UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended March 31, 2021

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

For the transition period from _____ to _____

Commission File No. 001-38169

TYME TECHNOLOGIES, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**45-3864597**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

1 Pluckemin Way – Suite 103, Bedminster, NJ 07921

(Address of Principal Executive Offices) (Zip Code)

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

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter, was approximately $102,067,373.

The number of shares outstanding of the registrant's common stock on June 7, 2021 was 172,206,894.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by Items 10, 11, 12, 13 and 14 is incorporated by reference into Part III hereof from portions of the Proxy Statement for the registrant's 2021 Annual Meeting of Stockholders.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this Annual Report on Form 10-K are "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the safe harbor created thereby. All statements contained in this Annual Report on Form 10-K other than statements of historical facts, including statements regarding our future results of operations and financial position, our business strategy and plans and our objectives for future operations, are forward-looking statements. Such forward-looking statements within this report include, without limitation, statements regarding our drug candidates (including SM-88 and TYME- 18) and their clinical potential and non-toxic safety profiles, our drug development plans and strategies, ongoing and planned preclinical or clinical trials, including the proposed TYME-19 proof-of-concept study, preliminary data results and the therapeutic design and mechanisms of our drug candidates. The words "believes," "expects," "hopes," "may," "will," "plan," "intends," "estimates," "could," "should," "would," "continue," "seeks," "anticipates," and similar expressions (including their use in the negative) are intended to identify forward-looking statements. Forward-looking statements can also be identified by discussions of future matters such as: the effect of the novel coronavirus (COVID-19) pandemic and the associated impact on the national and global economy as well as impacts on the Company's ongoing clinical trials and ability to analyze data from those trials; the cost of development and potential commercialization of our lead drug candidate and of other new products; expected releases of interim or final data from our clinical trials; possible collaborations; and the timing, scope, status, objectives of our ongoing and planned trials; the success of management transitions; and other statements that are not historical. The forward-looking statements contained in this report are based on management's current expectations and projections which are subject to uncertainty, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. These statements involve known and unknown risks, uncertainties and other factors which may cause the Company's actual results, performance or achievements to be materially different from any historical results and future results, performance or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include but are not limited to: the severity, duration, and economic impact of the COVID-19 pandemic; that the information is of a preliminary nature and may be subject to change; uncertainties inherent in the cost and outcomes of research and development, including the cost and availability of acceptable-quality clinical supply, and in the ability to achieve adequate start and completion dates, as well as uncertainties in clinical trial design and patient enrollment, dropout or discontinuation rates; 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 or other drug candidates 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 or other drug candidates; the ability of TYME and its collaborators to develop and realize collaborative synergies; competitive developments; and the factors described in the section captioned "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K, as well as subsequent reports we file from time to time with the U.S. Securities and Exchange Commission (available at www.sec.gov).

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

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

GENERAL

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

Throughout this fiscal year 2021 Form 10-K, we have used terms which are defined below:

AEs	Adverse events	GLP	Good laboratory practices
ANDA	Abbreviated New Drug Application	HIPAA	Health Insurance Portability and Accountability Act of 1996
API	Active Pharmaceutical Ingredients	HITECH	Health Information Technology for Economic and Clinical Health Act
ASC	Accounting Standards Codification	HR+	hormone receptor positive
ASU	Accounting Standards Update	HER2-	Human epidermal growth factor receptor 2 negative
ATM	At-the-Market offering	IEC	Independent Ethics Committee
CARES	Coronavirus Aid, Relief, and Economic Security	INDs	Investigational New Drugs
CBR	Clinical benefit rate	IITs	Investigator Initiated Trials
CCPA	California Consumer Privacy Act	IP	Intellectual Property
CDK4/6	A gene that makes a protein involved in the cell cycle (the process a cell goes through each time it divides). Mutations (changes) in the CDK4/6 gene may cause cells to divide too quickly or in an uncontrolled way.	IRB	Institutional Review Board
cGMP	Current good manufacturing practice	KOLs	Key opinion leaders
CMBTs	Cancer metabolism-based therapies	LLC	Limited Liability Company
CMC	Chemistry, manufacturing and controls	MAA	Marketing Authorization Application
CMO	Contract Manufacturing Organization	MPS	Methoxsalen, phenytoin, and sirolimus
CMS	Centers for Medicare & Medicaid Services	M2PS	Melanin, melanotan II, phenytoin, and sirolimus
COSO	Committee of Sponsoring Organizations of the Treadway Commission	NCCN	National Comprehensive Cancer Network
CR	Complete responses	NDA	New Drug Application
CRO	Contract/Clinical Research Organization	NOL	Net Operating Loss
CT	Computerized Tomography	ORR	Objective response rate
CTCs	Circulating Tumor Cells	OS	Overall survival
DMC	Data Monitoring Committee	PanCAN	Pancreatic Cancer Action Network
DOP1	Department of Oncology Products 1	PCAOB	Public Company Accounting Oversight Board
DOP2	Department of Oncology Products 2	PFS	Progression free survival
DOR	Duration of response	PHSA	Public Health Service Act
ECOG PS	Eastern Cooperative Oncology Group Performance Status	PI	Principal Investigator
EMA	European Medicines Agency	PR	Partial responses
EPS	Earnings Per Share	PSA	Prostate specific antigen
ESG	Environmental, social and governance	R&D	Research and Development
ETASU	Elements to assure safe use	RECIST	Response Evaluation Criteria In Solid Tumors
FASB	Financial Accounting Standards Board	REMS	Risk evaluation mitigation strategies
FCPA	Foreign Corrupt Practices Act	rPFS	Radiographic progression-free survival
FDA	Food and Drug Administration	ROU	Right-of-use
FDAMA	Food and Drug Administration Modernization Act of 1997	SAEs	Serious adverse events
FDCA	Federal Food, Drug, and Cosmetic Act	SD	Stable disease
FIH	First in Human	SEC	U.S. Security and Exchange Commission
GAAP	Generally Accepted Accounting Principles	SOX	Sarbanes-Oxley Act of 2002
GCP	Good clinical practices	SPA	Securities Purchase Agreement
GDPR	General Data Protection Regulation	USPTO	United States Patent and Trademark Office

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to numerous risks and uncertainties. If any of those risks materializes, it could have a material adverse effect on our business, operating results and financial condition, and cause the trading price of our common stock to decline. You should carefully review and consider the full discussion of our risk factors in the section titled "Risk Factors" in Item 1A of this Annual Report on Form 10-K. These risks include, among others, the following:

- Our two co-founders each hold a substantial ownership interest in our Company, which gives them the ability to influence certain decision making and Mr. Hoffman has certain rights to our intellectual property that may allow him to use our IP in ways that could be inconsistent with our use.
- Our share price is likely to be volatile due to factors beyond our control and may drop below prices paid by investors; investors could lose all of their investment in our Company.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish substantial rights.
- The novel coronavirus (COVID-19) and its impact on business and economic conditions could adversely affect our business, results of operations and financial condition, and the extent and duration of those effects will be uncertain.
- Our proprietary lead drug product, SM-88, is in clinical development in three principal areas. We are currently participating in the advancement of clinical trials for pancreatic cancer, breast cancer, and sarcoma. We are considering additional clinical trials in other solid tumors and/or hematologic malignancies. Clinical drug development is expensive, time-consuming and uncertain, and we may ultimately not be able to obtain regulatory approval for the commercialization of our lead candidate.
- We have limited experience with completing large-scale or pivotal Phase II or III clinical trials, obtaining FDA approvals or commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability or could result in delays or the failure to obtain required regulatory approval of our products.
- If we are unable to identify, recruit and retain enough qualified patients for our clinical trials, it could delay or prevent development of our drug candidates and adversely affect our future business prospects.
- If clinical trials for our drug candidates are prolonged, delayed or stopped, we may be unable to obtain regulatory approval and commercialize our drug on a timely basis, which would require us to incur additional costs and delay revenue.
- The results of previous studies may not be predictive of future results, our progress in future trials for one drug candidate may not be indicative of progress in trials for other drug candidates and the results of our current and planned clinical trials may not satisfy the requirements of the FDA, the EMA or other non-U.S. regulatory authorities.
- Preclinical development programs and preclinical mechanism research activities may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all.
- We may not be successful in our efforts to use and expand our technology platform to build a pipeline of product candidates.
- We have filed patent applications relating to additional product candidates based on our technology platform. However, to date, the FDA and other regulatory authorities have not approved products that utilize this technology platform.
- Even if we obtain marketing approval for one or more of our drug candidates in a major pharmaceutical market such as the United States or Europe, we may never obtain approval or commercialize in other major markets, which would limit our ability to realize the drug's full market potential.
- SM-88, TYME-18, TYME-19 or any other drug product we may develop may have serious adverse, undesirable or unacceptable side effects, which may delay or prevent marketing approval. If such side effects are identified during the development of a product candidate we may develop or following such candidate's approval, if any, we may need to abandon our development of such product candidate, the commercial profile of any approved label may be limited and/or we may be subject to other significant negative consequences following marketing approval, if any.
- Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval and commercialization of our product candidates and may affect the prices we obtain. Our successful

commercialization will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement and pricing policies.

