UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

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

For the fiscal year ended March 31, 2018

☐ **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	Name of Exchange on Which Registered
Common Shares, $.0001 par value	**The NASDAQ Stock Market LLC**

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

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

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

Indicate by checkmark 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 and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by checkmark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by checkmark 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	☐ (Do not check if a smaller reporting company)	Smaller Reporting Company	☐
		Emerging Growth Company	☐

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

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

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

The number of shares outstanding of the registrant's common stock on June 6, 2018 was 101,226,479.

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 2018 Annual Meeting of Shareholders.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

GENERAL

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

PART I

ITEM 1. BUSINESS

Executive Summary of Our Business

We are a clinical-stage biotechnology company developing novel cancer therapeutics that are intended to be effective across many tumor types while also being relatively non-toxic compared to conventional therapies. Tyme has reported clinical data on over 100 cancer patients who have used our lead clinical program, SM-88, which is a novel combination therapy based on dysfunctional metyrosine derivatives. As of June 2018, SM-88 has shown complete or partial imaging responses in 15 different cancer subtypes, including solid tumors, sarcomas, gliomas and hematological malignancies, without demonstrating drug-related severe adverse events (" AEs "). Tyme has two ongoing Phase II clinical trials in metastatic pancreatic cancer and biomarker-recurrent prostate cancer, and has previously completed a 30-patient Phase I trial (the " First Human Study " or " FHS "), which has shown what we believe to be promising data, and maintains an ongoing expanded access program outside of the FHS that has treated 77 patients to date as a part of a compassionate use program under Institutional Review Board ("IRB") supervision or FDA Individual Investigational New Drug (" INDs ") application.

Tyme has and intends to continue to work towards its overall corporate mission of developing effective cancer therapies that can extend patients' lives while not compromising on the quality of life gained.

SM-88: Completed Studies

In October 2017, we announced that we had completed a long-term follow-up analysis of patients from the First Human Study, who were originally enrolled during 2012. The FHS involved 30 patients with actively progressing metastatic cancer who had failed or refused available treatment options across solid tumor types. The FHS was initially designed as a six-to-twelve-week study to determine safety of SM-88 in the end-stage treatment setting. When multiple patients showed what we define as Clinical Benefit under Response Evaluation Criteria In Solid Tumors 1.1 (" RECIST ") criteria, treatment was continued for some patients over multiple years. RECIST 1.1 is a standardized criterion established by the National Institute of Health (" NIH ") for the assessment of changes in tumor burden in patients. The criterion has fixed thresholds for changes in size, number of monitored lesions, lymph node involvement of the cancer, and other factors. The primary assessment for change in tumor size is determined by computerized axial tomography (" CAT ") or CT imaging. Other imaging techniques such as magnetic resonance imaging (" MRI ") or positron emission tomography (" PET ") scans can be used to determine the development of new lesions, or resolution of lesions, but are not currently acceptable under this criterion for the quantification for the change in tumor volume. This study was conducted under IRB supervision without U.S. Food and Drug Administration (" FDA ") approval of an investigational new drug application (" IND "). Initial data from the FHS was published at conferences, including the American Society of Clinical Oncologists (" ASCO "), and then used to receive FDA IND approval for SM-88 to enter a Phase Ib/II prostate cancer trial in 2015. We believe our FHS indicated that SM-88 was well-tolerated and showed preliminary activity across a number of different cancer types in terms of tumor regression, biomarker improvement, and overall survival.

In the FHS, patients achieved median overall survival (" OS ") to 29.8 months from the start of treatment with SM-88 and a 33% monotherapy objective response rate (" ORR "), consisting of four complete responses (" CR ") and six partial responses (" PR "), based on RECIST, which sets forth certain criteria for assessing treatment outcomes. Five FHS patients survived for over five years after commencing SM-88 treatment. All FHS patients improved or maintained Eastern Cooperative Oncology Group Performance Status (" ECOG PS "), a five-point scale to measure quality of life after initiating SM-88 therapy and overall survival was comparable for patients who entered the trial with ECOG PS ranging from 0 (asymptomatic) to 2 (unable to perform any work-related activities).

We have also reported multiple subgroup analyses of FHS patients. As of September 2017, 67% of FHS patients were reported to have had no additional systemic therapies other than SM-88 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 median OS (38 months) than patients who received subsequent treatments beyond SM-88 (28 months). In addition, patients with two or more prior systemic therapies (n=11) 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 OS as follows: breast cancer, 35 months (n=14); lung cancer, 25 months (n=5); and pancreatic cancer, 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.

Given the duration of survival combined with lack of documented disease progressions in many SM-88 patients, we believe that traditional RECIST response criteria, a commonly used clinical endpoint based primarily on static radiographic scans that measure tumor diameter, may not fully reflect the therapeutic benefit from SM-88 and that measuring metabolic function through PET standardized uptake values (" SUV ") imaging may more accurately correlate the effect of SM-88. For the ASCO general meeting in June 2018 (" ASCO 2018 "), we published data comparing the impact of SM-88 therapy using RECIST or PET analysis. Eleven patients had comparative evaluable data between the two imaging modalities, of whom 10 eventually experienced a CR or PR under RECIST criteria. All subjects experienced a greater decrease using PET (median -48% SUV) than RECIST (median -1% tumor diameter). As treatment continued, the early SUV response had an 85.7% positive predictive value for CR or PR response in RECIST. A patient would be considered to have stable disease (" SD ") under RECIST if his or her tumor volume remained in a narrow, specified range, even if there was a substantial reduction to the PET scan values suggesting that the tumor was metabolically inactive. Because the overall survival data suggest that patients with SD according to RECIST 1.1 may also have clinical benefit, we include the commonly used calculation of Clinical Benefit Rate (" CBR "), which includes patients achieving RECIST CR, PR and SD designations.

Additionally, as published in a retrospective analysis for ASCO 2018, from data available up to September 2017, 77 advanced cancer patients had been treated outside of the FHS with SM-88 (the " Compassionate Use Patients ") as part of a compassionate use program under IRB supervision. When performing this updated review, we required patient data providing information that could be evaluated to measure response criteria that are recognized by regulatory bodies, such as RECIST criteria. These criteria require imaging such as CT or MRI. Some patients in this group may have only had metabolic or PET imaging, or a mixture of PET/CT that does not support RECIST response criteria. 53 of the 77 Compassionate Use Patients had such evaluable data, as determined by both baseline and follow-up CT (CAT) scans following at least six-weeks of therapy. Compassionate Use Patients also began with actively progressive disease and generally followed the same or similar SM-88 treatment plan as the FHS patients, however 43% (23/53) received SM-88 therapy in combination with other cancer treatments, while 57% or 30/53 received SM-88 as a monotherapy. 45% (24/53) of patients experienced a CR or PR and an additional 30% (16/53) achieved SD (75% Clinical Benefit).

The following table combines the 30 patients from the FHS and 53 evaluable Compassionate Use Patients into several subgroups based on data available through September 2017. Note that the percentage of patients included is based on the number evaluable:

Category	# of Patients (1)	ORR (CR/PR)	Median OS (months)
Combination Therapy	23/81 (28%)	39% (4%/35%)	8.5
Monotherapy	58/81 (72%)	43% (19%/24%)	22.8
Duration SM-88: **2-6 months**	60/83 (72%)	28% (5%/23%)	9.6
Duration SM-88: >6 months	23/83 (28%)	74% (39%/35%)	25.3
Visceral & bone metastases	17/39* (44%)	41% (18%/24%)	11.7
ECOG PS ≥ 2	30/66 (45%)	47% (20%/27%)	9.6
ECOG PS 0 or 1	36/66 (55%)	39% (17%/22)	24.5

* 39 of the 81 patients had complete records on both visceral and bone metastases. Patients in which baseline status of either of these items were unknown were excluded from this calculation.

(1) Due to the nature of compassionate use programs, for which the data gathered is not specifically governed by a formal study protocol, not all data was available for all patients. If such data was not available, such patient was excluded from the related calculation.

The safety summary of the drug-related adverse events in the First Human Study (FHS) is summarized in the table below. Due to the nature of compassionate use programs as opposed to a study subject to a more defined protocol, detailed safety findings were not compiled. There were however, no drug-related adverse events reported in any of the full 77 patients.

Drug-Related Adverse Events Reported in the First Human Study (n=30) [1]

Adverse Event	Grade 1	Grade 2	Grade 3/4	Total
Hyperpigmentation	29 (97%)	1 (3%)	—	30 (100%)
Fatigue [2]	13 (43%)	4(13%)	—	17(57%)
Pain [2]	3(10%)	1(3%)	—	4(13%)
Pruritis	1(3%)	—	—	1(3%)
Burning Sensation	1(3%)	—	—	1(3%)
Total	**29(97%)**	**5(17%)**	**—**	**30(100%)**

1. Includes all adverse events deemed as possibly, probably or definitely drug-related.
2. Generally transient

Through these two programs, patients being treated with SM-88 have achieved CRs or PRs across 15 different cancer types, including some of the most common and difficult to treat cancers, such as pancreatic, prostate, breast, lung, glioma, ovarian, sarcoma and colon cancer. As of the release of the interim results in September 2017, SM-88 had not been associated with any drug-related moderate or severe AEs. Based on preliminary data from the FHS and the Compassionate Use Patients suggesting SM-88 may have broad potential applicability and acceptable toxicity, we believe that SM-88 may ultimately have potential as a treatment for a wide range of cancers prior to the end-stage setting.

SM-88: Currently Enrolling Phase II Trial for Pancreatic Cancer

Pancreatic cancer is one of the deadliest major cancers, with a one-year survival rate of 20% at diagnosis according to the American Cancer Society. The poor prognosis is partially due to more than 80% of cases being metastatic at the time of diagnosis. When patients with pancreatic cancer are resistant to first line therapy – as were all 12 pancreatic patients who were treated in our FHS and compassionate use program, survival is often only a few months and clinical response rates are very low. Based on our initial results described below and the dire state of the disease, we have initiated a Phase II trial in refractory pancreatic cancer patients during the first half of 2018. On September 29, 2017, we submitted an SM-88 IND to the FDA for pancreatic cancer patients. On March 14, 2018 we announced that the FDA has accepted our IND application allowing us to initiate our currently enrolling Phase II clinical trial for SM-88 in pancreatic cancer. As of the date of this report, we have opened eleven sites across the U.S. and have patients enrolled in the study. We anticipate making the first presentation of interim data by early 2019.

SM-88: Retrospective Review of Pancreatic Patients

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

SM-88: Currently Enrolling Phase II Prostate Cancer Trial

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

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

Reported Adverse Event by Grade in Phase Ib/II Prostate Trial

	Possibly Related	Total
Grade 1	5/13 patients (38%) [1]	5/13 patients (38%)
Grade 2	0	2/13 patients (22%) [2]
Grade 3	0	1/13 patients (11%) [3]
Grade 4	0	0
Total Patients	5/13 (38%)	5/13 (38%)
Total AEs [4]	6	14

1. "Possibly Related" AEs: vitiligo, hot flashes, bradycardia (observed at baseline), intestinal bloating, flatulence
2. Grade 1 & 2 AEs accounted for 19 of the 20 (95%) AEs reported
3. Hyperkalemia in a subject taking Potassium (K+) sparing diuretic
4. Twelve of the 20 total AEs reported by two patients. In total eight of 13 subjects (62%) reported AEs.

Other Clinical and Development Plans

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

We intend to initiate additional Phase II studies in these or other cancers as resources become available. We may also develop other products for oncology using alternate delivery platforms as well as alternate product compositions. SM-88 is generally intended as an oral therapy that is broadly applicable to cancers; however, alternate routes of delivery may be more appropriate for use by certain patients or as treatment for certain types of cancer. For example, we have developed a prototype injectable formulation that may be beneficial for patients with a compromised digestive system and as a result are not able to absorb the oral formulation. Confronted with this situation, applicable end-stage First Human Study patients were administered with small SM-88 subcutaneous doses (of the tyrosine derivative component) in combination with an oral SM-88 dose to ensure absorption and we believe treating physicians for SM-88 Compassionate Use Patients also treated these end-stage patients with SM-88 by subcutaneous and/or oral delivery. We also have other alternative formulations, at various stages of development, such as transdermal and nasal, that we believe could provide an effective alternative therapeutic effect for patients with certain forms of cancer, including breast cancer and glioblastoma.

SM-88 Mechanism of Action

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

SM-88 is intended to disrupt the cancer cell's unique microenvironment following uptake of our tyrosine derivative. We believe that when the cancer cell attempts to use the dysfunctional tyrosine derivative for protein synthesis to create mucin, the process fails and the mucin layer begins to deteriorate. Mucin acts as a protective layer around the cancer cell that defends the tumor from the elements in the body outside the cancer cell. Without a stable protective coating from mucin, tumor cells become exposed to the host immune system. Mucin is also involved in the upregulation of enzymes that neutralize reactive oxygen species (" ROS "). The erosion of the mucin can therefore also result in a heightened state of oxidative stress in cancer cells. Excessive oxidative stress is recognized to trigger a natural cell death process called apoptosis, that leads programmed destruction of the cell.

Development Strategy and Key Product Properties

Our goal is to develop cancer therapies that are both effective cancer treatments and less toxic than current treatment options. Key elements of our strategy to achieve this goal are:

- **Successfully advance SM-88 through clinical development, including registration trials and commercial launch** . We intend to pursue a worldwide development and commercialization plan for SM-88.
- **Continue to invest in our technology platform and IP portfolio to further build our pipeline** . We plan to expand our R&D efforts to encompass multiple indications and products within the oncology field. We have undertaken additional early development programs for improved formulations of SM-88 as well as wholly new compounds.

- **Build a balanced portfolio of proprietary and partnered programs.** We plan to independently develop and commercialize multiple drug candidates for human indications within the oncology field. For targets outside our core areas of interest or where a partner can contribute specific expertise, we intend to evaluate potential collaborations with strategic partners and/or potential acquisitions of other companies that can augment our expertise and technology, as well as a means to acquire rights or ownership of additional IP. We also contemplate exploring global development partners and arrangements, where appropriate.

By using SM-88 to disrupt key aspects of cancer's unique metabolism, our intention is to create a therapy that is:

- **Broadly effective across different cancer types** – Because a vast majority of cancers use the same metabolic process, we believe that they likely also have the same susceptibilities to the components of SM-88, regardless of origin;
- **Highly specific to cancer** – As supported by the current safety data reported for over 100 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. We believe the primary effects of SM-88 are derived from the modified tyrosine component;
- **Well-tolerated/ Broad Therapeutic Margin** – Safety findings are available for over 100 patients, including relatively asymptomatic patients from our Phase II prostate cancer trials, and there have been no reported drug-related serious adverse events. Further studies in relatively healthy individuals have not shown significant side effects;
- **Suitable for monotherapy or combination therapy** – Although most of Tyme's clinical and compassionate use experience has been in monotherapy, SM-88's differentiated mechanism of action (" MOA ") and safety profile may also allow it to be effective in combination with other cancer therapeutics with lower potential for overlapping toxicities; and
- **A Potentially effective treatment for patients who have failed other therapeutic options** – Cancers typically develop resistance mechanisms that can make them less responsive to subsequent chemotoxic treatments and patients can accumulate toxicities that can make them ineligible for subsequent treatments. However, as the fundamental metabolism of the cancer related to SM-88 and amino acid/tyrosine uptake does not appear to commonly change with traditional cancer treatments, and SM-88's relatively low toxicity profile, we believe SM-88 can be an effective alternative to existing subsequent standard of care treatments.

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

- SM-88 has demonstrated its potential as an effective and selective combination drug product treatment, with encouraging antitumor activity in 15 different types of cancer to date.
- To date, SM-88 has not shown significant toxic side effects at current therapeutic dose levels and we believe the novel mechanism of action should allow a range of potential combinations with existing treatment modalities.
- Tyme has created multiple delivery forms of SM-88 for the purpose of optimizing therapies for certain cancers/patients, including subcutaneous, intranasal, and transdermal formulations.
- We currently retain all commercial rights for SM-88 in connection with the treatment of cancer and have undertaken an extensive multinational patent effort to protect those rights.
- We have a technology base and patent portfolio supporting SM-88 and have filed patents for additional drug candidates to provide a pipeline of oncology drug development programs based on our technology platform.

Competition

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

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

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, development and regulatory plans in addition to proprietary scientific knowledge provide us with certain competitive advantages, we currently have limited financial resources and 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 whom has significantly greater financial resources than us. Any drugs that we successfully develop and commercialize will compete with existing therapies and new potential therapies that may become available in the future.

Our products, if approved for sale, would eventually be subject to competition from generic drug manufacturers. Manufacturers of generic pharmaceuticals generally invest far less in Research and Development (" 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, Intellectual Property (" IP ") protection is weak or nonexistent and we would be forced to compete with generic or counterfeit versions of our products in such countries whether or not we hold legal exclusivity.

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

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

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

Intellectual Property

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

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

Tyme has filed more than 60 patent applications in the US and abroad, with five U.S. patents issued thus far. The patents encompass SM-88 as well as citing inventions that fight cancer and aid in the creation of novel mechanisms to further that effort. Our policy is to file patent applications to protect technology, inventions and improvements to inventions that are commercially important to the development of our business. We have and will continue to seek U.S. and international patent protection for a variety of technologies, including: pharmaceutical compositions, methods for treating diseases of interest, methods for manufacturing the pharmaceutical compositions and research tools and methods. We also intend to seek patent protection or rely upon trade secret rights to protect other technologies that may be used to discover and validate targets and that may be used to identify and develop novel products. We will also seek protection, in part, through confidentiality and proprietary information agreements.

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

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, 2018, we have two active INDs with the U.S. FDA, both associated with SM-88. The two INDs are associated with the relevant FDA departments that over see 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.

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

The FDA may grant a 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 any of these requirements to conduct preclinical or clinical trials or receive any regulatory approvals including priority or accelerated evaluation.

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 a drug is designated as a breakthrough therapy, the FDA will expedite the development and review of such drug for trial and market approval. All requests for Breakthrough Therapy Designation will be reviewed within 60 days of receipt and FDA will either grant or deny the request.

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

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

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

AE Reporting and cGMP Compliance

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

Orphan Drug

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

Other Healthcare Laws and Compliance Requirements

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

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 follows roughly the same lines as in the U.S. and likewise generally involves satisfactorily completing each of the following:

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

Preclinical Studies

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

Clinical Trial Approval

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

A new 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 2019, 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 co-ordination of the evaluation with the possible

assistance of a further member of the Committee acting as a Co-Rapporteur. After approval, the Rapporteur(s) continue to monitor the product throughout its life cycle. The CHMP is required to issue an opinion within 210 days of receipt of a valid application, though the clock is stopped if it is necessary to ask the applicant for clarification or further supporting data. The process is complex and involves extensive consultation with the regulatory authorities of member states and a number of experts. Once the procedure is completed, a European Public Assessment Report is produced. If the CHMP concludes that the quality, safety and efficacy of the medicinal product are sufficiently proven, it adopts a positive opinion. The CHMP's opinion is sent to the European Commission, which uses the opinion as the basis for its decision whether or not to grant a marketing authorization. If the opinion is negative, information is given as to the grounds on which this conclusion was reached. After a drug has been authorized and launched, it is a condition of maintaining the marketing authorization that all aspects relating to its quality, safety and efficacy must be kept under review. Sanctions may be imposed for failure to adhere to the conditions of the marketing authorization. In extreme cases, the authorization may be revoked, resulting in withdrawal of the product from sale.

Mutual Recognition Procedure and Decentralized National Procedure

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

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

Accelerated Assessment Procedure

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 course of the IND program through the End-of-Phase II (" EOP2 "), we will conduct the manufacturing, CMC and GMP programs towards commercial manufacturing. The overall manufacturing program includes, but is not limited to, the development of product and process specifications, producing and validating standards and the development of suitable analytical methods for test and release, as well as stability testing. Before and during the use of contract manufacturers, we (or qualified designee) will conduct audits to ensure compliance with the mutually agreed process descriptions and cGMP regulations. Our manufacturers themselves must comply with their in-house quality assurance programs and be available for inspections by regulatory agencies, including the FDA and European drug regulatory agencies. During the development of our drug candidates, we 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 a combination drug that is comprised of four active ingredients. Three of the components of SM-88 previously received regulatory approval in areas other than cancer treatment. The four active ingredients that comprise SM-88 are organic compounds of low molecular weight, generally called small molecules. They can be manufactured in reliable and reproducible synthetic processes from readily available starting materials. The chemistry is amenable to scale-up and we do not believe unusual equipment could be required in the manufacturing process.

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

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

For future work involving the drug product, it is anticipated that manufacture process development work will continue, with focus of manufacturing improvements, and 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 remaining three APIs in SM-88 are available from several contract manufacturers, each holding Drug Master Files at the FDA for their respective API's. We believe that the loss of or the inability of, any of single source to provide our required ingredients would not have any substantive delaying effect on our research program, clinical trials or future commercial sale of SM-88, as we believe other sources are readily available.

Research and development expenses were $8,839,661 for the fiscal year ended March 31, 2018, $6,111,587 for the fiscal year ended March 31, 2017, $3,823,966 for the fiscal year ended December 31, 2015, and $808,472 for the three months ended March 31, 2016.

Employees

As of March 31, 2018, we had a total of 11 full-time employees, all located in the United States. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We have not experienced any work stoppages, and we consider our relations with our employees to be good. Of the 11 employees, six perform research and development activities and 5 serve in general and administrative functions. Our Chief Executive Officer, Steve Hoffman, is also our Chief Science Officer and, as such, may be considered engaged in R&D activities, for purposes of the immediately preceding sentence, as well as his being categorized as serving in an administrative capacity Based upon their roles and activities with the Company, certain other employees may also be categorized as serving in more than one role. Where necessary, we have entered into consulting contracts to provide us with subject matter expertise. We believe there is available a sufficient number of contractors with appropriate subject matter expertise for our current and near-term needs.

Corporate Information

We were reincorporated on September 18, 2014 under the laws of the State of Delaware, after being incorporated in Florida as Global Group Enterprises Corp. on November 22, 2011, as discussed further below under Corporate History; Significant Organizational Events. We are incorporated under the laws of the State of Delaware. Our principal executive office is located at 17 State Street, 7 th floor, New York, NY 10004. Our telephone number is 212-461-2315. Our website address is *www.tymeinc.com* .

Corporate History; Significant Organizational Events

Overview

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

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

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

Merger Agreement

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

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

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

The Merger Agreement contained representations and warranties and pre- and post-closing covenants of each party and customary closing conditions. Breaches of the representations and warranties under the Merger Agreement are subject to indemnification provisions. Each of the Pre-Merger Tyme Stockholders initially received in the Merger 95% of the shares to which each such stockholder was entitled under the terms of the Merger Agreement, with the remaining 5% of such shares being held in escrow for two years to satisfy post-closing claims for indemnification by the Company and then distributed in June of 2017. The Merger Agreement also contained a

provision providing for a post-Merger share issuance, as a means for which claims for indemnity may be made by the Pre-Merger Tyme Stockholders. Pursuant to this provision, up to one million additional shares (" R&W Shares ") of our Common Stock could have been issued to the Pre-Merger Tyme Stockholders during the one-year period following the Merger for breaches of representations and warranties of the pre-Merger Company contained in the Merger Agreement. The foregoing mechanisms are the exclusive remedies of the Company on the one hand and the Pre-Merger Tyme Stockholders on the other hand for satisfying indemnification claims under the Merger Agreement, other than claims based on fraud or willful misconduct.

