A Unique Therapeutic Approach Designed to Disrupt Cancer’s Innate Metabolic Function

TYME is an emerging biotechnology company developing cancer therapeutics that are intended to be broadly effective across tumor types and have low toxicity profiles. Unlike targeted therapies that attempt to regulate specific mutations within cancer, our therapeutic approach is designed to take advantage of a cancer cell’s innate metabolic weaknesses to compromise its defenses, leading to cell death through oxidative stress and exposure to the body’s natural immune system.

TYME’s lead cancer metabolism-based therapy (CMBT™), SM-88, is an oral investigational modified proprietary tyrosine derivative that is hypothesized to interrupt the metabolic processes of cancer cells by breaking down the cells’ key defenses and leading to cell death through oxidative stress and exposure to the body’s natural immune system. Clinical trial data have shown that SM-88 has demonstrated encouraging tumor responses across 15 different cancers, both solid and liquid tumors, including pancreatic, lung, breast, prostate and sarcoma cancers with minimal serious Grade 3 or higher adverse events.

TYME has multiple cancer metabolism-based assets and other formulations for SM-88 in the pipeline, including injectable, intranasal, and transdermal that are expected to be advanced into the clinical setting. TYME has an expanding patent portfolio broadly covering compositions, methods, manufacturing and use of its pipeline to 2032, and beyond.

We are committed to delivering CMBTs for patients with advanced, difficult-to-treat cancers while reducing the burden on our healthcare system. To learn more about TYME technologies and/or request an interview with our management team please contact us at 212-461-2315 or e-mail us at investorrelations@tymeinc.com.

PATIENTS: Our trial is studying patients with 3rd-line pancreatic cancer. There are 10,000 patients in the US actively seeking 3rd line treatment. No FDA approved treatments and no oncology guideline recommendations

ESMO GI: SM-88 showed 3x expected survival of 6.4 months median overall survival in recent trial results with many of the top pancreatic cancer centers participating

PIVOTAL TRIALS: TYME’s Pivotal trial just launched and a second pivotal trial in partnership with PanCAN (one of the largest pancreatic cancer foundations in the world) has opened trial sites

PIPELINE: Expanding into other metastatic cancers, including prostate, sarcomas, breast and blood cancers

SAFETY: Commonly used treatments have serious adverse effects in >50% of patients. SM-88 has only had 4% (2/49) of patients with serious adverse events related to SM-88
TYME Announces Third Quarter Fiscal 2020 Financial and Operating Results

- Strategic collaboration with Eagle Pharmaceuticals entitles TYME to receive up to a total of $40 million, which included $20 million upfront already received and $20 million in potential milestone payments.
- TYME-88-Panc pivotal trial started enrollment using oral SM-88 as a potential treatment for patients with third-line pancreatic cancer.
- PanCAN opened an initial site in its Precision PromiseSM adaptive randomized Phase II/III registration-intent trial for patients with pancreatic cancer using oral SM-88 in second-line monotherapy.
- TYME & Joseph Ahmed Foundation’s sarcoma study started enrollment for the investigator-initiated HopES Phase II trial using oral SM-88 as maintenance monotherapy in patients with previously treated metastatic Ewing’s sarcoma and salvage monotherapy in clinically advanced sarcomas.
- Capital resources better position TYME to complete current stages of trials in pancreatic cancer and sarcoma, advance planning for clinical trials in metastatic breast, prostate and hematological cancers, as well as continue developing pre-clinical and mechanism data.

NEW YORK, NY, February 5, 2020 -- Tyme Technologies, Inc. (NASDAQ: TYME), an emerging biotechnology company developing cancer metabolism-based therapies (CMBTs™), announced financial and operating results for its fiscal third quarter ended December 31, 2019. Most recently, the TYME-88-Panc pivotal trial started enrollment using oral SM-88 (racemetyrosine) as a potential treatment for patients with third-line pancreatic cancer; in January 2020, PanCAN opened an initial site in its Precision PromiseSM adaptive randomized Phase II/III registration-intent trial for patients with pancreatic cancer using oral SM-88 in second-line monotherapy; and enrollment started in the investigator-initiated sarcoma HopES Phase II trial using oral SM-88 as maintenance monotherapy in patients with previously treated metastatic Ewing’s sarcoma and salvage monotherapy in clinically advanced sarcomas.

“We have quickly evolved our science of cancer metabolism-based therapies from the conceptual to its practical application as we begin enrollment of patients in multiple SM-88 pivotal trials this year,” said Mr. Steve Hoffman, Chairman and Chief Executive Officer of TYME. “Importantly, we continue to embark on new opportunities and build a model for sustainable growth by expanding our goals and objectives and broadening our clinical and regulatory plans. We look forward with great enthusiasm to executing on our strategy to advance potential therapies for patients with advanced cancer.”
Third Quarter Fiscal 2020 Financial Results:

As of the third quarter ended December 31, 2019, the Company had approximately $11.5 million in cash and cash equivalents compared to $15.3 million as of the second quarter ended September 30, 2019. On January 7, 2020, TYME received an additional $20.0 million from the sale and issuance of 10,000,000 shares of common stock of the Company to Eagle Pharmaceuticals in a private placement, which resulted in TYME having cash and cash equivalents of $31.5 million.

TYME’s operational cash burn rate for the third quarter of fiscal year 2020 was $4.5 million compared to $4.2 million for the second quarter of fiscal year 2020 and $5.3 million for the third quarter of fiscal 2019. The burn rate which was generally consistent with our previous projections and predominantly reflected costs associated with our ongoing TYME-88-Panc Phase II trial as well as the launch of the pivotal phase of our TYME-88-Panc trial to evaluate SM-88 as a potential treatment for patients with third-line pancreatic cancer. Based on active clinical trials, the initiation of the Precision PromiseSM trial, and other business developments, TYME continues to anticipate that its quarterly cash usage, or “cash burn rate”, will average between $5.0 to 6.0 million per quarter for fiscal year 2020.

Based on U.S. GAAP (Generally Accepted Accounting Principles), net loss was $7.0 million for the third quarter ended December 30, 2019, or a net loss per basic and diluted share of $0.06, as compared to a net loss of $8.0 million for the third quarter ended December 31, 2018, or a net loss per basic and diluted share of $0.08. The decrease in losses was substantially due to timing of activity related to Part 1 of our TYME-88-Panc trial as well our recently completed Phase II prostate clinical trial.

Adjusted net loss for the three months ended December 31, 2019 was $4.9 million, or an adjusted net loss per share of $0.05, compared to adjusted net loss of $6.0 million, or an adjusted net loss per share of $0.06, for the three months ended December 31, 2018, after adjusting for the change in fair value of warrant liability and amortization of employees, directors and consultants stock options. Adjusted net loss and adjusted net loss per share are non-GAAP measures. See “Use of Non-GAAP Measures” below for a reconciliation to the comparable GAAP measures.

TYME has reported its full financial results for the quarter ended December 31, 2019 in the Company’s Form 10-Q filed with the Securities and Exchange Commission (“SEC”). TYME’s 10-Q is located on the Company’s website under recent SEC filings at ir.tymeinc.com.

Anticipated Upcoming Key Events
TYME currently expects the following key events in calendar year 2020:

**First half of calendar 2020:**

- Present preclinical data for SM-88
- Advance enrollment in TYME-88-Panc pivotal study and the HopES Phase II Trial
- Initiate enrollment in PanCAN’s Precision Promise\textsuperscript{SM} adaptive randomized Phase II/III registration-intent trial in patients with pancreatic cancer using oral SM-88 in second-line monotherapy
- Present preclinical data for TYME-18
- Present preliminary Health Economic Outcomes study on total cost of care for pancreatic cancer patients

**Second half of calendar 2020:**

- Publish SM-88 Phase II prostate study
- Advance SM-88 clinical programs into other tumor types potentially including metastatic breast, recurrent prostate and/or hematological cancers
- Advance PanCAN’s Precision Promise\textsuperscript{SM} adaptive Phase II/III trial evaluating SM-88 in patients with first-line pancreatic cancer in combination with gemcitabine and Abraxane
- Present and/or publish final data from Part 1 of TYME-88-Panc study
- Complete enrollment in TYME-88-Panc pivotal study
- Advance plans for TYME-18 IND program

**Summary of Recent Developments**

**Tyme Technologies and Eagle Pharmaceuticals Announce Strategic Collaboration to Advance Innovative Oral SM-88 for the Treatment of Patients with Cancer**

TYME and Eagle announced the formation of a U.S. strategic collaboration focused on the co-promotion of TYME’s lead CMBT candidate, oral SM-88, in advanced cancers. Under the terms of the securities purchase agreement, TYME received a $20 million upfront cash payment for 10 million restricted shares of TYME common stock at $2.00 per share. In addition, TYME will receive a $20 million milestone payment upon the successful completion of the first to occur of the following three events: (1) achievement of the primary endpoint of overall survival in its TYME-88-Panc pivotal trial; or (2) achievement of the primary endpoint of overall survival in the PanCAN Precision Promise\textsuperscript{SM} SM-88 registration arm; or (3) U.S. Food and Drug Administration (FDA) approval of SM-88 in any cancer. This payment would be split into a $10 million milestone cash payment and a $10 million investment in TYME at a 15% premium to the then prevailing market price. Eagle’s shares will be restricted from sale until the earlier of three months following the milestone event or the three-year anniversary of the agreement.
Under the terms of the co-promotion agreement, Eagle Pharmaceuticals will undertake 25% of the promotional sales effort for SM-88 in the U.S. oncology market and receive 15% of the net U.S. revenues of SM-88, and TYME will be responsible for the remaining promotional effort. TYME will also be responsible for clinical development, regulatory approval, commercial strategy, marketing, reimbursement and manufacturing of SM-88. TYME retains the remaining 85% of net U.S. revenues and reserves the right to repurchase Eagle’s co-promotion right for $200 million.

As part of this collaboration between TYME and Eagle, there is also the potential to evaluate oral SM-88 in combination therapy or as monotherapy through leveraging Eagle’s oncology pipeline and expertise in oncology settings, which may include trials in breast or lung cancers and other tumor types.

**TYME Announces First Patient Dosed in TYME-88-Panc Pivotal Trial to Evaluate SM-88 as Oral Treatment for Patients with Metastatic Pancreatic Cancer**

The first pancreatic cancer patient was dosed in Part 2 of the TYME-88-Panc pivotal trial designed to support approval of SM-88, TYME’s leading cancer metabolism-based therapy, for the third-line treatment of patients with metastatic pancreatic cancer. CMBTs are proprietary investigational compounds that are believed to disrupt cancer cells’ protein synthesis, leading to a breakdown of the cancer’s key defenses and cell death. In clinical trials, SM-88 has demonstrated encouraging tumor responses across 15 different cancers, including pancreatic, prostate, sarcoma, breast, lung, and lymphoma cancers with minimal serious grade 3 or higher adverse events.

**TYME and The Joseph Ahmed Foundation Announce First Patient Dosed in HopES Phase II Trial Evaluating the Potential Benefits of Oral SM-88 for Patients with High-Risk Sarcomas**

The first sarcoma cancer patient was dosed at the Sarcoma Oncology Center in the HopES Phase II trial designed to evaluate SM-88 for the treatment of high-risk sarcomas, which are ultra-rare cancers with high unmet medical need.

**TYME Rings Nasdaq Opening Bell on November 27 to Honor All Stakeholders Committed to Finding a Cure for Patients with Pancreatic Cancer**

TYME rang the Nasdaq Opening Bell on Wednesday, November 27, to honor the many stakeholders who are committed to finding a cure for patients with pancreatic cancer during Pancreatic Cancer Awareness Month. TYME was joined by employees, oncologists, researchers and representatives of leading patient advocacy organizations for pancreatic cancer, namely the Pancreatic Cancer Action Network (PanCAN) and the Lustgarten Foundation.

**About SM-88**
SM-88 is an oral investigational modified proprietary tyrosine derivative that is hypothesized to interrupt the metabolic processes of cancer cells by breaking down the cells’ key defenses and leading to cell death through oxidative stress and exposure to the body’s natural immune system. Clinical trial data have shown that SM-88 has demonstrated encouraging tumor responses across 15 different cancers, including pancreatic, lung, breast, prostate and sarcoma cancers with minimal serious grade 3 or higher adverse events. SM-88 is an investigational therapy that is not approved for any indication in any disease.

About Tyme Technologies

Tyme Technologies, Inc., is an emerging biotechnology company developing cancer therapeutics that are intended to be broadly effective across tumor types and have low toxicity profiles. Unlike targeted therapies that attempt to regulate specific mutations within cancer, the Company’s therapeutic approach is designed to take advantage of a cancer cell’s innate metabolic weaknesses to compromise its defenses, leading to cell death through oxidative stress and exposure to the body’s natural immune system. For more information, visit www.tymeinc.com. Follow us on social media: @tyme_Inc, LinkedIn, Instagram, Facebook and YouTube.

Use of Non-GAAP Financial Measures

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

Forward-Looking Statements/Disclosure Notice

In addition to historical information, this press release contains forward-looking statements under the Private Securities Litigation Reform Act that involve substantial risks and uncertainties. Such forward-looking statements within this press release include, without limitation, statements regarding our drug candidates, including SM-88 and TYME-18, and their clinical potential and non-toxic safety profiles, our drug development plans and strategies, ongoing and planned clinical trials, preliminary data results and the therapeutic design and mechanisms of our drug candidates; and readers can identify
forward-looking statements by sentences or passages involving the use of terms such as “believes,” “expects,” “hopes,” “may,” “will,” “plan,” “intends,” “estimates,” “could,” “should,” “would,” “continue,” “seeks,” or “anticipates,” and similar words including their use in the negative or by discussions of future matters such as the cost of development and potential commercialization of our lead drug candidate and of other new products, expected releases of interim or final data from our clinical trials, possible collaborations, the timing, scope and objectives of our ongoing and planned clinical trials and other statements that are not historical. The forward-looking statements contained in this press release are based on management’s current expectations, which are subject to uncertainty, risks and changes in circumstances that are difficult to predict and many of which are outside of TYME’s control. These statements involve known and unknown risks, uncertainties and other factors which may cause the Company’s actual results, performance or achievements to be materially different from any historical results and future results, performances or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include, but are not limited to, that the information is of a preliminary nature and may be subject to change; uncertainties inherent in the cost and outcomes of research and development, including the cost and availability of acceptable-quality clinical supply and the ability to achieve adequate clinical study design and start and completion dates; the possibility of unfavorable study results, including unfavorable new clinical data and additional analyses of existing data; risks associated with early, initial data, including the risk that the final data from any clinical trial may differ from prior or preliminary study data; final results of additional clinical trials that may be different from the preliminary data analysis and may not support further clinical development; that past reported data are not necessarily predictive of future patient or clinical data outcomes; whether and when any applications or other submissions for SM-88 may be filed with regulatory authorities; whether and when regulatory authorities may approve any applications or submissions; decisions by regulatory authorities regarding labeling and other matters that could affect commercial availability of SM-88; the ability of TYME and its collaborators to develop and realize collaborative synergies; competitive developments; and the factors described in the section captioned “Risk Factors” of TYME’s Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission on June 12, 2019, as well as subsequent reports we file from time to time with the U.S. Securities and Exchange Commission available at www.sec.gov.

The information contained in this press release is as of its release date and TYME assumes no obligation to update forward-looking statements contained in this release as a result of future events or developments.

For Investor Relations & Media Inquiries:
Contact:
1-212- 461-2315
investorrelations@tymeinc.com
media@tymeinc.com
The non-GAAP financial measures for the three months ended December 31, 2019 and 2018 provide management with additional insight into the Company’s results of operations from period to period by excluding certain non-operational and non-cash charges, and are calculated using the following adjustments to net loss:

a) The warrants issued as part of an equity offering on April 2, 2019 are measured at fair value using a Monte Carlo model which takes into account, as of the valuation date, factors including the current exercise price, the remaining contractual term of the warrant, the current price of the underlying stock, its expected volatility, the risk-free interest rate for the term of the warrant and the estimates of the probability of a fundamental

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### Tyme Technologies, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations (Unaudited)

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended December 31,</th>
<th>Nine Months Ended December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2019</td>
<td>2018</td>
</tr>
<tr>
<td><strong>Revenues</strong></td>
<td>$—</td>
<td>$—</td>
</tr>
<tr>
<td><strong>Operating expenses:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>3,453,459</td>
<td>4,525,228</td>
</tr>
<tr>
<td>General and administrative (including $58,500, $132,000, $307,000 and $794,000 of related party legal expenses, respectively)</td>
<td>3,090,223</td>
<td>3,550,224</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>6,543,682</td>
<td>8,075,452</td>
</tr>
<tr>
<td>Loss from operations</td>
<td>(6,543,682)</td>
<td>(8,075,452)</td>
</tr>
<tr>
<td><strong>Other income (expenses):</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in fair value of warrant liability</td>
<td>(425,795)</td>
<td>—</td>
</tr>
<tr>
<td>Interest income</td>
<td>38,257</td>
<td>28,718</td>
</tr>
<tr>
<td>Interest expense</td>
<td>(26,310)</td>
<td>(1,222)</td>
</tr>
<tr>
<td>Total other income (expenses)</td>
<td>(413,848)</td>
<td>27,496</td>
</tr>
<tr>
<td>Net loss</td>
<td>$ (6,957,530)</td>
<td>$ (8,047,956)</td>
</tr>
<tr>
<td>Basic and diluted loss per common share</td>
<td>$ (0.06)</td>
<td>$ (0.08)</td>
</tr>
<tr>
<td>Basic and diluted weighted average shares outstanding</td>
<td>112,071,354</td>
<td>103,009,449</td>
</tr>
</tbody>
</table>
transaction occurring. The warrant liability is revalued at each reporting period or upon exercise. Changes in fair value are recognized in the consolidated statements of operations and are excluded from adjusted net loss and adjusted net loss per share.

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

Adjusted basic net loss per share is computed by dividing adjusted net loss by the weighted average number of shares of Company common stock outstanding for the period and adjusted diluted loss per share is computed by also including common stock equivalents outstanding for the period. During the periods presented, the calculation excludes any potential dilutive common shares and any equivalents as they would have been anti-dilutive as the Company incurred losses for the periods then ended.