- We currently have very limited marketing, sales or distribution infrastructure. If we are unable to develop full sales, marketing and distribution capabilities on our own or through collaborations or if we fail to achieve adequate pricing and/or reimbursement, we will not be successful in commercializing our candidates.
- Even if SM-88 obtains regulatory approval, it will remain subject to ongoing regulatory requirements and oversight.
- Even if approved, if SM-88 does not achieve broad market acceptance among physicians, patients, the medical community and third-party payors, our revenue generated from its sales will be limited.
- We are subject to manufacturing risks that could substantially increase our costs and limit the supply of our current drug candidates and any other drug product we may develop.
- The drug candidates that we may develop will face significant competition and, if competitors develop and market products that are more effective, safer or less expensive than our drug, our commercial opportunity will be negatively impacted.
- If any drug liability lawsuits are successfully brought against us or any of our collaborators, we may incur substantial liabilities and may be required to limit commercialization of our drug candidates and any other drug product we may develop.
- We have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We have no products approved for commercial sale and to date we have not generated any revenue or profit from drug sales. We may never realize revenue or profitability.
- To achieve on our long-term business objectives, we will require substantial additional funding, which may require us to agree to restrictions on our operations or may not be available to us on acceptable terms or at all and, if not available, may require us to delay, scale back or cease our drug development programs or operations.
- We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of these trials.
- We intend to rely on third-party contract manufacturing organizations to manufacture and supply our drug candidates for us. If one of our suppliers or manufacturers fails to perform adequately or fulfill our needs, we may be required to incur significant costs and devote significant efforts to find new suppliers or manufacturers. We may also face delays in the development and commercialization of our drug candidates and any other drug product we may develop.
- We have entered into a co-promotion agreement and may enter into additional license or collaboration agreements with third parties with respect to SM-88 and any other product candidates we may develop that may place the development or promotion of our product candidates partially or entirely outside of our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us. If such collaborations are not successful, our drug candidates we may choose to develop may not reach their full market potential.
- We recently completed a comprehensive review of our development strategy and product candidate portfolio, which may result in additional changes to certain development programs and may have a material impact on our business, results of operations and financial condition.
- Our internal computer systems or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drug development program.
- Our ability to successfully commercialize our technology and drug candidate may be materially adversely affected if we are unable to obtain and maintain effective IP.
- We may not be able to protect our IP rights throughout the world.
- Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.
- Health care reform measures could hinder or prevent the commercial success of our drug candidates.

If approved, the marketing for SM-88 or other drug candidate, will be limited to the specific approved cancer or antiviral indications, as applicable, and, if we want to expand the indications for which these drug candidates may be marketed, additional regulatory approvals will need to be obtained, which may not be granted.

PART I

ITEM 1. BUSINESS

Executive Summary of Our Business

TYME is an emerging biotechnology company developing cancer metabolism-based therapies (CMBTs™) that are intended to be effective across a broad range of solid tumors and hematologic cancers, while also maintaining patients' quality of life through relatively low toxicity profiles. TYME's therapeutic approach is designed to take advantage of a cancer cell's innate metabolic requirements to cause cancer cell death. Our lead first-in-class CMBT compound is SM-88 (racemetryrosine). Early clinical results demonstrated by SM-88 in multiple advanced cancers, including pancreatic, prostate, sarcomas and breast, reinforce the potential of our emerging CMBT pipeline. Moreover, we also believe our pipeline offers hope to patients for a new future in long-term management of various cancers.

Our lead clinical CMBT compound, SM-88, is an oral investigational modified proprietary tyrosine derivative that is hypothesized to interrupt the metabolic processes of cancer cells by breaking down the cells' key defenses and leading to cell death through oxidative stress and exposure to the body's natural immune system. To date, clinical trial data have shown that SM-88 has achieved confirmed tumor responses across 15 different cancers, both solid and liquid tumors, including pancreatic, lung, breast, prostate, sarcoma and lymphoma cancers with minimal drug-related serious Grade 3 or higher adverse events, which we believe is rare for investigational compounds.

Strategic Review

In November 2020, TYME appointed Richard Cunningham as its new Chief Executive Officer. His initial priority was to build a management team better equipped to transition the Company to its next phase of growth. In January 2021, he commenced a comprehensive strategic review examining every facet of the Company. The goals of the review were to assess the Company's existing opportunities, explore untapped opportunities that may have been overlooked and maximize the efficiency of our capital expenditures in an effort to unlock TYME's full potential. In February 2021, Mr. Cunningham led an effort to raise $100 million in capital that we believe will provide significant runway for the Company to execute on its move-forward strategy.

The strategic review process encompassed an extensive review of internal and external resources, the design of and results from our preclinical and clinical trials, the likelihood of approval by the Food and Drug Administration ("FDA") or similar regulatory authorities outside the United States, the potential market for pipeline candidates, the costs and complexities of manufacturing to ensure a safe and sustainable supply of investigational compounds can be delivered to patients, the potential of competing products, the likelihood of any challenges to our intellectual property, regardless of merit, the ongoing and potential effects of COVID-19 or any future pandemics, and industry and market conditions generally. The review included internal and external assessments by industry experts, key opinion leaders ("KOLs") and advisors with considerable experience in the various areas we sought to probe and explore.

The strategic review process resulted in the following key takeaways:

First in Human study and Compassionate Use Program data with responses across 15 cancer types shows potential for broad development options, however focus is critical.

The First in Human ("FIH") study was designed as a safety study enrolling all-comers of solid tumors that had exhausted or refused available treatment options. Ultimately the trial yielded a 33% objective response rate ("ORR") based on Response Evaluation Criteria In Solid Tumors 1.1 ("RECIST") criteria, another 57% experiencing stable disease for median duration of 11 months, and a median overall survival of 29.8 months. The results of the FIH study were published in the journal, Investigational New Drugs, in March 2019. This trial, together with the Compassionate Use Program, as described below under the caption "Completed Studies", ultimately resulted in observed anti-tumor responses in 15 different cancer types, and with minimal drug-related serious Grade 3 or higher serious adverse events. These results offer TYME multiple potential development options, however, they also highlight the importance of focusing in on the

settings that offer the most strategic approach, as well as on following our scientific and biomarker findings.

Breast cancer is a priority indication for development.

Our review of the results from study of SM-88 for the treatment of breast cancer in the FIH study and Compassionate Use programs indicate that hormone receptor positive ("HR+") and human epidermal growth factor receptor 2 negative ("HER2-") disease ("HR+/HER2-") is a distinct opportunity. Accordingly, we have identified breast cancers as a strategic priority as we look to expand our indications within our portfolio for SM-88 and to validate previously seen results in areas of unmet need. Anti-tumor activity was observed in several key breast cancer conditions, however, the strongest data were in the patients with HR+/HER2- disease where complete responses were observed. Furthermore, important changes are occurring in the treatment paradigm of this patient group. In particular, a broadly used and successful class of drugs, CDK4/6 inhibitors, previously approved for use in advanced lines of metastatic therapy, has since been approved and is transitioning use to earlier stages of metastatic disease, as well as pre-metastatic settings. There are limited FDA-approved treatment options following CDK4/6 inhibitors in this disease, other than chemotherapy treatment. Therefore, we believe SM-88's safety and efficacy profile could offer an alternative treatment option for these patients prior to advancing to chemotherapy treatment. To address this, together with clinicians at Georgetown University, we entered into an agreement to conduct a trial to study the activity and overall profile of SM-88 for use in patients after failing or progressing on a CDK4/6 inhibitor, as an alternative to a chemotherapy option. The Phase II OASIS trial, as described below under the caption "Ongoing Studies", will be conducted at several Georgetown University/MEDSTAR sites, enrolling up to 50 women with HR+/HER2- metastatic breast cancer after failing or progressing after a CDK4/6 inhibitor.

Pancreatic cancer second-line Precision Promise trial is the priority in this cancer.

We undertook a comprehensive review of the two ongoing trials evaluating SM-88 in pancreatic cancer—Precision Promise, the Pancreatic Cancer Network-sponsored trial that is evaluating SM-88 as a second-line therapy, and TYME-88-Panc (Part 2), our clinical trial evaluating SM-88 as a third-line therapy. As part of that process, we reviewed our overall pancreatic cancer clinical trial spending and evaluated the cost benefit per investment to determine how they might each impact the Company and our overall strategy. Our findings indicated we were wholly invested in one indication with nearly all of our aggregate clinical investment in pancreatic cancer. Furthermore, we identified that the two concurrent pancreatic cancer trials in third-line and second-line appear to be operating on similar enrollment timelines and determined that there were more efficient uses of capital.