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

The Merger was treated as a recapitalization or reverse acquisition for financial accounting purposes. Tyme is considered the acquirer for accounting purposes and our historical financial statements before the Merger have been replaced by the historical financial statements of Tyme before the Merger.

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

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

We and the Pre-Merger Tyme Stockholders entered into additional agreements concerning the registration or sale of shares of our Common Stock, in certain circumstances, the terms of which have expired prior to March 31, 2018.

All descriptions of the Merger Agreement, herein are qualified in their entireties by reference to the texts thereof incorporated by reference herein and listed as an exhibit hereto.

Split-Off Transaction

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

Bridge Financing by Tyme

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

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

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

The PPO and PPO Note

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

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

The PPO was exempt from registration under Section 4(a)(2) of the Securities Act. The sole investor in the PPO was GEM. The Bridge Note investor designated GEM as the party to receive the Conversion Shares. GEM was a principal stockholder of our pre-Merger company, and the purchaser of the Bridge Note is the manager of GEM.

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

At-the-Market Sales of Common Stock

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

Public Stock 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. The Company intends to use the net proceeds from the offering for research and further development of its lead clinical program SM-88 and for

general corporate purposes, including capital expenditures, working capital and general and administrative expenses. The Company may also use a portion of the net proceeds to acquire or invest in businesses, products and technologies that are complementary to its own, although it has no current plans, commitments or agreements with respect to any acquisitions as of the date hereof.

Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and other filings with the United States Securities and Exchange Commission, or the SEC, and all amendments to these filings, are available, free of charge, on our website at www.tymeinc.com as soon as reasonably practicable following our filing of any of these reports with the SEC. You can also obtain copies free of charge by contacting our Investor Relations department at our office address listed above. The SEC also maintains a website that contains all the materials we file with, or furnish to, the SEC. Its website is www.sec.gov.

Corporate Governance Developments

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

ITEM 1A. RISK FACTORS

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

Risks Related to Owning Our Stock

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

Steve Hoffman, our Chief Executive Officer, Chief Science Officer and a director, beneficially owned 26.3% and Michael Demurjian, our Chief Operating Officer, Executive Vice President and a director, beneficially owned 26.3% of our outstanding common stock as of May 30, 2018. As a result, these individuals are positioned to exercise significant influence over our Company's management and affairs, including, but not limited to, electing our Board of Directors and exercising managerial influence and voting rights in connection with fundamental corporate transactions, and take action that may not reflect the best interests of all of the stockholders of our Company.

Further, the Company has granted Mr. Hoffman perpetual, exclusive non-royalty bearing license with respect to certain patents and patent applications that the Company uses for SM-88 for all fields other than in connection with the treatment of cancer. This license to Mr. Hoffman may limit the Company's ability to profit from alternative

uses of SM-88, if such uses were to be discovered. Additionally, the use of these patent or patent applications could be associated with a negative event outside of the control of the Company and outside the treatment of cancer, which in either case may have an adverse effect on our business.

Our share price is likely to be volatile due to factors beyond our control and may drop below prices paid by investors.

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

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

- general market conditions and market conditions for biopharmaceutical stocks; and
- overall fluctuations in U.S. equity markets.

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

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

Until such time, if ever, as we can generate substantial revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, grants and licensing and development agreements in connection with any collaborations. We do not have any committed external source of funds and no revenue source. To the extent that we raise additional capital through the sale of equity 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. Debt financing, if available at all, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, drug candidates, future revenue streams or grant licenses on terms that are not favorable to us. We cannot give any assurance that we will be able to obtain additional funding if and when necessary or on satisfactory terms. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, scale back or eliminate one or more of our development programs or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

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

We are authorized to grant equity awards, including stock grants and stock options, to our employees, directors and consultants, covering up to 12.5% of our shares of common stock outstanding from time to time pursuant to our 2015 Equity Incentive Plan (the " 2015 Plan ") and, subject to stockholder approval, up to 2,750,000 shares of our common stock, pursuant to our recently amended and restated 2016 Director Plan (the " 2016 Director Plan "). Future issuances, as well as the possibility of future issuances, under our 2015 Plan or 2016 Director Plan or other equity incentive plans could cause the market price of our common stock to decrease.

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

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us and our business. Securities and industry analysts may choose not to publish research on our Company. If an insufficient number of, securities or industry analysts provide coverage of our Company, the trading price for our stock would likely be negatively impacted. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. Further, if one or more of these analysts cease coverage of our Company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common

stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Because our board is responsible for appointing the members of our management team, these provisions could, in turn, affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions:

- 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 of directors to fill any and all vacancies on the board of directors;
- 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 of directors, which include, among other things, requirements for proposing stockholders to disclose information about derivative or short positions; and
- authorize our Board of Directors to issue, without stockholder approval, shares of currently undesignated preferred stock; such ability to issue previously undesignated preferred stock makes it possible for our board to establish a "poison pill" and issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

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

Investors could lose all their investment in our Company.

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

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

In the future, to raise needed financing, we are likely to issue our authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of our stockholders at the time of such issuances. We are authorized to issue an aggregate of 300,000,000 shares of common stock and 10,000,000 shares of "blank check" preferred stock. We also have an effective "shelf" registration statement on Form S-3 that allows us to issue securities in registered offerings and 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 of directors to issue additional stock may prevent or make more difficult certain transactions, including a sale or merger of our Company . Our board is authorized to issue up to 10,000,000 shares of preferred stock with powers, rights and preferences designated by it. (See "Preferred Stock" in "Description of

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

Our common stock has historically been characterized by low and/or erratic trading volume, and the intraday per share price of our common stock has fluctuated from $1.22 to $11.25 between March 31, 2015 and July 31, 2017, the date we became listed on the Nasdaq Capital Market. The intraday per share price of our common stock has fluctuated from $2.05 to $9.05 between August 1, 2017 and March 31, 2018, 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, 2018 the average daily trading volume for our common stock was approximately 128,049 shares. Subsequent to our common stock becoming listed on the Nasdaq Capital Market, the average daily trading value for our common stock was approximately 189,000 shares. In addition, the price of our common stock has been volatile. Our common stock had a closing price of $2.88 on April 3, 2017 and ended fiscal year 2018 at a closing price of $2.23. During the fiscal year 2018, our common stock had a low trading price of $2.05, which occurred on March 21, 2018, and had a high closing price of $9.47, which occurred on September 7, 2017.

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

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

We do not anticipate paying dividends on our common stock.

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

We are a "controlled company" within the meaning of the Nasdaq corporate governance rules, and we take, and intend to continue to take, advantage of exemptions from certain corporate governance requirements.

We meet the definition of a "Controlled Company," under the Nasdaq corporate governance rules, because our co-founders, Messrs. Hoffman and Demurjian, collectively, beneficially own more than 50% of the voting power of our common stock and have agreed to vote together on certain matters submitted for a stockholder vote. The Company, therefore, is exempt from certain of Nasdaq's corporate governance requirements, including the requirement that the majority of our board of directors be independent, and the requirement to maintain a nominating and corporate governance committee and a compensation committee composed entirely of independent directors. We currently rely on the exemption and do not maintain a nominating and corporate governance committee. Currently, the majority of our board is independent and we have a compensation committee consisting of only independent directors, but we remain a controlled company, and accordingly, investors do not have the same protections afforded to stockholders of companies that are subject to all of Nasdaq's corporate governance requirements.

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

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

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

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

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

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

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

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

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the U.S. Food and Drug Administration (the " FDA "), the European Medicines Agency (the " EMA "), national competent authorities in Europe and other non-U.S. regulatory authorities, which establish regulations that differ from country to country. We are not permitted to market SM-88 and any other drug product we may develop in the United States or in other countries until we receive approval of a New Drug Application (an " NDA ") from the FDA or marketing approval from applicable regulatory authorities outside the United States. Since SM-88 is in the early stages of development, it is subject to the risk of failure inherent in the drug development process. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA or EMA. Obtaining approval of an NDA or a Marketing Authorization Application (" MAA ") can be a lengthy, expensive and uncertain process. In addition, failure to comply with the FDA, EMA and/or other non-U.S. regulatory requirements prior to regulatory approval, could subject our Company to administrative or judicially imposed sanctions, which include, but are not limited to:

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

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

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

- regulatory agencies might not approve or might require changes to manufacturing processes or facilities; and
- regulatory agencies may change their approval policies or adopt new regulations.

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

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

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

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

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

We or our clinical trial sites may not be able to identify, recruit and enroll 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 the early stages of development. We are conducting our first Phase II clinical trials and their successful completion is subject to numerous factors that can cause interruptions or delays, many of which may be beyond our control. Should we experience any interruption or delay, our plans and expected future revenue could be adversely affected and could result in our inability to continue our operations.

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

- slower than expected rate of subject recruitment and enrollment;
- slower than projected IRB or Independent Ethics Committee (“ IEC ”) review and approval;
- the Data Monitoring Committee (“ DMC ”) for a clinical trial requires the clinical trial be delayed or stopped or requests major or minor modifications to the clinical trial;
- failure of subjects to complete their full participation in clinical trial or return for post-treatment follow-up;
- unforeseen safety issues, including severe or unexpected drug-related adverse effects experienced by subjects, including the possibility of death;

- lack of SM-88 efficacy during the clinical trials;
- poor trial design for one or more of our clinical trials;
- withdrawal of participation by a Principal Investigator (" PI ") in one or more of our clinical trials;
- withdrawal of participation by one of our Clinical Research Organizations (" CRO ");
- inability or unwillingness of subjects or clinical investigators to comply with clinical trial procedures;
- resolution of data discrepancies;
- inadequate CRO management and/or monitoring in one or more of our clinical trials;
- the need to repeat, reconstruct or terminate a clinical trial due to inconclusive or negative results or unforeseen complications in testing; and
- a request by the FDA to abandon our current drug development programs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If marketing authorization is obtained for our lead drug candidate, SM-88, the drug could continue to be under review by regulatory authorities. As a result, authorization could be subsequently withdrawn or restricted at any time for 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.

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

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

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

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

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

In order to market any products in a country or territory, we must establish and comply with numerous and varying regulatory requirements of such countries or territories regarding safety and efficacy. Clinical trials conducted in one country may not be acceptable for review by regulatory authorities in other countries and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures differ among countries and can involve additional testing and validation as well as varying administrative review periods. Seeking regulatory approvals in multiple countries could result in significant delays, difficulties and costs and may require additional nonclinical or clinical trials, which would be costly and time-consuming or even delay or prevent the introduction of SM-88 in those countries. In addition, our failure to obtain regulatory approval in one country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any drug candidates approved for sale in any jurisdiction, including international markets and we therefore do not have experience in obtaining regulatory approval. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to create stockholder value for SM-88 will be harmed.

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

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

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

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

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 drug candidate we may develop or following such drug product's approval, if any, we may need to abandon our development of SM-88 or such other drug product, the commercial profile of any approved label may be limited and/or we may be subject to other significant negative consequences following marketing approval, if any.

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

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

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

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

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

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may require post-market clinical trials to assess possible serious risks associated with SM-88 or such other drug product, which will require us to provide the FDA with additional data;
- we may be required to change the way SM-88 or such other drug product is administered, conduct additional clinical trials or change the labeling of the drug;
- we may be subject to limitations on how we may promote SM-88 or such other drug product;
- sales of SM-88 or such other drug product may never gain traction or could decrease significantly;
- we may be subject to litigation or drug liability claims; and
- our reputation may suffer.

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

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

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

- limitations or warnings contained in the approved labeling for SM-88;
- changes in the standard of care for the targeted therapy;
- limitations in the approved clinical indications for SM-88;
- demonstrated clinical safety and efficacy of SM-88 compared to other drugs;
- lack of significant adverse effects;
- limitations on how we promote SM-88;
- sales, marketing and distribution support;
- availability and extent of reimbursement from managed care plans and other third-party payors;
- timing of market introduction and perceived effectiveness of competitive drugs;
- the degree of cost-effectiveness of SM-88;
- availability of alternative therapies, whether or not at a similar or lower cost, including generic and over-the-counter drugs;
- the extent to which SM-88 is approved for inclusion on formularies of hospitals and managed care organizations;
- whether SM-88 is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy;
- adverse publicity about SM-88 or favorable publicity about competitive drugs;
- convenience and ease of administration; and
- potential drug liability claims.

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

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

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

- We do not have experience in manufacturing SM-88 in bulk quantity or at commercial scale. We plan to contract with external manufacturers to develop a larger scale process for manufacturing SM-88 in parallel with our Phase II trial of SM-88. We may not succeed in the scaling up of our process or we may need a larger manufacturing process for SM-88 than what we have planned. Any changes to our manufacturing processes may result in the need to obtain additional regulatory approvals. Difficulties in achieving commercial-scale production or the need for additional regulatory approvals could delay the development and regulatory approval of SM-88 and ultimately affect our success.
- The process of manufacturing drugs, such as SM-88, is extremely susceptible to loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in drug characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, drug defects and other supply disruptions. If microbial, viral or other contaminations are discovered in SM-88 or in the manufacturing facilities in which SM-88 is made, such manufacturing facilities may need to be closed for an extended time to investigate and remedy the contamination.
- A shortage of one or more SM-88 drug substance(s) or ingredients.
- The manufacturing facilities in which SM-88 is made could have delays in manufacturing due to delays created by other sponsor company drug manufacturing runs, which could affect our manufacturing runs.
- An unforeseen increase in ingredients procurement or other manufacturing costs.
- The manufacturing facilities in which SM-88 is made could be adversely affected by equipment failures, labor shortages, labor strikes, natural disasters, power failures, lack of phone or internet services, riots, crime, act of foreign enemies, war, nationalization, government sanction, blockage, embargo, any extraordinary event or circumstance beyond control and numerous other factors.
- We and our manufacturing partners must comply with applicable cGMP and local and state regulations and guidelines. Compliance with cGMP can be time consuming and expensive. Further, cGMP may not be flexible in situations where business pressures would normally call for immediate ingenuity. We or our manufacturing partners may encounter difficulties in achieving quality controls and quality assurance and may experience shortages in qualified personnel. We and our manufacturing partners will be subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm compliance with applicable regulatory requirements. Any failure to follow cGMPs or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging or storage of SM-88 that result from a failure at the facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize SM-88. This could lead to significant delays in the availability of our drug for clinical trials or the termination or clinical hold on a trial or the delay or prevention of a filing or approval of marketing applications for SM-88. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for SM-88, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we and/or our manufacturing partners are not able to maintain regulatory compliance, we may not be permitted to market SM-88 and/or may be subject to drug recalls, seizures, injunctions or criminal prosecution.
- Any adverse developments affecting manufacturing operations for SM-88, if approved for marketing by the FDA, may result in shipment delays, inventory shortages, lot inspection failures, drug withdrawals or recalls or other interruptions in the supply of SM-88. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet regulator-approved manufacturing specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives; and
- Drug products that have been produced and stored for later use may degrade, become contaminated or suffer other quality defects, which could cause the affected products to no longer be suitable for its intended use in clinical trials or other development activities. If the defective drug cannot be replaced in a timely fashion, we may incur significant delays in our development programs that could adversely affect the value of SM-88.

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

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

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

To the extent that we enter into collaborative agreements for marketing, sales and/or distribution, our revenue may be lower than if we directly marketed and sold SM-88. In addition, any revenue we receive will depend in
whole or in part upon the efforts and success of these third-party collaborators, which are likely not to be entirely within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize SM-88. If we are not successful in commercializing SM-88, either on our own or through collaborations with one or more third parties, our future revenues will suffer, we may incur significant and additional losses and we may be forced to curtail operations. These factors would have an adverse effect on our share price.

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

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

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

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

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

In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, was adopted in March 2010. The Health Care Reform Law is a far reaching law intended to broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The costs and restrictions impacted by the Health Care Reform Law may impact our competitiveness or availability opportunity.

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

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

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

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

In addition, the Health Care Reform Law, among other things, increased rebates a manufacturer must pay to the Medicaid program, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, established a new Medicare Part D coverage gap discount program in which manufacturers must provide 50% point-of-sale discounts on products covered under Part D and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain health care services through bundled payment models. Further, the new law imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance were enacted, which may affect our business practices with health care practitioners. The goal of the Health Care Reform Law is to reduce the cost of health care and substantially change the way health care is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the Health Care Reform Law may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of and the price we may charge for, any products we develop that receive regulatory approval. We also cannot predict the impact of the Health Care Reform Law on our business or financial condition.

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

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

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

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

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

- injury to our reputation;
- withdrawal of subjects in our clinical trials;
- withdrawal of clinical trial sites or entire trial programs;
- increased regulatory scrutiny;
- significant litigation costs;
- substantial monetary awards to or costly settlements with patients or other claimants;
- drug recalls or a change in the indications for which they may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize SM-88 or such other drug product.

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

We hold clinical trial insurance for the SM-88 Phase II clinical trial. We also intend to obtain drug liability insurance coverage at appropriate levels for our operations, which will vary as the level of our operations vary during our growth from a R&D company to a company manufacturing and/or marketing drugs to the public. Our 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 they have experience in creating and marketing various products, our chief executive and chief operation officers have never previously organized, managed or completed FDA-required submissions and clinical trials concerning new drug products. While we intend to retain employees, advisors and consultants with experience in the FDA approval process and have retained and utilized a number of such advisors and consultants currently and in the past, the lack of experience by our chief executive and operating officers could result in: delays in obtaining necessary regulatory approvals, both in conducting clinical trials and final marketing approvals; additional costs; and the possibility that approvals will not be obtained due to the failure to comply with the regulatory approval process; such delays, costs and/or failure would likely adversely affect our business, financial condition and results of operations and could possibly cause us to cease our operations in their entirety

Risks Related to our Financial Condition and Need for Additional Capital

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

We are a clinical-stage pharmaceutical company with a limited operating history. We have incurred significant losses since our inception. As of March 31, 2018, our accumulated deficit was $52,831,581. Our losses have resulted principally from expenses incurred in the discovery and development of SM-88 and from general and administrative expenses incurred while building our business infrastructure. We expect to continue to incur losses for the near future. Furthermore, we expect these losses to increase as we continue our research and development of and seek regulatory approval for our drug candidate SM-88 and any other drug candidates we may develop, prepare for and

begin to commercialize SM-88 or any other regulatory-approved products and add infrastructure and personnel to support our drug development efforts and operations as a public company. The net losses and negative cash flows from operations incurred to date, together with expected future losses, have had and likely will continue to have, an adverse effect on our stockholders' equity and working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

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

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

- completing research and clinical development of SM-88, including successful completion of required clinical trials;
- obtaining marketing approval for SM-88;
- developing a sustainable and scalable manufacturing process for SM-88 and maintaining supply and manufacturing relationships with third parties that can conduct the process and provide adequate (in amount and quality) drugs to support clinical development and the market demand for SM-88, if approved;
- launching and commercializing SM-88, either directly or with a collaborator or distributor;
- establishing sales, marketing and distribution capabilities in the United States and in other markets, such as the EU;
- obtaining market acceptance of SM-88 as a viable treatment option;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and/or developing new drug candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

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

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

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

- the number and characteristics of drug candidates that we pursue;

- the scope, progress, timing, cost and results of nonclinical and clinical development and research;
- the costs, timing and outcome of our seeking and obtaining FDA, EMA and other non-U.S. regulatory approvals;
- the costs associated with manufacturing SM-88, as well as other potential drug candidates, and establishing sales, marketing and distribution capabilities;
- our ability to maintain, expand and defend the scope of our IP portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other IP rights;
- the extent to which we acquire or in-license other products or technologies;
- our need and ability to hire additional administrative, managerial, scientific, operational and medical personnel;
- the effect of competing products that may limit market penetration of SM-88 and any other drug candidates we may develop;
- the amount and timing of revenues, if any, we receive from commercial sales of SM-88 or any other drug candidates for which we receive marketing approval in the future;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and the economic and other terms, timing of and ultimate success of any future collaboration, licensing or other arrangements, including the timing of achievement of milestones and receipt of any milestone or royalty payments under such agreements.

Until we can generate sufficient drug and royalty revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. Any additional fundraising efforts may divert management's attention from day-to-day activities and financing may not be available to us when we need it or financings may not be available on favorable terms. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our drug candidates, technologies, future revenue streams or research programs and/or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, as we expect to do, the ownership interests of our then existing stockholders could be diluted and the terms of these securities may include liquidation or other preferences that adversely affect stockholders' rights.

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

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

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

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

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

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

Risks Related to our Reliance on Third Parties

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

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

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

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

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

All manufacturers used to formulate the components of SM-88 must comply with cGMP requirements, which are enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance and the documentation and maintenance of records. Manufacturers of our drug candidates may be unable to comply with cGMP requirements and/or with other FDA, state and foreign regulatory

requirements. The FDA or similar foreign regulatory agencies may also implement new standards at any time or change their interpretation and enforcement of existing standards for the manufacture, packaging or testing of drug products. We have little control over our manufacturers' compliance with these regulations and standards and a failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in drug approval, drug seizure or recall or withdrawal of a drug approval. If the safety of any drug supplied is compromised due to a manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize SM-88 and as a result, may be held liable for any injuries sustained. Any of these factors could cause a delay of clinical trial completion, regulatory submission, approval or commercialization of SM-88, increase our costs or impair our reputation.

We currently rely on single-source suppliers for each of the drug components in SM-88.Supplies are obtained through limited term supply agreements under individual purchase orders. At this time, no supply agreements place exceeds 18 months. Although we believe alternative sources of supplies exist, the number of third-party suppliers with the necessary manufacturing and regulatory expertise and facilities is limited, could be more expensive and it could take a significant amount of time to source, any of which would adversely affect our business. New suppliers of SM-88 would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable IP laws to the method of manufacturing the drug candidate. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party IP rights could result in a significant interruption of supplies and could require the new manufacturer(s) to bear significant additional costs which may be passed on to us.

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

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

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

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

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

- collaborators may have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of SM-88 or any other drug candidate we may choose to develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical program, stop a clinical trial, abandon SM-88 or other drug candidate, repeat or conduct new clinical trials or require a new formulation of SM-88 or other drug candidate;
- collaborators could independently develop or develop with third parties, products that compete directly or indirectly with SM-88;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our IP rights or may use our IP or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our IP or proprietary information or expose us to potential liability;
- collaborators may not aggressively or adequately pursue litigation against Abbreviated New Drug Application (“ ANDA ”) filers or may settle such litigation on unfavorable terms;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of SM-88 or any other drug candidate we may develop or results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, sometimes at-will, without penalty;
- collaborators may own or co-own IP covering our products that results from our collaborating with them and, in such cases, we would not have the exclusive right to commercialize such IP; and
- a collaborator’s sales and marketing activities or other operations may not be in compliance with applicable laws and could result in civil or criminal proceedings.

Risks Related to the Operation of our Company

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

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

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

To date, our drug discovery process and development program has been led by Steve Hoffman, our chief executive and science officer. He has been instrumental in providing scientific, technical and business expertise. We do not

currently maintain "key person" insurance on Mr. Hoffman or any of our other executives or employees. While we may, in the future, seek to obtain key man insurance on Mr. Hoffman and/or such other executives and employees, we may not be able to obtain the insurance at favorable rates or at all. Any insurance proceeds we may receive under such "key person" insurance may not adequately compensate us for the loss of Mr. Hoffman's or other insured's services. Development of SM-88 could ultimately continue without Mr. Hoffman's or others' contributions, but future development of SM-88 and all other drug products in our pipeline would be adversely affected without his continued involvement.