### Reconciliation of Net Loss to Adjusted Net Loss

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended December 31,</th>
<th></th>
<th>Nine Months Ended December 31,</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2019</td>
<td>2018</td>
<td>2019</td>
<td>2018</td>
</tr>
<tr>
<td>Net loss (GAAP)</td>
<td>$(6,958,000)</td>
<td>$(8,048,000)</td>
<td>$(16,276,000)</td>
<td>$(21,786,000)</td>
</tr>
<tr>
<td>Adjustments:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in fair value of warrant liability</td>
<td>426,000</td>
<td>—</td>
<td>(2,594,000)</td>
<td>—</td>
</tr>
<tr>
<td>Amortization of employees, directors and consultants stock options</td>
<td>1,602,000</td>
<td>2,000,000</td>
<td>4,673,000</td>
<td>6,702,000</td>
</tr>
<tr>
<td>Adjusted net loss (non-GAAP)</td>
<td>$(4,930,000)</td>
<td>$(6,048,000)</td>
<td>$(14,197,000)</td>
<td>$(15,084,000)</td>
</tr>
</tbody>
</table>

### Reconciliation of Net Loss Per Share to Adjusted Net Loss Per Share

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended December 31,</th>
<th></th>
<th>Nine Months Ended December 31,</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2019</td>
<td>2018</td>
<td>2019</td>
<td>2018</td>
</tr>
<tr>
<td>Net loss per share (GAAP)</td>
<td>$ (0.06)</td>
<td>$ (0.08)</td>
<td>$ (0.15)</td>
<td>$ (0.21)</td>
</tr>
<tr>
<td>Adjustments:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in fair value of warrant liability</td>
<td>*</td>
<td>—</td>
<td>(0.02)</td>
<td>—</td>
</tr>
<tr>
<td>Amortization of employees, directors and consultants stock options</td>
<td>0.01</td>
<td>0.02</td>
<td>0.04</td>
<td>0.07</td>
</tr>
<tr>
<td>Adjusted net loss per share (non-GAAP)</td>
<td>$ (0.05)</td>
<td>$ (0.06)</td>
<td>$ (0.13)</td>
<td>$ (0.14)</td>
</tr>
</tbody>
</table>

* The effect of the change in fair value of the warrant liability was negligible to the adjusted net loss per share.
TYME Presents Updated Data at ESMO GI 2019 from TYME-88-Panc Phase II Study Demonstrating Encouraging Overall Survival Trends in Patients with Advanced Pancreatic Cancer

- In this poor prognosis population, SM-88 demonstrated median overall survival (OS) of 6.4 months as of April 25, 2019
- Efficacy indicators showed strong correlation with greater overall survival (OS). These indicators included achieving stable disease (SD) or better and decreases in circulating tumor cells (CTCs)
- Patients who achieved SD or better had a statistically significant (p=0.02) improvement in survival with a 92% reduction in risk of death
- Patients who achieved at least an 80% reduction in CTC burden demonstrated a 60% decrease in risk of death
- The study supports SM-88’s well-tolerated safety profile, with only 4% of patients having a serious adverse event (SAE) that was deemed to be at least possibly related to SM-88
- Based on these results, TYME plans to initiate a randomized pivotal trial for use of SM-88 in patients with pancreatic cancer in Q3’2019
- TYME management will be hosting a conference call on July 9th at 8:30AM EDT to discuss the SM-88 data presented at the ESMO GI Congress.

NEW YORK, July 5, 2019 (GLOBE NEWSWIRE) -- Tyme Technologies, Inc. (NASDAQ: TYME), an emerging biotechnology company developing cancer metabolism based therapies (CMBTs™), announced that its multicenter open-label Phase II TYME-88-Panc study evaluating SM-88 (racemetyrosine) as an oral monotherapy in patients with advanced pancreatic cancer continues to demonstrate encouraging results and a well-tolerated safety profile. The data from the TYME-88-Panc study were presented at the European Society of Medical Oncology 21st World Congress on Gastrointestinal Cancer (ESMO GI) on July 4, 2019 in Barcelona, Spain.

“We believe that these outcomes further justify advancing the development of SM-88. These survival results compare very favorably to the analysis of 19 prospective pancreatic...
cancer trials where the median reported survival after progressing on third-line therapy was 2.0–2.5 months based on reported historical trials,” said Giuseppe Del Priore, M.D., M.P.H., Chief Medical Officer at Tyme Technologies. “Given that there are no effective options to treat this patient population, we plan to move forward with our SM-88 pivotal trial in pancreatic cancer. We are increasingly encouraged that SM-88 has the potential to be a new treatment approach for late-stage pancreatic patients.”

Updated results from the ongoing multicenter open-label Phase II TYME-88-Panc study (Abstract #160) involved 49 heavily pretreated patients with radiographically progressive metastatic pancreatic cancer who had significant disease related morbidity before receiving Tyme’s investigational agent SM-88. More than 80% of patients had received at least two prior lines of therapy. Of the 49 patients, 38 patients were evaluable for efficacy, as defined in the protocol. TYME-88-Panc is a two-part study in which Part 1 was intended to determine optimal dosing and assess if early clinical benefit supported further development of SM-88 in pancreatic cancer. This study is being performed under a TYME IND with input from the FDA prior to study initiation.

In this study, based on information available as of April 25, 2019, the median overall survival of evaluable patients (38 of 49) was 6.4 months. Certain efficacy indicators correlated with greater OS, including achieving SD or better and decreases in CTCs.

A RECIST clinical benefit rate (CBR) of stable disease or better was achieved by 44% of patients (11 of 25) with available imaging. Notably, patients achieving stable disease or better demonstrated a statistically significant (p=0.02) improvement in survival with a 92% reduction in risk of death (hazard ratio=0.08). The CBR was durable with majority of these patients remaining in stable disease or better at more than 7 months after receiving treatment with SM-88.

The measurement of CTCs is emerging as an important prognostic indicator in patients with pancreatic cancer. This is now the second TYME study in cancer patients showing that SM-88 reduces CTCs. In a previous study of patients with prostate cancer, SM-88 treatment was also associated with a reduction in CTC count (JCO 37, 2019 supp 7S; 83). In the TYME-88-Panc study, a median reduction of 63% in CTC burden was observed in evaluable patients. Importantly, patients (10 of 24) with available results reaching an 80% reduction or greater in CTCs demonstrated a 60% decrease in risk of death (hazard ratio=0.40).

“Responses are very rare in later line pancreatic cancer so overall response rates are close to zero. The SM-88 trial has demonstrated encouraging new data on efficacy indicators, including a meaningful clinical benefit rate, and a reduction in circulating tumor cells, that both correlate with extended survival,” said Allyson Ocean, MD, a pancreatic cancer specialist at New York-Presbyterian Hospital/Weill Cornell Medical Center and Associate Professor of Medicine at the Weill Medical College of Cornell University. “Research results to date also indicate that SM-88 has a favorable toxicity profile. To have both results with one drug is extremely important. There are no FDA approved treatments for 3rd line pancreatic cancer and no NCCN or ASCO guideline recommendations. These patients are in desperate need of effective therapies.”
In addition to these findings from the TYME-88-Panc study, data were also presented on subgroup analyses. TYME identified several screening criteria that were associated with rapidly declining prognostic factors defined as greater than 2 lines of prior therapy; age greater than 75 years old; albumin less than 3.5 g/dl. Patients with no indicators of poor prognosis had a better trend in survival.

TYME identified key sub-groups of patients who performed better. Patients with 1 or 2 prior lines of therapy had a better trend in survival. Female patients had a statistically significant (p=0.01) trend toward better survival. These encouraging findings warrant further clinical evaluation of these subgroups.

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

The TYME-88-Panc research results are from an investigational study. SM-88 is not approved for the treatment of patients with any disease condition.

Details of this study were presented at the European Society of Medical Oncology 21st World Congress on Gastrointestinal Cancer in Barcelona, Spain on Wednesday, July 4, 2019, from 10:00 AM CET to 5:15 PM CET during the Poster Session: “Esophageal, Liver, Gastric, Pancreatic and other GI Tumors” at the Poster Hall. The poster is available on our website (www.tymeinc.com/data-publications).

TYME management will be hosting a conference call for analysts and investors on July 9th at 8:30AM EDT to discuss the SM-88 data presented at the ESMO GI Congress. Those interested in participating in the call should dial: (877) 705-6003 (Domestic) / (201) 493-6725 (International); and enter passcode: 13692152. The call will also be viewable via webcast, which can be accessed through the “Investors” tab of the company's website (ir.tymeinc.com). A replay of this conference call will also be available via webcast shortly after the event and will remain available for two weeks.

The SM-88 Poster presented at ESMO GI is as follows:

**Title:** SM-88 Therapy in High-Risk Poor Prognosis Pancreatic Cancer (PDAC).([Link to poster](#))

**Authors:** Marcus Smith Noel, Andrea Wang-Gillam, Allyson J. Ocean, Sant P. Chawla, Vincent Chung, Giuseppe Del Priore, Vincent J. Picozzi

**About Advanced Pancreatic Cancer**
Advanced pancreatic cancer is a difficult-to-treat cancer with the lowest survival rates among all cancer types. Across all patients with pancreatic cancer, relative 5-year survival is 8% and is less than 3% for those with advanced disease. The median survival for patients in end-stage of the disease is approximately 3 months. There are two main types of pancreatic cancer - adenocarcinomas, which accounts for
approximately 90% of all pancreatic cancer, and neuroendocrine tumors. Pancreatic cancer is relatively uncommon with new cases accounting for only 2.1% of all newly diagnosed cancers. However, pancreatic cancer is the fourth most common cause of cancer death for men and women in the United States.

About SM-88
SM-88 is an investigational modified proprietary tyrosine derivative that is hypothesized to interrupt the metabolic processes of cancer cells by breaking down the cells’ key defenses and leading to cell death through oxidative stress and exposure to the body’s natural immune system. Clinical trial data have shown that SM-88 has demonstrated encouraging tumor responses across 15 different cancers, including pancreatic, lung, breast, prostate and sarcoma cancers with minimal serious grade 3 or higher adverse events.

About Tyme Technologies
Tyme Technologies, Inc. is an emerging biotechnology company developing cancer metabolism-based therapeutics that are intended to be broadly effective across tumor types and have low toxicity profiles. Unlike targeted therapies that attempt to regulate specific mutations within cancer, the Company’s therapeutic approach is designed to take advantage of a cancer cell’s innate metabolic weaknesses to compromise its defenses, leading to cell death through oxidative stress and exposure to the body’s natural immune system. For more information, visit www.tymeinc.com. Follow us on social media: @tyme_inc, LinkedIn, Instagram, Facebook and YouTube.

Forward-Looking Statements/Disclosure Notice
In addition to historical information, this press release contains forward-looking statements under the Private Securities Litigation Reform Act that involve substantial risks and uncertainties. Such forward-looking statements within this press release include, without limitation, statements regarding our drug candidate SM-88 and its clinical potential and non-toxic safety profiles, our drug development plans and strategies, ongoing and planned clinical trials, preliminary data results and the therapeutic design and mechanisms of our drug candidates; and readers can identify forward-looking statements by sentences or passages involving the use of terms such “believes,” “expects,” “hopes,” “may,” “will,” “plan,” “intends,” “estimates,” “could,” “should,” “would,” “continue,” “seeks,” or “anticipates,” and similar words (including their use in the negative) or by discussions of future matters such as the development and potential commercialization of our lead drug candidate and of other new products, expected releases of interim or final data from our clinical trials, possible collaborations, the timing, scope and objectives of our ongoing and planned clinical trials and other statements that are not historical. The forward-looking statements contained in this press release are based on management’s current expectations, which are subject to uncertainty, risks and changes in circumstances that are difficult to predict and many of which are outside of TYME’s control. These statements involve known and unknown risks, uncertainties and other factors which may cause the TYME’s actual results, performance or achievements to be materially different from any historical results and future results, performances or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include, but are not limited to, that the information is of a preliminary nature and may be subject to change;
uncertainties inherent in research and development, including the ability to achieve clinical study start and completion dates; the possibility of unfavorable study results, including unfavorable new clinical data and additional analyses of existing data; risks associated with early, initial data, including the risk that the final Phase II data may differ from prior study data or preliminary Phase II data; final results of additional clinical trials that may be different from the preliminary data analysis and may not support further clinical development; that past reported data are not necessarily predictive of future patient or clinical data outcomes; whether and when any applications or other submissions for SM-88 may be filed with regulatory authorities; whether and when regulatory authorities may approve any applications or submissions; decisions by regulatory authorities regarding labeling and other matters that could affect commercial availability of SM-88; competitive developments; and the factors described in the section captioned “Risk Factors" of TYME's Annual Report on Form 10-K for fiscal year ended March 31, 2019, filed with the U.S. Securities and Exchange Commission on June 12, 2019, as well as subsequent reports we file from time to time with the U.S. Securities and Exchange Commission (available at www.sec.gov).

The information contained in this press release is as of its release date and TYME assumes no obligation to update forward-looking statements contained in this release as a result of future events or developments.

1Manax et al 2019 J Clin Oncol 37, 2019 (suppl 4; abstr 226)
2Statistics adapted from the American Cancer Society's (ACS) publication, Cancer Facts & Figures 2018.

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Source: Tyme Technologies, Inc.
TYME to Ring Nasdaq Opening Bell on November 27 to Honor All Stakeholders Committed to Finding a Cure for Patients with Pancreatic Cancer

- Pancreatic Cancer Expected to be the Second Leading Cause of Cancer-Related Death in the U.S. by 2020;
- TYME’s oral SM-88 represents a new approach designed to selectively disrupt protein synthesis in cancers - demonstrated responses in 15 different cancer types across four separate studies
- Data presented at ESMO GI 2019 from TYME-88-PANC Phase II study demonstrated encouraging overall survival trends in patients with metastatic pancreatic cancer
- TYME Expects Enrollment of Patients in the Pivotal Stage of TYME-88-Panc Trial to Evaluate Oral SM-88 for Third-Line Treatment of Patients with Metastatic Pancreatic Cancer by Year-End

NEW YORK, November 25, 2019 (GLOBE NEWSWIRE) -- Tyme Technologies, Inc. (NASDAQ: TYME), an emerging biotechnology company developing cancer metabolism-based therapies (CMBTs™), today announced it will ring the Nasdaq Opening Bell on Wednesday, November 27, to honor the many stakeholders who are committed to finding a cure for patients with pancreatic cancer during Pancreatic Cancer Awareness Month. TYME will be joined by employees, oncologists, researchers and representatives of leading patient advocacy organizations for pancreatic cancer, namely the Pancreatic Cancer Action Network (PanCAN) and the Lustgarten Foundation.

CMBTs are proprietary investigational compounds that are believed to disrupt cancer cells’ protein synthesis, leading to a breakdown of the cancer’s key defenses and cell death. In clinical trials, SM-88 has demonstrated encouraging tumor responses across 15 different cancers, including pancreatic, prostate, sarcoma, breast, lung, and lymphoma cancers with minimal serious grade 3 or higher adverse events.

"Our ultimate goal is to transform lives and give hope to people suffering from pancreatic cancer every single day," said Steve Hoffman, CEO of TYME. "We are committed to execute on our strategy of investing in the science of next-generation CMBTs to create disease-altering medicines for patients with metastatic cancers. Moreover, we are excited about the potential of SM-88 as a first-in-class cancer metabolism-based therapy and are looking forward to evaluating this promising new approach in our new pivotal study."
TYME has launched the pivotal stage of the TYME-88-Panc study designed as a multi-center randomized (1:1), controlled pivotal trial that will evaluate the efficacy and safety of SM-88 used with MPS (methoxsalen, phenytoin, sirolimus) in patients with metastatic adenocarcinoma of the pancreas whose disease has progressed or recurred and have received two lines of prior systemic therapy. Approximately 250 patients will be randomized to receive 920 mg of SM-88 with MPS (Arm A n=125) or one of three pre-defined single agent therapies (Arm B n=125). Patients will be treated until there is unacceptable toxicity, disease progression or if any treatment discontinuation criteria are met. The primary endpoint is overall survival (OS). Key exploratory endpoints include progression free survival (PFS), clinical benefit response rate (CBR), defined as patients achieving stable disease or better, circulating tumor cells (CTCs) and quality of life (QOL). The study will include leading pancreatic cancer research sites across the United States. 

[Click here to learn more.]

Patients and physicians can access www.TYMETRIALS.com for more information about ongoing SM-88 clinical trials. SM-88 is not approved for the treatment of patients with any disease condition.

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Tyme Technologies and Eagle Pharmaceuticals Announce Strategic Collaboration to Advance Innovative Oral SM-88 for the Treatment of Patients with Cancer

- Collaboration leverages combined capabilities of Tyme Technologies and Eagle Pharmaceuticals to maximize potential of oral SM-88 by advancing pivotal trials and commercialization.
- TYME recently launched the TYME-88-PANC pivotal trial to evaluate oral SM-88 for third-line treatment of patients with metastatic pancreatic cancer.
- TYME is entitled to receive up to a total $40 million as follows:
  o an initial $20 million upfront. In return, Eagle will receive 10 million restricted shares of TYME’s common stock at $2.00 per share.
  o a second $20 million milestone payment upon achieving primary endpoints in pivotal trial results or approval of a cancer indication in the U.S. for SM-88. This payment will be split into a $10 million milestone cash payment and a $10 million investment in TYME at a 15% premium to the then prevailing market price.
- Eagle will be responsible for 25% of the promotional sales effort of SM-88 and will receive 15% of net revenues of SM-88 in the U.S.
- TYME retains all commercial rights to SM-88 outside the U.S. and reserves the right to repurchase Eagle’s U.S. co-promotion right for $200 million.
- Oral SM-88 represents a novel therapeutic approach designed to selectively disrupt protein synthesis in cancer cells with demonstrated tumor responses in 15 different cancer types across multiple studies.
- In a Phase II study of patients with actively progressing metastatic pancreatic cancer who had failed previous therapy, evaluable patients on SM-88 demonstrated median overall survival of 6.4 months as of April 25, 2019; patients who achieved stable disease or better had a statistically significant (p=0.02) improvement in survival with a 92% reduction in risk of death.