The enrollment rates for TYME-88-Panc trial have progressed more slowly than the Company initially anticipated, due in large part to the COVID-19 pandemic, and our current projections for enrollment for these trials indicate that Precision Promise is likely to complete enrollment in a similar timeline to TYME-88-Panc, (Part 2). Furthermore, while considering additional investments in TYME-88-Panc to accelerate enrollment, we identified higher-than-expected drop-out rates in patients randomized to the chemotherapy control arm, which could potentially impact the interpretive and regulatory utility of the data. Based on the comparative enrollment rates, the potential to reach patients earlier in disease progression in the second-line Precision Promise trial, potential impacts on data utility and expected resources needed for study success, we made the decision to focus our resource allocation and development priorities toward second-line treatments with the Precision Promise trial and other indications could provide a diversified portfolio. Accordingly, the Company has decided to stop enrollment in TYME-88-Panc and to begin the process of closing down the trial.

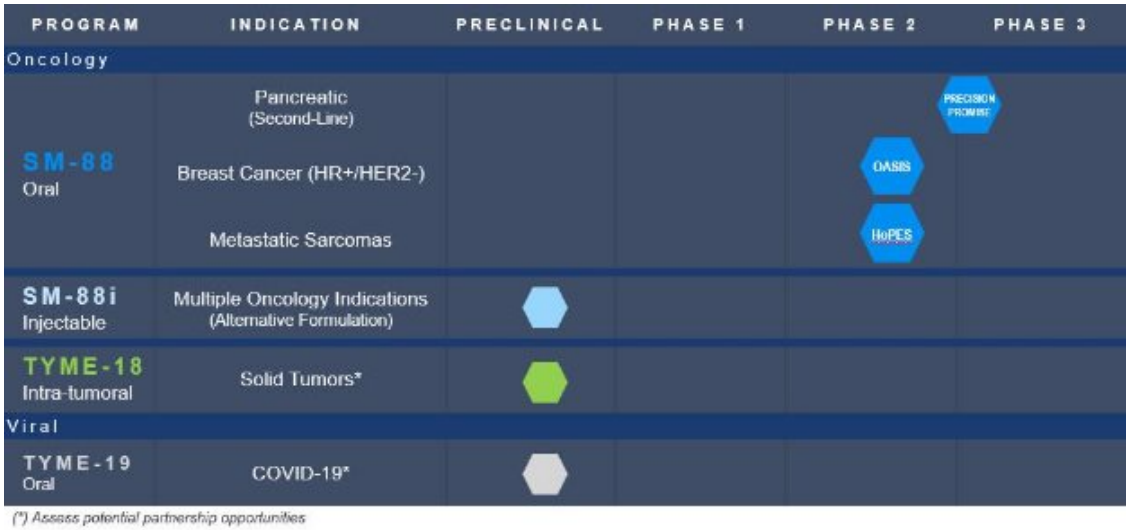
Need to identify targeted patient populations.

The number of clinical trials incorporating pharmacogenomic and/or pharmacogenetic analysis to stratify patients for predictive response, safety, or dosing, has more than doubled since 2010 and represents 42% of oncology trials in 2019. Predictive biomarker-based therapies are designed to predict tumor response to a specific therapy by providing information regarding which molecular alterations are driving cancer growth.

Predictive biomarkers can be used to select for which patient population a treatment is likely to have an effect and can enable TYME to employ a more targeted approach, which could result in better trial designs, and potentially deliver better outcomes for patients and increase the likelihood of future clinical success. Therefore, the Company launched a SM-88 biomarker initiative. As part of this initiative, we have engaged a leading global drug discovery, research and development company, as well as leading academic institutions to assist us in expanding our understanding of the biological mechanisms of SM-88, and other potentially targetable aspects of cancer metabolism. Our goals are to identify actionable biomarkers of sensitivity and activity of SM-88 in different cancers, as well as to identify potential combination strategies for SM-88 with existing standards of care. The work to support the biomarker initiative is expected to include use of existing cancer models, human derived cancer models and organoids, as well as patient genomic samples and ultimately patient tumor biopsy analysis. Some of the analyses planned include genomic analysis, gene transcription analysis, epigenetic changes, and alterations in multiple aspects of cellular metabolism. Together with our collaborators, we intend to use these findings to identify potential patient biomarkers and to attempt to validate them in future clinical settings.

Need to identify clear development pathway for TYME-19.
COVID-19 and the landscape for TYME-19 are each rapidly evolving, which highlights the importance of navigating the environment appropriately. As we progress the TYME-19 preclinical program, we will assess the changing market and potential partners as we continue our focus in oncology.

Our Pipeline



SM-88 Ongoing Studies

Precision Promise (second-line Pancreatic cancer)

In 2019, we entered into an agreement for SM-88 to be included in an experimental arm in the novel Precision Promise adaptive randomized Phase II/III trial platform ("Precision Promise") with registration intent sponsored by the Pancreatic Cancer Action Network ("PanCAN"). The objective of Precision Promise is to expedite the study and approval of promising therapies for pancreatic cancer by bringing multiple stakeholders together, including academic, industry and regulatory entities.

In this trial which began in early 2020, SM-88 with the conditioning agents methoxsalen, phenytoin, and sirolimus ("MPS") is being studied as monotherapy treatment arm for patients who have failed one prior line of

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

In patients with pancreatic cancer treated previously with SM-88 from both the Phase II TYME-88-Panc trial, the FIH study, and Compassionate Use Program, a majority of patients with tumor responses and long-term stable disease occurred in less heavily pretreated patients with one or fewer prior lines of systemic therapy.

In the US, there are about 60,000 new diagnosis of pancreatic cancer each year, and 80% of these cases are not eligible for potentially curative surgery. Of the approximately 40,000 metastatic patients who start systemic therapy, unfortunately, most patients relapse. Physician consultants have reported that approximately half of these first-line patients ultimately receive a second-line systemic treatment. The FDA-approved treatment options for second-line metastatic pancreatic cancer are limited, and several older chemotherapy combinations currently represent the current standard of care (NCCN guidelines). According to estimates from American Cancer Society, Evaluate Pharma, The Oncology Pharmacist (April 2020), and Syneos Health, the estimated potential U.S. market in 2019 for first-, second-, and third-line branded pancreatic cancer therapies reached $3.8 billion, $2.0 billion, and $0.5 billion, respectively.

Although we do not have details of the enrollment of the SM-88 cohort, the next likely event in the trial would be a determination of potential "graduation" from the Phase II portion of the trial to the Phase III confirmatory portion of the trial. This determination occurs based on the survival of up to the first 100 patients. If SM-88 "graduates", the goal of the Phase III trial is to enroll up to an additional 75 patients to accumulate sufficient statistical data to confirm the level of benefits observed. The FDA has stated that positive data from this trial could be used to support a NDA application.

OASIS (Metastatic HR+/HER2- Breast Cancer After CDK4/6 Inhibitors)

In June 2021, we announced an agreement with Georgetown University to support a Phase II trial for SM-88 in patients with metastatic breast cancer who have HR+/HER2-. This represents approximately 73% of the annual breast cancer diagnosis in the US each year. According to estimates from Data Monitor and Syneos Health, there are approximately 150,000 metastatic breast cancer diagnoses in the US each year. According to Data Monitor, company reported sales figures, and Syneos Health analyses, the total 2019 U.S. market revenues for drug treatment for metastatic breast cancer were $7.7 billion.

The OASIS trial is an investigator-initiated prospective open-label Phase II trial evaluating the efficacy and safety of SM-88 with MPS for the treatment of metastatic hormone-receptor positive, HER2- breast cancer after treatment with a CDK4/6 inhibitor. This trial is designed as a two-stage trial, enrolling up to 50 patients to receive SM-88 with MPS without additional therapies in patients who have failed or progressed after receiving two hormonal agents and a CDK4/6 inhibitor. The primary endpoint of this trial is ORR, with secondary endpoints including duration of response ("DOR"), clinical benefit rate ("CBR") at >24 weeks, progression free survival ("PFS"), and safety. The trial will be conducted at Georgetown University at a total of five sites within the Georgetown/MEDSTAR system located in Washington DC, Maryland, and New Jersey. Patient enrollment is expected to begin in the third quarter of calendar year 2021.

This trial is being conducted as a follow up to the encouraging anti-tumor efficacy observed from the initial trials of SM-88 in this specific patient sub-group. In the FIH study and Compassionate Use Program, several heavily pretreated metastatic HR+/HER2- breast cancer patients displayed tumor responses to SM-88, including several complete responses. This trial is aimed to further explore this signal and will also collect cell-free DNA from patients from different time-points with a goal of better understanding potential biomarkers of response and other aspects of SM-88's mechanism of action. TYME has also established an academic collaboration with an investigator at Georgetown University to explore the mechanism of SM-88 and MPS, including models of CDK 4/6 resistance.