We are highly reliant on our executives, but certain of them, including our chief executive and science officer, Steven Hoffman, our chief operating officer, Michael Demurjian, 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. For example, Mr. Demurjian is party to litigation related to family real estate and probate matters that may require a significant amount of his time and attention, which may distract him from his duties to Tyme.

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, 2018, we had 11 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. Our current management has limited experience in managing a company that had the life sciences research and development and operational growth we anticipate for our Company. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

Our operations could be subject to equipment failures, labor shortages, labor strikes, earthquakes, power shortages, telecommunications failures, floods, hurricanes, typhoons, fires, extreme weather conditions, terrorist activities, medical epidemics, riots, crime, act of foreign enemies, war, nationalization, government sanction, blockage, embargo and other natural or manmade disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and could increase our costs and expenses. Our corporate headquarters is located in New York, New York. Our current and future, third-party collaborators, future partners, supplies, CROs and investigational sites are or will be, located throughout the United States or internationally and may be located near major high-risk terrorist targets, earthquake faults, flood and fire zones. The ultimate impact on us, our significant partners and suppliers as well as our and their general infrastructures being located near major high-risk terrorist targets, earthquake faults, flood and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major terrorist attack, earthquake, fire, flood or other natural or manmade disaster.

Our business is also subject to risks associated with conducting international business. If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business. Some of our third-party collaborators, future partners,

suppliers, CROs and investigational sites could be located outside the United States. Accordingly, our future success could be harmed by a variety of factors, which include, but are not limited to:

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

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

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

Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cybersecurity incidents resulting in the failure of our systems to operate effectively or to integrate with other systems, including those of third-parties with whom we rely on for research, clinical trial services or other business and administrative services, or a breach in security or other unauthorized access of these systems, may affect our ability to manage and maintain our operations. A breach in security, unauthorized access resulting in misappropriation, theft, or sabotage with respect to our proprietary and confidential information, including research or clinical data, could require significant investments of capital and time to remediate and could adversely affect our business, financial condition and results of operations. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding patients in our clinical trials or other studies or our employees, could harm our reputation, require us to comply with federal and/or state breach notification laws, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. There can be no assurance that the security measures we have implemented to protect our information technology systems and infrastructure will prevent service interruptions or security breaches that could adversely affect our business.

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

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

Risks Related to Intellectual Property

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

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

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

The patent position of specialty pharmaceutical and biotechnology companies generally is highly uncertain and involves complex legal and factual questions for which many legal principles remain unresolved. In recent years, patent rights have been the subject of significant litigation and, as a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent

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

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

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

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

Filing, prosecuting and defending patents for SM-88 or any other drug product we may develop throughout the world would be prohibitively expensive. Competitors may use our technologies in countries where we have not obtained patent protection to develop their own drugs and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as in the United States. These products may compete with our drug products in countries where we do not have any issued patents and our patent claims or other IP rights may not be effective or sufficient to prevent them from so competing. Many companies

have encountered significant problems in protecting and defending IP rights in foreign countries. The legal systems of a number of countries, particularly a number of developing countries, do not favor the enforcement of patents and other IP protection, including those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights. Further, the initiation of proceedings to enforce or protect our patent rights in foreign countries could result in substantial cost and divert our efforts and attention from other aspects of our business.

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

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

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

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

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

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

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

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

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

- if our competitors file patent applications that claim technology also claimed by us or our licensors or collaborators, we or our licensors or collaborators may be required to participate in interference or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third-party with a dominant patent position;
- if third parties initiate litigation claiming that our processes or products infringe their patent or other IP rights, we and our licensors or collaborators will need to defend against such proceedings; and
- if a license to necessary drug technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other IP rights and/or that we breached our obligations under the license agreement and we and our collaborators would need to defend against such proceedings.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Government Regulations

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

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

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

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

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

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

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

On January 20, 2017, President Trump signed an executive order directing federal agencies with authorities and responsibilities under the Health Care Reform Law to exercise all available authority and discretion to waive, defer, grant 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 seems to contemplate discretion for federal agencies to delay or stop the implementation of certain Health Care Reform Law taxes and requirements. As a result, the practical effect of the January 2017 Executive Order is unclear.

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

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

Judicial challenges to the Health Care Reform Act, the January 2017and October 2017 Executive Orders, The Tax Cuts and Jobs Act, cessation of the CSR Payments and other 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 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 require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the U.S. Department of Health and Human Services (" HHS ") information related to physician payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family members;
- HIPAA, the Health Information Technology for Economic and Clinical Health Act and their respective implementing regulations, which govern the conduct of certain electronic healthcare transactions and protect the security and privacy of protected health information; and state-law equivalents of each of the above federal laws, such as anti-kickback, false claims and transparency laws which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers.

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

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

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

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

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

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

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA or EMA regulations, to provide accurate information to the FDA or EMA or intentional failures to report financial information or data accurately or to disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation and subjects. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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

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

The FDCA requires that an applicant for approval of a generic form of a branded drug certify either that its generic drug does not infringe any of the patents listed by the owner of the branded drug in the Approved Drug Products

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

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

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

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

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

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

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

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

Being a public company is expensive and administratively burdensome.

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

- maintain and evaluate a system of internal controls over financial reporting in compliance with the requirements of Section 404 of SOX and the related rules and regulations of the SEC and the Public Company Accounting Oversight Board;
- maintain policies relating to disclosure controls and procedures;
- prepare and distribute periodic reports, proxy statements, Forms 8-K and other reports and filings in compliance with our obligations under applicable federal securities laws;
- institute a more comprehensive compliance function, including with respect to corporate governance; and
- involve, to a greater degree, our outside legal counsel and accountants in the above activities and incur additional expenses relating to such involvement.

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

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

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

Management's determination that a material weakness exists in our internal controls over financial reporting could have a material adverse impact on our ability to produce timely and accurate financial statements and could negatively impact our business and the market for our Common Stock.

Section 404 of SOX requires us to include in our Annual Reports on Form 10-K an assessment by management of the effectiveness of our internal control over financial reporting. Additionally, because we are no longer an

"emerging growth company," we are now required to include an attestation report of our independent public accounting firm with respect to the effectiveness of our internal controls over financial reporting. Based upon an evaluation conducted in connection with the preparation of Tyme's audited consolidated financial statements as of March 31, 2018, management concluded that our internal controls over financial reporting were not effective due to the material weaknesses in our internal controls over financial reporting. The matters involving internal controls and procedures that our management considered to be material weaknesses were: ineffective information technology general controls, ineffective controls over financial disclosure and reporting and lack of sufficient and timely review over account balances. We believe that the material weaknesses set forth above did not have an effect on our financial results.

We began implementing certain practices and procedures to address the foregoing material weaknesses with plans to complete the remediation of the foregoing deficiencies in the future. We continue to identify and implement actions to improve the effectiveness of our internal controls over financial reporting and disclosure controls and procedures, but there can be no assurance that such remediation efforts will be successful. We have also incurred and expect to continue to incur or expend, substantial accounting and other expenses and significant management time and resources. Our future assessment, or the future assessment by our independent registered public accounting firm, may reveal additional material weaknesses in our internal controls. Failure to remediate a material weakness or the discovery of any future potential material weaknesses, could result in future misstatements in our financial statements or in documents we file with the SEC and could have a negative impact on our business and the market for our Common Stock. For more information on our material weaknesses and the status of our remediation efforts, see Item 9A - Controls and Procedures, which includes Management's Report on Internal Controls Over Financial Reporting.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal executive offices are located at 17 State Street, 7 th 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 an office in Red Bank, New Jersey, where we lease and occupy approximately 150 square feet of office space. The original lease for this office has expired and it is currently rented month-to-month with 30 days termination notice. We estimate our total annual costs for this office at approximately $6,600 per year.

We believe that our existing facilities are adequate for our current 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

None.

ADDITIONAL ITEM. EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers and their positions as of May 30, 2018 were:

	Title and Business Experience	Age
Steve Hoffman	Mr. Hoffman has been 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.	55
Michael Demurjian	Mr. Demurjian has been Chief Operating 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 position as Chief Operating Officer and Executive Vice President of our Company, which commenced in March of 2015, he leads the teams in studies and data collection activities for our submissions to regulatory authorities, including the FDA.	54
Ben R. Taylor	Mr. Taylor has been President and Chief Financial Officer since April 2017.	41
Dr. Giuseppe Del Priore	Dr. Del Priore has been Chief Medical Officer since November 2015. Dr. Del Priore also served on our Advisory Board from April 2015 to November 2015.	55
Dr. Jonathan Eckard	Dr. Eckard has been Chief Scientific Affairs Officer of Tyme since August 2017.	44

PART II

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

Public market for our common stock

Our common stock has been traded on the Nasdaq Capital Market under the symbol "TYME" since July 27, 2017. Prior to July 27, 2017, our common stock was quoted on the over-the counter (" OTC ") Markets, QB Tier, under the symbol "TYMI" for each of the periods listed below. Before September 26, 2014, the common stock of our predecessor was quoted on the OTC Markets, QB Tier, under the symbol of our predecessor, "GGET." Prior to March 12, 2015, there were no reported sales of common stock of our predecessor on the OTC Market. Our transfer agent is Continental Stock and Transfer and Trust Company.

The following table sets forth, for the periods indicated, the prices of the common stock in the OTC market, as reported and summarized by OTC Markets Group, Inc, prior to July 27, 2017 and the high and low closing prices as reported by the Nasdaq Capital Market since July 27, 2017 for our common stock for the fiscal quarter indicated. These quotations represent inter-dealer quotations, without adjustment for retail markup, markdown, or commission and may not represent actual transactions. Prior to July 27, 2017, there is an absence of an established trading market for our common stock, as the market is limited, sporadic and highly volatile, which may have affected the prices listed below.

Quarter Ended	High	Low	Mean Daily Trading Volume (shares)
March 31, 2016	$11.25	$5.00	1,209
June 30, 2016	$11.00	$4.99	643
September 30, 2016	$10.00	$3.20	3,475
December 31, 2016	$ 4.20	$1.01	8,683
March 31, 2017	$ 3.99	$2.01	5,153
June 30, 2017	$ 3.55	$2.63	3,640
September 30, 2017	$ 9.50	$2.65	41,008
December 31, 2017	$ 8.30	$3.20	142,134
March 31, 2018	$ 7.35	$2.05	331,883

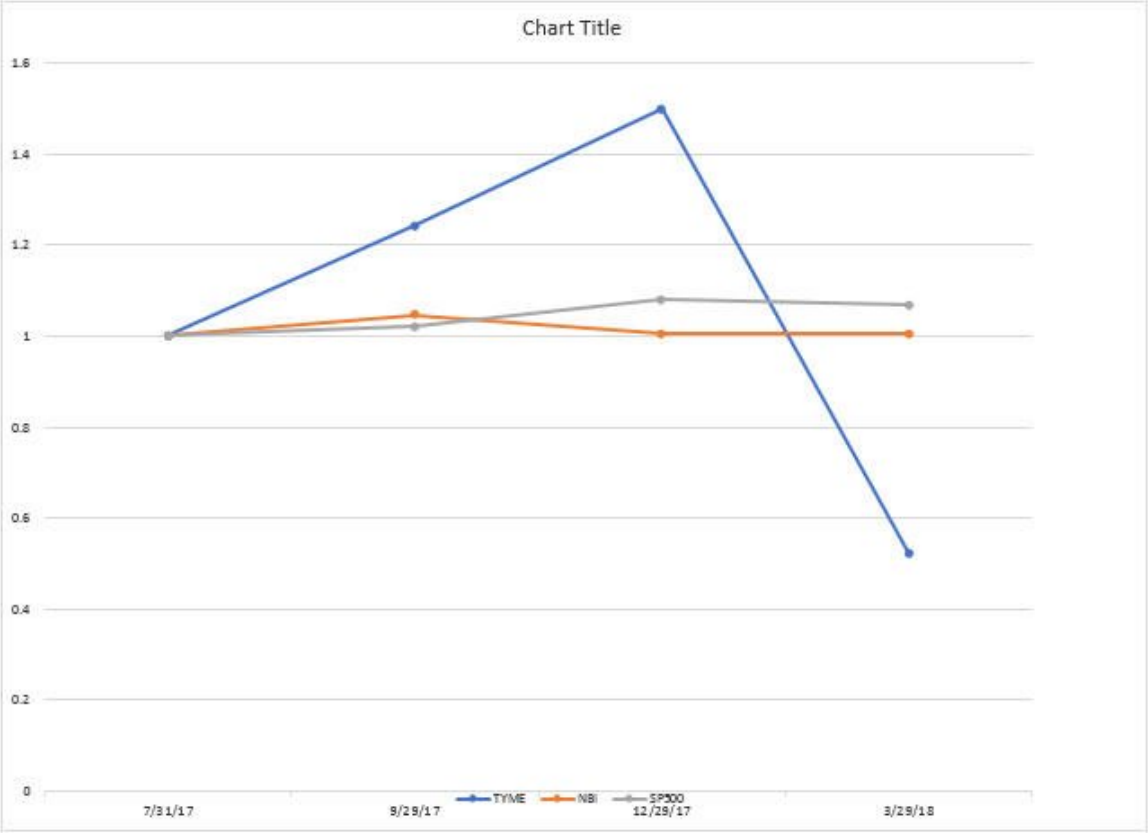
The closing price of TYME stock as of June 6, 2018 was $3.18.

The following graph and related information shall not be deemed "soliciting material" or be "filed" with the SEC, nor shall such information be incorporated by reference into any further filing, except to the extent we specifically incorporate it into any such filing.

COMPARISON CUMULATIVE TOTAL RETURN

The following graph compares the performance of our company stock to the Nasdaq Biotechnology Index, and to the S & P 500 over the period from July 27, 2017 through March 31, 2018. The comparison assumes $100 was invested after the market closed on July 27, 2017 in our common stock and in each of the foregoing indices. The stock price performance included in this graph is not necessarily indicative of future stock price performance.

Comparison of Cumulative Total Return
Assumes Initial Investment of $100
March 2018



Holders; Shares Outstanding

We had a total of 101,226,479 shares of our common stock outstanding on June 6, 2018, held by approximately 200 stockholders of record. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in "street name" by brokers and other nominees.

Dividend Policy

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

Securities Authorized for Issuance Under Equity Compensation Plan

Reference is made to the information in Item 12 of this report under the caption "Compensation Plan and Additional Equity Information as of March 31, 2018," which is incorporated herein by this reference.

ITEM 6. SELECTED FINANCIAL DATA

The following tables set forth our selected financial data for the periods indicated. The following statement of operations data for the years ended March 31, 2018 and 2017, the three months ended March 31, 2016 and the

year ended December 31, 2015 and the selected balance sheet data as of March 31, 2018 and 2017 are derived from our audited financial statements appearing elsewhere in this report. The statement of operations data for the year ended December 31, 2014 and November 30, 2013, and the balance sheet data as of December 31, 2015 and 2014, and November 30, 2013 have been derived from audited financial statements previously filed with the SEC that are not included herein.

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

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

	Year ended November 30,	Year ended December 31,		Quarter Ended March 31,	Year Ended March 31,	
	2013	2014	2015	2016	2017	2018
	(in thousands, except share and per share data)					
Statement of Operations Data:						
Operating expenses:						
Research and development	$ —	$ 761	$ 3,824	$ 808	6,112	8,840
General and administrative	—	1,823	4,776	1,943	9,095	10,520
Total operating expenses	(57)	2,584	8,600	2,751	15,207	19,360
Loss from operations	(57)	(2,584)	(8,600)	(2,751)	(15,207)	(19,360)
Interest Expense	—	(77)	(3,503)	—	—	—
Other Income	—	—	376	—	—	390
Net loss	$ (57)	$ (2,661)	$ (11,727)	$ (2,751)	(15,207)	(18,970)
Basic and diluted loss per option share	$ 0.0	$ (0.04)	$ (0.15)	$ (0.03)	(0.18)	(0.21)
Basic and diluted weighted average shares outstanding	52,000,800	68,000,000	77,848,850	83,786,260	84,454,587	90,567,476

	November 30, 2013	December 31, 2014	December 31, 2015	March 31, 2017	March 31, 2018
	(in thousands, except share and per share data)				
Balance Sheet Data:					
Cash and cash equivalents	$ 0	$ 9	$ 4,446	$ 10,483	$ 28,976
Total assets	0	167	4,490	10,719	31,018
Total liabilities	43	2,640	1,474	3,327	4,546
Total stockholders' equity (deficit)	(43)	(2,473)	3,016	7,392	26,472

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing in this Annual Report. Some of the information

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

Overview

We are a clinical-stage biotechnology company developing novel cancer therapeutics that are intended to be effective across many tumor types while also maintaining low toxicity. Our lead clinical program, SM-88, is a first-in-class combination therapy based on dysfunctional metyrosine derivatives. We currently have two ongoing phase II clinical trials in metastatic pancreatic cancer and biomarker-recurrent prostate cancer. Previously, SM-88 has been used clinically in over 100 patients, primarily for the treatment of metastatic cancers.

On October 27, 2016, our Board of Directors determined to change the fiscal year of the Company from a year ending on December 31 of each year to a year ending on March 31 of each year. The Company's report covering the transition period from January 1, 2016 through March 31, 2016 was filed via transition report on Form 10-QT. As a result of this change, we provided herein disclosures of our results, financial conditions and liquidity for (i) the year ended March 31, 2018 compared to the year ended March 31, 2017; (ii) the year ended March 31, 2017 to the year ended December 31, 2015; and (iii) the three months ended March 31, 2016 compared to the three months ended March 31, 2015.

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

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

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

On November 2, 2017, the Company entered into an equity distribution agreement (" Equity Distribution Agreement ") with Canaccord Genuity Inc. (" Canaccord "), to commence an at-the-market offering (the " ATM Financing Facility ") pursuant to which the Company may, from time to time, sell shares of the Company's common stock, having an aggregate offering price up to $30,000,000, through Canaccord, as the Company's sales agent. In the year ended March 31, 2018, the Company raised approximately $6,151,000 in gross proceeds through the ATM Financing Facility via sale of 1,543,364 shares of our common stock and paid Canaccord aggregate commissions of $184,559.

In March 2018, we raised approximately $21.89 million of net proceeds (after underwriting discounts and commissions but before expenses) through an underwritten registered public offering of 10,350,000 shares of our common stock. The Offering was made pursuant to the Company's registration statement on Form S-3 (Registration No. 333-211489), which was declared effective by the U.S. Securities and Exchange Commission on August 16, 2017, a base prospectus dated August 16, 2017 and a prospectus supplement dated March 1, 2018.

Critical Accounting Policies and Recent Accounting Pronouncements

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

Research and Development Expenses

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

Income Taxes

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

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

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

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

We had unrecognized tax benefits of $469,000 and $617,000 at March 31, 2018 and 2017, 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, as well as various U.S. state jurisdictions. The federal and state income tax returns are generally subject to tax examinations for the period April 1, 2016 through March 31, 2017, January 1, 2016 through March 31, 2016, the years ended December 31, 2015 and 2014. 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.

On December 22, 2017, H.R. 1 (also, known as the Tax Cuts and Jobs Act (the " Act ")) was signed into law. Among its numerous changes to the Internal Revenue Code, the Act reduces the U.S. federal corporate tax rate from 35% to 21%. As a result, the most significant impact on the financial statements is a reduction of approximately $3.2 million for the deferred tax assets related to net operating losses and stock based compensation. Such reduction is offset by changes to the Company's valuation allowance.

Stock-Based Compensation

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

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

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

The expected volatility of options granted has been determined using the method described under ASC 718 using the expected volatility of similar companies. The expected term of options granted to employees in the current fiscal period has been based on the term by using the simplified "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.

Prior to the three months ended December 31, 2017, the Company used the full contractual term as the expected term in its Black Scholes model to estimate stock option value. The Company used the full contractual term because there was no history of exercise activity and the stock was thinly-traded on the OTC market.

Beginning in the three months ended December 31, 2017, the Company determined the use of the simplified method was more appropriate than the full contractual term due to the increased trading volume and activity during the quarter and the increased market and demand for shares.

Based on the these factors, the Company deemed it no longer appropriate to use the full contractual term for expected life, because these changes in the business indicate the likelihood that there will be exercise activity before completion of the full contractual term.

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.

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

Results of Operations

Year ended March 31, 2018 Compared to Year Ended March 31, 2017

Net loss for the year ended March 31, 2018 was $18,969,493, compared to $15,206,781 for the year ended March 31, 2017. The increase in the net loss for the year ended March 31, 2018, as compared to the net loss for the year ended March 31, 2017 is due to increased operating costs and expenses in 2018, as highlighted below.

Revenues and Other Income

During the years ended March 31, 2018 and March 31, 2017, 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, 2018, operating costs and expenses totaled $19,359,878, compared to $15,206,781 for the year ended March 31, 2017, representing an increase of $4,153,097. Operating costs and expenses were comprised of the following:

- Research and development expenses were $8,839,661 for the year ended March 31, 2018, compared to $6,111,587 for the year ended March 31, 2017, representing an increase of $2,728,074. All research and development expenditures have been incurred in respect of our lead drug candidate, SM-88, its technology platform, and related clinical trials. Research and development activities primarily consist of the following:
    - Salary expense for research and development personnel was $1,160,559 for the year ended March 31, 2018, compared to $923,816 for the year ended March 31, 2017, representing a $236,743 increase between the comparable periods, primarily due to the addition of personnel in key management positions. These expenses are expected to increase in future periods due to the addition of personnel and certain recently approved salary increases.
    - Consulting and study expenses were $3,422,503 for the year ended March 31, 2018, compared to $2,233,698 for the year ended March 31, 2017, representing an increase of $1,188,805 between the comparable periods. This increase was in large part due to the costs related to increased activity in our Phase II clinical trials and preparations for initiating our Phase II pancreatic clinical trial. These types of expenses are expected to vary between future accounting periods as we continue to develop our drug candidates and seek related governmental approvals, which may lead to expansion of our current clinical trials or the initiation of new trials for different cancer indications.
    - Stock based compensation, related to stock options granted, was $3,565,784 for the year ended March 31, 2018, compared to $2,629,073 for the year ended March 31, 2017, representing a $936,711 increase between the periods, primarily due to option grants to research and development employees.
    - Bonus expense to research and development employees, including related employer payroll taxes, was $551,718 for the year ended March 31, 2018, compared to $0 for the year ended March 31, 2017, representing a $551,718 increase between the periods. The bonus pool was approved by the Board of Directors as recommended by a third-party compensation consultant.
- General and administrative expenses were $10,520,217 for the year ended March 31, 2018, compared to $9,095,194 for the year ended March 31, 2017, representing an increase of $1,425,023. The general and administrative expenses include:
    - Stock based compensation, primarily related to stock options granted, was $4,123,909 for the year ended March 31, 2018, compared to $5,095,813 for the year ended March 31, 2017, representing a $971,904 decrease between the periods, primarily due to option grants to management and board of director members during the prior period.

- Legal, professional services, accounting and auditing for the year ended March 31, 2018, was $3,168,822, compared to $2,413,703 for the year ended March 31, 2017 representing an increase of $755,119 primarily related to financing initiatives.
- Salary expense for non-research and development personnel was $1,150,050 for the year ended March 31, 2018, compared to $978,179 for the year ended March 31, 2017, representing a $171,871 increase between the comparable periods due to increased headcount.
- Bonus expense to general and administrative employees, including related employer payroll taxes, was $851,556 for the year ended March 31, 2018, compared to $0 for the year ended March 31, 2017, representing a $851,556 increase between the periods. The bonus pool was approved by the Board of Directors as recommended by a third-party compensation consultant.