NEW YORK, NY & WOODCLIFF LAKE, NJ, January 7, 2020 -- Tyme Technologies, Inc. (Nasdaq: TYME) (“TYME”), an emerging biotechnology company developing cancer metabolism-based therapies (CMBTs™), and Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) (“Eagle”), today announced the formation of a U.S. strategic collaboration focused on the co-promotion of TYME’s lead CMBT candidate oral SM-88 in advanced cancers. CMBTs are proprietary investigational compounds that are believed to disrupt cancer cells’ protein synthesis, leading to a breakdown of the cancer’s key defenses and cell death. In clinical trials, oral SM-88 has demonstrated complete or partial responses across 15 different cancers, including pancreatic,
prostate, sarcoma, breast, lung, and blood cancers with minimal serious grade 3 or higher adverse events.

“TYME’s approach is unique and transformational. Targeting cancer’s metabolism by disrupting protein synthesis has advantages over existing treatment approaches in terms of both efficacy and safety,” said Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals. “This collaboration provides an excellent opportunity to continue expanding our presence in the oncology space, as well as to evaluate potential combination opportunities with SM-88 in our existing pipeline. We look forward to leveraging our oncology sales infrastructure to maximize the commercialization of SM-88 in the U.S., if approved. As always, our goal remains to deliver innovative, next-generation therapeutics to address patient needs and to create value for our shareholders,” concluded Tarriff.

Terms of the Agreements

Under the terms of the securities purchase agreement, TYME will receive a $20 million upfront cash payment for 10 million restricted shares of TYME common stock at $2.00 per share. In addition, TYME will receive a $20 million milestone payment upon the successful completion of the first to occur of the following three events: (1) achievement of the primary endpoint of overall survival in its TYME-88-Panc pivotal trial; or (2) achievement of the primary endpoint of overall survival in the PanCAN Precision PromisesSM SM-88 registration arm; or (3) U.S. Food and Drug Administration (FDA) approval of SM-88 in any cancer. This payment would be split into a $10 million milestone cash payment and a $10 million investment in TYME at a 15% premium to the then prevailing market price. Eagle’s shares will be restricted from sale until the earlier of three months following the milestone event or the three-year anniversary of the agreement.

Under the terms of the co-promotion agreement, Eagle Pharmaceuticals will undertake 25% of the promotional sales effort for SM-88 in the U.S. oncology market and receive 15% of the net U.S. revenues of SM-88, and TYME will be responsible for the remaining promotional effort. TYME will also be responsible for clinical development, regulatory approval, commercial strategy, marketing, reimbursement and manufacturing of SM-88. TYME retains the remaining 85% of net U.S. revenues and reserves the right to repurchase Eagle’s co-promotion right for $200 million.

As part of this partnership between TYME and Eagle, there is also the potential to evaluate oral SM-88 in combination therapy or as monotherapy through leveraging Eagle’s oncology pipeline and expertise in oncology settings, which may include trials in breast or lung cancers and other tumor types.

“We are extremely pleased to establish this collaboration with Eagle Pharmaceuticals who shares our passion and commitment to improving the lives of patients with advanced cancers. After a thorough due diligence process by both parties, each came away with great respect for each organization’s capabilities and potential,” said Steve Hoffman, Chairman and Chief Executive Officer of TYME. “This alliance provides TYME with the
commercial and capital resources to advance our leadership position in the field of cancer metabolism and the potential to expand our capabilities and accelerate clinical programs that will create value for all of our stakeholders, most importantly for the patients we serve."

**About SM-88**

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Clinical results of SM-88, based on data as of April 25, 2019, from the Phase II portion of the TYME-88-Panc study, were presented at the European Society of Medical Oncology 21st World Congress on Gastrointestinal Cancer in Barcelona, Spain on Wednesday, July 4, 2019 ([TYME-88-Panc poster](#)). The study demonstrated a median overall survival in evaluable patients (38 of 49) of 6.4 months. These survival results compare very favorably to the analysis of 19 prospective pancreatic cancer trials where the median reported survival after progressing on second-line therapy was 2.0 – 2.5 months\(^1\) based on reported historical trials. In the Phase II portion of the TYME-88-Panc study, a RECIST CBR of stable disease or better was achieved by 44% of patients (11 of 25) with available imaging. Patients achieving stable disease or better demonstrated a statistically significant (p=0.02) improvement in survival with a 92% reduction in risk of death (hazard ratio=0.08). The CBR was durable with a majority of patients remaining in stable disease or better for more than 7 months after receiving treatment with SM-88. The study showed a median reduction of 63% in CTC burden in evaluable patients. Patients (10 of 24) with available results reaching an 80% reduction or greater in CTCs demonstrated a 60% decrease in risk of death (hazard ratio=0.40).

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

**About Advanced Pancreatic Cancer**

Advanced pancreatic cancer is a difficult-to-treat cancer with the lowest survival rates among all cancer types. Across all patients with pancreatic cancer, relative 5-year survival is 8% and is less than 3% for those with advanced disease.\(^2\) The median survival for patients in end-stage of the disease is approximately 3 months. There are two main types of pancreatic cancer - adenocarcinomas, which accounts for approximately 90% of all pancreatic cancer, and neuroendocrine tumors. Pancreatic cancer is relatively uncommon with new cases accounting for only 2.1% of all newly diagnosed cancers.
However, pancreatic cancer is the fourth most common cause of cancer death for men and women in the United States.

**About Precision PromiseSM**

Precision PromiseSM is an adaptive randomized Phase III registration-ready clinical trial. The objective of Precision PromiseSM is to expedite the study and approval of promising therapies for pancreatic cancer by bringing multiple stakeholders together, including academic, industry and regulatory entities. The primary goal of SM-88’s inclusion is to study SM-88 as a monotherapy treatment arm for patients who have failed one prior line of chemotherapy. Additionally, it is planned that SM-88 will be evaluated in combination with gemcitabine (Gemzar ®) and nab-paclitaxel (Abraxane ®) for first-line patients. The primary end point of these randomized trials is overall survival.

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**About Eagle Pharmaceuticals**

Eagle is a specialty pharmaceutical company focused on developing and commercializing innovative and differentiated injectable products that address the shortcomings, as identified by physicians, pharmacists and other stakeholders, of existing commercially successful injectable products. Additional information is available on the Company’s website at www.eagleus.com.

**Forward-Looking Statements/Disclosure Notice**

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding the potential benefits of, and plans relating to the collaboration between Eagle Pharmaceuticals and Tyme Technologies; the ability of Tyme and Eagle to develop synergies as collaborators; the potential of SM-88 as a therapeutic drug; the ability of Tyme to achieve the milestone events described herein; Eagle’s and Tyme’s ability and willingness to perform their respective obligations under the transaction agreements; and the benefit of each company’s strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "would," "could," "potential," "possible," "hope" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying
Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from current expectations and beliefs. For example, there can be no guarantee that any product candidate will be successfully developed or complete necessary preclinical and clinical phases, or that development of any of product candidates will successfully continue. There can be no guarantee that any positive developments will result in stock price appreciation. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other important factors, including: results of clinical trials and preclinical studies, including subsequent analysis of existing data and new data received from ongoing and future studies; the content and timing of decisions made by the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; the ability to obtain and maintain requisite regulatory approvals and to enroll patients in planned clinical trials; unplanned cash requirements and expenditures; competitive factors; the ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates; the ability to maintain key collaborations; and general economic and market conditions. These and other risks are described in greater detail under the caption "Risk Factors" included in each company's public filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and neither company has any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

1 Manax et al 2019 J Clin Oncol 37, 2019 (suppl 4; abstr 226)
2 Statistics adapted from the American Cancer Society's (ACS) publication, Cancer Facts & Figures 2018.

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TYME Announces First Patient Dosed in TYME-88-Panc Pivotal Trial to Evaluate SM-88 as Oral Treatment for Patients with Metastatic Pancreatic Cancer

- Oral SM-88 represents a new approach designed to selectively disrupt protein synthesis in cancers - demonstrated responses in 15 different cancer types across four separate studies
- Data presented at ESMO GI 2019 from TYME-88-PANC Phase II study demonstrated encouraging overall survival trends in patients with metastatic pancreatic cancer
- Targeted mechanism of action has resulted in fewer than 4% of patients experiencing serious adverse events related to SM-88 in prior clinical trials

NEW YORK, January 8, 2020 (GLOBE NEWSWIRE) -- Tyme Technologies, Inc. (NASDAQ: TYME), an emerging biotechnology company developing cancer metabolism-based therapies (CMBTs™), today announced that the first pancreatic cancer patient has been dosed in Part 2 of the TYME-88-Panc pivotal trial designed to support approval of SM-88 (racemetyrosine) for the third-line treatment of patients with metastatic pancreatic cancer. CMBTs are proprietary investigational compounds that are believed to disrupt cancer cells' protein synthesis, leading to a breakdown of the cancer's key defenses and cell death. In clinical trials, SM-88 has demonstrated encouraging tumor responses across 15 different cancers, including pancreatic, prostate, sarcoma, breast, lung, and lymphoma cancers with minimal serious grade 3 or higher adverse events.

"Patients with metastatic pancreatic cancer have a very poor prognosis. For those 10,000 patients actively seeking third-line treatment, there are currently no FDA-approved therapies and no oncology guideline recommendations for active therapy. We are passionate about advancing new treatment options for these patients " said Giuseppe Del Priore, M.D., Chief Medical Officer at TYME. "In clinical trials, SM-88 has demonstrated clinical responses across 15 different tumor types in clinical trials involving approximately 180 patients. We are excited about the potential of SM-88 as a first-in-class cancer metabolism-based therapy and are looking forward to evaluating this promising new approach in our pivotal study."

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

Recent results, based on data as of April 25, 2019, from Part 1 of the TYME-88-Panc study, were presented at the European Society of Medical Oncology 21st World Congress on Gastrointestinal Cancer in Barcelona, Spain on Wednesday, July 4, 2019 (link to poster). The study demonstrated a median overall survival in evaluable patients (38 of 49) of 6.4 months. These survival results compare very favorably to the analysis of 19 prospective pancreatic cancer trials where the median reported survival after progressing on second-line therapy was 2.0 – 2.5 months; based on reported historical trials. In Part 1 of the TYME-88-Panc study, a RECIST CBR of stable disease or better was achieved by 44% of patients (11 of 25) with available imaging. Patients achieving stable disease or better demonstrated a statistically significant (p=0.02) improvement in survival with a 92% reduction in risk of death (hazard ratio=0.08). The CBR was durable with majority of patients remaining in stable disease or better for more than 7 months after receiving treatment with SM-88. The study showed a median reduction of 63% in CTC burden in evaluable patients. Of the 24 patients with available results, those reaching an 80% reduction or greater in CTCs (10 of 24) demonstrated a 60% decrease in risk of death (hazard ratio=0.40).

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†Manax et al 2019 J Clin Oncol 37, 2019 (suppl 4; abstr 226)
‡Statistics adapted from the American Cancer Society’s (ACS) publication, Cancer Facts & Figures 2018.

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TYME and The Joseph Ahmed Foundation Announce First Patient Dosed in Phase II (HopES) Trial Evaluating the Potential Benefits of Oral SM-88 for Patients with High-Risk Sarcomas

- New oral approach aimed at disrupting cancer metabolism in high-risk sarcomas; 12,000 cases annually in U.S. alone
- Oral SM-88 represents a new approach designed to selectively disrupt protein synthesis in cancers with demonstrated responses in 15 different cancer types across four separate studies
- Targeted mechanism of action has resulted in fewer than 2% of patients experiencing serious adverse events related to SM-88 in all clinical trials

NEW YORK, NY, January 15, 2020 -- (GLOBE NEWSWIRE) -- Tyme Technologies, Inc. (NASDAQ: TYME), an emerging biotechnology company developing cancer metabolism-based therapies (CMBTs™), today announced the first sarcoma cancer patient has been dosed at the Sarcoma Oncology Center in the HopES Phase II trial designed to evaluate SM-88 (racemetyrosine) for the treatment of high-risk sarcomas, which are ultra-rare cancers with high unmet medical need. CMBTs are proprietary investigational compounds that are believed to disrupt cancer cells’ protein synthesis, leading to a breakdown of the cancer’s key defenses and cell death.

"The partnership with The Joseph Ahmed Foundation and the Sarcoma Oncology Center allows us to advance our commitment to addressing unmet treatment needs for rare cancers and continue advancing our unique scientific approach through cancer metabolism-based therapies. Our lead clinical investigational therapy, oral SM-88, has the potential to change the course of care for patients with high-risk sarcomas," said Giuseppe Del Priore, M.D., M.P.H., Chief Medical Officer at TYME. "We look forward to the findings of the HopES trial and to continue strengthening our research efforts to potentially provide transformative options for patients with high-risk sarcomas and other metastatic cancers."

"There are significant knowledge gaps about high-risk sarcomas, such as Ewing’s sarcoma, including the role of cancer metabolism-based medicines, and the related outcomes for patients," said Sant Chawla, M.D., founder of the Sarcoma Oncology Center, Santa Monica, CA and lead investigator for the HopES trial. "This study has the potential to provide valuable real-world evidence that can help advance care for patients with high-risk sarcomas. We are excited to partner with TYME to further advance the
science of cancer metabolism, research and education in these rare cancers so that patients can have better, safer options."

The HopES trial is a prospective open-label Phase II trial evaluating the efficacy and safety of SM-88 in two cohorts of patients. Up to 24 evaluable patients (12 per cohort) will be enrolled. The first cohort will evaluate oral SM-88 as maintenance monotherapy following standard primary or palliative treatments for Ewing's sarcoma patients with a high risk of relapse or disease progression. The second cohort will determine the clinical benefits of SM-88 as salvage monotherapy for patients with clinically advanced sarcomas. The Joseph Ahmed Foundation is providing funding and patient support for this investigator-initiated Phase II (HopES) trial of SM-88 in patients with previously treated metastatic sarcoma. The primary objectives are to measure efficacy events, including overall response, stable disease and progression free survival. Secondary objectives include duration of response, overall survival, clinical benefit rate using response evaluation criteria in solid tumors (RECIST 1.1), and incidence of treatment-emergent adverse events. Learn more at TYMETRIALS.com.

About Sarcomas and Ewing's Sarcoma

Sarcomas are rare cancers in adults but are more common in children. There are approximately 12,000¹ new sarcoma cases annually in the U.S. alone. There are many "subtypes" of sarcoma, as it can arise in many tissue structures throughout the body (nerves, muscles, joints, bone, fat, blood vessels – collectively referred to as the body's "connective tissues"). Sarcomas are most frequently found in the limbs, as this is where the majority of the body’s connective tissues are found but can also present within the sites of more “common” cancers (e.g., breast sarcoma, stomach sarcoma, lung sarcoma, ovarian sarcoma, etc.). Sarcoma cancers often grow hidden deep in the body and are often diagnosed when the tumor size limits effective treatment options.

Ewing's sarcoma is a primary bone cancer within a group of cancers known collectively as the Ewing's sarcoma family of tumors. Ewing's sarcoma is a type of tumor that forms in the bone or soft tissue. It is a rare type of cancer that is often overlooked and receives minimal recognition and research funding. Although Ewing's sarcoma is typically a pediatric cancer, (it accounts for 30% of bone cancers in children), it can also be found in adults. The most commonly affected areas include the pelvis, thigh, lower leg, upper arm, and chest wall.

About SM-88

SM-88 is an oral investigational modified proprietary tyrosine derivative that is believed to interrupt the metabolic processes of cancer cells by breaking down the cells' key defenses and leading to cell death through oxidative stress and exposure to the body’s natural immune system. Clinical trial data have shown that SM-88 has demonstrated encouraging tumor responses across 15 different cancers, including pancreatic, lung, breast, prostate and sarcoma cancers with minimal serious grade 3 or higher adverse events.
About the Joseph Ahmed Foundation

The Joseph Ahmed Foundation (JAF) is a 501(c)(3) non-profit organization that was founded in 2016 by the family of Joseph Ahmed, who lost his courageous battle with Ewing’s Sarcoma eight months after his diagnosis on September 1, 2014, at the age of 16. Through their tragic loss and grief, Joseph's loved ones established the Joseph Ahmed Foundation which is dedicated to raising public awareness for the importance of early detection of the disease, and the urgent need of funding for research and development of innovative treatment and therapies to treat Ewing’s Sarcoma and other forms of pediatric cancer. JAF’s mission is to provide resources for research programs and support services through fundraising, philanthropic donations, corporate sponsorship and grants. JAF is comprised of passionate board members and volunteers who all share the same vision, finding a cure. The foundation can be reached at 212-867-8667. The global website is www.thejosephahmedfoundation.org

About Tyme Technologies

Tyme Technologies, Inc., is an emerging biotechnology company developing cancer therapeutics that are intended to be broadly effective across tumor types and have low toxicity profiles. Unlike targeted therapies that attempt to regulate specific mutations within cancer, the Company’s therapeutic approach is designed to take advantage of a cancer cell’s innate metabolic weaknesses to compromise its defenses, leading to cancer cell death through oxidative stress and exposure to the body’s natural immune system. For more information, visit www.tymeinc.com. Follow us on social media: @tyme_Inc, LinkedIn, Instagram, Facebook and YouTube.

Forward-Looking Statements/Disclosure Notice

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1https://www.cancer.org/cancer/soft-tissue-sarcoma/about/key-statistics.html

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Health Economic Research Study Demonstrates Increased Use of New Medicines in the Treatment of Patients with Pancreatic Cancer Reduces Total Cost of Care

- The study shows that for every additional $1 spent on innovative medicines for pancreatic cancer between 2009 to 2016, there was a reduction in non-medicine spending of $8 to $9
- This preliminary study reported that cost of procedures is markedly reduced when budgets are funded towards better pharmacotherapy
- Non-drug spending represented the majority of patient care costs
- More effective, better tolerated oral therapies for pancreatic cancer may lead to further reduction of burden on the healthcare system

NEW YORK, NY, January 27, 2020 -- (GLOBE NEWSWIRE) -- Tyme Technologies, Inc. (NASDAQ: TYME), an emerging biotechnology company developing cancer metabolism based therapies (CMBTs™), announced the results of a health economic outcomes study demonstrating that the therapeutic benefit of increasing the use of novel medicines is so great that it is driving a decrease in the actual total cost of healthcare. The supporting data from the study were presented at the American Society of Clinical Oncology’s 2020 Gastrointestinal Cancers Symposium (ASCO GI) held on January 23 to 25, 2020 in San Francisco, California.

Health technology assessment programs are increasingly using real-world patient data to assess the effect of new medicines on total cost of care. This study analyzed such data to measure the impact of new pancreatic cancer therapies on other non-therapeutic medical expenditures.