HoPES Trial (Ewing's Sarcoma, and Mixed Refractory Sarcoma)

In early 2020, the open-label Phase 2 investigator sponsored trial of SM-88 therapy in sarcoma opened. This trial has two cohorts each expecting to enroll 12 patients. The first is SM-88 with MPS as salvage treatment in patients with mixed rare sarcomas, and the other is SM-88 with MPS as maintenance treatment for patients with metastatic

Ewing's sarcoma who had not progressed on prior therapy. The primary objectives are to measure ORR and PFS. Secondary objectives include duration of response, OS, CBR using RECIST, and incidence of treatment-emergent adverse events. The Joseph Ahmed Foundation is providing funding and patient support for this trial, and the trial is being conducted by principal investigator Dr. Chawla at the Sarcoma Oncology Center in Santa Monica, CA.

Initial results from approximately 13 patients were published in the Proceedings for the 2021 ASCO General Meeting. These results included several patients with long-term stable disease, and the median duration of treatment on SM-88 was significantly longer than the respective treatments the patient received in the most recent line of therapy. Additionally, there have been no reported drug-related serious adverse events ("SAEs") related to SM-88.

The trial was initiated after anti-tumor efficacy and other clinical benefits were observed in several patients with Ewing's Sarcoma and other heavily pre-treated sarcomas in the FIH study and Compassionate Use Program. This included objective tumor responses in two Ewing's sarcoma patients. Upon review of the data, Dr. Chawla approached TYME with an interest in examining SM-88 in a clinical trial.

Ewing's Sarcoma is an ultra-rare cancer that can affect adolescents and younger adults, with approximately 200 cases diagnosed in the US per year. Broadly there are over 50 types of sarcomas, totaling about 12,000 new cases diagnosed in the US each year. While there have been some recent developments for certain sarcomas, there remains a high need for additional effective therapies, especially for patients with metastatic disease.

SM-88 Biomarker Initiative

Following feedback from the recent strategic review, the Company has begun a comprehensive translational biomarker initiative. We have employed a multi-faceted approach incorporating a leading global drug discovery, research and development company together with several complementary academic collaborators. The overall goals of this initiative are to identify targeted patient populations with actionable biomarkers of sensitivity and/or activity to SM-88 in various cancers, to identify potential complementary combination drugs strategies for SM-88, and potentially to identify other cancer metabolism targets for treatment. Additionally, we intend to incorporate liquid and tumor biopsies to future clinical trials in furtherance of these biomarker identification goals. We anticipate this initiative will have several stages, and to last likely over at least this 2022 fiscal year and potentially beyond.

Mayo Collaboration

In March 2021, TYME expanded its pancreatic cancer research collaboration with Mayo Clinic to perform in-depth analysis of pancreatic cancer cell gene expression, epigenetic, and metabolism changes from SM-88 treatment. In addition, the collaborator at Mayo has created and characterized multiple pancreatic cancer organoids that could help in the identification of biomarkers and examine the possible impact SM-88 has on the tumor microenvironment.

NYU Collaboration

In July 2019, TYME began a research collaboration with NYU School of Medicine examining multiple aspects of SM-88 mechanisms. The work is expected to explore the impact of SM-88 on clinical models, including viability, general pharmacodynamics, genomic and RNA transcription analysis, and detailed impact on cancer metabolism. In addition, patient derived cancer models, and related animal experiments will explore immunohistochemical signals of SM-88 effects and comprehensive immunomodulatory impact of the tumor microenvironment, as well as exploration of SM-88 in combination with standard approved cancer therapies.

Georgetown Collaboration

In May 2021, TYME initiated a research collaboration with a research investigator at Georgetown University, to examine the effects of SM-88 in breast cancer. This collaboration will examine the effects of SM-88 and MPS in various breast cancer models in culture and animal models. The project will explore metabolomics, gene expression analysis, and protein array analysis following SM-88 exposure to characterized cancer cell lines, including cell lines with acquired resistance to CDK4/6 inhibitors.

Preclinical Pipeline Programs

TYME-19 – For COVID-19

TYME-19 is an oral, synthetically produced member of the bile acid family that is being developed for the potential treatment of COVID-19. From the Company's metabolic understanding of bile acids, it was able to identify TYME-19 as a well characterized candidate and a potential treatment of corona viruses. A patent has been issued for TYME-19 for the treatment of COVID-19.

Bile acids can cellular modulate lipid and glucose metabolism as well as remediate dysregulated protein folding each that are relevant to viral infection of a host cell. Existing literature has shown that certain bile acids can have antiviral properties in a range of different viruses, including prior corona viruses.

Our initial preclinical in vitro experiments displayed effectiveness against COVID-19 infection and replication, and we will continue to conduct additional preclinical experiments to support the potential utility of TYME-19 in the treatment of COVID-19 and disease variants. With the ever-changing dynamics of this disease area, the Company's intent with this program is to prepare this agent for clinical testing, while learning from the ongoing work in an effort to identify an optimal clinical setting where TYME-19 could potentially offer clinical benefits and for which there may be a sustainable market.

Given TYME's focus on oncology, we expect that at the proper time, identifying a potential partner to assist in the ongoing development of this asset may be an opportune strategic pathway.

TYME-18 – Intra-Tumoral Therapy

TYME-18 is a pre-clinical CMBT compound that is designed to be delivered intratumorally. TYME-18 is a combination of a proprietary surfactant system and natural sulfonic/bile acid that is designed to disrupt energy metabolism and have lytic function for potential treatment of inoperable tumors. TYME-18 is distinct in composition from SM-88. However, like SM-88, it aims to enhance the susceptibility of a cancer to the highly acidic and toxic tumor microenvironment, while minimizing the impact to normal tissues.

In initial preclinical xenograft mouse studies, TYME-18 was able to completely resolve over 90 percent (11/12 mice) of established colorectal tumors within 12 days versus an average of over 600 percent growth in the control animals.

TYME-18 is currently in preclinical development, and as with TYME-19, we expect at the proper time, to identify a potential partner with a focus on surgical oncology to assist in the ongoing development of TYME-18.

Completed Studies

First in Human Study

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

The results of the FIH study were published in the journal, *Investigational New Drugs,* in March 2019, including data from the trial's initiation in January 2012 through September 2017. Patients were treated with monotherapy SM-88 and achieved median overall survival ("OS") of 29.8 months, median PFS of 13 months, and a 33% ORR. The ORR consisted of four complete responses ("CR") and six partial responses ("PR"), based on RECIST. In addition, 57% of patients (17/30) achieved RECIST stable disease ("SD") with a median SD duration of 11 months. Five FIH study patients with metastatic cancer survived for over five years after commencing SM-88 treatment. All FIH study patients improved or maintained Eastern Cooperative Oncology Group Performance Status ("ECOG

PS"), a measure of quality of life, after initiating SM-88 therapy, and OS was comparable for patients who entered the trial with ECOG PS ranging from 0 (asymptomatic) to 2 (unable to perform any work-related activities).

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

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

Compassionate Use Program

In parallel with and following the FIH study, we also allowed advanced cancer patients' access to SM-88 through a compassionate use program under Institutional Review Board ("IRB") supervision (the "Compassionate Use Patients"). In early 2018, we performed a retrospective analysis on 53 Compassionate Use Patients who had available data and received at least six weeks of treatment. These patients had their scans reviewed by independent radiologists to determine response under RECIST, and 75% of these patients (40 of 53) were deemed to have experienced Clinical Benefit, consisting of 8 CRs, 16 PRs and 16 SD designations.

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

Phase II Prostate Trial

In 2019 we completed our Phase II clinical data for bio-marker recurrent prostate cancer and the final results were published in the peer-reviewed journal, *Investigational New Drugs*, on September 13, 2020.

The Phase II trial of SM-88 in patients with non-metastatic, biochemical-recurrent prostate cancer enrolled 23 patients with rising prostate-specific antigen levels, detectable circulating tumor cells ("CTCs") and no radiographically detectable metastases. The study duration was six months, per the study protocol, although some patients were granted a waiver to remain on treatment for longer periods. Seventy-four percent (74%) of patients (17/23) had previously received androgen deprivation therapy as treatment for prostate cancer. All enrolled patients were given daily oral SM-88 with MPS for the duration of treatment.

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

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

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

Discontinuing Programs

TYME-88-PANC (Part 2) (third-line Metastatic Pancreatic Cancer)

In fiscal year 2020, we launched our pivotal study for SM-88 in the third-line treatment of pancreatic cancer through an amendment to our ongoing TYME-88-Panc trial, with the first patient dosed in December 2019. As described above, the COVID-19 pandemic significantly impacted enrollment of this trial, such that it appears it is likely to complete enrollment in a similar timeline to the second-line Precision Promise pancreatic cancer trial. There has also been a higher than expected dropout of patients randomized to the chemotherapy control arm, which could potentially impact the interpretative and regulatory utility of the data.