Other Income/Expenses

Interest expense

For the years ended March 31, 2018 and 2017, the Company did not enter into debt financing arrangements, and as such did not incur any interest expense.

Other Income

Other income for the year ended March 31, 2018 was $390,385, which represents a non-cash gain recorded on the remeasurement of a derivative liability due to the expiration of anti-dilution protection on warrants. Certain holders of our outstanding securities that acquired our securities in March and April 2017 private placement transactions (the " 2017 Private Placement Investors ") had limited anti-dilution protection that could have resulted in additional dilution to our stockholders. The anti-dilution protection expired without additional shares issued. The resulting change in the fair value of the derivative was recognized as other income for the relevant period.

For the year ended March 31, 2017, the Company did not recognize other income.

Income Tax

Our effective tax rate for the years ended March 31, 2018 and 2017 was zero percent. Our tax rate in the current period was primarily affected by the reduction of our net deferred tax assets due to tax reform, which was offset by a valuation allowance and in the prior year was affected primarily by changes in state income taxes, which was offset by a valuation allowance.

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

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

Revenues and Other Income

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

Operating Costs and Expenses

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

- Research and development expenses were $6,111,587 for the year ended March 31, 2017, compared to $3,823,966 for the year ended December 31, 2015, representing an increase of $2,287,621. All research and development expenditures have been incurred in respect of our lead drug candidate, SM-88, and its technology platform. Research and development activities primarily consist of the following:
  - Salary expense for research and development personnel was $923,816 for the year ended March 31, 2017, compared to $773,853 for the year ended December 31, 2015, representing a $149,963 increase between the comparable periods, primarily due to an increase in the number of employees.
  - Consulting and study expenses were $2,233,698 for the year ended March 31, 2017, compared to $1,969,617 for the year ended December 31, 2015, representing an increase of $264,081 between the comparable periods. These types of expenses are anticipated to vary between future accounting periods as we continue to develop our drug candidates and seek governmental approval of such drug candidates.
  - Stock based compensation, primarily related to stock options granted, was $2,629,073 for the year ended March 31, 2017, compared to $250,000 for the year ended December 31, 2015, representing a $2,379,073 increase between the periods, primarily due to option grants to research and development employees.
- General and administrative expenses were $9,095,194 for the year ended March 31, 2017, compared to $4,775,806 for the year ended December 31, 2015, representing an increase of $4,319,388, primarily due to increased stock compensation expense. The general and administrative expenses include:
  - Stock based compensation, primarily related to stock options granted, was $5,095,813 for the year ended March 31, 2017, compared to $685,859 for the year ended December 31, 2015, representing a $4,409,954 increase between the periods, primarily due to option grants to management and board of director members.
  - Legal, professional services, accounting and auditing for the year ended March 31, 2017, was $2,413,703, compared to $2,460,469 for the year ended December 31, 2015 representing a decrease of $46,766.
  - Salary expense for non-research and development personnel was $978,179 for the year ended March 31, 2017, compared to $944,561 for the year ended December 31, 2015, representing a $33,618 increase between the comparable periods.

Other Income/Expenses

Interest expense

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

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

Other Income

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

Income Tax

Our effective tax rate for the years ended March 31, 2017 and December 31, 2015 was zero percent. Our tax rate was affected primarily by changes to state income taxes and valuation allowance in both years as well as certain permanent differences in 2015.

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

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

Revenues and Other Income

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

Operating Costs and Expenses

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

Research and development expenses were $808,472 for the three months ended March 31, 2016, compared to $514,317 for the three months ended March 31, 2015, representing an increase of $294,155. All research and development expenditures have been incurred in respect of our lead oncology drug candidate, SM-88, and its associated technology platform. Research and development activities primarily consist of the following:

- Salary expense for research and development personnel was $212,193 for the three months ended March 31, 2016, compared to $307,058 for the three months ended March 31, 2015, a decrease of $94,865 between the comparable periods. The decrease is due to the fact that during the three months ended March 31, 2015, research and development personnel were awarded bonus compensation totaling $135,560 in connection with the Merger. This decrease is offset by a new hire during the three months ended March 31, 2016.
- Consulting and study expenses were $456,551 for the three months ended March 31, 2016, compared to $152,259 for the three months ended March 31, 2015, representing an increase of $304,292 between the comparable periods. These types of expenses are anticipated to vary between future accounting periods as we continue to develop our oncology drug candidates and seek governmental approval of such drug candidates.

- For the three months ended March 31, 2016 we incurred compensation expense of $100,000 related to the Scientific Advisory Board that was established as of September 30, 2015 compared to $0 for the three months ended March 31, 2015.

General and administrative expenses were $1,942,655 for the three months ended March 31, 2016, compared to $1,583,820 for the three months ended March 31, 2015, representing an increase of $358,835, with this increase principally attributed to the recognition of non-cash compensation expense related to stock options of $1,137,435 for the three months ended March 31, 2016. For the three months ended March 31, 2015, we had no compensation expense related to stock options. The general and administrative expenses for the respective periods include:

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

Liquidity and Capital Resources

Liquidity and Capital Requirements Outlook

During fiscal year 2018, we raised gross proceeds of approximately $32.1 million through the issuance of our common stock. Most recently in March 2018, we raised aggregate gross proceeds of $23.3 million before underwriting discounts and commissions and expenses of the offering through an underwritten public offering. Previously, on November 2, 2017, the Company entered into the Equity Distribution Agreement with Canaccord, to commence the ATM Financing Facility pursuant to which the Company may, from time to time, subject to certain rules and regulations, sell shares of the Company's common stock, par value $0.0001 per share, having an aggregate offering price up to $30.0 million, through Canaccord, as the Company's sales agent. In the year ended March 31, 2018, the Company raised approximately $6.2 million in aggregate gross proceeds before commissions and expenses through the ATM Financing Facility and incurred related costs, including commission to Canaccord, of approximately $0.3 million. At March 31, 2018, there remained approximately $24.0 million of availability to sell shares through the facility. Additionally, in April 2017, we raised $2.7 million in gross proceeds through a private placement transaction. The proceeds of those offerings are being used by the Company for continued clinical studies and development activities and other general corporate and operating expenses.

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 continue to be in connection with conducting immediate Phase II clinical trials of our SM-88 drug candidate for prostate cancer and pancreatic cancer and additional or related studies and investigations.

Additionally, following a review of the Company's employee and director compensation program performed in conjunction with an independent third-party compensation consultant, in May 2018, our board of directors approved certain changes to these compensation programs, which are designed to address the Company's unique business attributes and to promote the Company's goals of attracting and retaining talent, aligning of the interests of executives with stockholders, and avoiding excessive risk taking. After consultation with the compensation consultant, the board approved employee cash bonuses for the completed 2018 fiscal year in an aggregate total amount of approximately $1.2 million, which amount is expected to be paid by the Company during June 2018. The Company's board also approved salary increases for certain of the Company's executives and expects that, during the course of fiscal 2019, it will expand its annual cash retainer program for non-employee directors such that they will each receive an annual cash retainer for board service of $50,000, as well as annual cash retainers for service on board committees, in amounts to be determined.

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 2019 compared to 2018 and is expected to approximate $5 million per quarter.

As of March 31, 2018, the Company has cash on hand of approximately $29.0 million and a working capital of approximately $26.5 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. The Company has developed an operational plan that manages expenses and delays initiation of certain operational initiatives to focus on core programs if appropriate funding is not available.

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

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

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

Cash Flows

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

	Year Ended March 31, 2018	Year Ended March 31, 2017	Three Months Ended March 31, 2016	Year Ended December 31, 2015
Net cash used in operating activities	$(11,879,260)	$ (5,861,127)	$ (1,373,257)	$ (6,610,156)
Net cash used in investing activities	$ —	$ —	$ —	$ —
Net cash provided by financing activities	$ 30,372,105	$ 10,238,795	$ 3,032,282	$11,046,716

Operating Activities

Our cash used in operating activities in the year ended March 31, 2018 totaled $11,879,260 which is the sum of (i) our net loss of $18,969,493, adjusted for non-cash expenses totaling $7,303,245 (which includes adjustments for equity-based compensation, depreciation and amortization and the issuance of common stock for services), and (ii) changes in operating assets and liabilities of $213,012. As noted above, we expect these amounts to increase in fiscal year 2019.

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

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

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

Investing Activities

There was no cash used in investing activities in any of the reported years.

Financing Activities

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

- In the year ended March 31, 2018, the Company raised approximately $5,824,000 in net proceeds after sales commissions and expenses of the offering through the ATM Financing Facility via sale of 1,543,364 shares of our common stock.
- In March 2018, we raised approximately $21.74 million in net proceeds after underwriting commissions and discounts and expenses of the offering through a public offering of 10,350,000 shares of our common stock.
- In April 2017, we raised $2.7 million in gross proceeds through a private placement of 1,069,603 shares of our common stock and 1,069,603 Warrants. Each Warrant entitles its holder to purchase one Warrant Share at an exercise price of $3.00 per Warrant Share, subject to adjustment.

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

- In October 2016, we raised $1.47 million in net proceeds through a private placement of 452,314 shares of our common stock.
- In March 2017, we raised $9.0 million in net proceeds through a private placement of 3,588,620 shares of our common stock and 3,588,620 common stock purchase warrants (each, a " Warrant "). Each Warrant entitles its holder to purchase one share of common stock (each, a " Warrant Share ") at an exercise price of $3.00 per Warrant Share, subject to adjustment.

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

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

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

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

Subsequent Events

On April 30, 2018, we entered into agreement to lease 4,752 square feet of office space at 17 State Street, 7th Floor, New York, New York 10004. The lease term is 28 months and cumulative monthly rent of $566,427 has been paid in advance and held in escrow. Our costs for this space approximate $250,000 per year.

On May 24, 2018, the Board approved an amendment and restatement of the 2016 Director Plan (the " Restated 2016 Director Plan ") to increase the number of shares authorized to be issued under the plan and to permit different award structures and different vesting schedules than currently provided for in the plan. The Board expects to submit the Restated 2016 Director Plan for approval by the stockholders at the 2018 annual meeting of stockholders. In addition, the Board approved the 2018 Employee Bonuses as recommended by the Compensation Committee, which consisted of (a) a bonus of $297,000 for the Company's Chief Executive Officer, Steve Hoffman, and (b) a bonus pool of $870,000 to be allocated among the Company's other employees. As the amounts related to fiscal year 2018, the amounts and estimated taxes were recorded and are included in accrued bonuses as of March 31, 2018. The Board also granted authority to the CEO to grant up to 750,000 option awards under the 2015 Equity Plan to non-executive employees, with such authority expiring on March 31, 2019.

Seasonality

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

Contractual Obligations and Commitments

At our current stage of development and at a stage where we have yet to secure material and recurring amounts of financial funding, we do not have any significant contractual obligations with the exception of certain purchase commitments discussed below.

Purchase Commitments

During fiscal year 2018, we entered into two contracts with manufacturers to supply certain components used in SM-88 in order to achieve favorable pricing on supplied products. These contracts have non-cancellable elements related to the scheduled deliveries of these products in future periods. Payments are made by us to the manufacturer when the products are delivered and of acceptable quality. The contracts are structured to match clinical supply needs for our ongoing trials and we expect the timing of associated payments to predominately occur during fiscal year 2019. Total outstanding future obligations associated with the contracts were $1.7 million at March 31, 2018, of which approximately $0.6 million subsequently has been paid.

Off-Balance Sheet Arrangements

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market risk is the potential loss arising from adverse changes in market rates and market prices such as interest rates, foreign currency exchange rates, and changes in the market value of equity instruments. We do not believe we are currently exposed to any material market risk. As of March 31, 2018, we had $29.0 million of cash on hand in U.S. bank accounts.

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, 2018 and 2017, the related consolidated statements of operations, shareholders' equity, and cash flows for each of the two years in the period ended March 31, 2018, the three months ended March 31, 2016, and the year ended the December 31, 2015 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, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended March 31, 2018, the three months ended March 31, 2016, and the year ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (" PCAOB "), the Company's internal control over financial reporting as of March 31, 2018, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (" COSO "), and our report dated June 13, 2018 expressed an adverse opinion.

Basis for opinion

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

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

/s/ GRANT THORNTON LLP

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

New York, NY
June 13, 2018

Tyme Technologies, Inc. and Subsidiaries
Consolidated Balance Sheets

	March 31, 2018	March 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 28,975,822	$ 10,482,977
Prepaid and other assets	2,038,780	228,362
Total current assets	31,014,602	10,711,339
Property and equipment, net	3,239	7,535
Total assets	$ 31,017,841	$ 10,718,874
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and other current liabilities (including $384,000 and $1,303,000 of related party accounts payable, respectively)	$ 2,817,090	$ 2,948,468
Accrued bonuses	1,248,690	—
Insurance note payable	480,094	—
Derivative liability	—	378,600
Total current liabilities	4,545,874	3,327,068
Total liabilities	4,545,874	3,327,068
Commitments and contingencies (See Note 8)		
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, 101,226,479 issued and outstanding at March 31, 2018, and 300,000,000 authorized, 91,692,641 issued and 88,192,641 outstanding at March 31, 2017	10,125	9,172
Common stock, $0.0001 par value, 58,823 shares subscribed at March 31, 2017	—	6
Additional paid in capital	79,293,423	41,419,714
Subscription receivable	—	(174,998)
Accumulated deficit	(52,831,581)	(33,862,088)
Total stockholders' equity	26,471,967	7,391,806
Total liabilities and stockholders' equity	$ 31,017,841	$ 10,718,874

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,		Three Months Ended March 31,	Year Ended December 31
	2018	2017	2016	2015
Operating expenses:				
Research and development	$ 8,839,661	$ 6,111,587	$ 808,472	$ 3,823,966
General and administrative (including $1,619,000, $1,477,000, $111,000 and $0 of related party legal expenses, respectively)	10,520,217	9,095,194	1,942,655	4,775,806
Total operating expenses	19,359,878	15,206,781	2,751,127	8,599,772
Loss from operations	(19,359,878)	(15,206,781)	(2,751,127)	(8,599,772)
Interest expense	—	—	—	3,503,301
Other income	(390,385)	—	—	(376,255)
Loss before income taxes	(18,969,493)	(15,206,781)	(2,751,127)	(11,726,818)
Income tax expense	—	—	—	—
Net loss	$(18,969,493)	$(15,206,781)	$ (2,751,127)	$(11,726,818)
Basic and diluted loss per common share	$ (0.21)	$ (0.18)	$ (0.03)	$ (0.15)
Basic and diluted weighted average shares outstanding	90,567,476	84,454,587	83,796,260	77,848,850

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, 2018 and 2017, Three Months Ended March 31, 2016, and Year Ended December 31, 2015

	Common Stock				Additional			Due from	Total Stockholders'
	Shares	Amount	Subscribed Shares	Subscribed Amount	Paid-in capital	Subscription Receivable	Accumulated Deficit	Stockholders/ Members	Equity (Deficit)
Balance, January 1, 2015	68,000,000	$ 6,800	—	—	$ 2,053,012	$ —	$ (4,177,362)	$ (355,766)	$ (2,473,316)
Repayment of stockholder loans	—	—	—	—	—	—	—	355,766	355,766
Common stock issued as part of the Merger	12,724,000	1,272	—	—	(1,272)	—	—	—	—
Issuance of common stock and warrants for services	300,000	30	—	—	824,970	—	—	—	825,000
Issuance of common stock and warrants in private placement offering for cash, net of associated expense	2,466,000	247	—	—	7,230,703	—	—	—	7,230,950
Issuance of common stock in private placement offering in exchange for subscription receivable	1,000,000	100	—	—	2,499,900	(2,500,000)	—	—	—
Issuance of common stock upon conversion of Bridge Note and accrued interest	2,310,000	231	—	—	2,404,243	—	—	—	2,404,474
Incremental value of the modification to Bridge Note conversion rate as an inducement to convert	—	—	—	—	3,465,000	—	—	—	3,465,000
Stock based compensation	36,370	5	—	—	324,995	—	—	—	325,000
Fair value of price protection feature associated with shares issued under the PPO and Bridge Note conversion	—	—	—	—	(376,300)	—	—	—	(376,300)
Amortization of employee stock options	—	—	—	—	485,859	—	—	—	485,859
Proceeds from the collection of stock subscription receivable	—	—	—	—	—	2,500,000	—	—	2,500,000
Net loss	—	—	—	—	—	—	(11,726,818)	—	(11,726,818)
Balance, December 31, 2015	86,836,370	$ 8,685	—	$ —	$18,911,110	$ —	$(15,904,180)	$ —	$ 3,015,615
Issuance of common stock in private placement offering for cash, net of associated expense	775,000	78	—	—	3,032,204	—	—	—	3,032,282
Stock based compensation	—	—	—	—	1,137,435	—	—	—	1,137,435
Net loss	—	—	—	—	—	—	(2,751,127)	—	(2,751,127)

Balance, March 31, 2016	87,611,370	$ 8,763	—	$—	$23,080,749	$ —	$(18,655,307)	$—	$ 4,434,205
Issuance of common stock and warrants in private placement offering for cash, net of associated expenses	3,529,797	353	—	—	9,000,537	—	—	—	9,000,890
Issuance of common stock in private placement offering in exchange for stock subscription receivable	7,692	1	—	—	24,998	(24,999)	—	—	—
Issuance of common stock and warrants in private placement offering for cash, net of associated expense	452,314	45	—	—	1,469,960	—	—	—	1,470,005
Stock Subscription Receivable Private placement of $9.2M	—	—	58,823	6	149,993	(149,999)	—		—
Derivative liability	—	—	—	—	(378,600)	—	—		(378,600)
Stock based compensation	—	—	—	—	7,721,837	—	—	—	7,721,837
Issuance of common stock for services	75,000	8	—	—	250,242	—	—	—	250,250
Issuance of stock to Scientific Advisory Board members	16,468	2	—	—	99,998	—	—	—	100,000
Net loss	—	—	—	—	—	—	(15,206,781)	—	(15,206,781)
Balance, March 31, 2017	91,692,641	$ 9,172	58,823	$ 6	$41,419,714	$(174,998)	$(33,862,088)	$—	$ 7,391,806
Issuance of common stock and warrants in private placement offering for cash, net of associated expenses of $130,300	1,069,603	107	—	—	2,596,993	—	—	—	2,597,100
Issuance of common stock from at-the-market financing facility, net of issuance costs of $327,939	1,543,364	154	—	—	5,823,863	—	—	—	5,824,017
Issuance of common stock in public offering for cash, net of associated expenses of $1,547,972	10,350,000	1,035	—	—	21,739,425	—	—	—	21,740,460
Proceeds from collection of stock subscription receivable	58,823	6	(58,823)	(6)	—	174,998	—	—	174,998
Stock based compensation	—	—	—	—	7,689,334	—	—	—	7,689,334
Issuance of common stock upon exercise of options and warrants	12,048	1	—	—	35,529	—	—	—	35,530
Derivative liability	—	—	—	—	(11,785)	—	—	—	(11,785)
Retirement and cancellation of shares of common stock	(3,500,000)	(350)	—	—	350	—	—	—	—
Net loss	—	—	—	—	—	—	(18,969,493)	—	(18,969,493)
Balance, March 31, 2018	101,226,479	$10,125	—	—	$79,293,423	—	$(52,831,581)	$—	$ 26,471,967

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		Three Months Ended March 31,	Year Ended, December 31
	2018	2017	2016	2015
Cash flows from operating activities:				
Net loss	$(18,969,493)	$(15,206,781)	$ (2,751,127)	$(11,726,818)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	4,296	4,281	1,062	4,292
Issuance of common stock for services	—	350,250	—	825,000
Stock—based compensation and stock issued to Scientific Advisory Board members	—	—	—	325,000
Amortization of employees, directors and consultants stock options,	7,689,334	7,721,837	1,137,435	485,859
Inducement for conversion of Bridge Note to common shares	—	—	—	3,465,000
Gain on remeasurement of derivative liability	(390,385)	—	—	(376,300)
Changes in operating assets and liabilities:				
Prepaid and other assets	(1,330,324)	(2,264)	36,786	109,421
Accounts payable and other current liabilities	(131,378)	1,271,550	202,587	278,390
Accrued bonuses	1,248,690	—	—	—
Net cash used in operating activities	(11,879,260)	(5,861,127)	(1,373,257)	(6,610,156)
Cash flows from financing activities:				
Insurance note payments	—	(232,100)	—	—
Repayment from stockholders/members	—	—	—	355,766
Proceeds from Bridge Note	—	—	—	960,000
Proceeds from private placement offering of common stock and warrants, net of issuance costs	2,597,100	10,470,895	3,032,282	7,230,950
Issuance of common stock from at-the-market financing facility	5,824,017	—	—	—
Proceeds from the collection of stock subscription receivable	174,998	—	—	2,500,000
Proceeds from public offering, net of issuance of costs	21,740,460			
Proceeds from exercise of stock options	35,530			
Net cash provided by financing activities	30,372,105	10,238,795	3,032,282	11,046,716
Net increase in cash	18,492,845	4,377,668	1,659,025	4,436,560
Cash and cash equivalents — beginning of period	10,482,977	6,105,309	4,446,284	9,724
Cash and cash equivalents — end of period	$ 28,975,822	$ 10,482,977	$ 6,105,309	$ 4,446,284
Supplemental Cash Flow Information:				
Cash paid for interest and income taxes are as follows:				
Interest	$ —	$ —	$ —	$ —
Income taxes	$ —	$ —	$ —	$ 675
Noncash investing and financing activities:				
Financing of insurance premiums	$ 480,094	$ —	$ 232,100	$ —
Conversion of the Bridge Note and all accrued interest into shares of common stock	$ —	$ —	$ —	$ 2,404,474
Subscribed and subscription receivable shares in conjunction with private placement offering	$ —	$ 174,998	$ —	$ 2,500,000
Inducement for conversion of Bridge Note to common shares	$ —	$ —	$ —	$ 3,465,000
Derivative liability associated with the price protection feature of shares of common stock issued	$ 11,785	$ 378,600	$ —	$ 376,300
Retirement and cancellation of shares of common stock	$ 350	$ —	$ —	$ —

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

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

Note 1. Nature of Business

Tyme Technologies, Inc. (" Tyme Tech ") is a Delaware corporation headquartered in New York, NY, with wholly owned subsidiaries, Tyme Inc. (" Tyme ") and Luminant Biosciences, LLC (" Luminant ") (collectively, 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, which was incorporated in Delaware in 2013. On October 27, 2016, the Board of Directors of Tyme Tech approved a change in fiscal year end from December 31 to March 31 of each year.

The Company is a clinical-stage biotechnology company developing novel cancer therapeutics that are intended to be effective across many tumor types while also maintaining low toxicity. Tyme's operations to date have been directed primarily toward research and development activities for human oncologic product candidates. The Company has completed an ongoing IND-enabled Phase Ib clinical study and has an ongoing Phase II clinical study for use of SM-88 in biomarker-recurrent prostate cancer patients and also recently initiated a Phase II clinical study in metastatic pancreatic cancer. The Company is also evaluating the expansion of its clinical programs to other types of cancer and may also seek to develop oncology drug candidates in addition to SM-88, its lead clinical program.

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

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

On March 5, 2015, Tyme Tech consummated a reverse triangular merger with Tyme (the " Merger "). (See Reverse Triangular Merger below.) The Merger resulted in Tyme becoming a wholly-owned subsidiary of Tyme Tech.

Reverse Triangular Merger

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

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

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

The Company granted Mr. Hoffman perpetual, exclusive non-royalty bearing license with respect to certain patents and patent applications that the Company uses for SM-88 for all fields other than in connection with the treatment of cancer.