“There is a great need to develop new treatments for pancreatic cancer that balance both efficacy and safety,” said Vincent J. Picozzi, M.D., Director of the Pancreaticobiliary Program at the Floyd & Delores Jones Cancer Institute at the Virginia Mason Medical Center. “The value of advancing treatments is apparent from our total cost of care analysis looking at both medical and pharmacotherapy costs. Our study looked at treatment inflation-adjusted expenses per patient for pancreatic cancer care between 2009 and 2016 and found that for every additional $1 spent on drugs for pancreatic cancer, there was a reduction in non-drug spending of $9.”

The study showed that between 2009 and 2016, average inflation-adjusted per patient spending on pancreatic cancer care declined from $37,000 to $10,000. Prescription drug spending increased during the same time period from $2,400 to $5,300 per person
(inflation adjusted). In effect, for every additional dollar spent on therapies for pancreatic cancer between 2009 to 2016, there was a reduction in non-drug spending of $9.00.

Total cost of care for patients in this analysis reached a maximum of $280,443 and $312,077 for first and second year of care respectively. Also, between 1997 and 2016 inflation adjusted first- and second-year non-medication charges on pancreatic cancer care averaged $66,999.96 and $105,308.60 respectively.

The study analyzed longitudinal patient-level data from the Medical Expenditure Panel Survey (MEPS, 1996 – 2017). The study evaluated 80 patients who had a diagnosis of pancreatic cancer and available prescription data. Individual age and employment status were accounted for as covariates. Notably, the data revealed that while prescription medicine expenses have increased as part of the total cost of treating patients with pancreatic cancer over the last ten years, the overall healthcare cost of treating pancreatic cancer patients has gone down.

All analyses were performed using R version 3.6.1 on Ubuntu 19.04. Means and standard deviations were computed for the raw and inflation-adjusted total health care costs excluding drug spending. Study averages were computed for the total health care costs, including prescription medicine costs for the period between 2009-2016 which included approval and use of novel treatment approaches such as Abraxane® (nab-paclitaxel), FOLFIRINOX and erlotinib. The prescription medicines expenses, and proportion of healthcare spending were also plotted along with a LOESS curve using the same parameters. All expenditures are adjusted for inflation using 2012 U.S. Dollars.

As a result of this health economic outcomes study, further analysis of a larger, longitudinal set of patient-level data is needed to more fully explore the relationship between spending on medical innovation, and reduction in total cost of patient care, as well as improvements in quality of life.

Details of this study were presented at the American Society of Clinical Oncology’s 2020 Gastrointestinal Cancers Symposium (ASCO GI) held on January 23 to 25, 2020 in San Francisco, California. The poster was presented on Friday, January 24, 2020, from 12:00 PM PT to 1:30 PM PT and 4:30 PM PT to 5:30 PM PT during the Poster Display Session in Poster Hall. The poster is available on our website (www.tymeinc.com/data-publications).

The health economic outcomes poster on pancreatic cancer presented at the ASCO GI Cancer Symposium in San Francisco is as follows:

**Title:** An Assessment of the Total Cost of Pancreatic Cancer Using Real-World Evidence

**Authors:** Vincent J. Picozzi1, Victoria G. Manax2, Kelly Feehan2, Zachary Wintrob3, Michele Korfin4, Giuseppe Del Priore4, Robert Goldberg5
Institutions: Virginia Mason Medical Center, Seattle, WA1, Pancreatic Cancer Action Network, Manhattan Beach, CA2, Roaketin, Inc., Buffalo, NY3, Tyme Technologies, Inc., NY, NY4, Center for Medicine in the Public Interest, NY, NY5

Session Date and Time: Friday, January 24, 2020, 12:00 PM PT – 1:30 PM PT and 4:30 PM PT – 5:30 PM PT
Session Title: Poster Display Session B: Hepatobiliary Cancer, Neuroendocrine/Carcinoid, Pancreatic Cancer, and Small Bowel Cancer
Abstract Number: 773
Poster Number: Board N18

About Advanced Pancreatic Cancer
Advanced pancreatic cancer is a difficult-to-treat cancer with the lowest survival rates among all cancer types. Across all patients with pancreatic cancer, relative 5-year survival is 8% and is less than 3% for those with advanced disease. The median survival for patients in end-stage of the disease is approximately 3 months. There are two main types of pancreatic cancer - adenocarcinomas, which accounts for approximately 90% of all pancreatic cancer, and neuroendocrine tumors. Pancreatic cancer is relatively uncommon with new cases accounting for only 2.1% of all newly diagnosed cancers. However, pancreatic cancer is the fourth most common cause of cancer death for men and women in the United States.

About SM-88
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About Tyme Technologies
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The New Oral Investigational Therapy That Attacks Cancer’s Unique Metabolism From the Inside, Out

By achieving proprietary cancer metabolism-based therapies (CBMTS) for difficult-to-treat metastatic cancers, they’re looking to do something different—themselves.

"This is a new generation approach that is designed to target cancer cells and allow patients to have a more normal quality of life," says Tom Tyler, president and chief executive officer of Tyne Technologies, Inc.

Attacking the cancer seriously has been the approach in recent years, but that’s changing.

New approach

"The approach is a spook of chemotherapy," says Tom Tyler. "It’s not trying to destroy cancer from the outside, it makes a Trojan horse into the cancer. You’re killing the cancer from the inside out.

"How it works—it’s a vessel that sends a special enzyme to the disease and the new vessel approach makes one of these enzymes inside stomach/digestive.

The new vessel can’t recognize the metabolism treatment as being foreign because the body doesn’t try to fight it. So, it’s having significant impact.

Now pancreatic cancer patients for example, every 500,000 Americans are diagnosed with the disease that happens when pancreatic cells grow out of control from a tumor. The outlook is grim – 90% of patients do not survive five years after diagnosis.

"Most treatments for pancreatic cancer kill the cancer cells in addition to the healthy cells," says Michael Kors, "few offer specialized offices. "This treatment was developed to target just the cancer cells."

The biotech company, TYNE, developed and is studying an investigational oral cancer metabolism-based therapy (CBMT) for patients with metastatic pancreatic cancer.

So far, the drug has not shown "encouraging tumor responses" across 150 patients in clinical trials, according to a press release. Kors says data was recently presented showing patients with the new oral CBMT pancreatic cancer has a prognosis of living to two to four years. But within the new vessel treatment, many of these same pancreatic cancer patients had lived an average of almost one half to two months.

The same drugs are being studied in patients with prostate and ovarian cancer.

TYNE’s oral CBMT is already being tried for other cancers in the near future. Right now, there is urgent need for cancer therapies since the United States has increased prevalence of late stage cancer patients. Improved outcomes

TYNE’s work helps to keep cancer patients have more options to improve and extend their quality of life. They welcome a broad range of patients to their trials, including recruiting patients who are very sick. Patients can take the therapies at home or stay at home with their families, instead of a clinic, hospital or doctor's office.

"We’re looking to improve outcomes for the patient but also looking to do in a way that adds value and is welcomed by the patient," says Kors. Initially, the new vessel therapy was easy to convert for patients to use.

"We’re working to ease the pain of these metabolic therapies into 2020, including 150 patients granted in speaking globally. TYNE plans to initiate a pivotal phase 1/2 trial for pancreatic cancer in the third quarter of 2019.

The two also present with the world’s largest patient advocacy group committed to finding a cure for pancreatic cancer, the Pancreatic Cancer Action Network, through their Pancreas TraxWalk platform to launch a digital pilot project using IBM Watson in second cancer pancreatic in the third quarter of 2019.

TYNE is raising funds to treat their cancer afflicting patients with chronic medical needs, says Kors. "Our focus is on direct treatment of brain metastases and targeting the cancer cell and sparing the healthy cell."

Karen Cicatelli, an advocate for @mlpilotproject.
A Trickster Enters the Fight Against Metastatic Cancers

This page is a continuation of the text from the previous page. It appears to be discussing a medical topic related to tricksters and their role in fighting against metastatic cancers. The text discusses various strategies and approaches to combating this disease, possibly involving unconventional or alternative methods. The content is technical and likely intended for a medical or scientific audience. Further details would require a thorough reading of the entire document.
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended:
December 31, 2019

or

Commission File Number: 001-38169

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

Delaware
(State or other jurisdiction of incorporation or organization)

45-3864597
I.R.S. Employer Identification No.)

17 State Street – 7th Floor
New York, New York 10004
(Address of principal executive offices)

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

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

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

<table>
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<tr>
<th>Title of each class</th>
<th>Trading Symbol(s)</th>
<th>Name of each exchange on which registered</th>
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<tbody>
<tr>
<td>Common Stock, $0.0001 par value</td>
<td>TYME</td>
<td>Nasdaq Capital Market</td>
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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

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

Large accelerated filer ☐ Accelerated filer ☒
Non-accelerated filer ☐ Smaller reporting company ☒
Emerging growth company ☐

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

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

The number of shares outstanding of the registrant’s common stock on January 28, 2020 was 122,839,504.
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<td>SIGNATURES</td>
<td>29</td>
</tr>
</tbody>
</table>
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q 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 within this report include, without limitation, statements regarding our drug candidates (including SM-88 and TYME-18) and their clinical potential and non-toxic safety profiles, our drug development plans and strategies, ongoing and planned clinical trials, preliminary data results and the therapeutic design and mechanisms of our drug candidates. The words “believes,” “expects,” “hopes,” “may,” “will,” “plan,” “intends,” “estimates,” “could,” “should,” “would,” “continue,” “seeks,” “anticipates,” and similar expressions (including their use in the negative), are intended to identify forward-looking statements. Forward-looking statements can also be identified by discussions of future matters such as the cost of development and potential commercialization of our lead drug candidate and of other new products, expected releases of interim or final data from our clinical trials, possible collaborations, the timing, scope and objectives of our ongoing and planned clinical trials and other statements that are not historical. The forward-looking statements contained in this report are based on management’s current expectations and projections which are subject to uncertainty, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. These statements involve known and unknown risks, uncertainties and other factors which may cause the Company’s actual results, performance or achievements to be materially different from any historical results and future results, performance or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include but are not limited to, that the information is of a preliminary nature and may be subject to change; uncertainties inherent in the cost and outcomes of research and development, including the cost and availability of acceptable-quality clinical supply and the ability to achieve adequate clinical study design and start and completion dates; the possibility of unfavorable study results, including unfavorable new clinical data and additional analyses of existing data; risks associated with early, initial data, including the risk that the final data from any clinical trials may differ from prior or preliminary study data; final results of additional clinical trials that may be different from the preliminary data analysis and may not support further clinical development; that past reported data are not necessarily predictive of future patient or clinical data outcomes; whether and when any applications or other submissions for SM-88 may be filed with regulatory authorities; whether and when regulatory authorities may approve any applications or submissions; decisions by regulatory authorities regarding labeling and other matters that could affect commercial availability of SM-88; the ability of TYME and its collaborators to develop and realize collaborative synergies; competitive developments; and the factors described in the section captioned “Risk Factors” in Part II, Item 1A of this Quarterly Report, as well as subsequent reports we file from time to time with the U.S. Securities and Exchange Commission (available at www.sec.gov).

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, achievements or events and circumstances reflected in the forward-looking statements will occur. Moreover, we operate in a competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from any forward-looking statements we make. We cannot assure you that forward-looking statements in this report or therein will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us to any other person that we will achieve our objectives and plans in any specified time frame, or at all. We disclaim any intent or duty to update any of these forward-looking statements after completion of this Quarterly Report on Form 10-Q to conform these statements to actual results or revised expectations.

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

#### Item 1. Financial Statements.

**Tyme Technologies, Inc. and Subsidiaries**  
**Condensed Consolidated Balance Sheets**

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2019 (unaudited)</th>
<th>March 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Current Assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>$11,465,613</td>
<td>$14,302,328</td>
</tr>
<tr>
<td>Prepaid rent</td>
<td>—</td>
<td>242,755</td>
</tr>
<tr>
<td>Prepaid clinical costs</td>
<td>470,836</td>
<td>592,134</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>293,799</td>
<td>1,001,898</td>
</tr>
<tr>
<td><strong>Total current assets</strong></td>
<td>12,230,248</td>
<td>16,139,115</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>6,477</td>
<td>10,363</td>
</tr>
<tr>
<td>Prepaid rent, net of current portion</td>
<td>—</td>
<td>101,148</td>
</tr>
<tr>
<td>Prepaid clinical costs, net of current portion</td>
<td>1,266,025</td>
<td>1,266,025</td>
</tr>
<tr>
<td>Operating lease right-of-use asset</td>
<td>229,478</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td>$13,732,228</td>
<td>$17,516,651</td>
</tr>
<tr>
<td><strong>Liabilities and Stockholders’ Equity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Current liabilities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts payable and other current liabilities (including $222,000 and $325,000 of related party accounts payable, respectively)</td>
<td>$3,535,264</td>
<td>$3,692,308</td>
</tr>
<tr>
<td>Severance payable</td>
<td>375,067</td>
<td>428,240</td>
</tr>
<tr>
<td>Accrued bonuses</td>
<td>1,301,359</td>
<td>1,495,248</td>
</tr>
<tr>
<td>Insurance note payable</td>
<td>—</td>
<td>597,339</td>
</tr>
<tr>
<td>Operating lease liability</td>
<td>58,892</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total current liabilities</strong></td>
<td>5,270,582</td>
<td>6,213,135</td>
</tr>
<tr>
<td><strong>Long-term liabilities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severance payable</td>
<td>1,358,333</td>
<td>1,635,634</td>
</tr>
<tr>
<td>Operating lease liability, net of current portion</td>
<td>10,164</td>
<td>—</td>
</tr>
<tr>
<td>Warrant liability</td>
<td>4,690,000</td>
<td>—</td>
</tr>
<tr>
<td><strong>Total liabilities</strong></td>
<td>11,329,079</td>
<td>7,848,769</td>
</tr>
<tr>
<td><strong>Commitments and contingencies (see Note 9)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Stockholders' equity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preferred stock, $0.0001 par value, 10,000,000 shares authorized, 0 shares issued and outstanding</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Common stock, $0.0001 par value, 300,000,000 shares authorized, 112,533,905 issued and outstanding at December 31, 2019, 300,000,000 authorized, 103,946,048 issued and outstanding at March 31, 2019</td>
<td>11,255</td>
<td>10,397</td>
</tr>
<tr>
<td>Additional paid in capital</td>
<td>104,482,186</td>
<td>95,472,181</td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>(102,090,292)</td>
<td>(85,814,696)</td>
</tr>
<tr>
<td><strong>Total stockholders' equity</strong></td>
<td>2,403,149</td>
<td>9,667,882</td>
</tr>
<tr>
<td><strong>Total liabilities and stockholders' equity</strong></td>
<td>$13,732,228</td>
<td>$17,516,651</td>
</tr>
</tbody>
</table>

The Notes to Condensed Consolidated Financial Statements are an integral part of these statements.
### Tyme Technologies, Inc. and Subsidiaries

#### Condensed Consolidated Statements of Operations

(UNAUDITED)

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended December 31,</th>
<th>Nine Months Ended December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2019</td>
<td>2018</td>
</tr>
<tr>
<td><strong>Revenues</strong></td>
<td>$ —</td>
<td>$ —</td>
</tr>
<tr>
<td><strong>Operating expenses:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>3,453,459</td>
<td>4,525,228</td>
</tr>
<tr>
<td>General and administrative (including $58,500, $132,000, $307,000 and $794,000 of related party legal expenses, respectively)</td>
<td>3,090,223</td>
<td>3,550,224</td>
</tr>
<tr>
<td><strong>Total operating expenses</strong></td>
<td>6,543,682</td>
<td>8,075,452</td>
</tr>
<tr>
<td>Loss from operations</td>
<td>(6,543,682)</td>
<td>(8,075,452)</td>
</tr>
<tr>
<td><strong>Other income (expenses):</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in fair value of warrant liability</td>
<td>(425,795)</td>
<td>—</td>
</tr>
<tr>
<td>Interest income</td>
<td>38,257</td>
<td>28,718</td>
</tr>
<tr>
<td>Interest expense</td>
<td>(26,310)</td>
<td>(1,222)</td>
</tr>
<tr>
<td><strong>Total other income (expenses)</strong></td>
<td>(413,848)</td>
<td>27,496</td>
</tr>
<tr>
<td><strong>Net loss</strong></td>
<td>$ (6,957,530)</td>
<td>$ (8,047,956)</td>
</tr>
<tr>
<td>Basic and diluted loss per common share</td>
<td>$ (0.06)</td>
<td>$ (0.08)</td>
</tr>
<tr>
<td>Basic and diluted weighted average shares outstanding</td>
<td>112,071,354</td>
<td>103,009,449</td>
</tr>
</tbody>
</table>