Following a comprehensive strategic review, considering, in part, the timeline and regulatory utility for this trial compared to the parallel Precision Promise trial and concentration of investment in this specific cancer, management concluded that it would be best to focus on the second-line Precision Promise trial that offers treatment options to patients earlier in their disease. Furthermore, the trial includes tumor biopsy and biomarker analyses that aligns with the Company's overall strategic focus to identifying patients with the best chance of benefit from our therapies.

Therefore, the Company has decided to stop enrollment and begin the process of closing down the trial. Patients currently on therapy will be allowed to continue treatment until progression or unacceptable toxicity. The closing of this trial may require several months to complete.

SM-88 Mechanism of Action

SM-88 is an orally administered cancer metabolism-based therapy that is chemically altered to be non-functional for fundamental tumor cell processes, including protein synthesis. Scientific literature has highlighted that cancer cells can have a significantly higher consumption of certain amino acids compared to healthy cells, and these amino acids are required for cancer cell growth and function. We believe that SM-88, our proprietary modified dysfunctional tyrosine is selectively consumed by cancer cells, and interrupts various cell functions, including protein synthesis, autophagy, and other cellular defenses, that ultimately leads to an oxidative stress-related apoptosis or cell death. We also believe this selective cancer uptake of non-essential amino acids is supported by the current safety profile for SM-88, that has shown minimal observed drug-related SAEs.

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

As a result of our strategic review, the Company intends to significantly increase its investment on exploring SM-88's mechanism of action and the current dosing regimen. We have engaged with the global research and development firm, Evotec, to aid in the execution of these activities. The Company has also expanded its academic pre-clinical research collaborations, including with the Mayo Clinic, Georgetown University, and NYU School of Medicine. In addition, in our recently announced OASIS breast cancer trial, the investigators will be collecting cell-free DNA from patients throughout their treatment. Working with a leading diagnostics company, the Company aims to leverage these samples to better understand response dynamics for SM-88 and to begin to identify potential biomarkers for SM-88 response and sensitivity.

The overall goals of these efforts are to potentially identify patient subsets or disease biomarkers that could be applied to patient selection in future, clinical trials, as well as identify potential optimal combinations with other anti-cancer mechanisms that could aid future clinical development.

Development Strategy and Key Product Properties

Our goal is to develop the Company's clinical programs that may help patients live longer and better lives through novel medicines that are both better and safer treatments than current cancer treatment options. Key elements of our strategy to achieve this goal are:

- **Successfully advance the development of SM-88 across a broad range of cancers**.
- **Work towards identifying actionable biomarkers for patient selection or treatment response to SM-88.** We have begun research with several collaborators with an aim to identify potential biomarkers for patient selection for treatment with SM-88.
- **Continue to invest in our technology platform and expand the breadth and depth of our IP portfolio**. We plan to expand our research and development ("R&D") efforts to encompass multiple cancer indications in both solid tumors and hematologic cancers. We have undertaken early development programs for additional delivery systems of our lead oral candidate, SM-88, as well as new investigational pipeline candidates to treat cancer patients with high unmet medical needs.
- **Build a balanced portfolio of proprietary and partnered programs.** We plan to independently develop and commercialize multiple drug candidates for human indications within the oncology field. For targets outside our core areas of interest or where a partner can contribute specific expertise, we intend to evaluate potential collaborations with strategic partners and/or potential acquisitions of other companies and/or their assets that can augment our expertise and technology, as well as a means to acquire rights or ownership of additional intellectual property ("IP"). We also contemplate exploring global development partners and arrangements, where appropriate.

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

- **Broadly effective across different cancer types** – Because a vast majority of cancers use the same metabolic process, known as the Warburg Effect, we believe that they could likely also have the same susceptibilities to SM-88 treatment, regardless of physiologic origin;
- **Highly specific to cancer** – As supported by the current safety data reported for approximately 180 patients, together with recent advances in radiographic imaging that use tyrosine-based agents to selectively image cancer cells, cancer appears to have a high affinity for tyrosine uptake compared to normal cells;
- **Well-tolerated/ broad therapeutic margin** – Safety findings are available for approximately 180 patients, and only two patients (1%) have reported any drug-related serious adverse events;
- **Suitable for monotherapy or combination therapy** – Although most of TYME's clinical and compassionate use experience has been in monotherapy, SM-88's differentiated mechanism of action and safety profile may also allow it to be effective in combination with other cancer therapeutics; and
- **Potentially effective treatment for patients who have failed other therapeutic options** – Current cancer therapies are often intended to inhibit or change a particular aspect of cancer's cellular function, known as selective pressure. However, cancers typically develop resistance mechanisms that can make them less responsive to subsequent selective pressure treatments, while at the same time patients also accumulate treatment-related toxicities that can make them ineligible for subsequent therapies. SM-88 is designed to avoid selective pressure and this fundamental limitation of traditional therapies by utilizing cancer's innate metabolic weaknesses to compromise its defenses, leading to cell death through oxidative stress and exposure to the body's natural immune system. We believe this novel mechanism of action may allow SM-88 to be used in traditional treatment-resistant patients and also limit development of resistance.

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

- Members of our management team have extensive experience with scientific research and clinical development in novel cancer therapies.
- SM-88 has demonstrated meaningful clinical benefit and well tolerated safety profile, in metastatic cancer patients across 15 different types of solid tumors and hematologic cancers.
- To date, SM-88 has shown a favorable safety profile and we believe the unique mechanism of action increases prospects for evaluation of the potential of SM-88 as a viable therapy in combination with existing treatment modalities.
- We have a strong and growing patent estate in various countries broadly covering compositions, methods, manufacturing and use in connection with the treatment of cancers.
- We have a technology base and patent portfolio supporting SM-88 and have filed patent applications for additional drug candidates to provide a pipeline of oncology drug development programs based on our technology platform.

Intellectual Property

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

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

TYME maintains a broad intellectual property portfolio of 217 patent applications granted and/or pending worldwide. The patents encompass SM-88 as well as inventions that fight cancer and aid in the creation of novel mechanisms to further that effort. Our policy is to file patent applications to protect technology, inventions and improvements to inventions that are commercially important to the development of our business. We have and will continue to seek U.S. and international patent protection for a variety of technologies, including: pharmaceutical compositions, methods for treating diseases of interest, methods for manufacturing the pharmaceutical compositions and research tools and methods. We also intend to seek patent protection or rely upon trade secret rights to protect other technologies that may be used to discover and validate targets and that may be used to identify and develop novel products. We will also seek protection, in part, through confidentiality and proprietary information agreements.

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

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

Competition

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

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

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, development and regulatory plans in addition to proprietary scientific knowledge provide us with certain competitive advantages, we currently have limited financial resources and no revenue source and face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions, each of which has significantly greater financial resources than us. Any drugs that we successfully develop and commercialize will compete with existing therapies and new potential therapies that may become available in the future.

Our products, if approved for sale, would eventually be subject to competition from generic drug manufacturers. Manufacturers of generic biopharmaceuticals generally invest far less in R&D and marketing than R&D companies such as us. We anticipate that any manufacturer of a generic version of our drugs will invest far less than we have in the past and intend to do in the future. They therefore, have the advantage in that they can price their drugs much lower than the brand-name drugs for which we obtain approval. Additionally, in many countries outside the United States, IP protection is weak or nonexistent and we would be forced to compete with generic or counterfeit versions of our products in such countries whether or not we hold legal exclusivity.

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

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

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

FDA Approval Process

SM-88 is subject to regulation in the U.S. by the FDA as a drug product. The FDA subjects drug products to extensive pre- and post-market regulation. The Public Health Service Act (“PHSA”), the Federal Food, Drug and

Cosmetic Act and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and the import and export of drugs. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications ("NDAs"), withdrawal of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or fines or civil or criminal penalties.

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

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

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

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

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

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

conducted outside of the U.S. under similar, GCP-compliant conditions in accordance with local applicable laws may also be acceptable to the FDA in support of product licensing.

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

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

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that the NDA is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most applications for standard review drugs are reviewed within 10 months from the date the application is accepted for filing. Although the FDA often meets its user fee performance goals, it can extend these timelines if necessary and its review may not occur on a timely basis at all. The FDA usually refers applications for novel drugs, which present complex questions of safety or efficacy, to an advisory committee - typically a panel that includes clinicians and other experts - for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the drug product unless it verifies that compliance with current good manufacturing practice ("cGMP") standards is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication(s) being studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional nonclinical or clinical testing or supplemental information for the FDA to reconsider the application. If or when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two to six months depending on the type of information that was included. FDA approval is never guaranteed, and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. The approval for a drug may be significantly more limited than requested in the application, including limitations on the specific diseases and dosages or the indications for use, which could restrict the commercial value of the product. The FDA may also require that certain contraindications, warnings or precautions be included in the product labeling. In addition, as a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy ("REMS") to further ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS or use of a companion diagnostic with a drug can materially affect the potential market and profitability of the drug. Moreover, product approval may require, as a condition of approval, substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

As of March 31, 2021, we have two active INDs with the FDA, both of which are associated with SM-88. The two INDs are active with the relevant FDA departments that oversee our ongoing trials, the Department of Oncology Products 1 ("DOP1") and the Department of Oncology Products 2 ("DOP2"). In addition, clinical investigators

have previously and may in the future request their own INDs in order to use SM-88 or other products in Investigator Initiated Trials ("IITs"). For example, the HopES trial for sarcoma is an IIT where the IND for SM-88 use is held directly by the clinical trial site.