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

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

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

Liquidity

The consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has historically funded its operations primarily through equity offerings. During fiscal year 2018, the Company raised gross proceeds of approximately $32.1 million through the issuance of its common stock. Most recently in March 2018, we raised aggregate gross proceeds of $23.3 million before underwriting discounts and commissions and expenses of the offering through an underwritten public offering. Previously on November 2, 2017, the Company entered into an equity distribution agreement (" Equity Distribution Agreement ") with Canaccord Genuity Inc. (" Canaccord "), to commence an at-the-market offering (the " ATM Financing Facility ") pursuant to which the Company may, from time to time, subject to certain rules and regulations, sell shares of the Company's common stock, par value $0.0001 per share, having an aggregate offering price up to $30.0 million, through Canaccord, as the Company's sales agent. In the year ended March 31, 2018, the Company raised approximately $6.2 million in aggregate gross proceeds before commissions and expenses through the ATM Financing Facility and paid Canaccord aggregate commissions of $0.3 million. At March 31, 2018, there remained approximately $24.0 million of availability to sell shares through the facility. Additionally, in April 2017, we raised $2.7 million in gross proceeds through a private placement transaction. The proceeds of those offerings are being used by the Company for continued clinical studies, drug commercialization and development activities and other general corporate and operating expenses.

For the year ended March 31, 2018, the Company had negative cash flow from operations of $11.9 million and net loss of $19.0 million, which included $7.3 million of non-cash expenses, primarily non-cash equity compensation expense. As of March 31, 2018, the Company had a working capital of approximately $26.5 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. The Company has developed an operational plan that manages expenses and delays initiation of certain operational initiatives to focus on core programs if appropriate funding is not available.

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

Basis of Presentation

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

Significant Accounting Policies

Principles of Consolidation

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

Risks and Uncertainties

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

Use of Estimates

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

Cash and Cash Equivalents

The Company considers all highly-liquid investments that have maturities of three months or less when acquired to be cash equivalents. The Company's cash and cash equivalents consisted of $28,975,822 at March 31, 2018 and $10,482,977 at March 31, 2017.

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 $28,725,822 at March 31, 2018 and $10,232,977 at March 31, 2017. Although the Company has exceeded the federally insured limit, it has not incurred losses related to these deposits. Management monitors the Company's accounts with these institutions to minimize credit risk.

Fair Value of Financial Instruments

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

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

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

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

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

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

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

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

An adjustment to the pricing method used within either Level 1 or Level 2 inputs could generate a fair value measurement that effectively falls in a lower level in the hierarchy. The Company had no assets or liabilities classified as Level 1, Level 2, or Level 3 for the year ended March 31, 2018. The Company had no assets or liabilities classified as Level 1 or Level 2 for the year ended March 31, 2017, the three months ended March 31, 2016 and the year ended December 31, 2015 and there were no material re-measurements of fair value with respect to financial assets and liabilities, during those periods, other than those assets and liabilities that are measured at fair value on a recurring basis. There were no transfers between Level 1, Level 2 and Level 3 in any of the periods reported.

Assets and liabilities measured at fair value on a recurring basis as of March 31, 2018 and 2017 are summarized below:

	Level 1	Level 2	Level 3	Total
March 31, 2018				
Liabilities:				
Derivative liability – anti-dilution feature	$ —	$ —	$ —	$ —
Total	$ —	$ —	$ —	$ —

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

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

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

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

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

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

The fair value of the derivative liability was written down to zero as of December 31, 2017 because the anti-dilution provision of the March 2017 Private Placement expired on September 10, 2017 and the anti-dilution provision of the April 2017 Private Placement expired on October 7, 2017, in each case with no shares issued pursuant to such provisions.

Prepaid and Other Assets

Prepaid and other assets represent expenditures made in advance of when the economic benefit of the cost will be realized, and which will be expensed in future periods with the passage of time. Prepaid and other assets consisted of $1.4 million of prepaid R&D and $480,000 of prepaid insurance as of March 31, 2018. Prepaid and other assets as of March 31, 2017 consisted primarily of prepaid insurance.

Property and Equipment, Net

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

Impairment of Long-Lived Assets

The Company assesses the recoverability of its long-lived assets, which include fixed assets, whenever significant events or changes in circumstances indicate impairment may have occurred. If indicators of impairment exist, projected future undiscounted cash flows associated with the asset are compared to its carrying amount to determine whether the asset's value is recoverable. Any resulting impairment is recorded as a reduction in the carrying value of the related asset in excess of fair value and a charge to operating results. For the years ended March 31, 2018 and 2017, the three months ended March 31, 2016 and the year ended December 31, 2015, 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 their operations and manages their business in one segment.

Derivative Liabilities

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

Basic and Diluted Loss Per Share

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

Stock-based Compensation

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

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected

term of the option, risk-free interest rates, the value of the common stock and expected dividend yield of the common stock. For awards subject to time-based vesting conditions, the Company recognizes stock-based compensation expense equal to the grant date fair value of stock options on a straight-line basis over the requisite service period, which is generally the vesting term. The Company accounts for forfeitures as they occur

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

Reclassification

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

Recent Accounting Pronouncements

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718) - Scope of Modification Accounting* , which amends the scope of modification accounting for share-based payment arrangements. The standard provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under ASC 718. Specifically, an entity would not apply modification accounting if the fair value, vesting conditions, and classification of the awards are the same immediately before and after the modification. The new standard is effective for annual periods beginning after December 15, 2017 and interim periods within those years. The Company will adopt ASU 2017-09 in its consolidated financial statements in the first quarter of fiscal year 2019. It is not expected to have a material impact.

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

In January 2017, the FASB issued ASU 2017-01, amending Business Combinations: Clarifying the Definition of a Business, to clarify the definition of a business with the objective of providing a more robust framework to assist management when evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The standard will be effective for the Company for its fiscal year beginning April 1, 2018, including interim periods within that fiscal year, with early application permitted. The amendments are to be applied prospectively to business combinations that occur after the effective date. The Company will adopt ASU 2017-01 in its consolidated financial statements in the first quarter of fiscal year 2019. It is not expected to have a material impact.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* . ASU 2016-15 clarifies how certain cash receipts and payments should be presented in the statement of cash flows. The new guidance is effective for annual periods beginning after December 15, 2017. Early adoption is permitted, provided that all of the amendments are adopted in the same period. The guidance requires application using a retrospective transition. The Company will adopt ASU 2016-15 in its consolidated financial statements in the first quarter of fiscal year 2019. It is not expected to have a material impact.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting* (" ASU 2016-09 "), which provides for simplification of certain aspects of employee share-based payment accounting including income taxes, classification of awards as either equity or liabilities, accounting for forfeitures and classification on the statement of cash flows. ASU 2016-09 was effective for the Company in the first quarter of 2018 and was applied prospectively on the area covered in this update. The Company has adopted this standard and it did not have a material impact on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* (" ASU 2016-02 "). The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 is effective for annual periods beginning after December 15, 2018. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact that the standard will have on its consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments - Overall (Subtopic 825-10), Recognition and Measurement of Financial Assets and Financial Liabilities* (" ASU 2016-1 "), which addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. ASU 2016-01 will be effective for the Company for annual periods and interim periods within those annual periods beginning after December 15, 2018 and early adoption is not permitted. The Company will adopt ASU 2016-01 in its consolidated financial statements in the first quarter of fiscal year 2019. It is not expected to have a material impact.

Note 3. Net Loss Per Common Share

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

	Year Ended March 31,		Three Months Ended March 31,	Year Ended December 31,
	2018	2017	2016	2015
Basic and diluted net loss per common share calculation				
Net loss	$(18,969,493)	$(15,206,781)	$ (2,751,127)	$(11,726,818)
Weighted average common shares outstanding — basic and diluted	90,567,476	84,454,587	83,796,260	77,848,850
Net loss per share of common stock — basic and diluted	$ (0.21)	$ (0.18)	$ (0.03)	$ (0.15)

The following outstanding securities at March 31, 2018, 2017, 2016 and December 31, 2015 have been excluded from the computation of diluted weighted average shares outstanding, as they would have been anti-dilutive:

	Year Ended March 31,		Three Months Ended	Year Ended December 31,
	2018	2017	2016	2015
Stock options	5,438,072	4,039,444	350,000	150,000
Warrants	5,615,641	4,556,038	937,651	476,267
Total	11,053,713	8,595,482	1,287,651	626,267

Note 4. Property and Equipment, Net.

Property and equipment, net consisted of the following:

	March 31, 2018	March 31, 2017
Machinery and equipment	$ 21,463	$ 21,463
Less: accumulated depreciation	18,224	13,928
	$ 3,239	$ 7,535

Depreciation expense was $4,296 and $4,281 for the year ended March 31, 2018 and 2017, $1,062 for the three months ended March 31, 2016, and $4,292 for the year ended December 31, 2015.

Note 5. Accounts Payable and Other Current Liabilities.

Accounts payable and other current liabilities consisted of the following:

	March 31, 2018	March 31, 2017
Legal	$ 421,128	$ 1,443,084
Consulting	78,101	60,317
Accounting and auditing	81,652	69,738
Research and development	1,678,675	644,546
Board of Directors and Scientific Advisory Board compensation	442,610	487,500
Insurance	—	232,100
Other	114,924	11,183
	$ 2,817,090	$ 2,948,468

Note 6. Debt.

Insurance Note Payable

During the year ended March 31, 2018, the Company entered into an agreement to finance Director and Officer insurance totaling $480,094 for the policy year ending in March 2019. As of March 31, 2018, there remained a balance of $480,094, recorded to Insurance note payable on the accompanying consolidated balance sheets.

During the year ended March 31, 2016, the Company entered into an agreement to finance Director and Officer insurance totaling $232,100 for the policy year ending in March 2017. As of March 31, 2017, no balance remained.

Bridge Notes Payable

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

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

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

Derivative Liability - PPO

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

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

Note 7. Stockholders' Equity.

Preferred Stock

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

Common Stock

Voting

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

Dividends

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

Liquidation

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

Escrow Shares

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

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

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

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

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

Registration Rights Agreement

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

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

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

Securities Purchase Agreements

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

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

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

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

Investors in the March 2017 Private Placement have limited anti-dilution protection. This provision provides that if the Company were to raise certain funds before the Anti-dilution Expiry Date (defined below) at an effective average consideration and/or exercise or conversion price per share price less than $2.55 per share, subject to exceptions for issuances of certain "exempt securities," anti-dilution protections could apply which could obligate the Company to issue additional securities to the March 2017 Private Placement investors. "Anti-dilution Expiry Date" means the earliest to occur of (i) the business day after we raise $10 million or more in one or more public or private offerings within six months of the applicable purchase date for the 2017 Private Placement Investors, or (ii) the six-month anniversary of the applicable purchase date for the 2017 Private Placement Investors. The provision had been accounted for as a derivative liability with a fair value of $378,600 and was subject to remeasurement (see Note 2) through the expiration of the anti-dilution provision at which time the write down of the derivative liability was recorded as other income.

April 2017 PPO

In April 2017, the Company raised $2.7 million in gross proceeds through a private placement (" April 2017 Private Placement ") of 1,069,603 shares of common stock and 1,069,603 common stock purchase warrants (each, a " Warrant "). Each Warrant entitles its holder to purchase one share of common stock (each, a " Warrant Share ") at an exercise price of $3.00 per Warrant Share. The warrants expire two years from the date of issuance and vest immediately. The warrants are included within additional paid-in capital on the statement of stockholders' equity and will not be subject to remeasurement.

At March 31, 2018, 5,556,107 common stock purchase warrants relating to securities purchase agreements were outstanding and exercisable.

The following summarizes the common stock warrant activity for the years ended March 31, 2018 and March 31, 2017:

	Warrant Shares of Common Stock	Weighted Average Exercise Price
Outstanding at March 31, 2016	937,651	5.00
Granted	3,618,387	3.02
Exercised	—	—
Cancelled	—	—
Outstanding at March 31, 2017	**4,556,038**	**$ 3.42**
Granted	1,069,603	3.00
Exercised	(10,000)	3.00
Cancelled	—	—
Outstanding at March 31, 2018	**5,615,641**	**3.34**

At-the-Market Financing Facility

On November 2, 2017, the Company entered into an equity distribution agreement (" Equity Distribution Agreement ") with Canaccord Genuity Inc. (" Canaccord "), to commence an at-the-market offering (the " ATM Financing Facility ") pursuant to which the Company may, from time to time, subject to certain rules and regulations, sell shares of the Company's common stock, par value $0.0001 per share, having an aggregate offering price up to $30,000,000, through Canaccord, as the Company's sales agent. In the year ended March 31, 2018, the Company raised approximately $6,151,000 in gross proceeds through the ATM via sale of 1,543,364 of our common stock. The Company incurred $327,939 of related costs which offset the proceeds. At March 31, 2018, there remained approximately $24,000,000 of availability to sell shares through the facility. Under the ATM Financing Facility, the Company is not required to issue the full available amount authorized and it may be cancelled at any time.

Public Offering

In March 2018, we raised approximately $23,288,000 in gross proceeds through a public offering of 10,350,000 shares of our common stock. The Offering was made pursuant to the Company's registration statement on Form S-3 (Registration No. 333-211489), which was declared effective by the U.S. Securities and Exchange Commission on August 16, 2017, a base prospectus dated August 16, 2017 and a prospectus supplement dated March 1, 2018.

Note 8. Commitments and Contingencies.

Contract Service Providers

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

Purchase Commitments

During fiscal year 2018, we entered into two contracts with manufacturers to supply certain components used in SM-88 in order to achieve favorable pricing on supplied products. These contracts have non-cancellable elements related to the scheduled deliveries of these products in future periods. Payments are made by us to the manufacturer when the products are delivered and of acceptable quality. The contracts are structured to match clinical supply needs for our ongoing trials and we expect the timing of associated payments to predominately occur during fiscal year 2019. Total outstanding future obligations associated with the contracts were $1.7 million at March 31, 2018 of which approximately $.6 million subsequently has been paid.

Employment Agreement

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

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

In the quarter ending September 30, 2017, the Company entered into an employment agreement with its Chief Scientific Affairs Officer of the Company. The Agreement provides for an annual salary of $200,000 and a term scheduled to expire on the one-year anniversary of the effective date of the agreement unless earlier terminated. Following the completion of a $10 million qualified offering by the Company, as such term is defined in the Agreement, bonus was paid equal to $155,000 multiplied by the number of years (or fraction thereof) that he has been employed by the Company on the date of the qualified offering. Mr. Eckard's annual salary would also increase to $355,000.

The Agreement (i) could renew for an additional one-year term unless timely notice of nonrenewal is given or the Employment Agreement is earlier terminated, (ii) provides for severance, in the event of termination by the Company without cause (as defined in the Agreement), equal to six months' salary (as in effect at the time of termination) and immediate vesting of 112,500 options for Company common stock and (iii) contemplates the establishment of a performance bonus opportunity based upon the achievement of performance criteria and goals approved by the Board and conditioned on Mr. Eckard's continued employment by the Company. The Board plans to establish a performance bonus plan during the Company's fiscal year ending March 31, 2019. See Subsequent Events (Note 13).

Pursuant to the Agreement, the Board granted to Mr. Eckard options to purchase up to 500,000 shares of the Company's common stock at a per-share exercise price of $4.31. Of such options, 50,000 vested upon execution of the Eckard Employment Agreement. The balance of the options is scheduled to vest over a four-year term in equal annual installments beginning on the one-year anniversary of the options' grant date, conditioned on continued employment by the Company on the applicable vesting date.

On November 22, 2017, the Company and the Company's Chief Financial Officer, entered into an alternative compensation arrangement was granted non-qualified stock options to purchase shares of the Company's common stock in lieu of $213,000 in potential salary payable in the future. The arrangement relates to fiscal year 2018 and not future periods. Such options consist of the right to purchase 129,957 shares of Company common stock at an exercise price per share of $4.10. The options have a contractual term of two years, and vest over a six-month term in equal monthly installments beginning on the one-month anniversary of the grant date, subject to continued service with the Company.

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.

Note 9. Related Party Transactions.

Due from Stockholders/Members

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

Sale of Excess Ingredient Materials

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

Legal

The Company was provided legal service by Drinker Biddle & Reath LLP (" DBR "). A partner of DBR is a director and has received equity compensation under the Company's equity compensation plans, and is entitled to receive, equity compensation payable to non-employee directors generally under the 2016 Director Plan, as well as cash compensation payable to non-employee directors generally. See note 10 below concerning the 2016 Director Plan. During the years ended March 31, 2018, and 2017, the three months ended March 31, 2016, and the year ended December 31, 2015, approximately $1,819,000 (of which approximately $200,000 was capitalized into equity), $1,477,000, $111,000, and $0, respectively, have been incurred as legal expenses associated with DBR, and the Company had approximately $384,000 and $1,303,000 in accounts payable and accrued expenses payable to DBR at March 31, 2018 and March 31, 2017, respectively.

Note 10. Equity Incentive Plan.

On March 5, 2015, the Company's Board of Directors adopted and the Company's stockholders approved, the Company's 2015 Equity Incentive Plan (the "2015 Plan"). A reserve of 10,000,000 shares of Company common stock has been established for issuance under the 2015 Plan. No more than an aggregate of 3,333,333 shares of common stock may be awarded during the twelve month period starting March 5 of each succeeding year. Awards under the 2015 Plan may include, but need not be limited to, one or more of the following: options, stock appreciation rights, restricted stock, performance grants, stock bonuses, and any other type of award deemed by the administrator to be consistent with the purposes of the 2015 Plan. The exercise price of all options awarded under the 2015 Plan must be no less than 100% of the fair market value of the Company common stock as determined on the date of the grant and have a term of no greater than ten years from the date of grant. In February 2018, the 2015 Plan was amended making available 12.5% of shares of common stock issued and outstanding. As of March 31, 2018, there were 7,363,190 shares available for grant under the 2015 Plan.

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

The 2016 Director Plan also authorized 750,000 shares for issuance. As of March 31, 2018, there were 600,000 shares available for grant under the Director Plan.

Stock Options

As of March 31, 2018, and 2017, there was approximately $9,656,000 and $13,375,000, respectively, of total unrecognized compensation related to non-vested stock options. The cost is expected to be recognized over the remaining weighted average remaining service period of 1.24 years.

During the years ended March 31, 2018 and 2017, the three months ended March 31, 2016, and the year ended December 31, 2015, approximately $7,689,334, $7,725,000, $1,137,000, and $811,000, respectively, have

been recognized as stock based compensation. During the years ended March 31, 2018 and 2017, the three months ended March 31, 2016, and the year ended December 31, 2015, approximately $4,123,000, $5,100,000, $1,137,000, and $811,000, have been recognized in general and administrative expense. During the years ended March 31, 2018 and 2017, approximately $3,566,000 and $2,625,000 have been recognized in research and development expense. There was no such expense recorded in research and development expense for the three months ended March 31, 2016 and the year ended December 31, 2015.

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.

Prior to the three months ended December 31, 2017, the Company used the full contractual term as the expected term in its Black Scholes model to estimate stock option value. The Company used the full contractual term because there was no history of exercise activity and the stock was thinly-traded on the OTC market.

Beginning October 1, 2017, the Company determined the use of the simplified method was more appropriate than the full contractual term due to the increased trading volume and activity during the quarter and the increased market and demand for shares.

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,		Three Months Ended March 31,	Year Ended December 31,
	2018	2017	2016	2015
Risk free interest rate	1.74%-2.70%	1.57%-2.49%	1.4%	1.65%
Expected volatility	65.95%-90.32%	80.74%-92.33%	79%	82.9%
Expected term	1-10 years	5-10 years	5 years	5 years
Dividend yield	0.0%	0.0%	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, 2018:

	Number of Options	Weighted Average Exercise Price
Outstanding at March 31, 2017	4,039,444	$ 6.15
Granted	1,920,120	$ 3.78
Exercised	(2,048)	$ 2.70
Forfeited/Cancelled	(519,444)	$ 8.23
Outstanding at March 31, 2018	5,438,072	$ 5.11
Options exercisable at March 31, 2018	2,891,909	$ 5.50

Weighted-average grant date fair value of options granted during the years ended March 31, 2018 and 2017, the three months ended March 31, 2016 and the year ended December 31, 2015 is $2.72, $5.34, $6.99 and $5.12, respectively.

	Stock Options Outstanding				Stock Options Vested			
Range of Exercise Price	Number Outstanding at March 31, 2018	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value	Number Vested at March 31, 2018	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value
$2.50-$8.75	5,438,072	$ 5.11	8.20	$ —	2,891,909	$ 5.50	7.78	$ —

The intrinsic value calculated as the excess of the market value of as March 31, 2018 over the exercise price of the options, is zero. The market value as of March 31, 2018 was $2.23 as reported by the NASDAQ Capital Market. The total intrinsic value of options exercised during the year ended March 31, 2018 was $7,065.

Stock Grants

On March 10, 2015, the Company adopted an independent director compensation policy and also adopted a compensation policy with respect to a special advisor to the Company's board of directors. Under such independent director compensation policy, each of those directors meeting the NASDAQ stock market definition of independent director is entitled to receive annual compensation in the amount of $100,000, one-half to be paid in cash on a quarterly basis, in arrears, and the remaining one-half of the compensation to be paid in the form of Company common stock on a quarterly basis, in arrears, with the shares valued at the closing sale price of the Company common stock on the last trading day of the applicable quarterly period. The special advisor at such time was being compensated in the same manner as the independent directors. Effective as of September 30, 2015, the Company established a Scientific and Medical Advisory Board and a compensation policy for the advisory board's members, substantially identical to the compensation policy described above in this paragraph for the Company's independent directors, was adopted. In May 2016, the Company replaced the stock component of the previous independent director compensation policy with the 2016 Director Plan and the Company likewise has determined to extend similar awards to the special advisor and members of the Scientific and Medical Advisory Board. During the fiscal year ending March 31, 2018, the Company discontinued the policy of compensating independent directors equally with the Scientific and Medical Advisory Board. On May 24, 2018, the Board approved the Restated 2016 Plan to allow different vesting schedules for non-employee directors. The Company expects to submit the Restated 2016 Plan for approval to the stockholders at the 2018 annual meeting of stockholders.

Note 11. Income Taxes.

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

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

The Company's loss before income taxes was $18,969,493, $15,206,781, $2,751,127, and $11,726,818, for the years ended March 31, 2018 and 2017, three months ended March 31, 2016, and year ended December 31, 2015, 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, 2018	March 31, 2017
Net operating loss carryforward	$ 5,736,229	$ 5,747,394
Research and development credit carryforward	410,369	310,727
Stock options - NQSOs	2,759,122	3,178,381
Accruals and other temporary differences	757,567	809,810
Gross deferred tax assets	9,663,287	10,046,312
Deferred tax valuation allowance	(9,663,287)	(10,046,312)
Net deferred taxes	$ —	$ —

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on the Company's history of operating losses since inception, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of March 31, 2018. The valuation allowance decreased by $383,025 for the year ended March 31, 2018 due primarily to stock option forfeitures and rate change.