The Notes to Condensed Consolidated Financial Statements are an integral part of these statements.
<table>
<thead>
<tr>
<th></th>
<th>Shares</th>
<th>Amount</th>
<th>Additional Paid-in Capital</th>
<th>Accumulated Deficit</th>
<th>Total Stockholders' Equity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Balance, April 1, 2019</strong></td>
<td>103,946,048</td>
<td>$10,397</td>
<td>$95,472,181</td>
<td>$(85,814,696)</td>
<td>$9,667,882</td>
</tr>
<tr>
<td><strong>Issuance of common stock from underwritten registered offering, net of associated expenses of $111,227</strong></td>
<td>8,000,000</td>
<td>800</td>
<td>3,884,372</td>
<td>—</td>
<td>3,885,172</td>
</tr>
<tr>
<td><strong>Cashless exercise of warrants</strong></td>
<td>4,889</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>Stock based compensation</strong></td>
<td>—</td>
<td>—</td>
<td>1,624,961</td>
<td>—</td>
<td>1,624,961</td>
</tr>
<tr>
<td><strong>Net loss</strong></td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(3,191,986)</td>
<td>(3,191,986)</td>
</tr>
<tr>
<td><strong>Balance, June 30, 2019</strong></td>
<td>111,950,937</td>
<td>$11,197</td>
<td>$100,981,514</td>
<td>$(89,006,682)</td>
<td>$11,986,029</td>
</tr>
<tr>
<td><strong>Stock based compensation</strong></td>
<td>—</td>
<td>—</td>
<td>1,446,062</td>
<td>—</td>
<td>1,446,062</td>
</tr>
<tr>
<td><strong>Net loss</strong></td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(6,126,080)</td>
<td>(6,126,080)</td>
</tr>
<tr>
<td><strong>Balance, September 30, 2019</strong></td>
<td>111,950,937</td>
<td>$11,197</td>
<td>$102,427,576</td>
<td>$(95,132,762)</td>
<td>$7,306,011</td>
</tr>
<tr>
<td><strong>Issuance of common stock from at-the-market financing facility, net of associated expenses of $165,157</strong></td>
<td>582,968</td>
<td>58</td>
<td>452,494</td>
<td>—</td>
<td>452,552</td>
</tr>
<tr>
<td><strong>Stock based compensation</strong></td>
<td>—</td>
<td>—</td>
<td>1,602,116</td>
<td>—</td>
<td>1,602,116</td>
</tr>
<tr>
<td><strong>Net loss</strong></td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(6,957,530)</td>
<td>(6,957,530)</td>
</tr>
<tr>
<td><strong>Balance, December 31, 2019</strong></td>
<td>112,533,905</td>
<td>$11,255</td>
<td>$104,482,186</td>
<td>$(102,090,292)</td>
<td>$2,403,149</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Shares</th>
<th>Amount</th>
<th>Additional Paid-in Capital</th>
<th>Accumulated Deficit</th>
<th>Total Stockholders' Equity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Balance, April 1, 2018</strong></td>
<td>101,226,479</td>
<td>$10,125</td>
<td>$79,293,423</td>
<td>$(52,831,581)</td>
<td>$26,471,967</td>
</tr>
<tr>
<td><strong>Stock based compensation</strong></td>
<td>—</td>
<td>—</td>
<td>2,519,269</td>
<td>—</td>
<td>2,519,269</td>
</tr>
<tr>
<td><strong>Net loss</strong></td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(6,722,796)</td>
<td>(6,722,796)</td>
</tr>
<tr>
<td><strong>Balance, June 30, 2018</strong></td>
<td>101,226,479</td>
<td>$10,125</td>
<td>$81,812,692</td>
<td>$(59,554,377)</td>
<td>$22,268,440</td>
</tr>
<tr>
<td><strong>Issuance of common stock from at-the-market financing facility, net of associated expenses of $103,237</strong></td>
<td>1,497,317</td>
<td>150</td>
<td>3,337,840</td>
<td>—</td>
<td>3,337,990</td>
</tr>
<tr>
<td><strong>Stock based compensation</strong></td>
<td>—</td>
<td>—</td>
<td>2,183,157</td>
<td>—</td>
<td>2,183,157</td>
</tr>
<tr>
<td><strong>Net loss</strong></td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(7,015,120)</td>
<td>(7,015,120)</td>
</tr>
<tr>
<td><strong>Balance, September 30, 2018</strong></td>
<td>102,723,796</td>
<td>$10,275</td>
<td>$87,333,689</td>
<td>$(66,569,497)</td>
<td>$20,774,467</td>
</tr>
<tr>
<td><strong>Issuance of common stock from at-the-market financing facility, net of associated expenses of $22,091</strong></td>
<td>282,555</td>
<td>29</td>
<td>714,246</td>
<td>—</td>
<td>714,275</td>
</tr>
<tr>
<td><strong>Exercise of options</strong></td>
<td>100,000</td>
<td>10</td>
<td>269,990</td>
<td>—</td>
<td>270,000</td>
</tr>
<tr>
<td><strong>Cashless exercise of warrants</strong></td>
<td>84,034</td>
<td>8</td>
<td>(8)</td>
<td>—</td>
<td>(8)</td>
</tr>
<tr>
<td><strong>Stock based compensation</strong></td>
<td>—</td>
<td>—</td>
<td>1,999,659</td>
<td>—</td>
<td>1,999,659</td>
</tr>
<tr>
<td><strong>Net loss</strong></td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(8,047,956)</td>
<td>(8,047,956)</td>
</tr>
<tr>
<td><strong>Balance, December 31, 2018</strong></td>
<td>103,190,385</td>
<td>$10,322</td>
<td>$90,317,576</td>
<td>$(74,617,453)</td>
<td>$15,710,445</td>
</tr>
</tbody>
</table>

The Notes to Condensed Consolidated Financial Statements are an integral part of these statements.
## Tyme Technologies, Inc. and Subsidiaries
### Condensed Consolidated Statements of Cash Flows
(UNAUDITED)

<table>
<thead>
<tr>
<th></th>
<th>Nine Months Ended</th>
<th>December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2019</td>
<td>2018</td>
</tr>
<tr>
<td><strong>Cash flows from operating activities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td>$(16,275,596)</td>
<td>$(21,785,872)</td>
</tr>
<tr>
<td>Adjustments to reconcile net loss to net cash used in operating activities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation</td>
<td>3,886</td>
<td>7,108</td>
</tr>
<tr>
<td>Amortization of employees, directors and consultants stock options</td>
<td>4,673,140</td>
<td>6,702,085</td>
</tr>
<tr>
<td>Change in fair value of warrant liability</td>
<td>$(2,593,601)</td>
<td>—</td>
</tr>
<tr>
<td>Change in operating assets and liabilities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prepaid rent</td>
<td>—</td>
<td>(404,591)</td>
</tr>
<tr>
<td>Prepaid clinical costs</td>
<td>121,298</td>
<td>(470,146)</td>
</tr>
<tr>
<td>Prepaid expenses and other assets</td>
<td>708,099</td>
<td>445,832</td>
</tr>
<tr>
<td>Operating lease right-of-use asset</td>
<td>218,419</td>
<td>—</td>
</tr>
<tr>
<td>Accounts payable and other current liabilities</td>
<td>(157,045)</td>
<td>(521,841)</td>
</tr>
<tr>
<td>Severance payable</td>
<td>(330,474)</td>
<td>(80,901)</td>
</tr>
<tr>
<td>Accrued bonuses</td>
<td>(193,889)</td>
<td>(80,901)</td>
</tr>
<tr>
<td>Operating lease liability</td>
<td>(34,938)</td>
<td>—</td>
</tr>
<tr>
<td>Net cash used in operating activities</td>
<td>$(13,860,701)</td>
<td>$(16,108,326)</td>
</tr>
<tr>
<td><strong>Cash flows from investing activities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purchase of property &amp; equipment</td>
<td>—</td>
<td>(15,544)</td>
</tr>
<tr>
<td>Net cash used in investing activities</td>
<td>—</td>
<td>(15,544)</td>
</tr>
<tr>
<td><strong>Cash flows from financing activities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insurance note payments</td>
<td>(597,339)</td>
<td>(441,078)</td>
</tr>
<tr>
<td>Proceeds from registered offerings, net of issuance costs</td>
<td>11,621,325</td>
<td>4,052,265</td>
</tr>
<tr>
<td>Proceeds from the exercise of stock options</td>
<td>—</td>
<td>270,000</td>
</tr>
<tr>
<td>Net cash provided by financing activities</td>
<td>11,023,986</td>
<td>3,881,187</td>
</tr>
<tr>
<td>Net increase (decrease) in cash and cash equivalents</td>
<td>(2,836,715)</td>
<td>(12,242,683)</td>
</tr>
<tr>
<td>Cash and cash equivalents – beginning</td>
<td>14,302,328</td>
<td>28,975,822</td>
</tr>
<tr>
<td>Cash and cash equivalents – ending</td>
<td>$11,465,613</td>
<td>$16,733,139</td>
</tr>
</tbody>
</table>

**Supplemental Cash Flow Information:**

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interest</td>
<td>$88,530</td>
<td>$7,279</td>
</tr>
<tr>
<td>Income taxes</td>
<td>$</td>
<td>$</td>
</tr>
</tbody>
</table>

**Noncash investing and financing activities:**

Cashless exercise of 78,431 warrants for 4,889 shares in 2019 and 301,959 warrants for 84,034 shares of common stock in 2018 | $                      | $            |

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

5
Tyme Technologies, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements
December 31, 2019
(Unaudited)

Note 1. Nature of Business

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

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

The Company’s lead clinical CMBT program, SM-88 (racemetyrosine), is a novel, oral, monotherapy investigational agent that has been studied in approximately 180 patients, including Phase I and II clinical trials for pancreatic, prostate and other cancers. TYME recently launched its pivotal study for SM-88 in the third-line treatment of pancreatic cancer through an amendment to its ongoing TYME-88-Panc trial (“Part 2”), with the first patient dosed in the third quarter of fiscal year 2020. TYME also partnered with the Pancreatic Cancer Action Network (“PanCAN”) to study SM-88 in an adaptive randomized Phase II/III trial with registration intent known as Precision PromiseSM. In Precision Promise, SM-88 is starting as second-line monotherapy and could expand to first-line combination therapy with standard of care. HopES is a Phase II investigator-initiated trial evaluating SM-88 monotherapy in late-stage sarcomas, under the direction of principal investigator Dr. Sant Chawla and in collaboration with The Joseph Ahmed Foundation. The first sarcoma cancer patient in the HopES trial was dosed in the fourth quarter of fiscal year 2020. The Company has also completed and presented final data from its Phase II clinical trial in prostate cancer. All of SM-88’s current clinical programs, as well as its completed Phase II prostate cancer trial, study SM-88 in use with three low-dose conditioning agents: methoxsalen, phenytoin, and sirolimus. The Company is actively evaluating the expansion of its clinical program to hematological, breast, prostate and other cancers as SM-88 has demonstrated complete or partial responses in 15 different forms of cancer with a well-tolerated safety profile.

The accompanying condensed consolidated financial statements include the results of operations of Tyme Technologies, Inc. and its wholly-owned subsidiaries.

Liquidity

The condensed consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has historically funded its operations primarily through equity offerings. In April 2019, the Company raised net proceeds of approximately $11.3 million after underwriting discounts and before expenses through an underwritten registered offering. Previously on November 2, 2017, the Company entered into an equity distribution agreement (the “Equity Distribution Agreement”) with Canaccord Genuity Inc. (“Canaccord”), with respect to an at-the-market (“ATM”) offering pursuant to which the Company, from time to time, sold shares of the Company’s common stock, par value $0.0001 per share (“Common Stock”), having an aggregate offering price up to $30.0 million, through Canaccord, as the Company’s sales agent (the “Canaccord ATM”). In the year ended March 31, 2019, the Company raised approximately $5.8 million in aggregate gross proceeds before commissions and expenses through the Canaccord ATM and paid Canaccord aggregate commissions of $0.2 million. The Company did not sell any shares through the Canaccord ATM during the nine months ended December 31, 2019. On October 2, 2019, TYME sent notice to Canaccord that it was terminating the Equity Distribution Agreement, effective October 12, 2019.

On October 18, 2019, TYME entered into an Open Market Sale AgreementSM (the “Sale Agreement”) with Jefferies LLC ("Jefferies") as sales agent, pursuant to which the Company may, from time to time, sell shares of Common Stock through Jefferies having an aggregate offering price of up to $30.0 million (the “Jefferies ATM”). In the quarter ended December 31, 2019, the Company raised approximately $0.6 million in aggregate gross proceeds before commissions and expenses through the Jefferies Sale Agreement and paid Jefferies aggregate commissions of $0.02 million.

Most recently (and subsequent to the quarter ended December 31, 2019) on January 7, 2020, the Company entered into a Securities and Purchase Agreement with Eagle Pharmaceuticals, ("Eagle"), pursuant to which the Company issued and sold to Eagle 10,000,000 shares of Common Stock, at a price of $2.00 per share, (see Note 14 - Subsequent Event). The proceeds of the aforementioned offerings are being used by the Company for continued clinical studies, drug commercialization planning and development activities and other general corporate and operating expenses.
For the nine months ended December 31, 2019, the Company had negative cash flow from operations of $13.9 million and net loss of $16.3 million, which included non-cash income of $2.6 million (related to change in fair value of warrant liability) and $4.7 million of non-cash expenses, primarily non-cash equity compensation expense. As of December 31, 2019, the Company had working capital of approximately $7.0 million.

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

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

Basis of Presentation

The accompanying condensed consolidated financial statements and related notes should be read in conjunction with our consolidated financial statements and related notes contained in our Annual Report on Form 10-K for the year ended March 31, 2019 filed with the Securities and Exchange Commission (the “SEC”) on June 12, 2019 (the “2019 10-K”). The condensed consolidated financial statements have been prepared in accordance with the rules and regulations of the SEC related to interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) have been condensed or omitted pursuant to such rules and regulations. The financial information contained herein is unaudited; however, management believes all adjustments have been made that are necessary to present fairly the results for the interim periods. All such adjustments are of a normal and recurring nature. The results of operations for the interim periods are not necessarily indicative of the results to be expected for the full year.

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

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

The Company’s significant accounting policies are disclosed in the audited financial statements for the year ended March 31, 2019 included in the Company’s 2019 10-K.

Reclassifications

The Company has reclassified certain prior period amounts to conform to the current period presentation. These reclassifications have no effect on the previously reported net loss or cash flows.

Fair Value of Financial Instruments

The carrying amounts reported in the Company’s condensed consolidated financial statements for cash, accounts payable, and other current liabilities approximate their respective fair values because of the short-term nature of these accounts. The fair value of the severance payable approximates the carrying value, which represents the present value of future severance payments. The fair value of the derivative liability is discussed in Note 6.
Derivative Warrant Liability

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

As noted in Note 8, Stockholders’ Equity, the Company classifies a warrant to purchase shares of its Common Stock as a liability on its condensed consolidated balance sheet if the warrant is a free-standing financial instrument that contains certain price protection features that cause the warrants to be treated as derivatives. Each warrant of this type is initially recorded at fair value at date of grant using the Monte Carlo simulation model, and is subsequently re-measured to fair value at each subsequent balance sheet date. Changes in fair value of the warrant are recognized as a component of other income (expense) in the consolidated statement of operations. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrant. The Company utilizes Level 3 fair value criteria to measure the fair value of the warrants.

Recent Accounting Pronouncements

The Company adopted ASU 2016-02, Leases (Topic 842) on April 1, 2019. For its long-term operating leases, the Company recognized an operating lease right-of-use asset and an operating lease liability on its condensed consolidated balance sheets. The lease liability is determined as the present value of future lease payments using an estimated rate of interest that the Company would pay to borrow equivalent funds on a collateralized basis at the lease commencement date. The right-of-use asset is based on the liability adjusted for any prepaid or deferred rent. The Company determines the lease term at the commencement date by considering whether renewal options and termination options are reasonably assured of exercise.

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

The Company elected the optional practical expedients to forgo applying guidance in Topic 842 to short-term leases (leases 12 or fewer months at commencement and no purchase option). The package of expedients allows an entity to forgo reassessing (1) whether a contract contains a lease, (2) classification of leases, and (3) whether capitalized costs associated with a lease meet the definition of “initial direct costs” in Topic 842.

Upon adoption, the Company recognized an operating right-of-use asset and operating lease liability in its condensed consolidated balance sheet of approximately $0.4 million and $0.1 million, respectively. The Company also classified prepaid rent of $0.3 million as an operating right-of-use asset upon adoption. There were no adjustments to the Company’s opening accumulated deficit upon adoption.

The impact of the adoption of Topic 842 on the condensed consolidated balance sheets as of April 1, 2019 was as follows:

<table>
<thead>
<tr>
<th></th>
<th>April 1, 2019 Prior to Adoption of ASC Topic 842</th>
<th>ASC Topic 842 Adjustment</th>
<th>April 1, 2019 As Adjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepaid rent</td>
<td>$343,903</td>
<td>$(343,903)</td>
<td>$0</td>
</tr>
<tr>
<td>Deferred rent</td>
<td>$—</td>
<td>$—</td>
<td>$—</td>
</tr>
<tr>
<td>Operating right-of-use assets</td>
<td>$—</td>
<td>$447,897</td>
<td>$447,897</td>
</tr>
<tr>
<td>Operating lease liability</td>
<td>$—</td>
<td>$103,994</td>
<td>$103,994</td>
</tr>
</tbody>
</table>

8
In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features. These amendments simplify the accounting for certain financial instruments with down round features. The amendments require companies to disregard the down round feature when assessing whether the instrument is indexed to its own stock, for purposes of determining liability or equity classification. This ASU is effective for the Company beginning with the quarter ending June 30, 2020. The Company has adopted this ASU effective April 1, 2019 and there was no impact on the consolidated financial statements.

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:

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended December 31, 2019</th>
<th>2018</th>
<th>Nine Months Ended December 31, 2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic and diluted net loss per common share calculation:</td>
<td>$ (6,957,530)</td>
<td>$ (8,047,956)</td>
<td>$ (16,275,596)</td>
<td>$ (21,785,872)</td>
</tr>
<tr>
<td>Net loss</td>
<td>112,071,354</td>
<td>103,009,449</td>
<td>111,961,971</td>
<td>101,963,833</td>
</tr>
<tr>
<td>Weighted average common shares outstanding — basic and diluted:</td>
<td>$ (0.06)</td>
<td>$ (0.08)</td>
<td>$ (0.15)</td>
<td>$ (0.21)</td>
</tr>
<tr>
<td>Net loss per share of common stock — basic and diluted</td>
<td>112,071,354</td>
<td>103,009,449</td>
<td>111,961,971</td>
<td>101,963,833</td>
</tr>
</tbody>
</table>

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

Warrants issued in April 2019, discussed further in Note 8, participate on a one-for-one basis with common stock in the distribution of dividends, if and when declared by the Board of Directors (the “Board”) on the Company’s Common Stock. For purposes of computing EPS, these warrants are considered to participate with common stock in the earnings of the Company and, therefore, the Company calculates basic and diluted EPS using the two-class method. Under the two-class method, net income for the period is allocated between common stockholders and participating securities according to dividends declared and participation rights in undistributed earnings. No income was allocated to the warrants for the three and nine months ended December 31, 2019 as results of operations was a loss for both periods.