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

The FDA may grant an NDA a priority review designation based both upon the request of an applicant and the results of the Phase III clinical trial(s) submitted in the NDA. This designation sets the target date at six months for FDA action on the application. Priority review is granted where preliminary trial results indicate that a product, if approved, has the potential to provide a safe and effective therapy for a situation where no satisfactory alternative therapy exists or where the product is possibly a significant improvement over existing marketed products. If these criteria are not met for priority review, the NDA is subject to the standard FDA review period of ten months. However, priority review designation does not change the scientific/medical standard for regulatory approval or the quality of evidence necessary to support approval. There can be no assurance that we would be able to satisfy the eligibility criteria for priority review or to receive regulatory approval under either standard review.

Breakthrough Therapy Approvals

The Food and Drug Administration Safety and Innovation Act provides another designation for an expedited FDA review process called Breakthrough Therapy Designation. A breakthrough therapy is a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If an investigational drug is designated as a breakthrough therapy, the drug will be eligible for all fast track designation features, including expedited development and review of such drug for trial and market approval. Interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. All requests for Breakthrough Therapy Designation are to be reviewed within 60 days of receipt and FDA will either grant or deny the request.

Fast Track Program

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

The Hatch-Waxman Act

Under the Hatch-Waxman Act, newly approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active moiety. The Hatch-Waxman Act prohibits having an effective approval date for an Abbreviated New Drug Application ("ANDA") or a Section 505(b)(2) NDA for another version of such drug during the five-year exclusive period; however, submission of an ANDA or Section 505(b)(2) NDA containing a paragraph IV certification is permitted after four years, which may trigger a 30-month stay of approval of the ANDA or Section 505(b)(2) NDA. Protection under the Hatch-Waxman Act will not prevent the submission or approval of another "full" NDA; however, the applicant for the "full" NDA would be required to conduct its own preclinical studies and adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosages or strengths of a currently approved

drug, if new clinical investigations conducted or sponsored by the applicant are determined by the FDA to be essential to the approval of the new or supplemental NDA.

In addition to non-patent marketing exclusivity, the Hatch-Waxman Act amended the Food, Drug and Cosmetic Act to require each NDA sponsor to submit with its application information on any patent that claims the active pharmaceutical ingredient, drug product (formulation and composition) and method-of-use for which the applicant submitted the NDA and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug. Generic applicants that wish to rely on the approval of a drug listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) must certify to each listed patent. The Orange Book is a listing of all drug products that have been approved by the FDA and their generic equivalences. We intend to submit for Orange Book listing all relevant patents for SM-88 and to vigorously defend any Orange Book-listed patents for our approved products.

The Hatch-Waxman Act also permits a patent term extension of up to five years as compensation for the patent term lost during product development and the FDA regulatory review process. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years after the FDA approves a marketing application. The patent term extension period is generally equal to the sum of one-half the time between the effective date of an IND and the submission date of an NDA and all the time between the submission date of an NDA and the approval of that application, up to a total of five years. Only one patent applicable to a regulatory review period that represents the first commercial marketing of that drug is eligible for the extension and it must be applied for prior to expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for patent term extension. We will consider applying for a patent term extension for some of our patents, to add patent life beyond the expiration date, depending on our ability to meet certain legal requirements permitting such extension and the expected length of clinical trials and other factors involved in the submission of an NDA. There can be no assurance that such an extension, if applied for, will be granted.

Advertising and Promotion

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

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

AE Reporting and cGMP Compliance

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

removals if a company fails to comply with regulatory standards, if the product encounters problems following initial marketing or if previously unrecognized problems are subsequently discovered.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition; generally, a disease or condition that affects fewer than 200,000 individuals in the U.S. annually. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not necessarily convey any advantage in or shorten the duration of the regulatory review and approval process. The first NDA applicant to receive FDA approval for a product to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the U.S. for the product for treatment of the specified indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee. Orphan drug exclusivity may be lost in the United States if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

In July 2020, the Company received from the FDA orphan drug designation for SM-88, as a potential treatment for patients with pancreatic cancer.

Other Healthcare Laws and Compliance Requirements

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

International Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Manufacturing

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

We currently purchase all our drug substance and drug products from contract manufacturers and intend to continue to do so on an as-needed purchase order basis. We have entered into limited term supply arrangements for certain SM-88 components related to supply for our clinical activities in order to secure favorable pricing terms. We intend to identify and qualify any further necessary contract manufacturers to provide all active pharmaceutical ingredients (“API”) and finished drug product services during the IND stages and before submission of an NDA to the FDA.

We have started some focused precommercial technical development activities toward commercial manufacturing. These precommercial manufacturing activities are expected to be able to support ongoing clinical manufacturing activities as needed. Our current intention is that, during the ongoing development of SM-88, other than our limited and focused precommercial activities, we will transition the needed manufacturing, CMC and GMP programs towards commercial third-party manufacturing when appropriate. The overall manufacturing program includes, but is not limited to, the development of product and process specifications, producing and validating standards and the development of suitable analytical methods for test and release, as well as stability testing. Before and during the use of contract manufacturers, we (or qualified designee) will conduct audits to ensure compliance with the mutually agreed process descriptions and cGMP regulations. Our manufacturers themselves must comply with their in-house quality assurance programs and be available for inspections by regulatory agencies, including the FDA and European drug regulatory agencies. During the development of our drug candidates, we anticipate scaling the manufacturing process to a suitable size. Increasing scale involves several steps and may involve modification of the process, in which case modifications to our CMC sections will occur, with continuous submissions to the FDA and EU regulatory authorities.

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

SM-88 is currently administered with the conditioning agents methoxsalen, phenytoin, and sirolimus. Methoxsalen, phenytoin, and sirolimus each previously received regulatory approval in areas other than cancer treatment. SM-88 and the three agents within MPS are organic compounds of low molecular weight, generally called small molecules. They can be manufactured in reliable and reproducible synthetic processes from readily available starting materials. The chemistry is amenable to scale-up and we do not believe unusual equipment would be required in the manufacturing process.

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

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

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

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

TYME has started a development program focused on a new potential treatment of COVID-19, TYME-19. The Company is assessing manufacturing and clinical and service options for the TYME-19 development program.

Employees and Human Capital

As of March 31, 2021, we had a total of 17 employees, all full-time and all located in the United States. Of this total workforce, eight employees were engaged in or directly supported our research and development activities and nine perform general and administrative functions. The roles of certain employees, including our Chief Science Officer, Steve Hoffman, include both R&D activities and general administrative functions, and, as such, for purposes of the immediately preceding sentence they are categorized in more than one role based on time spent on each function. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We have not experienced any work stoppages, and we consider our relations with our employees to be good. In order to enable us to further develop and potentially commercialize SM-88 and other pipeline candidates we will need to maintain and continue to hire additional experienced personnel as well as to rely on third-party consultants for certain activities.
The success of our business is fundamentally connected to the well-being of our employees. We provide competitive compensation and benefits programs to help meet the needs of our employees. In addition to salaries, these programs include potential annual discretionary bonuses, equity awards, healthcare and insurance benefits, health savings and flexible spending accounts, paid time off, family leave, and flexible work schedules, among others. We have also historically offered our employees the ability to work remotely as well as in our office and expect to continue to do so in the future. These benefits provide our employees choices where possible so they can customize their benefits to meet their needs and the needs of their families, as well as access to tools and resources to help them improve or maintain their health status and encourage engagement in healthy behaviors to improve their physical and mental health.

In response to the COVID-19 pandemic and “shelter in place” and similar orders issued by state and local governments, we restricted access to our New Jersey office, as well as suspended any non-essential business travel. Since March 2020, our employees have conducted their work remotely, and they otherwise have had minimal presence in our office for essential activities. The safety, health and well-being of our employees is paramount. As such, we will consider ongoing government regulations and local health conditions before lifting any restrictions on travel or allowing any gatherings at our offices.
Consultants

Where necessary, we have entered into consulting contracts to provide us with subject matter expertise. We believe there is a sufficient number of available contractors with appropriate subject matter expertise for our current and near-term needs. We retain each consultant according to the terms of a consulting agreement. Under such agreements, we generally pay them a consulting fee and reimburse them for out-of-pocket expenses incurred in performing their services for us. In addition, we have in the past and may again in the future grant options to purchase our common stock to consultants, subject to the vesting requirements contained in their consulting agreements. Our consultants may be employed by other entities and therefore may have commitments to their employer, or may have other consulting or advisory agreements that may limit their availability to us.