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, 2018	Year Ended March 31, 2017	Three Months Ended March 31, 2016	Year Ended December 31, 2015
U.S. statutory income tax rate	31.5%	34%	34%	34%
State income taxes, net of federal benefit	—	—	4.9	7.9
Stock options	(7.0)	—	(14.1)	—
Permanent differences	0.6	—	—	(12.8)
Tax rate change	(27.7)	(5.4)	(21.7)	—
Provision to return true-up		7.3	15.6	8.0
R&D credit carryforwards	0.5	0.8	1.5	1.8
Valuation allowance	2.1	(36.7)	(20.2)	(38.9)
Effective tax rate	— %	— %	— %	— %

As of March 31, 2018, the Company had gross U.S. federal net operating loss carryforwards of approximately $27,300,000 net of uncertain tax positions, which may be available to offset future income tax

liabilities and will begin to expire at various dates starting in 2033. As of March 31, 2018, none of the Company's state net operating losses have value due to the apportionment rule in the states where state income tax returns are currently filed. As of March 31, 2018, the Company had gross federal research and development tax credit carryforwards of $483,000, 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 certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, as well as similar state tax provisions. This could limit the amount of NOLs that the Company can utilize annually to offset future taxable income or tax liabilities. The amount of the annual limitation, if any, will be determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has completed several financing transactions since its inception which may have resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code, or could result in a change in control in the future.

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

	Year Ended March 31,	
	2018	2017
Gross unrecognized tax benefits at beginning of year	$ 617,233	$331,545
Increases (decreases) in tax positions for current period	(148,066)	285,688
Gross unrecognized tax benefits at end of year	$ 469,167	$617,233

As of March 31, 2018, the Company had $469,167 of unrecognized tax benefits, which were offset with the net operating loss and valuation allowance on the consolidated balance sheet. None of the gross unrecognized tax benefits would affect the effective tax rate at March 31, 2018, 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 April 1, 2016 through March 31, 2017, January 1, 2016 through March 31, 2016, the years ended December 31, 2015 and 2014. 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.

On December 22, 2017, H.R. 1 (also, known as the Tax Cuts and Jobs Act (the "Act")) was signed into law. Among its numerous changes to the Internal Revenue Code, the Act reduces the U.S. federal corporate tax rate from 35% to 21%. As a result, the most significant impact on the financial statements is a reduction of approximately $3.2 million for the deferred tax assets related to net operating losses and stock based compensation. Such reduction is offset by changes to the Company's valuation allowance.

The Company has completed the accounting for the tax impact of the Act as of March 31, 2018 and has recorded no provisional amounts.

Note 12. Quarterly Information (unaudited)

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

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

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

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

Note 13. Subsequent Events.

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

On April 30, 2018 we entered into agreement to lease 4,752 square feet of office space at 17 State Street, 7 th Floor, New York, New York 10004. The lease term is 28 months and cumulative monthly rent of $566,427 has been paid in advance and held in escrow. Our costs for this space approximates $250,000 per year.

On May 24, 2018, the Board approved an amendment and restatement of the 2016 Director Plan (the " Restated 2016 Director Plan ") to increase the number of shares authorized to be issued under the plan and to permit different award structures and different vesting schedules than currently provided for in the plan. The Board expects to submit the Restated 2016 Director Plan for approval by the stockholders at the 2018 annual meeting of stockholders. In addition, the Board approved the 2018 Employee Bonuses as recommended by the Compensation Committee, which consisted of (a) a bonus of $297,000 for the Company's CEO, Steve Hoffman, and (b) a bonus pool of $870,000 to be allocated among the Company's other employees. As the amounts related to fiscal year 2018, the amounts and estimated taxes were recorded and are included in accrued bonuses as of March 31, 2018. The Board also granted authority to the CEO to grant up to 750,000 option awards under the 2015 Equity Plan to non-executive employees, with such authority expiring on March 31, 2019.

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

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

that as of March 31, 2018, our disclosure controls and procedures were not effective. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its 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 Principal Executive Officer and Principal Financial Officer have concluded that at March 31, 2018, due to the material weaknesses in our internal control over financial reporting noted below, our disclosure controls and procedures were not effective. We intend to implement remedial measures designed to address these material weaknesses.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Management assessed the effectiveness of our internal control over financial reporting as of March 31, 2018. 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, 2018, our Chief Executive Officer and Chief Financial Officer concluded that as of such date, our internal control over financial reporting was not effective due to the material weaknesses described below. A material weakness is a deficiency, or a combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be presented or detected on a timely basis.

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

The matters involving internal controls and procedures that our management considered to be material weaknesses were as follows:

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

- Inadequate journal entry review and supporting documentation.

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

Management's Remediation Initiatives

Management began implementing certain practices and procedures to address the foregoing material weaknesses with plans to complete the remediation of the foregoing deficiencies in the future. Such remediation efforts are discussed below.

Management's Actions and Plans to Remediate Material Weaknesses:

Management believes that progress has been made during the year ended March 31, 2018, and through the date of this report, to remediate the underlying causes of the material weaknesses in internal control over financial reporting and has taken the following steps to remediate such material weaknesses:

- We have recently hired a corporate controller who will provide oversight and define deliverables and responsibilities for the outside accounting and financial reporting advisory firm as well as increase our technical expertise within the accounting function.
- We have held and intend to continue to enhance our periodic meetings with our outside accounting and financial reporting advisory firm to discuss operating results, significant transactions, conclusions reached regarding technical accounting matters and financial reporting disclosures.
- We have implemented disbursement, general ledger, and human resources systems that provide key control functionality. Within these systems, we plan to modify and improve security administration and other access level and systemic controls. Where this is inherently limited, we will establish more effective compensating controls outside the system.

Management will be taking the following steps to further remediate the material weaknesses as follows:

- We will formalize processes and policies, including financial closing processes with analytical reviews and implementation of policies for ITGC. Where necessary, we will implement relevant key controls.
- We will establish a disclosure committee which will include both finance and non-finance representatives.
- We will improve processes that allow for proactive review of significant transactions, including the creation of a centralized repository for significant agreements.
- We will continue to develop processes that segregate duties consistent with control objectives.
- We will establish a periodic review by financial management of account balance detail, journal entry posting activity and account reconciling items.
- We will work with system vendors and the outside accounting and financial reporting advisory firm to create or modify reports that are relied upon in making financial and business decisions.

The material weaknesses will not be considered remediated until the applicable remedial controls operate for a sufficient period and management has concluded, through testing, that the controls are operating effectively.

Changes in Internal Control over Financial Reporting

Other than as described above under "Management Remediation Initiatives", there have been no changes in our internal control over financial reporting during our fourth fiscal quarter ended March 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Tyme Technologies, Inc.

Opinion on internal control over financial reporting

We have audited the internal control over financial reporting of Tyme Technologies, Inc. (a Delaware corporation) and subsidiaries (the " Company ") as of March 31, 2018, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (" COSO "). In our opinion, because of the effect of the material weaknesses described in the following paragraphs on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of March 31, 2018, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by COSO.

A material weakness is a deficiency, or combination of control deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in management's assessment.

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

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (" PCAOB "), the consolidated financial statements of the Company as of and for the year ended March 31, 2018. The material weaknesses identified above was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2018 consolidated financial statements, and this report does not affect our report dated June 13, 2018 which expressed an unqualified opinion on those financial statements.

Basis for opinion

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

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial

reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and limitations of internal control over financial reporting

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

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

/s/ GRANT THORNTON LLP

New York, New York
June 13, 2018

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 30, 2018 regarding our Board of Directors:

Name	Age	Position(s) with the Company/Principal Occupation	Date Elected to Our Board of Directors
Steve Hoffman	55	Director, Chief Executive Officer and Chief Science Officer of the Company	March 5, 2015*
Michael Demurjian	54	Director, Chief Operating Officer and Executive Vice President of the Company	March 5, 2015*
Dr. Gerald Sokol	75	Director/Chief of Radiation Oncology, University of South Florida's Tampa General Hospital	March 10, 2015
Timothy C. Tyson	66	Director/Chairman and Chief Executive Officer, Avara Pharmaceutical Services	March 10, 2015
Paul Sturman	57	Director/Chief Executive Officer, Nature's Bounty Co.	March 2, 2017
James Biehl	54	Director/Partner, Drinker Biddle & Reath LLP	March 30, 2017
David Carberry	65	Director/Former Chief Financial Officer of Excellis Health Solutions, LLC (Retired)	March 30, 2017
Tommy G. Thompson	76	Director/Chairman and Chief Executive Officer, Thompson Holdings	August 28, 2017**
Don DelGolyer	57	Director/Chief Executive Officer, Vertice Pharma LLC	May 24, 2018

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

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

Executive Officers

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

Other Information

Other information required by this Item 10 is incorporated by reference to, and will be contained in, our definitive proxy statement, which will be filed within 120 days after March 31, 2018.

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, 2018.

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, 2018.

The following table provides certain information with respect to all of our equity compensation plans in effect as of March 31, 2018:

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, 2018	5,438,072(1)	$ 5.11	7,963,190
Equity compensation plans not approved by stockholders prior to March 31, 2018	59,534(2)	$ 5.00	—
Total Equity	5,497,606	$ 5.11	7,963,190

(1) Includes 5,438,072 shares of our common stock issuable under option awards made prior to March 31, 2018 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 $5.11 per share. For a description of the terms of the 2015 Equity Incentive Plan and 2016 Director Plan, please see Note 10 to the consolidated financial statements presented elsewhere herein.

(2) Includes 59,534 shares of our common stock issuable upon the exercise of certain warrants to purchase common stock as of March 31, 2018 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 7,963,190 shares of our common stock issuable under awards eligible to be made (and not outstanding) as of March 31, 2018 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, 2018.

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, 2018.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) DOCUMENTS FILED AS PART OF THIS REPORT

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

1. FINANCIAL STATEMENTS AND SUPPLEMENTAL DATA

(b) EXHIBITS

See Exhibit Index.

ITEM 16. FORM 10-K SUMMARY

Omitted at the company's option.

Exhibit Number	Description
2.1	Agreement and Plan of Merger and Reorganization, dated as of March 5, 2015, by and among Tyme Technologies, Tyme Acquisition Corp., Tyme, Inc. and other signatories thereto. (Incorporated by reference to Exhibit 2.1 to our Current Report on Form 8-K, filed with the SEC on March 11, 2015.)
2.2	Agreement and Plan of Merger, dated September 12, 2014, between Global Group Enterprises Corp. and Tyme Technologies, Inc. (Incorporated by reference to Exhibit 2.1 to our Current Report on Form 8-K, filed with the SEC on September 19, 2014.)
3.1	Amended and Restated Certificate of Incorporation of Tyme Technologies, Inc. (Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K, filed with the SEC on September 19, 2014.)
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Tyme Technologies, Inc., effective April 2, 2018 (Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K, filed with the SEC on April 2, 2018.)
3.3	Amended and Restated By-Laws of Tyme Technologies, Inc., effective April 2, 2018. (Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K, filed with the SEC on April 2, 2018.)
3.4*	Amended and Restated By-Laws of Tyme Technologies, Inc., effective April 2, 2018. (marked copy.)
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.)
10.1	License Agreement, dated as of July 9, 2014, between Steven Hoffman and Tyme Inc. (Incorporated by reference to Exhibit 10.11 to our Current Report on Form 8-K, filed with the SEC on March 11, 2015.)
10.2	Equity Distribution Agreement, dated as of November 2, 2017, by and between Tyme Technologies, Inc. and Canaccord Genuity, Inc. (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on November 6, 2017.)
10.3†	2015 Equity Incentive Plan of Tyme Technologies, Inc. (Incorporated by reference to Exhibit 10.8 to our Current Report on Form 8-K, filed with the SEC on March 11, 2015.)
10.4†	Amendment No. 1 to the Tyme Technologies, Inc. 2015 Incentive Plan, effective May 6, 2016. (Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q, filed with the SEC on August 9, 2016.)
10.5†	Amendment No. 2 to the Tyme Technologies, Inc. 2015 Incentive Plan, effective February 5, 2018. (Incorporated by reference to Exhibit 99.1 to our Current Report on Form 8-K, filed with the SEC on April 2, 2018.)
10.6†	Form of Nonqualified Stock Option Agreement under the Tyme Technologies, Inc. 2015 Equity Incentive Plan. (Incorporated by reference to Exhibit 99.3 to our Current Report on Form 8-K, filed with the SEC on April 2, 2018.)
10.7†	Amended and Restated 2016 Stock Option Plan for Non-Employee Directors, effective May 24, 2018. (Incorporated by reference to Exhibit 99.2 to our Current Report on Form 8-K, filed with the SEC on May 31, 2018.)
10.8†	Form of Nonqualified Stock Option Agreement under the Tyme Technologies, Inc. 2016 Stock Option Plan for Non-Employee Directors. (Incorporated by reference to Exhibit 99.4 to our Current Report on Form 8-K, filed with the SEC on April 2, 2018.)
10.9†	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.)
10.10†	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.)
10.11†	Employment Letter Agreement, dated as of March 15, 2017, between Tyme Technologies, Inc. and Ben R. Taylor. (Incorporated by reference to Exhibit 10.11 to our Annual Report on Form 10-K filed with the SEC on June 12, 2017.)
10.12†	Option Agreement, dated as of March 27, 2017, between Tyme Technologies, Inc. and Ben R. Taylor. (Incorporated by reference to Exhibit 10.12 to our Annual Report on Form 10-K filed with the SEC on June 12, 2017.)
10.13†	Employment Letter Agreement, dated August 1, 2017, by and between Tyme Technologies, Inc. and Jonathan Eckard (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q filed with the SEC on November 2, 2017.)
21.1*	List of Subsidiaries.

23.1*	Consent of Independent Public Accounting Firm.
24.1*	Power of Attorney (Included in Signature Page of Form 10-K).
31.1*	Rule 13(a)-14(a)/15(d)-14(a) Certification of Principal Executive Officer.
31.2*	Rule 13(a)-14(a)/15(d)-14(a) Certifications of Principal Financial Officer.
32.1*	Rule 1350 Certifications.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Schema Document.
101.CAL*	XBRL Calculation Linkbase Document.
101.DEF*	XBRL Definition Linkbase Document.
101.LAB*	XBRL Label Linkbase Document.
101.PRE*	XBRL Presentation Linkbase Document.

† Management contract or compensatory plan or arrangement
* Filed herewith

SIGNATURE S

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

Dated: June 13, 2018

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

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

Signature	Title	Date
/s/ Steve Hoffman Steve Hoffman	Chief Executive Officer and Director (Principal Executive Officer)	June 13, 2018
/s/ Michael Demurjian Michael Demurjian	Chief Operating Officer and Director	June 13, 2018
/s/ Ben R. Taylor Ben R. Taylor	Chief Financial Officer and President (Principal Financial Officer and Principal Accounting Officer)	June 13, 2018
/s/ Gerald Sokol Gerald Sokol	Director	June 13, 2018
/s/ Paul L. Sturman Paul L. Sturman	Director	June 13, 2018
/s/ David Carberry David Carberry	Director	June 13, 2018
/s/ Timothy C. Tyson Timothy C. Tyson	Director	June 13, 2018
/s/ James Biehl James Biehl	Director	June 13, 2018
/s/ Tommy G. Thompson Tommy G. Thompson	Director	June 13, 2018
/s/ Donald W. DeGolyer Donald W. DeGolyer	Director	June 13, 2018

AMENDED AND RESTATED

BY-LAWS

OF

TYME TECHNOLOGIES, INC.

(Incorporated Under the Laws of the State of Delaware)

(effective April 2, 2018)

~~**BY-LAWS**~~

ARTICLE I
OFFICES

Tyme Technologies, Inc. (the "Corporation") shall maintain a registered office in the State of Delaware. The Corporation may also have other offices at such places, either within or without the State of Delaware, as the Board of Directors may from time to time designate or the business of the Corporation may require.

ARTICLE II
STOCKHOLDERS

Section 1. Place of Meetings . Meetings of the stockholders for the election of directors or for any other purpose shall be held on such date, at such time and at such place, either within or without the State of Delaware, as shall be designated from time to time by the Board of Directors and stated in the notice of the meeting or in a duly executed waiver of notice thereof. Only if so determined by the Board of Directors, in its sole discretion, (a) stockholders may, by means of remote communication, participate in a meeting of stockholders and be deemed present in person and vote thereat and/or (b) a meeting of stockholders may be held not at any place, but may instead be held solely by means of remote communication, both as provided in the General Corporation Law of the State of Delaware (the "DGCL").

Section 2. Annual Meeting . The Annual Meeting of Stockholders shall be held on such date and at such time as shall be designated from time to time by the Board of Directors and stated in the notice of the meeting, at which meeting the stockholders shall elect by a plurality vote a Board of Directors and transact only such other business as is properly brought before the meeting in accordance with these By-Laws. Notice of the Annual Meeting, stating the place (if any), date and hour of the meeting, the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, and the record date for determining the stockholders entitled to vote and to receive notice of the meeting shall be given as permitted by law to each stockholder not less than ten (10) nor more than sixty (60) days before the date of the meeting.

Section 3. Special Meetings . Unless otherwise prescribed by law or the Amended and Restated Certificate of Incorporation (such Certificate, as amended from time to time, including resolutions adopted from time to time by the Board of Directors establishing the designation, rights, preferences and other terms of any class or series of capital stock, the "Certificate of Incorporation"), special meetings of the stockholders ~~may~~ shall be called only ~~at the request of a majority~~ by, and in accordance with, the duly adopted resolution of the Board of Directors ~~by the Chairman of the Board, if any, the Chief Executive Officer, if any, or the President of the Corporation~~ . Notice of a Special Meeting stating the place (if any), date and hour of the meeting, the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, the record date for determining the stockholders entitled to vote and to receive notice of the meeting, and the purpose or purposes for which the meeting is called, shall be given not less than ten (10) nor more than sixty (60) days before the date of the meeting to each stockholder entitled to vote at such meeting. Only such business as is specified in the notice of special meeting shall come before such meeting.

Section 4. Quorum . Except as otherwise provided by law or by the Certificate of Incorporation, the holders of shares of capital stock issued and outstanding entitled to vote thereat representing at least a majority of the votes entitled to be cast thereat, present in person or represented by proxy, shall constitute a quorum at all meetings of the stockholders for the transaction of business. Whether or not a quorum is present, the chairman of the meeting, or the stockholders entitled to vote thereat, present or represented by proxy, holding shares representing at least a majority of the votes so present or represented and entitled to be cast thereon, shall have the power to adjourn the meeting from time to time, without notice other than announcement at the meeting. At such adjourned meeting at which a quorum shall be present or represented, any business may be transacted which might have been transacted at the meeting as originally noticed. If the adjournment is for more than thirty (30) days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder entitled to vote at the meeting. When a quorum is once present, it is not broken by the subsequent withdrawal of any stockholder.

Section 5. Appointment of Inspectors of Election . The Board of Directors shall, in advance of sending to the stockholders any notice of a meeting of the holders of any class of shares, appoint one or more inspectors of election ("inspectors") to act at such meeting or any adjournment or postponement thereof and make a written report thereof. The Board of Directors may designate one or more persons as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is so appointed or if no inspector or alternate is able to act, the Chairman of the Board, or if none, the Secretary shall appoint one or more inspectors to act at such meeting. Each inspector, before entering upon the discharge of such inspector's duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of such inspector's ability. The inspectors shall not be directors, officers or employees of the Corporation.

Section 6. Voting . Except as otherwise provided by law or by the Certificate of Incorporation, each stockholder of record of any class or series of stock other than the Common Stock, par value $0.0001 per share, of the Corporation ("Common Stock") shall be entitled on each matter submitted to a vote at each meeting of stockholders to such number of votes for each share of such stock as may be fixed in the Certificate of Incorporation, and each stockholder of record of Common Stock shall be entitled at each meeting of stockholders to one vote for each share of such stock, in each case, registered in such stockholder's name on the books of the Corporation on the date fixed pursuant to Section 5 of Article VI of these By-Laws as the record date for the determination of stockholders entitled to notice of and to vote at such meeting, or if no such record date shall have been so fixed, then at the close of business on the day next preceding the day on which notice of such meeting is given.

Each stockholder entitled to vote at any meeting may vote either in person or by proxy duly appointed.

At all meetings of stockholders all matters, except as otherwise provided by law, the Certificate of Incorporation or these By-Laws, shall be determined by the affirmative vote of the stockholders present in person or represented by proxy holding shares representing at least a majority of the votes so present or represented and entitled to be cast thereon, and where a separate vote by class is required, a majority of the votes represented by the shares of the stockholders of such class present in person or represented by proxy and entitled to be cast thereon shall be the act of such class. Notwithstanding the immediately preceding sentence, the Board of Directors, when establishing a matter to be voted at a meeting of stockholders, may establish a voting requirement greater than the voting requirement set forth in the immediately preceding sentence with respect to such matter.

The vote on any matter, including the election of directors, shall be by written ballot, or, if authorized by the Board of Directors, in its sole discretion, by electronic ballot given in accordance with a procedure set out in the notice of such meeting. Each ballot shall state the number of shares voted.

Proxy cards solicited by the Corporation or the Board of Directors shall be returned in envelopes addressed to the inspectors, any transfer agent with respect to capital stock of the Corporation and/or any third party, as determined from time-to-time by the Board of Directors, who shall receive, inspect and tabulate the proxies. Comments on proxies, consents or ballots shall be transcribed and provided to the Secretary with the name and address of the stockholder. Nothing in this Article II shall prohibit the inspector from making available to the Corporation, prior to, during or after any annual or special meeting, information as to which stockholders have not voted and periodic status reports on the aggregate vote.

Unless otherwise provided by law, the Certificate of Incorporation or these By-Laws, any action required to be taken at any annual or special meeting of stockholders, or any action which may be taken at any annual or special meeting of stockholders, may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing, setting forth the action so taken, shall be signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted and shall be delivered to the Corporation by delivery to its registered office in the State of Delaware, its principal place of business or an officer or agent of the Corporation having custody of the book in which proceedings of meetings of stockholders are recorded. Delivery made to the Corporation's registered office in the State of Delaware shall be by hand or by certified or registered mail, return receipt requested.

Section 7. List of Stockholders Entitled to Vote . The officer of the Corporation who has charge of the stock ledger of the Corporation shall prepare and make, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Nothing contained in this Section shall require the Corporation to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, during ordinary business hours, for a period of at least ten (10) days prior to the meeting, either (i) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (ii) during ordinary business hours, at the principal place of business of the Corporation. In the event that the Corporation determines to make the list available on an electronic network, the Corporation may take reasonable steps to ensure that such information is available only to stockholders of the Corporation. If the meeting is to be held at a place, the list shall also be produced and kept at the time and place of the meeting during the whole time thereof and may be inspected by any stockholder of the Corporation who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting at the principal place of business of the Corporation and on any reasonably accessible electronic network that the Corporation made available under this Section 7.

Section 8. Stock Ledger . The stock ledger of the Corporation shall be the only evidence as to who are the stockholders entitled to examine the stock ledger, the list required by Section 7 of this Article II or the books of the Corporation, or to vote in person or by proxy at any meeting of stockholders.

Section 9. Advance Notice of Stockholder-Proposed Business at Annual Meeting .

(a) At any Annual Meeting of Stockholders, only such business shall be conducted as shall have been properly brought before the meeting. To be properly brought before the Annual Meeting, business must be ~~either~~ (~~a~~ 1) specified in the notice of meeting (or any supplement thereto) given by or at the direction of the Board of Directors, (~~b~~ 2) otherwise properly brought before the meeting by or at the direction of the Board of Directors or (~~c~~ 3) otherwise properly brought before the meeting by a stockholder of record.