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

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stock options</td>
<td>11,808,482</td>
<td>8,931,305</td>
</tr>
<tr>
<td>Warrants</td>
<td>8,937,651</td>
<td>5,283,915</td>
</tr>
<tr>
<td>Total</td>
<td>20,746,133</td>
<td>14,215,220</td>
</tr>
</tbody>
</table>

Note 4. Accounts Payable and Other Current Liabilities

Accounts payable (including accounts payable to a related party – see Note 11) and other current liabilities consisted of the following:

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2019</th>
<th>March 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal</td>
<td>$ 430,578</td>
<td>$ 602,129</td>
</tr>
<tr>
<td>Consultant and professional services</td>
<td>169,223</td>
<td>170,257</td>
</tr>
<tr>
<td>Accounting and auditing</td>
<td>205,270</td>
<td>331,119</td>
</tr>
<tr>
<td>Research and development</td>
<td>2,105,912</td>
<td>1,907,787</td>
</tr>
<tr>
<td>Board of Directors and Scientific Advisory Board Compensation</td>
<td>490,125</td>
<td>489,393</td>
</tr>
<tr>
<td>Other</td>
<td>134,155</td>
<td>191,623</td>
</tr>
<tr>
<td>Total</td>
<td>$ 3,535,263</td>
<td>$ 3,692,308</td>
</tr>
</tbody>
</table>
Note 5. Severance Payable

On March 15, 2019 the Company entered into a Release Agreement related to the separation of employment of its then-Chief Operating Officer. The agreement provides for salary continuance for five years, reimbursement of health benefits for three years and a modification to his outstanding stock options to extend the post-termination exercise period for his vested options from three months to five years. The Company recorded severance expense at its present value of $2.5 million (using a discount rate of 6%) for the year ended March 31, 2019, including $0.4 million relating to the stock option modification. The severance liability payable as of December 31, 2019 and March 31, 2019 was $1.7 million and $2.1 million, respectively.

Note 6. Fair Value Measurements

The carrying amounts reported in the Company’s condensed consolidated financial statements for cash, accounts payable, and other current liabilities approximate their respective fair values because of the short-term nature of these accounts. The fair value of the severance payable approximates the carrying value, which represents the present value of future severance payments. The fair value of the derivative liability is discussed below.

Fair value is defined as the price that would be received if selling 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.

The fair value hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets (Level 1), and the lowest priority to unobservable inputs (Level 3). The Company’s financial assets are classified within the fair value hierarchy based on the lowest level of inputs that is significant to the fair value measurement. The three levels of the fair value hierarchy, and their applicability to the Company’s financial assets, are described below.

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date of identical, unrestricted assets.

Level 2: Quoted prices for similar assets, or inputs that are observable, either directly or indirectly, for substantially the full term through corroboration with observable market data. Level 2 includes investments valued at quoted prices adjusted for legal or contractual restrictions specific to the security.

Level 3: Pricing inputs are unobservable for the assets. Level 3 assets include private investments that are supported by little or no market activity. 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 material re-measurements of fair value with respect to financial assets and liabilities, during the periods presented, other than those assets and liabilities that are measured at fair value on a recurring basis.

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

The fair value of the warrants is considered a Level 3 valuation and was determined using a Monte Carlo simulation model. This model incorporated several assumptions at each valuation date including: the price of the Company’s Common Stock on the date of valuation, its expected volatility, the remaining contractual term of the warrant, the risk free interest rate over the term and estimates of the probability of fundamental transactions occurring (See Note 8 for further discussion of the issuance of Common Stock from an underwritten registered offering).
The Company’s financial instruments measured at fair value on a recurring basis are as follows:

<table>
<thead>
<tr>
<th>Description</th>
<th>Total</th>
<th>Quoted prices in active markets (Level 1)</th>
<th>Significant other observable inputs (Level 2)</th>
<th>Significant unobservable inputs (Level 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>December 31, 2019</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warrant liability</td>
<td>$4,690,000</td>
<td>—</td>
<td>—</td>
<td>$4,690,000</td>
</tr>
<tr>
<td><strong>March 31, 2019</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warrant liability</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Description</th>
<th>December 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beginning balance, March 31, 2019</td>
<td>$—</td>
</tr>
<tr>
<td>Fair value of liability-classified warrants issued with common stock</td>
<td>7,283,601</td>
</tr>
<tr>
<td>Change in fair value of warrant liability</td>
<td>(2,593,601)</td>
</tr>
<tr>
<td>Ending balance</td>
<td>$4,690,000</td>
</tr>
</tbody>
</table>

**Note 7. Debt**

**Insurance Note Payable**

During the year ended March 31, 2019, the Company entered into a short-term financing arrangement with its insurance carrier related to payment of premium for its Director and Officer liability insurance coverage totaling $0.6 million for the policy year ending on March 18, 2020. As of December 31, 2019 and March 31, 2019, there remained a balance of $0 million and $0.6 million, respectively, recorded to insurance note payable on the accompanying consolidated balance sheets.

**Note 8. Stockholders’ Equity**

The following summarizes the common stock warrant activity for the nine months ended December 31, 2019:

<table>
<thead>
<tr>
<th>Warrant Shares of Common Stock</th>
<th>Weighted Average Exercise Price</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outstanding at March 31, 2019</strong></td>
<td>$3.42</td>
</tr>
<tr>
<td>Granted</td>
<td>$2.00</td>
</tr>
<tr>
<td>Exercised</td>
<td>$3.00</td>
</tr>
<tr>
<td>Expired</td>
<td>$3.00</td>
</tr>
<tr>
<td><strong>Outstanding at December 31, 2019</strong></td>
<td>$2.31</td>
</tr>
</tbody>
</table>

At each of December 31, 2019 and March 31, 2019, 8,907,884 and 4,469,836, respectively, of common stock purchase warrants relating to securities purchase agreements were outstanding and exercisable.
Warrants

The Company has warrants to purchase its common stock outstanding as of December 31, 2019, as follows:

<table>
<thead>
<tr>
<th>Issued</th>
<th>Classification</th>
<th>Warrants Outstanding</th>
<th>Exercise Price</th>
<th>Expiration</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2015</td>
<td>Equity</td>
<td>446,500</td>
<td>$ 5.00</td>
<td>December 2025</td>
</tr>
<tr>
<td>February 2016</td>
<td>Equity</td>
<td>461,384</td>
<td>$ 5.00</td>
<td>February 2026</td>
</tr>
<tr>
<td>July 2016</td>
<td>Equity</td>
<td>29,767</td>
<td>$ 5.00</td>
<td>June 2026</td>
</tr>
<tr>
<td>April 2019</td>
<td>Liability</td>
<td>8,000,000</td>
<td>$ 2.00</td>
<td>April 2024</td>
</tr>
</tbody>
</table>

At-the-Market Financing Facility

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

On October 18, 2019, the Company commenced the Jefferies ATM and during the three months ended December 31, 2019, the Company raised approximately $0.6 million in gross proceeds via sale of 582,968 shares of Common Stock. The Company incurred $0.2 million of related costs which offset the proceeds. At December 31, 2019 there remained approximately $29.4 million of availability to sell shares through the Jefferies ATM. On October 2, 2019, the Company sent notice terminating the Canaccord ATM effective October 12, 2019. During the nine months ended December 31, 2019, the Company did not sell shares under Canaccord ATM. At March 31, 2019, there remained approximately $17.9 million of availability to sell shares through the Canaccord ATM. In the year ended March 31, 2019, the Company raised approximately $5.8 million in gross proceeds through the Canaccord ATM via sale of 2,383,884 shares of Common Stock. The Company incurred $0.2 million of related costs which offset the proceeds.

April 2019 - Registered Offering

In April 2019, the Company completed an underwritten registered offering (the “Offering”) of 8,000,000 shares of Common Stock at a price of $1.50 per share. The total net proceeds of the Offering were $11.3 million after deducting underwriter’s discounts and before expenses related to the Offering.

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

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

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

The Company determined that the Warrants should be recorded as a derivative liability on the condensed consolidated balance sheet due to the Warrants’ contractual provisions requiring issuance of registered common shares upon exercise and certain price protection rights. At the issuance date, the Warrants were recorded at the fair value of $7.3 million as determined using the Monte Carlo pricing simulation. The Warrants were re-measured at December 31, 2019 and the change in fair value for the three and nine months ending December 31, 2019 of approximately $(426) thousand and $2.6 million, respectively, was recorded as a component of other income (expense) within the condensed consolidated statement of operations.
The following table details key inputs and assumptions used in the Monte Carlo simulation models used to estimate the fair value of the warrant liability as of December 31, 2019 and April 2, 2019, respectively:

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2019</th>
<th>April 2, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stock price</td>
<td>$1.40</td>
<td>$1.85</td>
</tr>
<tr>
<td>Volatility</td>
<td>57%</td>
<td>48%</td>
</tr>
<tr>
<td>Remaining term (years)</td>
<td>4.25</td>
<td>5.00</td>
</tr>
<tr>
<td>Expected dividend yield</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Risk-free rate</td>
<td>1.66%</td>
<td>2.28%</td>
</tr>
</tbody>
</table>

**Note 9. Commitments and Contingencies**

**Contract Service Providers**

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

On June 30, 2019, the Company amended the Clinical Research Funding and Drug Supply Agreement dated October 9, 2018, with PanCAN, to enroll individuals diagnosed with pancreatic cancer in a platform style clinical research study. Stage 1 of the study was initiated in the fourth quarter of fiscal year 2020. After taking into consideration amounts already paid, the remaining estimated cost to the Company is approximately $7.0 million, subject to enrollment adjustments, and is expected to be incurred over two years.

**Purchase Commitments**

The Company has entered into contracts with manufacturers to supply SM-88 and certain related conditioning agents, in order to achieve favorable pricing on supplied products. These contracts have non-cancellable elements related to the scheduled deliveries of these products in future periods. Payments are made by us to the manufacturer when the products are delivered and of acceptable quality. The contracts are structured to match clinical supply needs for our ongoing trials and we expect the timing of associated payments to predominately occur during fiscal year 2020. Total outstanding future obligations associated with the contracts were $2.3 million at December 31, 2019.

**Legal Proceedings**

From time to time, the Company may be involved in litigation, claims or other contingencies arising in the ordinary course of business. The Company would accrue a liability when a loss is considered probable and the amount can be reasonably estimated. When a material loss contingency is reasonably possible but not probable, the Company would not record a liability, but instead would disclose the nature and the amount of the claim, and an estimate of the loss or range of loss, if such estimate can be made. Legal fees are expensed as incurred. The Company is not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on us, our business, operating results or financial condition.

**Note 10. Leases**

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

Total Company rent expense, including short term rentals, was approximately $79,000 and $235,000 for the three and nine months ended December 31, 2019, respectively, and approximately $66,000 and $173,000 for the three and nine months ended December 31, 2018, respectively.

Operating lease right-of-use (“ROU”) assets and liabilities on the condensed consolidated balance sheet represents the present value of the remaining lease payments over the remaining lease terms. ROU assets also include any initial direct costs incurred and any lease payments made at or before the lease commencement date, less lease incentives received. Payments for additional monthly fees to cover the Company's share of certain facility expenses are not included in operating lease right-of-use assets and liabilities. The Company uses its incremental borrowing rate of 6.0% to calculate the present value of its lease payments, as the implicit rates in the leases are not readily determinable.
As of December 31, 2019, the future minimum lease payments under non-cancellable operating lease agreements for which the Company has recognized operating lease right-of-use assets and lease liabilities were as follows:

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remainder of fiscal year 2020</td>
<td>$15,300</td>
</tr>
<tr>
<td>Fiscal year 2021</td>
<td>56,000</td>
</tr>
<tr>
<td>Total remaining lease payments</td>
<td>71,300</td>
</tr>
<tr>
<td>Less: present value adjustment</td>
<td>(2,200)</td>
</tr>
<tr>
<td>Total operating lease liabilities</td>
<td>69,100</td>
</tr>
<tr>
<td>Less: current portion</td>
<td>(58,900)</td>
</tr>
<tr>
<td>Operating lease liabilities, net of current portion</td>
<td>$10,200</td>
</tr>
</tbody>
</table>

Note 11. Related Party Transactions

Legal

Drinker Biddle & Reath LLP ("DBR") has provided legal services to the Company. A partner of DBR was a member of the Company’s Board and had received, and was entitled to receive in the future, cash compensation payable to non-employee directors generally and equity compensation payable to non-employee directors under the Amended and Restated 2016 Stock Option Plan for Non-Employee Directors (the “2016 Director Plan”). See Note 12, Equity Incentive Plan. On September 10, 2018, the Company entered into an employment agreement with the partner and he was appointed as the Company’s Chief Legal Officer and Secretary. He ceased to be a non-employee director on September 10, 2018 and he resigned as a member of the Board, effective September 30, 2018. On September 1, 2018, the partner resigned from the partnership of DBR and he assumed the consulting role “of Counsel” with the firm. Legal fees incurred associated with DBR were approximately $170,000 and $620,000 for the three and nine months ended December 31, 2019, respectively, and $132,000 and $794,000 for the three and nine months ended December 31, 2018, respectively. At December 31, 2019 and March 31, 2019, the Company had approximately $222,000 and $325,000, respectively, in accounts payable and accrued expenses payable to DBR.

Note 12. Equity Incentive Plan

Stock Options

As of December 31, 2019, there was approximately $5.6 million of total unrecognized compensation expense related to non-vested stock options. The cost is expected to be recognized over the remaining weighted average service period of 1.53 years. As of December 31, 2019, there were 4,906,208 shares available for grant under the Company’s 2015 Equity Incentive Plan and 2016 Director Plan.

Stock based compensation expense recognized was as follows:

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended December 31, 2019</th>
<th>Nine Months Ended December 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>General and administrative</td>
<td>$959,000</td>
<td>$1,316,000</td>
</tr>
<tr>
<td>Research and development</td>
<td>643,000</td>
<td>684,000</td>
</tr>
<tr>
<td>Total</td>
<td>$1,602,000</td>
<td>$2,000,000</td>
</tr>
</tbody>
</table>

The Company uses the Black-Scholes option pricing model to determine the fair value of stock options granted. For employees and non-employees, the compensation expense 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 for 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, non-employees and consultants in the current fiscal period has been based on the term by using the simplified method as allowed under SAB No. 110 and ASU 2018-7.
The weighted average assumptions used to determine such values are presented in the following table:

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2019</th>
<th>December 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk free interest rate</td>
<td>1.39% - 2.38%</td>
<td>2.90%</td>
</tr>
<tr>
<td>Expected volatility</td>
<td>71.65% - 76.22%</td>
<td>74.89%</td>
</tr>
<tr>
<td>Expected term (in years)</td>
<td>2.5 - 6</td>
<td>5.8</td>
</tr>
<tr>
<td>Dividend yield</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

The following is a summary of the status of the Company’s stock options as of December 31, 2019:

<table>
<thead>
<tr>
<th></th>
<th>Number of Options</th>
<th>Weighted Average Exercise Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding at March 31, 2019</td>
<td>8,953,527</td>
<td>$4.13</td>
</tr>
<tr>
<td>Granted</td>
<td>3,117,280</td>
<td>$1.48</td>
</tr>
<tr>
<td>Expired</td>
<td>(262,325)</td>
<td>$4.10</td>
</tr>
<tr>
<td>Outstanding at December 31, 2019</td>
<td>11,808,482</td>
<td>$3.43</td>
</tr>
<tr>
<td>Options exercisable at December 31, 2019</td>
<td>7,385,758</td>
<td>$4.23</td>
</tr>
</tbody>
</table>

The intrinsic value calculated as the excess of the market value as of December 31, 2019 over the exercise price of the options, is $141,900. The market value per share as of December 31, 2019 was $1.40 as reported by the NASDAQ Capital Market.

Note 13. Income Taxes

A valuation allowance is recorded if it is more likely than not that a deferred tax asset will not be realized. The Company weighed available positive and negative evidence and concluded that a full valuation allowance should continue to be maintained on its net deferred tax assets.

The Company is required to evaluate uncertain tax positions taken or expected to be taken in the course of preparing the Company’s condensed consolidated financial statements to determine whether the tax positions are more likely than not of being sustained by the applicable tax authority. As of December 31, 2019, the Company’s uncertain tax positions remain unchanged. Due to the full valuation allowance, none of the gross unrecognized tax benefits would affect the effective tax rate at December 31, 2019, if recognized.

The Company had no income tax related penalties or interest for periods presented in these condensed consolidated financial statements related to uncertain tax positions due to available net operating loss carryforwards, which would be recorded as tax expense should the Company accrue for such items.

Note 14. Subsequent Events

Securities Purchase Agreement

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

On January 7, 2020, the Company entered into a Co-Promotion Agreement (the "Agreement") with Eagle, whereby Eagle agreed to provide sales representatives to cover 25% of the Company’s sales force requirements and will receive 15% of the net sales of all SM-88 products in the U.S. during the term of the Agreement. TYME will also be responsible for clinical development, regulatory approval, commercial strategy, marketing, reimbursement and manufacturing of SM-88. TYME retains the remaining 85% of net U.S. revenues and reserves the right to repurchase Eagle’s co-promotion right for $200 million.
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

The disclosures in this Quarterly Report are complementary to those made in our Annual Report on Form 10-K filed with the SEC on June 12, 2019 (the “2019 10-K”). 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 Quarterly Report as well as our audited financial statements, notes thereto and Management’s Discussion and Analysis of Financial Condition and Results of Operations included in our 2019 Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly 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 report and of our 2019 Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. As used in this report, unless the context suggests otherwise, “we,” “us,” “our,” “the Company,” “TYME” or “Tyme Technologies” refer to Tyme Technologies, Inc. together with its subsidiaries. All amounts in Management’s Discussion and Analysis of Financial Condition and Results of Operations are approximate.

Overview

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

Our lead clinical CMBT program, SM-88 (racemetyrosine), is a novel, oral, monotherapy investigational agent that has been studied in approximately 180 patients, including Phase I and II clinical trials for pancreatic, prostate and other cancers. We recently launched our pivotal study for SM-88 in the third-line treatment of pancreatic cancer through an amendment to our ongoing TYME-88-Panc trial (“Part 2”); with the first patient dosed in the third quarter of fiscal year 2020 and anticipated enrollment completion by the end of calendar year 2020 and data expected in 2021. We currently estimate the cost of the TYME-88-Panc trial (Part 2) to range from $15 million to $20 million, with such costs anticipated to extend through calendar year 2021. We also partnered with the Pancreatic Cancer Action Network (“PanCAN”) to study SM-88 in an adaptive randomized Phase II/III trial with registration intent known as Precision PromiseSM. In Precision Promise, SM-88 is starting as second-line monotherapy and could expand to first-line combination therapy with standard of care. The remaining estimated cost for Precision Promise Stage 1 is approximately $7.0 million, subject to enrollment adjustments, which is expected to be incurred over two years. HopES is a Phase II investigator-initiated trial evaluating SM-88 monotherapy in late-stage sarcomas, under the direction of principal investigator Dr. Sant Chawla and in collaboration with The Joseph Ahmed Foundation. The first sarcoma cancer patient in the HopES trial was dosed in the fourth quarter of fiscal year 2020. We also completed and presented final data from our Phase II clinical trial in prostate cancer. All of SM-88’s current clinical programs, as well as its completed Phase II prostate cancer trial, study SM-88 in use with three low-dose conditioning agents: methoxsalen, phenytoin, and sirolimus. The Company is actively evaluating the expansion of our clinical program to hematological, breast, prostate and other cancers as SM-88 has demonstrated complete or partial responses in 15 different forms of cancer with a well-tolerated safety profile.