Collaboration with Eagle Pharmaceuticals

On January 7, 2020, TYME and Eagle Pharmaceuticals, Inc. (“Eagle”) entered into a Securities Purchase Agreement (the “Eagle SPA”), pursuant to which the Company issued and sold to Eagle 10,000,000 shares of common stock, at a price of $2.00 per share. The Eagle SPA provides that Eagle will, subject to certain conditions, make an additional payment of $20 million upon the occurrence of a milestone event, which is defined as the earlier of (i) achievement of the primary endpoint of overall survival in the TYME-88-Panc pivotal trial; or (ii) achievement of the primary

endpoint of overall survival in the PanCAN Precision Promise SM-88 registration arm; or (iii) FDA approval of SM-88 in any cancer indication. This payment would be split into a $10 million milestone cash payment and a $10 million investment in TYME at a 15% premium to the then prevailing market price. Eagle's shares will be restricted from sale until the earlier of three months following the milestone event or the three-year anniversary of the agreement.

Also, on January 7, 2020, we entered into a Co-Promotion Agreement with Eagle (the "Co-Promote"), whereby Eagle agreed to provide sales representatives to cover 25% of the Company's sales force requirements and will receive 15% of the net sales of all SM-88 products in the U.S. during the term of the Co-Promote. TYME will also be responsible for clinical development, regulatory approval, commercial strategy, marketing, reimbursement and manufacturing of SM-88. TYME retains the remaining 85% of net U.S. revenues and reserves the right to repurchase Eagle's rights under the Co-Promote for $200 million.

Corporate Information

We were reincorporated on September 18, 2014 under the laws of the State of Delaware, after being incorporated in Florida as Global Group Enterprises Corp. on November 22, 2011, as discussed further below under Corporate History; Significant Organizational Events. Our principal executive office is located at One Pluckemin Way, Bedminster, NJ 07921. Our telephone number is 212-461-2315. Our website address is *www.tymeinc.com*.

Corporate History; Significant Organizational Events

We were originally incorporated in Florida as Global Group Enterprises Corp. on November 22, 2011. Effective as of September 18, 2014, we reincorporated in the State of Delaware and later engaged in a merger and certain other transactions. As a result of these events and related transactions, among other things, we (i) changed our jurisdiction of incorporation from Florida to Delaware; (ii) changed our name from Global Group Enterprises Corp. to Tyme Technologies, Inc., and (iii) acquired our current clinical-stage pharmaceutical business.

At-the-Market Sales of Common Stock

In November 2017, we entered into an equity distribution agreement with Canaccord Genuity Inc. ("Canaccord"), pursuant to which we were able to sell shares of our common stock, par value $0.0001 per share ("Common Stock") having an aggregate offering price of up to $30.0 million through Canaccord, as our sales agent, in an at-the-market offering (the "ATM"). In total, we sold 3,927,248 shares of our Common Stock under this equity distribution agreement for net proceeds of $11.5 million after commissions of $0.4 million and other transaction expenses.

In October 2019, TYME terminated the equity distribution agreement with Canaccord and entered into an Open Market Sale Agreement℠ (the "Sale Agreement") with Jefferies LLC ("Jefferies") as sales agent, pursuant to which the Company may, from time to time, sell shares of Common Stock through Jefferies having an aggregate offering price of up to $30.0 million (the "Jefferies ATM"). Since its initiation, we raised approximately $7.3 million in net proceeds after commissions and other transaction expenses and sold 5,815,254 shares of Common Stock.

Underwritten Securities Offerings

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

Registered Direct Offering

On February 8, 2021, the Company closed its registered direct offering of 40,000,000 shares of its Common Stock at a purchase price of $2.50 per share. The gross proceeds of the offering were $100 million, prior to deducting placement agent's fees and other offering expenses payable by TYME. The net proceeds to the Company, after deducting placement agent fees and other offering expenses payable by the Company, were approximately $93.8 million.

Exchange Agreements

On May 20, 2020, the Company entered into exchange agreements with holders (the "Holders") of the April 2019 Warrants. The April 2019 Warrants were offered and issued pursuant to the Company's previous shelf registration statement on Form S-3 (Registration No. 333-211489).

Pursuant to exchange agreements (the "Share Exchange Agreements") with Holders of April 2019 Warrants to purchase 5,833,333 shares of Common Stock in the aggregate, the Company issued an aggregate of 2,406,250 shares of Common stock (the "Exchange Shares") in exchange for such April 2019 Warrants. Concurrently therewith, each such Holder executed and delivered to the Company a leak-out agreement (a "Share Leak-Out Agreement") that contains trading restrictions with respect to the Exchange Shares, which (i) for the first 90 days, prohibit any sales of Exchange Shares, (ii) for the subsequent 90 days, limit sales of Exchange Shares on any day to 2.5% of that day's trading volume of Common Stock, and (iii) prohibit new short positions or short sales on Common Stock for the combined 180 day period.

The Company also entered into an exchange agreement (the "Warrant Exchange Agreement") with another Holder of April 2019 Warrants to purchase 2,166,667 shares of Common Stock in the aggregate. Pursuant to the Warrant Exchange Agreement, the Company issued such Holder a new warrant (the "May 2020 Warrant") to purchase the same number of shares of Common Stock. The May 2020 Warrant has the same expiration date, April 2, 2024, as the April 2019 Warrants, but has an exercise price of $1.80 and does not include the price protection, anti-dilution provisions or other restrictions on Company action from the April 2019 Warrants. Concurrently therewith, such Holder executed and delivered to the Company a leak-out agreement that contains trading restrictions on sales of Common Stock issued upon exercise of the May 2020 Warrant that are substantially similar to the restrictions on Exchange Shares in the Share Leak-Out Agreement, provided that the leak-out restrictions will only apply to the first 893,750 shares of Common Stock issued pursuant to the May 2020 Warrant.

Available Information

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

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

ITEM 1A. RISK FACTORS

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

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Risks Related to Owning Our Stock

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

Steve Hoffman, our Chief Science Officer and a director, owned approximately 14.2% of our outstanding common stock as of March 31, 2021. Additionally, Michael Demurjian, our former Chief Operating Officer, also owned approximately 14.4% of our outstanding common stock as of March 31, 2021. As such, Mr. Hoffman and Mr. Demurjian will each be positioned to exercise significant influence over our Company's affairs, including, but not limited to, electing members of our Board of directors and exercising influence and voting rights in connection with structural defenses and anti-takeover measures, and fundamental corporate transactions, and they may seek action that may not reflect the best interests of all of the stockholders of our Company.

Additionally, the Company has granted Mr. Hoffman perpetual, exclusive non-royalty bearing license rights with respect to certain patents and patent applications that the Company uses for SM-88 in all fields other than in connection with the treatment of cancer. Further, in his employment agreement, Mr. Hoffman has agreed that all intellectual property ("IP") he develops or has developed during his employment with us that relate to the Company's or any of its affiliates' businesses, research and development or existing products (or products under development) or services is the property of the Company, but only with respect to the treatment of cancer in humans and certain other indications. Likewise, Mr. Demurjian agreed that all IP he had developed during his employment with us is the property of the Company, but only with respect to the treatment of cancer in humans.

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

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

All readers of this report should consider an investment in our common stock as speculative, involving a high degree of risk, and invest in our common stock only if the purchaser can withstand a significant loss and wide fluctuations in the market value of an investment. Potential investors should be aware that the value of an investment in our Company may go down as well as up. In addition, there can be no certainty that the market value of an investment in our Company will fully reflect its underlying value.

Investors may be unable to sell their shares of our common stock at or above the price they paid for their shares due to fluctuations in the market price of our common stock arising from factors affecting our drug discovery and development objectives as well as changes in our operating performance or prospects. In addition, the stock market has recently experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks, as a result of, among other reasons, the ongoing COVID-19 pandemic and related government and economic reactions, which are further described in this section. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. Some of the factors that may cause the market price of our common stock to fluctuate include, but are not limited to:

- results and timing of our clinical trials and clinical trials of our competitors' products;
- the failure or discontinuation of any of our development programs;

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

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

Our common stock has historically been characterized by low and/or erratic trading volume, and the intraday per share price of our common stock has fluctuated from $0.85 to $4.99 between April 1, 2020 and March 31, 2021, the date of our last completed fiscal year.
As of July 31, 2017, our common stock became quoted on the Nasdaq Capital Market under the symbol "TYME." Historically, the public market for our common stock has been characterized by low and/or erratic trading volume, often resulting in price volatility. For the fiscal year ended March 31, 2021, the average daily trading volume for our common stock was approximately 3,322,287 shares. In addition, the price of our common stock has been volatile. Our common stock had a closing price of $1.02 on April 1, 2020, and ended fiscal year 2021 at a closing price of $1.78. During the fiscal year 2021, our common stock had a low closing price of $0.87, which occurred on October 30, 2020 and November 2, 2020, and had a high closing price of $3.53, which occurred on February 3, 2021.