For business to be properly brought before an Annual Meeting by a stockholder, ~~the~~ (i) if such business relates to the nomination of a person for election as a director of the Corporation, the procedures in Article II, Section 10 must be complied with and (ii) if such business relates to any other matter, the business must constitute a proper matter under these By-Laws and Delaware law for stockholder action and such stockholder must (x) have given timely notice thereof in writing to the Secretary of the Corporation ~~and must have been~~ in accordance with the procedures of Section 9(b) below, (y) be a stockholder of record ~~at such time.~~ as of the date of the giving of the notice required by this Section 9 and on the record date for the determination of stockholders eligible to vote at the Annual Meeting, and (z) be entitled to vote at such Annual Meeting.

(b) To be timely, a stockholder's notice must be ~~delivered to or mailed and~~ received in writing by the Secretary of the Corporation at the principal executive offices of the Corporation not less than ninety (90) nor more than one hundred twenty (120) days prior to the one year anniversary of the date of the Annual Meeting of the previous year; provided, however, that in the event that the Annual Meeting is called for a date that is not within thirty (30) days before or after such anniversary date, or if no Annual Meeting was held in the previous year, notice by the stockholder in order to be timely must be so received not earlier than one hundred twenty (120) days prior to such Annual Meeting and not later than the close of business on the tenth (10th) day following the day on which notice of the date of the Annual Meeting was mailed or public disclosure of the date of the Annual Meeting was made, whichever first occurs. In no event shall the adjournment or postponement of an Annual Meeting (or the public disclosure thereof) commence a new time period (or extend any time period) for the giving of a stockholder notice.

A stockholder's notice to the Secretary pursuant to this Section 9 shall set forth : (A) as to each matter the stockholder proposes to bring before the Annual Meeting (~~i~~ 1) a brief description of the business desired to be brought before the Annual Meeting and the reasons for conducting such business at the Annual Meeting, ~~(ii~~ and (2) the text of the proposal (including the exact text of any resolutions proposed for consideration and, in the event that such business includes a proposal to amend the By-Laws, the exact text of the proposed amendment), and (B) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the proposal is being made (1) the name and address, as they appear on the Corporation's books, of the stockholder proposing such business and of such beneficial owner , (~~iii~~ 2) the class and number of shares of the Corporation that are ~~beneficially owned by the~~ , directly or indirectly, owned, beneficially or of record, by such stockholder and such beneficial owner, (~~iv~~ 3) a description of any material interest of ~~the~~ such stockholder ~~in such business and (v)~~ or such beneficial owner and the respective affiliates and associates of, or others acting in concert with, such stockholder or such beneficial owner in such business, (4) a description of any agreement, arrangement or understanding between or among such stockholder and/or such beneficial owner and any other person or persons (including their names) in connection with the proposal of such business or who may participate in the solicitation of proxies in favor of such proposal, (5) a description of any agreement, arrangement or understanding (including any derivative or short positions, swaps, profit interests, options, warrants, convertible securities, stock appreciation or similar rights, hedging transactions, and borrowed or loaned shares) that has been entered into by, or on behalf of, such stockholder or such beneficial owner, the effect or intent of which is to mitigate loss to, manage risk or benefit of share price changes for, or increase or decrease the voting power of, such stockholder or such beneficial owner with respect to shares of stock of the Corporation, (6) any other information relating to ~~the person or the proposal that is~~ such stockholder and such beneficial owner that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for the business proposed pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended (the "Exchange Act") (or any successor provision or law) or applicable law ~~.~~

, (7) a representation that such stockholder intends to appear in person or by proxy at the Annual Meeting to bring such business before the meeting and (8) a representation whether such stockholder and/or such beneficial owner intends or is part of a group that intends (x) to deliver a proxy statement and/or form of proxy to holders of at least the percentage of the Corporation's outstanding capital stock required to approve or adopt the proposal (and such representation shall be included in any such proxy statement and form of proxy) and/or (y) otherwise to solicit proxies or votes from stockholders in support of such proposal (and such representation shall be included in any such solicitation materials). Not later than 10 days after the record date for the meeting, the information required by Items (A)(2) and (B)(1)-(6) of the prior sentence shall be supplemented by the stockholder giving the notice to provide updated information as of the record date. Notwithstanding anything in these By-Laws to the contrary, no business shall be conducted at ~~an~~ any Annual Meeting of stockholders except in accordance with the procedures ~~set forth~~ in this Section 9 ~~; provided, however, that nothing in this Section 9 shall be deemed to preclude discussion by any stockholder of any business properly brought before the Annual Meeting.~~ ; provided that any stockholder proposal that complies with Rule 14a-8 of the proxy rules (or any successor provision) promulgated under the Exchange Act and is to be included in the corporation's proxy statement for an Annual Meeting of stockholders shall be deemed to comply with the notice requirements of this Section 9(b). A stockholder shall not have complied with this Section 9(b) if the stockholder (or beneficial owner, if any, on whose behalf the proposal is made) solicits or does not solicit, as the case may be, proxies in support of such stockholder's proposal in contravention of the representations with respect thereto required by this Section 9.

(c) The Chairman of an Annual Meeting shall, if the facts warrant, determine and declare to the meeting that business was not properly brought before the meeting in accordance with the provisions of this Section 9 and if he should so determine, he shall so declare to the meeting and any such business not properly brought before the meeting shall not be transacted.

(d) Except as otherwise required by law, nothing in this Section 9 shall obligate the Corporation or Board of Directors to include in any proxy statement or other stockholder communication distributed on behalf of the Corporation or the Board of Directors information with respect to any proposal submitted by a stockholder.

(e) Notwithstanding the foregoing provisions of this Section 9, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) does not appear at the Annual Meeting to present business, such business shall not be considered, notwithstanding that proxies in respect of such business may have been received by the Corporation.

(f) For purposes of this Section 9, to be considered a "qualified representative of the stockholder," a person must be authorized by a written instrument executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting of stockholders and such person must produce such written instrument or electronic transmission, or a reliable reproduction of the written instrument or electronic transmission, at the meeting of stockholders.

(g) For purposes of this Section 9, "public disclosure" shall include disclosure in a press release reported by the Dow Jones News Service, Associated Press or comparable national news service or in a document publicly filed by the corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Exchange Act.

Section 10. Nomination of Directors; Advance Notice of Stockholder Nominations . ~~Only~~

(a) Except for persons elected in accordance with Article III, Section 2 of these By-Laws to fill a vacancy or newly created directorship, only persons who are nominated in accordance with the procedures set forth in this Section 10 shall be eligible for election as directors at a meeting of stockholders. Nominations of persons for election to the Board of Directors of the Corporation at the Annual Meeting or at any special meeting of stockholders called in the manner set forth in Article II, Section 3 hereof for the purpose of electing directors may be made ~~at a meeting of stockholders~~ (i) by or at the direction of the Board of Directors, (ii) by any nominating committee or person appointed for such purpose by the Board of Directors, or (iii) by any stockholder of record of the Corporation ~~entitled to vote for the election of directors at the meeting who~~ who (x) timely complies with the notice procedures ~~set forth in this Section 10. Such nominations, other than those made by, or at the direction of, or under the authority of the Board of Directors, shall be made pursuant to timely notice in writing to the Secretary of the Corporation by~~ in accordance with Section 10(b) below, (y) is a stockholder of record ~~at such time.~~ as of the date of the giving of the notice required by Section 10 below and on the record date for determination of the stockholders eligible to vote at such meeting, and (z) is entitled to vote at such meeting.

(b) To be timely, a stockholder's notice ~~shall be delivered to or mailed and~~ pursuant to this Section 10 must be received in writing by the Secretary of the Corporation at the principal executive offices of the Corporation ~~(a~~ as follows: (i) in the case of an Annual Meeting, not less than ninety (90) nor more than one hundred twenty (120) days prior to the one year anniversary of the date of the Annual Meeting of the previous year; provided, however, that in the event that the Annual Meeting is called for a date that is not within thirty (30) days before or after such anniversary date, or if no Annual Meeting was held in the previous year, notice by the stockholder in order to be timely must be so received not earlier than one hundred twenty (120) days prior to such Annual Meeting and not later than the close of business on the tenth (10th) day following the day on which notice of the date of the annual meeting was mailed or public disclosure of the date of the Annual Meeting was made, whichever first occurs; ~~and~~ or (~~b~~ ii) in the case of a special meeting of stockholders called in the manner set forth in Article II, Section 3 hereof for the purpose of electing directors, not earlier than one hundred twenty (120) days prior to such special meeting and not later than the close of business on the tenth (10th) day following the day on which notice of the date of the special meeting was mailed or public disclosure of the date of the special meeting was made, whichever first occurs. In no event shall the adjournment or postponement of a meeting (or the public disclosure thereof) commence a new time period (or extend any time period) for the giving of a stockholder notice.

~~Such stockholder's notice to the Secretary shall set forth (a) as to each person whom the stockholder proposes to nominate for election or re-election as a director, (i) the name, age, business address and residence address of the person, (ii) the principal occupation or employment of the person, (iii) the class and number of shares of capital stock of the Corporation, if any, which are beneficially owned by the person and (iv) any other information relating to the person that is required to be disclosed in solicitations for proxies for election of directors pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended (or any successor provision or law) or applicable law; and (b) as to the stockholder giving the notice (i) the name and record address of the stockholder and (ii) the class and number of shares of capital stock of the Corporation which are beneficially owned by the stockholder.~~

The stockholder's notice to the Secretary shall set forth: (A) as to each proposed nominee (1) such person's name, age, business address and, if known, residence address, (2) such person's principal occupation or employment, (3) the class and number of shares of the Corporation that are, directly or indirectly, owned, beneficially or of record, by such person, (4) a description of all direct and indirect compensation and other material monetary agreements, arrangements and understandings during the past three years, and any other material relationships, between or among (x) the stockholder, the beneficial owner, if any, on whose behalf the nomination is being made and the respective affiliates and associates of, or others acting in concert with, such stockholder and such beneficial owner, on the one hand, and (y) each proposed nominee, and his or her respective affiliates and associates, or others acting in concert with such nominee(s), on the other hand, including all information that would be required to be disclosed pursuant to Item 404 of Regulation S-K if the stockholder making the nomination and any beneficial owner on whose behalf the nomination is made or any affiliate or associate thereof or person acting in concert therewith were the "registrant" for purposes of such Item and the proposed nominee were a director or executive officer of such registrant, and (5) any other information relating to the person that is required to be disclosed in solicitations for proxies for election of directors pursuant to Regulation 14A under the Exchange Act (or any successor provision or law) or applicable law and (B) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination is being made (1) the name and address of such stockholder, as they appear on the Corporation's books, and of such beneficial owner, (2) the class and number of shares of the Corporation that are, directly or indirectly, owned, beneficially or of record, by such stockholder and such beneficial owner, (3) a description of any agreement, arrangement or understanding between or among such stockholder and/or such beneficial owner and each proposed nominee and any other person or persons (including their names) pursuant to which the nomination(s) are being made or who may participate in the solicitation of proxies in favor of electing such nominee(s), (4) a description of any agreement, arrangement or understanding (including any derivative or short positions, swaps, profit interests, options, warrants, convertible securities, stock appreciation or similar rights, hedging transactions, and borrowed or loaned shares) that has been entered into by, or on behalf of, such stockholder or such beneficial owner, the effect or intent of which is to mitigate loss to, manage risk or benefit of share price changes for, or increase or decrease the voting power of, such stockholder or such beneficial owner with respect to shares of stock of the Corporation, (5) any other information relating to such stockholder and such beneficial owner that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for the business proposed pursuant to Regulation 14A under the Exchange Act (or any successor provision or law) or applicable law, (6) a representation that such stockholder intends to appear in person or by proxy at the meeting to nominate the person(s) named in its notice and (7) a representation whether such stockholder and/or such beneficial owner intends or is part of a group that intends (x) to deliver a proxy statement and/or form of proxy to holders of at least the percentage of the Corporation's outstanding capital stock reasonably believed by such stockholder or such beneficial owner to be sufficient to elect the nominee (and such representation shall be included in any such proxy statement and form of proxy) and/or (y) otherwise to solicit proxies or votes from stockholders in support of such nomination (and such representation shall be included in any such solicitation materials). Not later than 10 days after the record date for the meeting, the information required by Items (A)(1)-(5) and (B)(1)-(5) of the prior sentence shall be supplemented by the stockholder giving the notice to provide updated information as of the record date. In addition, to be effective, the stockholder's notice must be accompanied by the written consent of the proposed nominee to serve as a director if elected. The Corporation may require any proposed nominee to furnish such other information as the Corporation may reasonably require to determine the eligibility of such proposed nominee to serve as a director of the Corporation or whether such nominee would be independent under applicable Securities and Exchange Commission and NASDAQ rules and the Corporation's publicly disclosed corporate governance guidelines, if applicable. A stockholder shall not have complied with this Section 10(b) if the stockholder (or beneficial owner, if any, on whose behalf the nomination is made) solicits or does not solicit, as the case may be, proxies or votes in support of such stockholder's nominee in contravention of the representations with respect thereto required by this Section 10.

(c) The Chairman of the meeting shall, if the facts warrant, determine and declare to the meeting that a nomination was not made in accordance with the foregoing procedures and, if he should so determine, he shall so declare to the meeting and the defective nomination shall be disregarded.

(d) Except as otherwise required by law, nothing in this Section 10 shall obligate the Corporation or Board of Directors to include in any proxy statement or other stockholder communication distributed on behalf of the Corporation or the Board of Directors information with respect to any nominee for director submitted by a stockholder.

(e) Notwithstanding the foregoing provisions of this Section 10, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) does not appear at the meeting to present a nomination, such nomination shall not be considered, notwithstanding that proxies in respect of such nomination may have been received by the Corporation.

(f) For purposes of this Section 10, the terms "qualified representative of the stockholder" and "public disclosure" shall have the same meaning as in Section 9.

ARTICLE III
DIRECTORS

Section 1. Number; Resignation; Removal. Except as otherwise required by the Certificate of Incorporation, the number of directors ~~which~~ that shall constitute the whole Board of Directors shall be fixed from time to time by resolution of the Board of Directors ~~, but shall not be less than one (1) nor more than eleven (11). Except as provided in Section 2 of this Article III and in the Certificate of Incorporation, a~~ in its sole discretion. A nominee for director shall be elected to the Board of Directors ~~by a plurality of the votes cast at the Annual Meeting of Stockholders~~ in accordance with the Certificate of Incorporation. ~~A~~ director may resign at any time upon notice to the Corporation. A director may be removed ~~, with or without cause, by the affirmative vote of holders of shares of capital stock issued and outstanding entitled to vote at an election of directors representing at least a majority of the votes entitled~~ in accordance with the Certificate of Incorporation.
~~to be cast thereon.~~

Section 2. Vacancies. Vacancies on the Board of Directors by reason of death, resignation, retirement, disqualification, removal from office or otherwise, and newly created directorships resulting from any increase in the authorized number of directors ~~may be filled by a majority of the remaining directors then in office, though less than a quorum, or by a sole remaining director, and the directors so elected shall hold office until the next Annual Meeting of Stockholders and until their successors are duly elected and qualified, or until their earlier resignation or removal. If there are no directors in office, then an election of directors may be held in the manner provided by~~ shall be solely and exclusively filed, and such directors shall serve on the Board of Directors, in accordance with the Certificate of Incorporation and the DGCL. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

Section 3. Duties and Powers. The business of the Corporation shall be managed by or under the direction of the Board of Directors which may exercise all such powers of the Corporation and do all such lawful acts and things as are not by statute or by the Certificate of Incorporation or by these By-Laws directed or required to be exercised or done solely by the stockholders.

Section 4. Meetings. The Board of Directors of the Corporation may hold meetings, both regular and special, either within or without the State of Delaware. Regular meetings of the Board of Directors may be held without notice at such time and at such place as may from time to time be determined by the Board of Directors. Special meetings of the Board of Directors may be called by the Chairman of the Board, the Chief Executive Officer, the President(s) or any director. Notice thereof stating the place, date and hour of the meeting shall be given to each director either (i) by mail or courier not less than forty-eight (48) hours before the date of the meeting or (ii) by telephone, telegram or facsimile or electronic transmission, not less than twenty-four (24) hours before the time of the meeting (provided that notice of any meeting need not be given to any director who shall either submit, before or after such meeting, a waiver of notice or attend the meeting without protesting, at the beginning thereof, the lack of notice).

Section 5. Quorum . Except as may be otherwise provided by law, the Certificate of Incorporation or these By- Laws, a majority of the entire Board of Directors shall be necessary to constitute a quorum for the transaction of business, and the vote of a majority of the directors present at a meeting at which a quorum is present shall be the act of the Board of Directors. Whether or not a quorum is present at a meeting of the Board of Directors, a majority of the directors present may adjourn the meeting to such time and place as they may determine without notice other than an announcement at the meeting.

Section 6. Action Without a Meeting . Unless otherwise provided by the Certificate of Incorporation or these By- Laws, any action required or permitted to be taken by the Board of Directors or any committee thereof may be taken without a meeting if all members of the Board of Directors or the committee consent in writing or by electronic transmission to the adoption of a resolution authorizing the action. The resolution and the consents thereto in writing or by electronic transmission by the members of the Board of Directors or committee shall be filed with the minutes of the proceedings of the Board of Directors or such committee.

Section 7. Participation by Telephone . Unless otherwise provided by the Certificate of Incorporation or these By- Laws, any one or more members of the Board of Directors or any committee thereof may participate in a meeting of the Board of Directors or such committee 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.

Section 8. Compensation . The directors may be paid their expenses, if any, for attendance at each meeting of the Board of Directors or any committee thereof and may be paid compensation as a director, committee member or chairman of any committee and for attendance at each meeting of the Board of Directors or committee thereof and each meeting of stockholders of the Corporation. No such payment shall preclude any director from serving the Corporation in any other capacity and receiving compensation therefore or entering into transactions otherwise permitted by the Certificate of Incorporation, these By-Laws or applicable law.

Section 9. Resignation . Any director may resign at any time. Such resignation shall be made in writing or by electronic transmission and shall take effect at the time specified therein, or, if no time be specified, at the time of its receipt by the Chairman of the Board, if any, the Chief Executive Officer, if any, the President or the Secretary. The acceptance of a resignation shall not be necessary to make it effective unless so specified therein.

ARTICLE IV
COMMITTEES

Section 1. Committees . The Board of Directors may designate one or more committees, each committee to consist of one or more of the directors of the Corporation. The Board of Directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of any such committee. Any committee, to the extent allowed by law and provided in the resolution establishing such committee or in these By-Laws, shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the Corporation, including the power to adopt a certificate of ownership and merger pursuant to Section 253 of the Delaware General Corporation Law, the authority to issue shares, and the authority to declare a dividend, except as limited by Delaware General Corporation Law or other applicable law, but no such committee shall have the power or authority in reference to the following matters:

(i) approving or adopting, or recommending to the stockholders, any action or matter expressly required by the Delaware General Corporation Law to be submitted to stockholders for approval or (ii) adopting, amending or repealing any By-Law of the Corporation. All acts done by any committee within the scope of its powers and duties pursuant to these By-Laws and the resolutions adopted by the Board of Directors shall be deemed to be, and may be certified as being, done or conferred under authority of the Board of Directors. The Secretary or any Assistant Secretary is empowered to certify that any resolution duly adopted by any such committee is binding upon the Corporation and to execute and deliver such certifications from time to time as may be necessary or proper to the conduct of the business of the Corporation.

Section 2. Resignation . Any member of a committee may resign at any time. Such resignation shall be made in writing or by electronic transmission and shall take effect at the time specified therein, or, if no time be specified, at the time of its receipt by the Chairman of the Board, or if none, by the Chief Executive Officer, President(s) or the Secretary.

The acceptance of a resignation shall not be necessary to make it effective unless so specified therein.

Section 3. Quorum . A majority of the members of a committee shall constitute a quorum. The vote of a majority of the members of a committee present at any meeting at which a quorum is present shall be the act of such committee.

Section 4. Record of Proceedings . Each committee shall keep a record of its acts and proceedings, and shall report the same to the Board of Directors when and as required by the Board of Directors.

Section 5. Organization, Meetings, Notices . A committee may hold its meetings at the principal office of the Corporation, or at any other place upon which a majority of the committee may at any time agree. Each committee may make such rules as it may deem expedient for the regulation and carrying on of its meetings and proceedings.

ARTICLE V
OFFICERS

Section 1. Genera l. The officers of the Corporation shall be elected by the Board of Directors and shall consist of a President, a Secretary and a Treasurer. The Board of Directors, in its discretion, may also elect and specifically identify as officers of the Corporation a Chairman of the Board, a Chief Executive Officer, a Chief Financial Officer, a Controller, one or more vice presidents, assistant secretaries and assistant treasurers, and such other officers and agents as in its judgment may be necessary or desirable. Any number of offices may be held by the same person, unless otherwise prohibited by law, the Certificate of Incorporation or these By-Laws. The officers of the Corporation need not be stockholders or directors of the Corporation. Any office named or provided for in this Article V (including, without limitation, Chairman of the Board, Chief Executive Officer, Chief Financial Officer, President, Secretary, Treasurer and Controller) may, at any time and from time to time, be held by one or more persons. Unless otherwise determined by the Board of Directors, if an office is held by more than one person, each person holding such office shall serve as a co-officer (with the appropriate corresponding title) and shall have general authority, individually and without the need for any action by any other co-officer, to exercise all the powers of the holder of such office of the Corporation specified in these By- Laws and shall perform such other duties and have such other powers as may be prescribed by the Board of Directors or such other officer specified in this Article V.

Section 2. Election; Removal; Remuneration . The Board of Directors at its first meeting held after each Annual Meeting of Stockholders shall elect the officers of the Corporation who shall hold their offices for such terms and shall exercise such powers and perform such duties as shall be determined from time to time by the Board of Directors and may elect additional officers and may fill vacancies among the officers previously elected at any subsequent meeting of the Board of Directors; and all officers of the Corporation shall hold office until their successors are chosen and qualified, or until their earlier resignation or removal. Any officer elected by the Board of Directors may be removed at any time, either for or without cause, by the affirmative vote of a majority of the Board of Directors.

Section 3. Voting Securities Owned by the Corporation . Powers of attorney, proxies, waivers of notice of meetings, consents and other instruments relating to securities owned by the Corporation may be executed in the name of and on behalf of the Corporation by the Chairman of the Board, if any, the Chief Executive Officer, if any, the President or the Secretary, and any such officer may, in the name and on behalf of the Corporation, take all such action as any such officer may deem advisable to vote in person or by proxy at any meeting of security holders of any corporation, company, partnership or other entity in which the Corporation may own securities, or to execute written consents in lieu thereof, and at any such meeting, or in giving any such consent, shall possess and may exercise any and all rights and powers incident to the ownership of such securities and which, as the owner thereof, the Corporation might have exercised and possessed if present. The Board of Directors may, by resolution, from time to time confer like powers upon any other person or persons.

Section 4. Chairman of the Board . The Chairman of the Board, if any, may be, but need not be, a person other than the Chief Executive Officer or the President of the Corporation. The Chairman of the Board may be, but need not be, an officer or employee of the Corporation. The Chairman of the Board shall preside at meetings of the Board of Directors and shall establish agendas for such meetings. In addition, the Chairman of the Board shall assure that matters of significant interest to stockholders and the investment community are addressed by management.

Section 5. Chief Executive Officer . The Chief Executive Officer, if any, shall, subject to the direction of the Board of Directors, have general and active control of the affairs and business of the Corporation and general supervision of its officers, officials, employees and agents. The Chief Executive Officer shall preside at all meetings of the stockholders and shall preside at all meetings of the Board of Directors and any committee thereof of which he is a member, unless the Board of Directors or such committee shall have chosen another chairman. The Chief Executive Officer shall see that all orders and resolutions of the Board are carried into effect, and in addition, the Chief Executive Officer shall have all the powers and perform all the duties generally appertaining to the office of the chief executive officer of a corporation. The Chief Executive Officer shall designate the person or persons who shall exercise his powers and perform his duties in his absence or disability and the absence or disability of the President.