Critical Accounting Policies and Significant Judgments and Estimates

This management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, warrant liability, and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. There have been no significant changes in our critical accounting policies and significant judgments and estimates as discussed in our 2019 10-K.
Derivative Warrant Liability

Certain freestanding common stock warrants that are related to the issuance of common stock are classified as liabilities and recorded at fair value due to characteristics that require liability accounting, primarily the obligation to issue registered shares of common stock upon notification of exercise and certain price protection provisions. Warrants of this type are subject to re-measurement at each balance sheet date and any change in fair value is recognized as a component of other income (expense) in the consolidated statement of operations. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrant. The Company utilizes Level 3 fair value criteria to measure the fair value of the warrants.

As noted in Item 1. Note 8, Stockholders’ Equity, the Company classifies a warrant to purchase shares of its common stock as a liability on its condensed consolidated balance sheet if the warrant is a free-standing financial instrument that contains certain price protection features which cause the warrants to be treated as derivatives. Each warrant of this type is initially recorded at fair value on date of grant using the Monte Carlo simulation model, and is subsequently re-measured to fair value at each subsequent balance sheet date. Changes in fair value of the warrant are recognized as a component of other income (expense) in the consolidated statement of operations. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrant.

Recent Developments

Consistent with our overall corporate mission of developing effective cancer therapies that can extend patients' lives while not compromising on their quality of life gained, during the three months ended December 31, 2019 and subsequently, we note the following activities:

• Strategic collaboration with Eagle Pharmaceuticals

  On January 7, 2020 we entered into a securities purchase agreement with Eagle Pharmaceuticals pursuant to which we issued and sold to Eagle 10,000,000 shares of our Common Stock in return for $20 million, which was paid at closing. We are also entitled to receive $20 million in potential future milestone payments. We also entered into a co-promotion agreement (the “Agreement”) with Eagle whereby Eagle agreed to provide sales representatives to cover 25% of the Company’s sales force requirements and will receive 15% of the net sales of all SM-88 products in the U.S. during the term of the Agreement., TYME will retain 85% of the net U.S. revenues and has the ability to repurchase Eagle’s rights under the Agreement for $200 million. (see Note 14 – Subsequent Events)

• TYME-88-Panc pivotal trial started enrollment using oral SM-88 as a treatment for patients with third line pancreatic cancer

  The first pancreatic cancer patient was dosed in Part 2 of the TYME-88-Panc pivotal trial designed to support approval of SM-88, TYME’s leading cancer metabolism-based therapy, for the third-line treatment of patients with metastatic pancreatic cancer.

• PanCAN initiated its Precision PromiseSM adaptive randomized Phase II/III trial with registration intent for patients with pancreatic cancer using oral SM-88 in second-line monotherapy. The study was listed on clinicaltrials.gov in the first quarter of calendar year 2020.

• TYME & Joseph Ahmed Foundation’s sarcoma study started enrollment for the investigator-initiated Phase II trial using oral SM-88 as maintenance monotherapy in patients with previously treated metastatic Ewing’s sarcoma and salvage monotherapy in clinically advanced sarcomas.

  In January 2020 the first sarcoma cancer patient was dosed at the Sarcoma Oncology Center in the HopES Phase II trial designed to evaluate SM-88 for the treatment of high-risk sarcomas, which are ultra-rare cancers with high unmet medical need.
Results of Operations

Three and Nine Months Ended December 31, 2019 Compared to Three and Nine Months Ended December 31, 2018

Net loss for the three months ended December 31, 2019 was $6,958,000 compared to $8,048,000 for the three months ended December 31, 2018; and the loss for the nine months ended December 31, 2019 was $16,276,000 compared to $21,786,000 for the nine months ended December 31, 2018. The decrease in losses for the three month period is due to decreased operating costs and expenses of $1,531,000 offset by $(426,000) expense change in the fair value of warrant liability. The decrease in losses for the nine month period is due to decreased operating costs and expenses of $2,841,000 and $2,594,000 income change in fair value of warrant liability.

Cash used in operating activities for the nine months ended December 31, 2019 was $13,861,000 compared to $16,108,000 for the nine months ended December 31, 2018. See Cash Flows section below for further details.

Revenues

During the three and nine month periods ended December 31, 2019 and 2018, the Company did not realize any revenues from operations. We do not anticipate any revenues until such time as one of our products has been approved for commercialization by appropriate regulatory authorities, or we enter into certain types of collaboration or licensing arrangements, none of which is anticipated to occur in the near future.

Operating Costs and Expenses

For the three months ended December 31, 2019, operating costs and expenses totaled $6,544,000 compared to $8,075,000 for the three months ended December 31, 2018, a decrease of $1,531,000. Operating costs and expenses were comprised of the following:

- Research and development expenses were $3,454,000 for the three months ended December 31, 2019, compared to $4,525,000 for the three months ended December 31, 2018, a decrease of $1,071,000. Substantially all research and development expenditures have been incurred in respect of our lead drug candidate SM-88 and its technology platform. Research and development activities primarily consist of the following:
  - Study and consulting expenses were $2,134,000 for the three months ended December 31, 2019, compared to $3,184,000 for the three months ended December 31, 2018, a decrease of $1,050,000 between the comparable periods. The decrease is mainly attributable to the timing of activity related to Part 1 of our TYME-88-Panc trial and our recently completed Phase II prostate clinical trial.
  - Salary and salary related expenses for research and development personnel were $677,000 for the three months ended December 31, 2019, compared to $657,000 for the three months ended December 31, 2018, an increase of $20,000 between the comparable periods.
  - Included in research and development expense for the three months ended December 31, 2019 is $643,000 of stock based compensation expense related to stock options granted to research and development personnel compared to $684,000 for the three months ended December 31, 2018, a decrease of $41,000 between comparable periods.
- General and administrative expenses were $3,090,000 for the three months ended December 31, 2019, compared to $3,550,000 for the three months ended December 31, 2018, a decrease of $460,000. The general and administrative expenses for the respective periods include:
  - During the three months ended December 31, 2019, other general and administrative expenses were $2,131,000 compared to $2,234,000 for the three months ended December 31, 2018. The decrease of approximately $103,000 primarily resulted from lower professional services and legal fees, partially offset by higher communication and general administration costs.
  - Stock based compensation expense related to stock options was $959,000 for the three months ended December 31, 2019 compared to $1,316,000 for the three months ended December 31, 2018, a decrease of $357,000, primarily attributable to fully vested grants having no current year expense and higher prior year expense associated with modification of vesting provisions of previously-issued grants.
For the nine months ended December 31, 2019, operating costs and expenses totaled $18,967,000 compared to $21,807,000 for the nine months ended December 31, 2018, a decrease of $2,840,000. Operating costs and expenses were comprised of the following:

- Research and development expenses were $9,292,000 for the nine months ended December 31, 2019, compared to $10,979,000 for the nine months ended December 31, 2018, a decrease of $1,687,000. Substantially all research and development expenditures have been incurred in respect of our lead drug candidate SM-88 and its technology platform. Research and development activities primarily consist of the following:
  - Study and consulting expenses were $5,427,000 for the nine months ended December 31, 2019, compared to $7,093,000 for the nine months ended December 31, 2018, a decrease of $1,666,000 between the comparable periods. The decrease is mainly attributable to the timing of activity related to Part 1 of our TYME-88-Panc Phase II trial and our recently completed Phase II prostate clinical trial.
  - Salary and salary related expenses for research and development personnel were $1,931,000 for the nine months ended December 31, 2019, compared to $1,718,000 for the nine months ended December 31, 2018, an increase of $213,000 between the comparable periods, primarily due to costs associated with an increased employee base, partially offset by a research and development payroll tax credit.
  - Included in research and development expense for the nine months ended December 31, 2019 is $1,925,000 of stock based compensation expense related to stock options granted to research and development personnel compared to $2,154,000 for the nine months ended December 31, 2018, a decrease of $229,000 between comparable periods. The decrease in expense is associated with the prior year’s fully vested grants having no current year expense, partially offset by new grants issued in the current year.

- General and administrative expenses were $9,675,000 for the nine months ended December 31, 2019, compared to $10,828,000 for the nine months ended December 31, 2018, a decrease of $1,153,000. The general and administrative expenses for the respective periods include:
  - Stock based compensation expense related to stock options was $2,748,000 for the nine months ended December 31, 2019 compared to $4,548,000 for the nine months ended December 31, 2018, a decrease of $1,800,000, primarily due to higher expenses in the prior year associated with modification of vesting provisions of previously-issued grants and the granting of fully-vested options to the Board of Directors in the nine months ended December 31, 2018, partially offset by new grants issued in the current year.
  - During the nine months ended December 31, 2019, other general and administrative expenses were $6,927,000 compared to $6,280,000 for the nine months ended December 31, 2018. The increase of approximately $647,000 primarily resulted from higher employee-related costs associated with our increased employee base, warrant issuance costs, higher communication and consulting costs. These costs were partially offset by lower professional, legal and accounting and auditing services.

Other income (expense)

For the three and nine months ended December 31, 2019, the Company had $426,000 expense and $2,594,000 of income relating to the change in fair value of the warrant liability during the period, compared to $0 for the three and nine months ended December 31, 2018.

For the three and nine months ended December 31, 2019, the Company had interest income on cash accounts of $38,000 and $186,000 compared to $29,000 for both the three and nine months ended December 31, 2018.

For the three and nine months ended December 31, 2019, the Company had interest expense of $26,000 and $89,000 primarily related to the amortization of the severance payable discount, compared to $1,000 and $7,000 for the three and nine months ended December 31, 2018.

Adjusted Net Loss and Adjusted Net Loss per Share

Adjusted net loss for the three months ended December 31, 2019 was $4,930,000 or $0.05 per share compared to $6,048,000 or $0.06 per share for the three months ended December 31, 2018. Adjusted net loss for the nine-month period ended December 31, 2019 was $14,197,000 or $0.13 per share compared to $15,084,000 or $0.14 per share for the same period in the prior year, after adjusting for change in fair value of warrant liability and amortization of employees, directors and consultants stock options. Adjusted net loss and adjusted net loss per share are non-GAAP measures. See “Use of Non-GAAP Measures” below for a reconciliation to the comparable GAAP measures.

20
Use of Non-GAAP Measures

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

Reconciliation of Net Loss to Adjusted Net Loss

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended December 31,</th>
<th>Nine Months Ended December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2019</td>
<td>2018</td>
</tr>
<tr>
<td>Net loss (GAAP)</td>
<td>$ (6,958,000)</td>
<td>$ (8,048,000)</td>
</tr>
<tr>
<td>Adjustments:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in fair value of warrant liability</td>
<td>426,000</td>
<td>—</td>
</tr>
<tr>
<td>Amortization of employees, directors and consultants stock options</td>
<td>1,602,000</td>
<td>2,000,000</td>
</tr>
<tr>
<td>Adjusted net loss (non-GAAP)</td>
<td>$ (4,930,000)</td>
<td>$ (6,048,000)</td>
</tr>
</tbody>
</table>

Reconciliation of Net Loss Per Share to Adjusted Net Loss

|                                | Three Months Ended December 31, | Nine Months Ended December 31, |
|                                | 2019                         | 2018                          | 2019                     | 2018                     |
| Net loss per share (GAAP)      | $ (0.06)                     | $ (0.08)                     | $ (0.15)                 | $ (0.21)                 |
| Adjustments:                   |                              |                               |                          |                          |
| Change in fair value of warrant liability | *                           | —                             | (0.02)                   | —                        |
| Amortization of employees, directors and consultants stock options | 0.01                         | 0.02                          | 0.04                     | 0.07                     |
| Adjusted net loss per share (non-GAAP) | $ (0.05)                 | $ (0.06)                     | $ (0.13)                 | $ (0.14)                 |

* The effect of the change in fair value of the warrant liability was negligible to the adjusted net loss per share.

The Non-GAAP Measures for the three and nine months ended December 31, 2019 and 2018 provide management with additional insight into the Company’s results of operations from period to period by excluding certain non-operational and non-cash charges, and are calculated using the following adjustments to net loss:

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

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

Adjusted basic net loss per share is computed by dividing adjusted net loss by the weighted average number of shares of Company common stock outstanding for the period, and adjusted diluted loss per share is computed by also including common stock equivalents outstanding for the period. During the periods presented, the calculation excludes any potential dilutive common shares and any equivalents as they would have been anti-dilutive as the Company incurred losses for the periods then ended.
Liquidity and Capital Resources

At December 31, 2019, we had cash and cash equivalents of $11.5 million, working capital of $7.0 million, and stockholders’ equity of $2.4 million.

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

<table>
<thead>
<tr>
<th>Net cash used in or provided by</th>
<th>Nine Months Ended December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2019</td>
</tr>
<tr>
<td>Net cash (used in) provided by operating activities</td>
<td>$ (13,861,000)</td>
</tr>
<tr>
<td>Net cash (used in) provided by investing activities</td>
<td>—</td>
</tr>
<tr>
<td>Net cash (used in) provided by financing activities</td>
<td>11,024,000</td>
</tr>
</tbody>
</table>

Operating Activities

Our cash used in operating activities in the nine months ended December 31, 2019 totaled $13.9 million, which is the sum of (i) our net loss of $16.3 million, adjusted for non-cash income of $2.6 million (related to change in fair value of warrant liability) and non-cash expenses totaling $4.7 million (principally amortization of stock-based compensation), and (ii) changes in operating assets and liabilities of $0.3 million.

Our cash used in operating activities in the nine months ended December 31, 2018 totaled $16.1 million, which is the sum of (i) our net loss of $21.8 million, adjusted for non-cash expenses totaling $6.7 million (principally amortization of stock-based compensation, including immediately vested options granted to the Board of Directors), and (ii) changes in operating assets and liabilities of $1.0 million, primarily due to increased prepaid clinical costs of $470,000 and decreases in accounts payable and other liabilities decreases of $52,000.

Investing Activities

No cash was used in investing activities for the nine months ended December 31, 2019.

During the nine months ended December 31, 2018, our investing activities consisted of purchases of $16,000 of machinery and equipment.

Financing Activities

In April 2019, the Company raised $11.3 million after underwriting discounts and before offering expenses through an underwritten registered offering of 8,000,000 shares of our common stock, $0.0001 par value per share (“Common Stock”), and 8,000,000 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 $2.00 per Warrant Share. The Warrants expire five years from the date of issuance and vested immediately. The warrants are recorded as a derivative liability on the statement of balance sheet and will be subject to remeasurement.

On October 18, 2019, TYME entered into an Open Market Sale AgreementSM (the “Sale Agreement”) with Jefferies LLC (“Jefferies”) as sales agent, pursuant to which the Company may, from time to time, sell shares of the Company’s Common Stock, having an aggregate offering price of up to $30,000,000 (the “Jefferies ATM”). For the three and nine months ended December 31, 2019, the Company raised approximately $0.6 million in gross proceeds via sale of 82,968 shares of common stock under the Jefferies ATM. The Company incurred $0.2 million of related costs which offset the proceeds. At December 31, 2019 there remained approximately $29.4 million of availability to sell shares through the Jefferies ATM.

Most recently (and subsequent to the quarter ended December 31, 2019) on January 7, 2020, the Company entered into a Securities and Purchase Agreement with Eagle Pharmaceuticals, Inc. (“Eagle”), pursuant to which the Company issued and sold to Eagle 10,000,000 shares of Common Stock, at a price of $2.00 per share, and received proceeds of $20 million. (see Note 14 - Subsequent Event).

During the nine months ended December 31, 2019, the Company made payments of $597,000 on the insurance note payable related to premiums for its Director and Officer liability insurance coverage.
We anticipate requiring additional capital to further fund the development of our product candidates as well as to engage in additional potential partnerships or collaborations. Significant funding will be needed in connection with the clinical development, regulatory approval and commercialization of SM-88, including as it relates to current clinical trial activity. In addition to other existing and potential trials, we currently estimate the cost of the TYME-88-Panc trial (Part 2) to range from $15 million and $20 million, with such costs anticipated to extend through calendar year 2021. We also partnered with the Pancreatic Cancer Action Network (“PanCAN”) to study SM-88 in an adaptive randomized Phase II/III trial with registration intent known as Precision PromiseSM. In Precision Promise, SM-88 is starting as second-line monotherapy and could expand to first-line combination therapy with standard of care. After taking into consideration amounts already paid, the remaining estimated cost to the Company is approximately $7.0 million, subject to enrollment adjustments, and is expected to be incurred over two years. Expansion of our currently announced clinical trials for SM-88, or advancement of current preclinical programs, could also result in additional associated costs.

Primarily as a result of its active clinical trials, the initiation of the Precision Promise trial, and the initiation of Part 2 of the Company’s ongoing TYME-88-PANC trial, as well as other business developments, the Company continues to anticipate that its quarterly cash usage, or “cash burn rate”, will average between $5.0 to $6.0 million per quarter for fiscal year 2020.

During the nine months ended December 31, 2018, there was $3,881,000 of financing activities, consisting of $4,052,000 of proceeds from the issuance of Common Stock from the Company’s at-the-market offering pursuant to the Equity Distribution Agreement, dated November 2, 2017 (the “Equity Distribution Agreement”), by and between the Company and Canaccord Genuity LLC (“Canaccord”), and offset by insurance note payments.

### Liquidity and Capital Requirements Outlook

The Company has historically funded its operations primarily through equity offerings of its Common Stock. During the three and nine months ended December 31, 2019, the Company raised approximately $0.6 million in gross proceeds via sale of 82,968 shares of common stock under the Jefferies ATM. The Company incurred $0.2 million of related costs which offset the proceeds. At December 31, 2019 there remained approximately $29.4 million of availability to sell shares through the Jefferies ATM.

