without the written consent of TYME.
- Eagle sales representatives and their sales management will be required to complete mandatory training before detailing SM-88 to an account. This training will need to be completed prior to launch date of SM-88 with follow up quarterly training. Prior to the launch of SM-88, the training will be a live training. Subsequently,

there will be at least 3 live trainings per year and the other training can be fulfilled via webcast. The training will include but is not limited to:

- Disease state education
- Current treatment education
- SM-88 clinical data education
- SM-88 prescribing information training
- SM-88 approved promotional materials
- Adverse Event Reporting
- Sales skills training
- Compliance training

Promotional Programs:

- In compliance with the PhRMA code and other guidelines (i.e. State guidelines), Eagle sales representatives will execute on promotional programs, utilizing the TYME approved presentation
- Eagle will be responsible for the delivery of the promotional programs to its SM-88 accounts and the cost associated with delivering the programs
- The target number of promotional programs will be defined prior to launch and will be discussed at the Sales Operations Committee; Promotional Programs will be addressed in the Sales Plan (as updated from time to time)

Operating Principles:

- TYME also retains the right to have sales representatives promoting SM-88 and/or engaging in other co- promotion agreements, the co-promotion arrangement with Eagle shall not be exclusive
- Eagle is responsible for all costs associated with its sales force. This includes, but is not limited to:
  - Cash compensation (salary and incentives)
  - Benefits
  - Travel and related expenses
  - Training expenses, including but not limited to meeting facility, travel and lodging, meals, print materials, contests, awards
  - Sales detail print materials
  - Delivery of promotional programs

Schedule 4.1.2
Qualifications and Criteria for Sales Representatives and their managers

[TO BE JOINTLY DEVELOPED AND MUTUALLY AGREED BY TYME AND EAGLE]

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 report dated May 22, 2020, with respect to the consolidated financial statements included in the Annual Report of Tyme Technologies, Inc. on Form 10-K for the year ended March 31, 2020. We consent to the incorporation by reference of said report 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, No. 333-227077, and No. 333-236259).

/s/ Grant Thornton LLP
New York, New York

May 22, 2020

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: May 22, 2020

/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: May 22, 2020

/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, 2020, 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: May 22, 2020

/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.