Section 6. Presiden t. The President shall have such powers and perform such duties as are prescribed by the Chief Executive Officer or the Board of Directors, and in the absence or disability of the Chief Executive Officer, the President shall have the powers and perform the duties of the Chief Executive Officer, except to the extent the Board of Directors shall have otherwise provided. In addition, the President shall have such powers and perform such duties generally appertaining to the office of the president of a corporation, except to the extent the Chief Executive Officer, if any, or the Board of Directors shall have otherwise provided.

Section 7. Vice Presiden t. The Vice Presidents of the Corporation shall perform such duties and have such powers as may, from time to time, be assigned to them by the Board of Directors, the Chief Executive Officer, if any, the President or these By-Laws.

Section 8. Secretary . Unless otherwise determined by the Board of Directors, the Secretary shall attend all meetings of the Board of Directors and of the stockholders and, unless the Board of Directors appoints another person to perform such service(s), record all votes and the minutes of all proceedings in a book to be kept for that purpose, and shall perform like duties for any committee appointed by the Board of Directors. The Secretary shall keep in safe custody the seal of the Corporation and affix it to any instrument when so authorized by the Board of Directors. The Secretary shall give or cause to be given, notice of all meetings of stockholders and special meetings of the Board of Directors and shall perform generally all the duties usually appertaining to the office of secretary of a corporation and shall perform such other duties and have such other powers as may be prescribed by the Board of Directors or these By-Laws. The Board of Directors may give general authority to any other officer to affix the seal of the Corporation and to attest the affixing by his signature.

Section 9. Assistant Secretary . The Assistant Secretary shall be empowered and authorized to perform all of the duties of the Secretary in the absence or disability of the Secretary and shall perform such other duties and have such other powers as may be prescribed by the Board of Directors, the Secretary or these By-Laws.

Section 10. Chief Financial Office r. The Chief Financial Officer, if any, shall have responsibility for the administration of the financial affairs of the Corporation and shall exercise supervisory responsibility for the performance of the duties of the Treasurer and the Controller, if any. The Chief Financial Officer shall render to the Board of Directors, at its regular meetings, or when the Board of Directors so requires, an account of all of the transactions effected by the Treasurer and the Controller and of the financial condition of the Corporation. The Chief Financial Officer shall generally perform all the duties usually appertaining to the affairs of a chief financial officer of a corporation and shall perform such other duties and have such other powers as may be prescribed by the Board of Directors or these By-Laws.

Section 11. Treasurer . The Treasurer shall have the custody of the corporate funds and securities and shall cause to be kept full and accurate accounts of receipts and disbursements in books belonging to the Corporation and shall deposit all monies and other valuable effects in the name and to the credit of the Corporation in such depositories as may be designated by persons authorized by the Board of Directors. The Treasurer shall disburse the funds of the Corporation as may be ordered by the Board of Directors, taking proper vouchers for such disbursements, and shall render to the Chairman of the Board, if any, the Chief Executive Officer, if any, the President and the Board of Directors whenever they may require it, an account of all of the transactions effected by the Treasurer and of the financial condition of the Corporation. The Treasurer shall generally perform all duties appertaining to the office of treasurer of a corporation and shall perform such other duties and have such other powers as may be prescribed by the Board of Directors, the Chief Executive Officer, if any, the President or these By-Laws.

Section 12. Assistant Treasurer . The Assistant Treasurers shall be empowered and authorized to perform all the duties of the Treasurer in the absence or disability of the Treasurer and shall perform such other duties and have such other powers as may be prescribed by the Board of Directors, the Treasurer or these By-Laws.

Section 13. Controller . The Controller, if any, shall prepare and have the care and custody of the books of account of the Corporation. The Controller shall keep a full and accurate account of all monies, received and paid on account of the Corporation, and shall render a statement of the Controller's accounts whenever the Board of Directors shall require. The Controller shall generally perform all the duties usually appertaining to the affairs of the controller of a corporation and shall perform such other duties and have such other powers as may be prescribed by the Board of Directors, the Chief Financial Officer, if any, the President or these By-Laws.

Section 14. Additional Powers and Duties . In addition to the foregoing especially enumerated duties and powers, the several officers of the Corporation shall perform such other duties and exercise such further powers as the Board of Directors may, from time to time, determine or as may be assigned to them by any superior officer.

Section 15. Other Officers . The Board of Directors may designate such other officers having such duties and powers as it may specify from time to time.

ARTICLE VI
CAPITAL STOCK

Section 1. Form of Certificate; Uncertificated Shares. The shares of the Corporation shall be represented by certificates, provided that the Board of Directors may provide by resolution or resolutions that some or all of any or all classes or series of its stock may be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the Corporation. Every holder of stock in the Corporation represented by a certificate shall be entitled to have a certificate signed in the name of the Corporation (i) by the Chairman of the Board, if any, the Chief Executive Officer, if any, the President or any Vice President and (ii) by the Treasurer or an Assistant Treasurer or the Secretary or an Assistant Secretary, representing the number of shares registered in certificate form. Except as otherwise provided by law or these By-Laws, the rights and obligations of the holders of uncertificated shares and the rights and obligations of the holders of certificates representing stock of the same class and series shall be identical.

Section 2. Signatures. Any signature required to be on a certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if he were such officer, transfer agent or registrar at the date of issue.

Section 3. Lost, Stolen or Destroyed Certificates. The Board of Directors may direct a new certificate to be issued in place of any certificate theretofore issued by the Corporation alleged to have been lost, stolen or destroyed, upon the making of an affidavit of that fact by the person claiming the certificate of stock to be lost, stolen or destroyed. When authorizing such issue of a new certificate, the Board of Directors may, in its discretion and as a condition precedent to the issuance thereof, require the owner of such lost, stolen or destroyed certificate, or his legal representative, to advertise the same in such manner as the Board of Directors shall require and/or to give the Corporation and/or its transfer agent a bond in such sum as it may direct as indemnity against any claim that may be made against the Corporation with respect to the certificate alleged to have been lost, stolen or destroyed.

Section 4. Transfers. Stock of the Corporation shall be transferable in the manner prescribed by law and in these By-Laws. Transfers of stock shall be made on the books of the Corporation only by the holder of record or by such person's attorney duly authorized, and upon the surrender of properly endorsed certificates for a like number of shares (or, with respect to uncertificated shares, by delivery of duly executed instructions or in any other manner permitted by applicable law).

Section 5. Record Date. In order that the Corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, or entitled to express consent to corporate action, or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board of Directors may fix, in advance, a record date, which shall not be more than sixty (60) days nor less than ten (10) days before the date of such meeting, nor more than sixty (60) days prior to any other action. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board of Directors may fix a new record date for the adjourned meeting.

Section 6. Beneficial Owners . The Corporation shall be entitled to recognize the exclusive right of the person registered on its books as the owner of a share to receive dividends and to vote as such owner, and to hold liable for calls and assessments a person registered on its books as the owner of shares, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of any other person, whether or not it shall have express or other notice thereof, except as otherwise provided by law.

Section 7. Dividends . Subject to the provisions of the Certificate of Incorporation or applicable law, dividends upon the capital stock of the Corporation, if any, may be declared by the Board of Directors at any regular or special meeting, and may be paid in cash, in property, or in shares of capital stock. Before payment of any dividend, there may be set aside out of any funds of the Corporation available for dividends such sum or sums as the Board of Directors from time to time, in its absolute discretion, deems proper as a reserve or reserves to meet contingencies, or for equalizing dividends, or for repairing or maintaining any property of the Corporation or for any proper purpose, and the Board of Directors may modify or abolish any such reserve.

Section 8. Common Stock . The voting, dividend and liquidation rights of the holders of shares of Common Stock are subject to, and qualified by, the rights of the holders of the preferred stock, if any, of the Corporation. Each share of Common Stock shall be treated identically as all other shares of Common Stock with respect to dividends, distributions, rights in liquidation and in all other respects.

ARTICLE VII
INDEMNIFICATION

Section 1. Indemnification Respecting Third Party Claims . The Corporation, to the full extent and in a manner permitted by Delaware law as in effect from time to time, shall indemnify, in accordance with the provisions of this Article, any person (including the heirs, executors, administrators or estate of any such person) who was or is made a party to or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding (including any appeal thereof), whether civil, criminal, administrative, or investigative (other than an action by or in the right of the Corporation or by any corporation, limited liability company, partnership, joint venture, trust, employee benefit plan or other enterprise of which the Corporation owns, directly or indirectly through one or more other entities, a majority of the voting power or otherwise possesses a similar degree of control), by reason of the fact that such person is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, member, manager, partner, trustee, fiduciary, employee or agent (a "Subsidiary Officer") of another corporation, limited liability company, partnership, joint venture, trust, employee benefit plan or other enterprise (any such entity for which a Subsidiary Officer so serves, an "Associated Entity"), against expenses, including attorneys' fees and disbursements, judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the Corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful; *provided, however* , that (i) the Corporation shall not be obligated to indemnify a person who is or was a director, officer employee or agent of the Corporation or a Subsidiary Officer of an Associated Entity against expenses incurred in connection with an action, suit, proceeding or investigation to which such person is threatened to be made a party but does not become a party unless the incurring of such expenses was authorized by or under the authority of the Board of Directors and (ii) the Corporation shall not be obligated to indemnify against any amount paid in settlement unless the Board of Directors has consented to such settlement.

The termination of any action, suit or proceeding by judgment, order, settlement or conviction or upon a plea of nolo contendere or its equivalent shall not, of itself, create a presumption that the person did not act in good faith and in a manner which such person reasonably believed to be in or not opposed to the best interests of the Corporation, and, with respect to any criminal action or proceeding, that such person had reasonable cause to believe that his conduct was unlawful. Notwithstanding anything to the contrary in the foregoing provisions of this Section 1, a person shall not be entitled, as a matter of right, to indemnification pursuant to this Section 1 against costs or expenses incurred in connection with any action, suit or proceeding commenced by such person against the Corporation or any Associated Entity or any person who is or was a director, officer, fiduciary, employee or agent of the Corporation or a Subsidiary Officer of any Associated Entity (including, without limitation, any action, suit or proceeding commenced by such person to enforce such person's rights under this Article, unless and only to the extent that such person is successful on the merits of such claim), but such indemnification may be provided by the Corporation in a specific case as permitted by Section 7 below in this Article.

Section 2. Indemnification Respecting Derivative Claims . The Corporation, to the full extent and in a manner permitted by Delaware law as in effect from time to time, shall indemnify, in accordance with the provisions of this Article, any person (including the heirs, executors, administrators or estate of any such person) who was or is made a party to or is threatened to be made a party to any threatened, pending or completed action or suit (including any appeal thereof) brought in the right of the Corporation to procure a judgment in its favor by reason of the fact that such person is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a Subsidiary Officer of an Associated Entity, against expenses (including attorneys' fees and disbursements) and costs actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the Corporation, except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the Corporation unless, and only to the extent that, the Delaware Court of Chancery or the court in which such action or suit was brought shall determine that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses and costs as the Court of Chancery or such other court shall deem proper; provided, however, that the Corporation shall not be obligated to indemnify a director, officer, employee or agent of the Corporation or a Subsidiary Officer of an Associated Entity against expenses incurred in connection with an action or suit to which such person is threatened to be made a party but does not become a party unless the incurrence of such expenses was authorized by or under the authority of the Board of Directors. Notwithstanding anything to the contrary in the foregoing provisions of this Section 2, a person shall not be entitled, as a matter of right, to indemnification pursuant to this Section 2 against costs and expenses incurred in connection with any action or suit in the right of the Corporation commenced by such person, but such indemnification may be provided by the Corporation in any specific case as permitted by Section 7 below in this Article.

Section 3. Determination of Entitlement to Indemnification . Any indemnification to be provided under either of Section 1 or 2 above in this Article (unless ordered by a court of competent jurisdiction or advanced as provided in Section 5 of this Article) shall be made by the Corporation only as authorized in the specific case upon a determination that indemnification is proper under the circumstances because the person to be indemnified had met the applicable standard of conduct set forth in such section of this Article. Such determination shall be made, with respect to a person who is a director or officer of the Corporation at the time of such determination, (i) by a majority vote of the directors who are not parties to the action, suit or proceeding in respect of which indemnification is sought, even though less than a quorum, or (ii) by majority vote of the members of a committee composed of at least two directors each of whom is not a party to such action, suit or proceeding, designated by majority vote of directors who are not parties to such action, suit or proceeding, even though less than a quorum, or (iii) if there are no directors who are not parties to such action, suit or proceeding, or if such directors so direct, by independent legal counsel in a written opinion, or (iv) by action of the stockholders taken as permitted by law and these By-Laws.

Such determination shall be made, with respect to any other person, by such officer or officers of the Corporation as the Board of Directors or the Executive Committee (if any) of the Board may designate, in accordance with any procedures that the Board of Directors, the Executive Committee or such designated officer or officers may determine, or, if any such officer or officers have not been so designated, by the Chief Legal Officer or the General Counsel of the Corporation. In the event a request for indemnification is made by any person referred to in Section 1 or 2 above in this Article, the Corporation shall use its reasonable best efforts to cause such determination to be made not later than sixty (60) days after such request is made after the final disposition of such action, suit or proceeding.

Section 4. Right to Indemnification upon Successful Defense and for Service as a Witness . (a) Notwithstanding the other provisions of this Article, to the extent that a present or former director or officer has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in either of Section 1 or 2 above in this Article, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees and disbursements) and costs actually and reasonably incurred by such person in connection therewith.

(b) To the extent any person who is or was a director, officer, employee or agent of the Corporation or a Subsidiary Officer of an Associated Entity has served or prepared to serve as a witness in, but is not a party to, any action, suit or proceeding (whether civil, criminal, administrative, regulatory or investigative in nature), including any investigation by any legislative or regulatory body or by any securities or commodities exchange of which the Corporation or an Associated Entity is a member or to the jurisdiction of which it is subject, by reason of his or her services as a director, officer, employee or agent of the Corporation, or his or her service as a Subsidiary Officer of an Associated Entity (assuming such person is or was serving at the request of the Corporation as a Subsidiary Officer of such Associated Entity), the Corporation may indemnify such person against expenses (including attorneys' fees and disbursements) and out-of-pocket costs actually and reasonably incurred by such person in connection therewith and, if the Corporation has determined to so indemnify such person, shall use its reasonable best efforts to provide such indemnity within sixty (60) days after receipt by the Corporation from such person of a statement requesting such indemnification, averring such service and reasonably evidencing such expenses and costs; it being understood, however, that the Corporation shall have no obligation under this Article to compensate such person for such person's time or efforts so expended.

Section 5. Advance of Expenses . (a) Expenses and costs incurred by any present or former director or officer of the Corporation in defending a civil, criminal, administrative, regulatory or investigative action, suit or proceeding shall, to the extent permitted by law, be paid by the Corporation in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking in writing by or on behalf of such person to repay such amount if it shall ultimately be determined that such person is not entitled to be indemnified in respect of such costs and expenses by the Corporation as authorized by this Article.

(b) Expenses and costs incurred by any other person referred to in Section 1 or 2 above in this Article in defending a civil, criminal, administrative, regulatory or investigative action, suit or proceeding may be paid by the Corporation in advance of the final disposition of such action, suit or proceeding as authorized by or under the authority of the Board of Directors upon receipt of an undertaking in writing by or on behalf of such person to repay such amount if it shall ultimately be determined that such person is not entitled to be indemnified by the Corporation in respect of such costs and expenses as authorized by this Article and subject to any limitations or qualifications provided by or under the authority of the Board of Directors.

Section 6. Notice of Action; Assumption of the Defense . Promptly after receipt by any person referred to in Section 1, 2 or 5 above in this Article of notice of the commencement of any action, suit or proceeding in respect of which indemnification or advancement of expenses may be sought under any such Section, such person (the "Indemnitee") shall notify the Corporation thereof. The Corporation shall be entitled to participate in the defense of any such action, suit or proceeding and, to the extent that it may wish, except in the case of a criminal action or proceeding, to assume the defense thereof with counsel chosen by it. If the Corporation shall have notified the Indemnitee of its election so to assume the defense, it shall be a condition of any further obligation of the Corporation under such Sections to indemnify the Indemnitee with respect to such action, suit or proceeding that the Indemnitee shall have provided an undertaking in writing to repay all legal or other costs and expenses subsequently incurred by the Corporation in conducting such defense if it shall ultimately be determined that the Indemnitee is not entitled to be indemnified in respect of the costs and expenses of such action, suit or proceeding by the Corporation as authorized by this Article. Notwithstanding anything in this Article to the contrary, after the Corporation shall have notified the Indemnitee of its election so to assume the defense, the Corporation shall not be liable under such Sections for any legal or other costs or expenses subsequently incurred by the Indemnitee in connection with the defense of such action, suit or proceeding, unless (a) the parties thereto include both (i) the Corporation and the Indemnitee, or (ii) the Indemnitee and other persons who may be entitled to seek indemnification or advancement of expenses under any such Section and with respect to whom the Corporation shall have elected to assume the defense, and (b) the counsel chosen by the Corporation to conduct the defense shall have determined, in their sole discretion, that, under applicable standards of professional conduct, a conflict of interest exists that would prevent them from representing both (i) the Corporation and the Indemnitee, or (ii) the Indemnitee and such other persons, as the case may be, in which case the Indemnitee may retain separate counsel at the expense of the Corporation to the extent provided in such Sections and Section 3 above in this Article.

Section 7. Indemnification Not Exclusive . The provision of indemnification to or the advancement of expenses and costs to any person under this Article, or the entitlement of any person to indemnification or advancement of expenses and costs under this Article, shall not limit or restrict in any way the power of the Corporation to indemnify or advance expenses and costs to such person in any other way permitted by law or be deemed exclusive of, or invalidate, any right to which any person seeking indemnification or advancement of expenses and costs may be entitled under any law, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's capacity as an officer, director, employee or agent of the Corporation or a Subsidiary Officer of an Associated Entity and as to action in any other capacity.

Section 8. Corporate Obligations; Reliance . The provisions of Sections 1, 2, 4(a) and 5(a) above of this Article shall be deemed to create a binding obligation on the part of the Corporation to the directors, officers, employees and agents of the Corporation, and the persons who are serving at the request of the Corporation as Subsidiary Officers of Associated Entities, on the effective date of this Article and persons thereafter elected as directors and officers or retained as employees or agents, or serving at the request of the Corporation as Subsidiary Officers of Associated Entities (including persons who served as directors, officers, employees and agents, or served at the request of the Corporation as Subsidiary Officers of Associated Entities, on or after such date but who are no longer so serving at the time they present claims for advancement of expenses or indemnity), and such persons in acting in their capacities as directors, officers, employees or agents of the Corporation, or serving at the request of the Corporation as Subsidiary Officers of any Associated Entity, shall be entitled to rely on such provisions of this Article.

Section 9. Further Changes . Neither the amendment nor repeal of this Article, nor the adoption of any provision of the Certificate of Incorporation inconsistent with this Article, shall eliminate or reduce the effect of such provisions in respect of any act or omission or any matter occurring prior to such amendment, repeal or adoption of an inconsistent provision regardless of when any cause of action, suit or claim relating to any such matter accrued or matured or was commenced, and such provision shall continue to have effect in respect of such act, omission or matter as if such provision had not been so amended or repealed or if a provision inconsistent therewith had not been so adopted.

Section 10. Successors . The right, if any, of any person who is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a Subsidiary Officer of an Associated Entity, to indemnification or advancement of expenses under Sections 1 through 9 above in this Article shall continue after he shall have ceased to be a director, officer, employee or agent or a Subsidiary Officer of an Associated Entity and shall inure to the benefit of the heirs, distributees, executors, administrators and other legal representatives of such person.

Section 11. Insurance . The Corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a Subsidiary Officer of any Associated Entity, against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the Corporation would have the power to indemnify such person against such liability under the provisions of this Article or applicable law.

Section 12. Definitions of Certain Terms . For purposes of this Article, references to "fines" shall include any excise taxes assessed on a person with respect to any employee benefit plan; references to "serving at the request of the Corporation" shall include any service as a director, officer employee or agent of the Corporation or as a Subsidiary Officer of any Associated Entity which service imposes duties on, or involves services by, such person with respect to any employee benefit plan, its participants, or beneficiaries; and a person who acted in good faith and in a manner such person reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "not opposed to the best interests of the Corporation" as referred to in this Article.

ARTICLE VIII
GENERAL

Section 1. Fiscal Year . The fiscal year of the Corporation shall be such date as shall be fixed by resolution of the Board of Directors from time to time.

Section 2. Corporate Seal. The corporate seal shall have inscribed thereon the name of the Corporation, the year of its organization and the words "Corporate Seal, Delaware" The seal may be used by causing it or a facsimile thereof to be impressed or affixed or reproduced or otherwise upon any paper, certificate or document.

Section 3. Disbursements . All checks, drafts or demands for money out of the funds of the Corporation and all notes and other evidences of indebtedness of the Corporation shall be signed by such officer or officers or such other person or persons as the Board of Directors may from time to time designate.

Section 4. Amendments . These By-Laws may be altered, amended or repealed, in whole or in part, or new By- Laws may be adopted by the stockholders or by the Board of Directors at any meeting ~~thereof; *provided*~~ thereof; *provided , however* , that notice of such alteration, amendment, repeal or adoption of new By-Laws shall be contained in the notice of such meeting of stockholders or in a notice of such meeting of the Board of Directors, as the case may be. Unless a higher percentage is required by law or by the Certificate of Incorporation as to any matter which is the subject of these By-Laws, all such amendments must be approved by either the affirmative vote of holders of shares of capital stock issued and outstanding entitled to vote thereon representing at least a majority of the votes and entitled to be cast thereon or by a majority of the entire Board of Directors then in office; provided , however , that any amendments to these Bylaws that was approved by the stockholders may not be altered, amended or repealed without the affirmative vote of the holders of shares in capital stock issued and outstanding and entitled to vote thereon representing at least a majority of the votes entitled to be cast thereupon.

Section 5. Definitions . As used in this Article and in these By-Laws generally, the term “entire Board of Directors” means the total number of directors which the Corporation would have if there were no vacancies.

EXHIBIT 21.1

List of Subsidiaries

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

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

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our reports dated June 13, 2018, with respect to the consolidated financial statements and internal control over financial reporting included in the Annual Report of Tyme Technologies, Inc. on Form 10-K for the year ended March 31, 2018. We consent to the incorporation by reference of said reports in the Registration Statements of Tyme Technologies, Inc. on Form S-3 (File No. 333-211489) and on Form S-8 (File No. 333-219856).

/s/ Grant Thornton LLP
New York, New York

June 13, 2018

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.; and

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

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

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

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

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

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

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

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

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

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

Date: June 13, 2018

/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.; and

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

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

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

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

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

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

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

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

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

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

Date: June 13, 2018

/s/ Ben R. Taylor
Ben R. Taylor
President and Chief Financial Officer
(Principal Financial Officer and Principal Accounting 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, 2018, 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 (15 U.S.C 78m or 78 *o* (d)); and

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

Date: June 13, 2018

/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 and Principal Accounting Officer)

THIS CERTIFICATION WILL NOT BE DEEMED "FILED" FOR PURPOSES OF SECTION 18 OF THE EXCHANGE ACT 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 OR THE EXCHANGE ACT, 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.