Previously, on November 2, 2017, the Company entered into the Equity Distribution Agreement with Canaccord, to commence an at-the-market offering pursuant to which the Company, from time to time, sold shares of the Company’s Common Stock, having an aggregate offering up to $30 million, through Canaccord, as the Company’s sales agent (the “Canaccord ATM”). In the year ended March 31, 2018, the Company raised approximately $6.2 million in gross proceeds through the Canaccord ATM. During the fiscal year ended March 31, 2019, the Company raised approximately $5.8 million in gross proceeds from the Canaccord ATM. On October 2, 2019, TYME sent notice to Canaccord that it was terminating the Equity Distribution Agreement, effective October 12, 2019.

As further discussed under “Financing Activities” above, in April 2019, the Company raised approximately $11.3 million, net of underwriting discounts and before offering expenses, through an underwritten registered offering of 8,000,000 shares of our Common Stock and 8,000,000 common stock purchase warrants.

As of December 31, 2019, the Company had cash on hand of approximately $11.5 million and working capital of approximately $7.0 million. On January 7, 2020 TYME received an additional $20 million proceeds from the sale of 10,000,000 shares of Common Stock to Eagle. (See Note 14 - Subsequent Event).

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

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

There is risk associated with any form of capital we may raise or seek to raise, which will vary with the type and source of capital. Additional equity financing may be dilutive to our stockholders. Debt financing may involve significant cash payment obligations and covenants that restrict our ability to operate as a business. Strategic collaborations and similar agreements may require committing operational resources, product rights or other valuable assets and may also introduce risks associated with the activities undertaken in collaboration and the ongoing relationship and interdependence between the parties. 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.

Seasonality

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

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not required for smaller reporting companies.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Under the supervision of and with the participation of management, including our principal executive officer and principal financial officer, we evaluated the effectiveness of our disclosure controls and procedures, as such term is defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities and Exchange Act of 1934, as amended, as of December 31, 2019. Based on such evaluation our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.
PART II – OTHER INFORMATION

Item 1. 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 1A. Risk Factors.

Our Annual Report on Form 10-K for the year ended March 31, 2019 includes a detailed discussion of our risk factors. Except as set forth below, at the time of this filing, there have been no material changes to the risk factors that were included in the Form 10-K.

To achieve our long-term business objectives, we will require substantial additional funding, which may require us to agree to restrictions on our operations or may not be available to us on acceptable terms or at all and, if not available, may require us to delay, scale back or cease our drug development programs or operations.

In addition to SM-88, we seek to advance multiple drug candidates through our research and clinical development process. The completion of the development, regulatory approval and the potential commercialization of SM-88 or any other 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 U.S. Food & Drug Administration, European Medicines Agency 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, including in collaboration with others;
• our ability to maintain, expand and defend the scope of our intellectual property (“IP”) portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other IP rights;
• the extent to which we acquire or in-license other products or technologies;
• our need and ability to increase our overall capacity and hire additional administrative, managerial, scientific, operational and medical personnel
• the effect of competing products that may limit market penetration of SM-88 and any other 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, which is expected to be offset by revenues we must share with collaborators; and
• our need to implement additional internal systems and infrastructure, including financial and reporting systems; and the economic and other terms, timing of and ultimate success of any future collaboration, licensing or other arrangements, including the timing of achievement of milestones and receipt of any milestone or royalty payments under such agreements.

Until we can generate sufficient drug and royalty revenue to finance our cash requirements, which we may never achieve, we expect to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, royalty agreements and other marketing and distribution arrangements. The demand for the equity and debt of biotechnology companies like ours is dependent upon many factors, including the general state of the financial markets. During times of extreme market volatility, capital may not be available on favorable terms, if at all. Any additional fundraising efforts may divert management’s attention from day-to-day activities and financing may not be available to us when we need it or financings may not be available on favorable terms. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances royalty rights or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our 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.
While we regularly consider options and opportunities to raise additional capital and obtain financing and will continue to seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all, and our negotiating position in capital generating efforts may worsen as existing resources are used. Additionally, if we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain adequate financing when needed and on favorable terms, we may have to delay, reduce the scope of or suspend one or more of our clinical trials or research and development programs or our commercialization efforts.

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

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

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

**We have entered into a co-promotion agreement and may enter into additional license or collaboration agreements with third parties with respect to SM-88 and any other drug candidates we may develop that may place the development or promotion of our 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 such collaborations are not successful, SM-88 and any other drug candidates we may choose to develop may not reach their full market potential.**

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

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

We may in the future enter into additional license or collaboration arrangements with other third parties with respect to SM-88 and any other drug candidates we may develop that may place the development or promotion of our 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, and could be subject to similar types of risks as described above. In addition, any collaborations are and will be subject to numerous risks, which may include, but are not limited to:
collaborators may have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of SM-88 or any other drug candidate we may choose to develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical program, stop a clinical trial, abandon SM-88 or other drug candidate, repeat or conduct new clinical trials or require a new formulation of SM-88 or other drug candidate;
- collaborators may be more established companies with a competitive advantage due to their larger size and cash resources or greater clinical development and commercialization capabilities and, as a result, we may not be able to obtain favorable terms for our arrangements;
- collaborators could independently develop or develop with third parties, products that compete directly or indirectly with SM-88;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our IP rights or may use our IP or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our IP or proprietary information or expose us to potential liability;
- collaborators may not aggressively or adequately pursue litigation against Abbreviated New Drug Application (“ANDA”) filers or may settle such litigation on unfavorable terms;
- 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.

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.
None.

Item 3. Defaults Upon Senior Securities.
None.

Item 4. Mine Safety Disclosures.
Not applicable.

Item 5. Other Information.
None.

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### Exhibit Number Table

<table>
<thead>
<tr>
<th>Exhibit Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>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.)</td>
</tr>
<tr>
<td>3.2</td>
<td>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.)</td>
</tr>
<tr>
<td>3.4</td>
<td>Amended and Restated By-Laws of Tyme Technologies, Inc., effective April 2, 2018. (Incorporated by reference to Exhibit 3.2 to our Current Report on Form 8-K, filed with the SEC on April 2, 2018.)</td>
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<tr>
<td>10.1</td>
<td>Open Market Sale Agreement, dated as of October 18, 2019, by and between Tyme Technologies, Inc. and Jefferies LLC. (Incorporated by reference to Exhibit 1.1 to our Current Report on Form 8-K, filed with the SEC on October 18, 2019.)</td>
</tr>
<tr>
<td>31.1 *</td>
<td>Rule 13(a)-14(a)/15(d)-14(a) Certification of Principal Executive Officer.</td>
</tr>
<tr>
<td>31.2 *</td>
<td>Rule 13(a)-14(a)/15(d)-14(a) Certification of Principal Financial Officer.</td>
</tr>
<tr>
<td>32.1 **</td>
<td>Section 1350 Certification of Chief Executive Officer and Principal Financial Officer.</td>
</tr>
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<td>101.INS *</td>
<td>XBRL Instance Document.</td>
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<td>101.CAL *</td>
<td>XBRL Calculation Linkbase Document.</td>
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<td>101.DEF *</td>
<td>XBRL Definition Linkbase Document.</td>
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<tr>
<td>101.LAB *</td>
<td>XBRL Label Linkbase Document.</td>
</tr>
<tr>
<td>101.PRE *</td>
<td>XBRL Presentation Linkbase Document.</td>
</tr>
</tbody>
</table>

* Filed herewith.

** Furnished herewith.
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: February 5, 2020

TYME TECHNOLOGIES, INC.

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

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

By: /s/ Barbara Galaini
    Barbara Galaini
    Corporate Controller
    (Principal Accounting Officer)
RULE 13a-14(a)/15d-14(a) CERTIFICATION

I, Steve Hoffman, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: February 5, 2020

/s/ Steve Hoffman
Steve Hoffman
Chief Executive Officer
(Principal Executive Officer)
Rule 13a-14(a)/15d-14(a) Certification

I, Ben R. Taylor, certify that:

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

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

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

4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: February 5, 2020

/s/ Ben R. Taylor
Ben R. Taylor
President and Chief Financial Officer
(Principal Financial Officer)
CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)

In connection with the Quarterly Report on Form 10-Q of Tyme Technologies, Inc. (the “Company”) for the quarter ended December 31, 2019, to which this certification is being filed as of the date hereof as an exhibit thereto (the “Report”), I, Steve Hoffman, Chief Executive Officer of the Company, and I, Ben R. Taylor, President and Chief Financial Officer of the Company, each certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(a) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (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: February 5, 2020

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

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

This certification will not be deemed “filed” for purposes of Section 18 of the 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.
Who We Are

TYME is an emerging biotechnology company focused on exploring novel therapeutic approaches designed to target cancer’s unique metabolism.

TYME is advancing proprietary Cancer Metabolism-Based Therapies (CMBTs™) for metastatic cancers.

TYME To Make An Impact

Our unique science gives us the potential to have a significant influence on the current cancer landscape:

- Offering metastatic cancer patients new treatment options to extend and improve quality of life
- Developing a first-in-class oral CMBT, SM-88, showing compelling initial clinical trial results across 15 cancers
- Advancing our pipeline of CMBTs to change the standard of cancer care

Despite medical innovation, patients with advanced cancer need more and better treatment options.

Progress In Our Science Driving Growth

**POSITIVE DATA READOUTS**

**ESMO GI Pancreatic:**
TYME-88-Panc Phase II Study demonstrating encouraging overall survival trends in patients with advanced pancreatic cancer

**ESMO Prostate:**
TYME SM-88 Phase II Prostate Cancer Study demonstrating encouraging clinical benefit in patients with recurrent prostate cancer

**ADVANCING CLINICAL DEVELOPMENT WITH ADVOCACY PARTNERS**

**TYME-88-PANC:** Enrolling Patients in TYME’s SM-88 Pivotal Trial in third-line pancreatic cancer

**PanCAN:** Opening trial sites in Precision Promise℠ Pivotal Trial with oral SM-88 monotherapy in second-line metastatic pancreatic cancer

**Joseph Ahmed Foundation (JAF):** Enrolling patients in SM-88 Phase II Clinical Trial in Ewing’s and high-risk sarcomas through collaboration with JAF and Dr. Chawla

**PUBLICATION**

Peer-reviewed publication of SM-88 First Human Study in the journal *Investigational New Drugs*

**REGULATORY**

FDA TYPE C meeting for pancreatic pivotal path

Granted pharmaceutical compositions and methods patent
Investment Rationale

High Barrier to Entry
TYME is one of only a few companies successfully advancing medical innovation in cancer metabolism

Unique Science Platform
Exploiting metabolic properties to create effective and tolerable therapies for patients with advanced cancers

Strong Patent Portfolio
Growing pipeline of CMBTs™ with robust patent portfolio of 173 patent applications granted and/or pending globally, extending to 2032, and beyond

Large & Growing Markets
The increasing prevalence of late-stage cancer patient in the U.S. creates an urgent need for more treatment options

Differentiating MOA
TYME is leading first-in-class research to leverage the Warburg Effect for treatments in monotherapy and in combination

Our Team

Steve Hoffman
Chairman, Chief Executive Officer

Ben R. Taylor
President, Chief Financial Officer

Michele Korfin
RPh, MBA, Chief Operating Officer

Jonathan Eckard
PhD, Chief Business Officer

Giuseppe Del Priore
MD, MPH, Chief Medical Officer

Delivering on Key Milestones Positions TYME for Long-Term Success

A Look Beyond:
Expanding Innovative Pipeline of Cancer Metabolism-Based Compounds (CMBTs™)

SM-88
Oral

Pancreatic: Third-Line
TYME-88-Panc Pivotal Part 2: Enrolling

Pancreatic: Second-Line Monotherapy
Precision Promise: Enrolling Shortly

Pancreatic: First-Line Combo w/ GA
Precision Promise: Initiate Following Second-Line

Prostate: Biomarker Recurrent
Completed

Metastatic Sarcomas*
HopES: Enrolling

Future Trials: Breast and Prostate

Future Trials: Hematology

SM-88i
Injectable

Digestively Compromised Patients

SM-88n
Nasal

Brain/Glioma

TYME-18
Intra-Tumoral

Solid Tumors

*Investigator-initiated trial
GA = gemcitabine/Abraxane®
Cancer Metabolism-Based Therapies (CMBTs™)

CMBTs are investigational proprietary compounds that are hypothesized to disrupt the protein synthesis of cancer cells by breaking down the cells’ key defenses and leading to cell death through oxidative stress and exposure to the body’s natural immune system. Clinical trial data have shown that our lead oral candidate, SM-88, has demonstrated encouraging tumor responses across 15 different cancers, including pancreatic, lung, breast, prostate, sarcoma and lymphoma cancers with minimal serious grade 3 or higher adverse events.

The Warburg Effect

- Discovered in the 1920s
- Relies on primitive aerobic glycolysis
- Inefficient use of glucose versus normal metabolism
- Results in high levels of damaging free radicals (ROS)
- Drives cell reliance on amino acids, especially tyrosine, for metabolism

Without this ability, cancer cells that lack oxygen quickly die.

~90% of cancers have an altered method of metabolism known as the Warburg Effect, which allows them to produce energy differently than normal healthy cells.

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vJune2019
TYME’s First-in-Class Approach Disrupts Cancer’s Metabolism To Cause Cell Death in 4 Steps

1. Induce Uptake of TYME’s Modified Dysfunctional Tyrosine

TYME is developing CMBTs™ that leverage the amino acids — such as Tyrosine — that cancer cells rely on but normal cells do not.

2. Protein Synthesis Fails

The modification creates a dysfunctional amino acid designed to arrest protein synthesis and cause cell death in cancer cells.

3. Decreased Cellular Defenses

CMBTs enhance the susceptibility of cancer cells to the highly acidic and toxic tumor microenvironment, while minimizing the impact to normal tissues.

4. Cell Death from Oxidative Stress

CMBTs are thought to interrupt the metabolic processes of cancer cells by breaking down the cells’ key defenses, leading to cell death through oxidative stress and exposure to the body’s immune system.

Administering CMBTs along with low doses of FDA-approved therapies is to enhance their toxic effects.

- Sirolimus increases tumor cells’ uptake of modified dysfunctional tyrosine by increasing levels of its transporter, LAT1.
- Phenytoin and methoxsalen increase oxidative stress.

As a result, malignant cells lose the ability to mitigate rising oxidative stress. The increased toxicity ultimately triggers apoptotic signaling and leads to cell death.
What is Pancreatic Cancer?

Pancreatic cancer is a deadly disease that occurs when cells in the pancreas grow out of control to form a tumor. The pancreas is responsible for digestion and for regulating blood sugar.

WHO IS AFFECTED?
- Most people diagnosed are over age 55
- More likely to affect men than women
- African Americans and Ashkenazic Jewish communities are at higher risk

WHAT ARE THE RISK FACTORS?
- Smoking
- Family history
- Diabetes
- Obesity
- Chronic pancreatitis
- Inherited mutation in the BRCA-2 gene

WHAT ARE THE SYMPTOMS?
- Jaundice (yellowing skin or eyes)
- Dark urine
- Abdominal pain
- Sudden or unexpected weight loss
- Changes in appetite
- Gallbladder or liver enlargement
- Blood clots
- Diabetes

HOW IS IT TREATED?
- The only way to cure pancreatic cancer is through surgery. Other treatments may help alleviate symptoms and prevent complications.
- Depending on the stage of pancreatic cancer, treatment may include:
  - Surgery
  - Chemotherapy and radiation
  - Immunotherapy
  - Pain control
  - Treatments being investigated include cancer metabolism-based therapies

For patients with metastatic pancreatic cancer who have already been treated with two previous therapies, there are no FDA-approved 3rd line treatments and no national oncology guideline recommendations.
WHAT IS THE PROGNOSIS?9-11

Over 90% of patients do not survive 5 years. Factors affecting prognosis include:

- **Tumor Size:** Tumors that have spread beyond the pancreas typically cannot be removed by surgery and carry a poorer prognosis.

- **Circulating Tumor Cells (CTCs):** CTCs are cancer cells that slough off tumors into the bloodstream. They may land in a new location to cause metastasis. Higher CTC levels are associated with a lower chance for survival.

Outlooks are especially poor for patients who have failed systemic therapies: an analysis of 19 prospective pancreatic cancer trials demonstrated a median survival time of just 2.0 – 2.5 months after progression from second-line therapy.12

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### TUMOR STAGE

<table>
<thead>
<tr>
<th>Stage Description</th>
<th>Percent of Patients Who Survive 5+ Years Following Diagnosis</th>
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<tbody>
<tr>
<td>Localized to pancreas only</td>
<td>34%</td>
</tr>
<tr>
<td>Restricted to pancreas and surrounding tissues</td>
<td>12%</td>
</tr>
<tr>
<td>Spread to distant tissues</td>
<td>3%</td>
</tr>
</tbody>
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TYME-88-PANC Clinical Trial: **SM-88 in Pancreatic Cancer**13,14

Prospective, open-label Phase II/III trial in previously treated metastatic pancreatic cancer

**OVERVIEW**

<table>
<thead>
<tr>
<th>Phase II</th>
<th>Phase III</th>
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<tbody>
<tr>
<td>49 heavily pretreated patients with radiographically progressive metastatic pancreatic cancer</td>
<td>Approximately 250 patients who have been previously treated with two systemic therapies</td>
</tr>
<tr>
<td>More than 80% of patients had received at least two prior lines of therapy</td>
<td>Randomized 1:1 to SM-88 920 mg or an investigator-chosen therapy</td>
</tr>
<tr>
<td>Randomized 1:1 to one of two doses of SM-88: 460 mg or 920 mg</td>
<td>Average patient age is 66</td>
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**OUTCOMES**

<table>
<thead>
<tr>
<th>Phase II</th>
<th>Phase III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple indicators of efficacy and safety</td>
<td>Overall survival</td>
</tr>
<tr>
<td>Change in tumor size as measured by CT scans</td>
<td>Clinical benefit rate (stable disease or better)</td>
</tr>
<tr>
<td>Change in CTC levels as measured through blood tests</td>
<td>Change in CTC levels as measured through blood tests</td>
</tr>
<tr>
<td></td>
<td>Quality of life indicators</td>
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**ABOUT SM-88**

- Investigational oral cancer metabolism-based therapy
- Thought to interrupt the metabolic processes of cancer cells by breaking down their key defenses, leading to cell death through oxidative stress and exposure to the immune system.
- Demonstrated encouraging tumor responses across 15 cancers—including pancreatic, lung, breast, prostate, sarcoma and lymphoma—with minimal serious grade 3 or higher adverse events.

**REFERENCES**