The market price of our common stock is subject to wide fluctuations due to a number of factors, including the results of preclinical and clinical testing of our products under development, our strategic plans regarding product development, decisions by collaborators regarding product development, regulatory developments, market conditions in the pharmaceutical and biotechnology industries, announcements concerning our competitors, adverse developments concerning proprietary rights, public concern as to the safety or commercial value of any products, impacts of public health crises, including the ongoing COVID-19 pandemic, and general economic conditions, many of which we cannot control.

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

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish substantial rights.
Until such time, if ever, as we can generate substantial revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, grants and licensing and development agreements in connection with any collaborations. We do not have any committed external source of funds and no revenue source. To the extent that we raise additional capital through the sale of equity, equity-linked securities or convertible debt securities, as we expect we will, then outstanding stockholders' ownership interests in our Company will be diluted and the terms of these new securities may include liquidation or other preferences that adversely affect rights of holders of our common stock. For example, as further described above in Item 1 of this Annual Report on Form 10-K under the caption "Collaboration with Eagle," in January 2020, we entered into a securities purchase agreement with Eagle, pursuant to which Eagle would be required, upon the Company's achievement of certain milestone events, to purchase Series A Preferred Stock of the Company that is convertible into common stock, which, upon conversion, if any, would result in additional dilution. Debt financing, if available at all, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. We cannot give any assurance that we will be able to obtain additional funding if and when necessary or on satisfactory terms. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, scale back or eliminate one or more of our development programs or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

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

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

In the future, to raise needed financing, we are likely to issue our authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of our stockholders at the time of such issuances. We are authorized to issue an aggregate of 300,000,000 shares of common stock and 10,000,000 shares of "blank check" preferred stock. We also have an effective "shelf" registration statement on Form S-3 that allows us to issue securities in registered offerings as well as an available ATM financing facility that allows us to sell shares of our common stock through a placement agent at market prices. We may issue additional shares of our common stock or other securities that are convertible into or exercisable for our common stock in connection with hiring or retaining employees, future acquisitions, future sales of our securities for capital raising purposes or for other business purposes. The future issuance of any such additional shares of our common stock may create downward pressure on the trading price of our common stock. We will need to raise additional capital in the near future to meet our working capital needs, and we regularly evaluate our capital needs and available sources of financing. There can be no assurance that we will not be required to issue additional shares, warrants or other convertible securities in the future in conjunction with these capital raising efforts, including at a price (or exercise prices) below the price a stockholder at the time of such securities issuance paid for such stockholder's stock.

The ability of our Board to issue additional stock may prevent or make more difficult certain transactions, including a sale or merger of our Company. Our Board is authorized to issue up to 10,000,000 shares of preferred stock with powers, rights and preferences designated by it. On January 7, 2020, the Board designated and reserved 10,000 shares as Series A Preferred in connection with the Eagle SPA (as further described above in Item 1 of this Annual Report on Form 10-K under the caption "Collaboration with Eagle"). Shares of Series A Preferred or other voting or convertible preferred stock could be issued or rights to purchase such shares could be issued, to create voting impediments or to frustrate persons seeking to affect a takeover or otherwise gain control of our Company. The ability of our Board to issue such additional shares of preferred stock, with rights and preferences it deems advisable, could discourage an attempt by a party to acquire control of our Company by tender offer or other means. Such issuances could therefore deprive stockholders of benefits that could result from such an attempt, such as the realization of a premium over the market price for their shares in a tender offer or the temporary increase in market price that such an attempt could cause. Moreover, the issuance of such additional shares of preferred stock to persons friendly to our Board could make it more difficult to remove incumbent managers and directors from office even if such change were to be favorable to stockholders generally.

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

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

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

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board. Because our

board is responsible for appointing the members of our management team, these provisions could, in turn, affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions:

- establish a board of directors having three classes of directors with a three-year term of office that expires as to one class each year, commonly referred to as a "staggered board";
- limit the manner in which stockholders can remove directors from our Board;
- exclusively empower the Board to fill any and all vacancies on the Board;
- authorize the board of directors to exclusively have the power to change and set the size of the board of directors;
- limit who may call stockholder meetings;
- include advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and for nominations to our Board, which include, among other things, requirements for proposing stockholders to disclose information about derivative or short positions; and
- authorize our Board to issue, without stockholder approval, shares of preferred stock; such ability to issue previously undesignated preferred stock makes it possible for our Board to establish a "poison pill" and issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. However, in connection with entering into a securities purchase agreement between the Company and Eagle in January 2020, the Board agreed to waive the provisions of Section 203 to the extent it is or could become applicable to Eagle.

We do not anticipate paying dividends on our common stock.

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

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

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

During 2020, the outbreak of the novel coronavirus (COVID-19) evolved into a global pandemic, which remains ongoing. The pandemic, including the fear of exposure to and the actual effects of the illness, together with the measures implemented to reduce its spread, which include restrictions on travel and large gatherings and requirements to shelter-in-place, have significantly impacted the global economy. It has disrupted global supply chains, lowered equity market valuations, created significant volatility and disruption in financial markets, and increased unemployment levels. The pandemic has impacted the Company mainly through site closures, care restrictions, delays in enrollment and patient retention, but the extent to which COVID-19 impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the virus and the actions to contain it or treat its impact, among others.

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

- Our clinical trials will likely continue to be affected by the pandemic. Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis have been disrupted and may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. In general, the pandemic has made it very difficult to recruit subjects and patients and to conduct clinical trials. The FDA issued guidance to be implemented without the normal prior public comment period as the FDA had concluded that public participation would not be feasible or appropriate. Guidance is not legally enforceable, but the FDA recommends the following of its guidance and guidance is particularly instructive during public health emergencies as the most efficient way for FDA to communicate broadly. Challenges are expected to continue to arise from quarantines, site closures, travel limitations, interruptions to the supply chain for investigational products, or other considerations if site personnel or trial subjects become infected with or quarantined due to COVID-19. These challenges may lead to difficulties in meeting protocol requirements, including protocol-specified procedures. The FDA emphasized that safety of trial participants is critically important. Decisions to continue or discontinue individual patients or a trial are expected to be made by trial sponsors in consultation with clinical investigators and Institutional Review Boards. COVID-19 screening procedures were implemented, and are likely to continue. As challenging as the clinical trial process is during normal times, the risks, strategic and operational challenges and the costs of conducting such trials has increased substantially during the pandemic. The impact of COVID-19 on our clinical development and clinical trials has been moderate, and our clinical trials will likely continue to be affected by the pandemic.

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

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

- Shelter-in-place orders or other mandated local travel restrictions could result in our employees or other personnel conducting research and development or manufacturing activities for the Company having no or limited access their laboratories or other facilities. A greater number of these personnel working remotely may also expose us to greater risks related to cybersecurity and cyber-liability.

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

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

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

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

- It may adversely impact our ability to file on a routine and timely basis our periodic reports or other filings under federal securities or other laws and regulations.

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

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. The extent to which the coronavirus further impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the coronavirus, the widespread availability and adoption of safe and effective vaccines against COVID-19 and other actions to contain it or treat its impact, and how quickly and to what extent normal economic and operating conditions resume, among others. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole. However, the likelihood of material impact on the Company and its operations increases the longer the virus impacts activity levels in the United States and across the world. Management will continue to monitor the situation closely and implement business continuity and emergency response plans as needed.

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

The risk of failure for drugs in clinical development is high and it is impossible to predict when our lead drug candidate for the treatment of cancer, SM-88, will prove effective or safe in humans or will receive regulatory approval. The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA, the European Medicines Agency (the "EMA"), national competent authorities in Europe and other non-U.S. regulatory authorities, which establish regulations that differ from country to country. We are not permitted to market SM-88 and any other drug product we may develop in the United States or in other countries until we receive approval of an NDA from the FDA or marketing approval from applicable regulatory authorities outside the United States. Since SM-88 is in clinical development, it is subject to the risk of failure inherent in the drug development process. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA or EMA. Obtaining approval of an NDA or a Marketing Authorization Application ("MAA") can be a lengthy, expensive and uncertain process, and we may experience delays as an impact of COVID-19. In addition, failure to comply with the FDA, EMA and/or other non-U.S. regulatory requirements prior to or following regulatory approval, could subject our Company to administrative or judicially imposed sanctions, which include, but are not limited to:

- restrictions on our ability to conduct clinical trials, including issuing full or partial clinical holds or other regulatory objections to ongoing or planned trials;
- recalls;

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

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

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

Any delay in obtaining or failure to obtain, required approvals could materially adversely affect our ability to generate revenue from SM-88, which would likely result in significant harm to our financial position and adversely impact our share price. Furthermore, any regulatory approval to market SM-88 may be subject to limitations on the indicated uses for which we may market the drug or to restrictions or post-approval commitments that render SM-88 not commercially viable. These limitations may limit the size of the market for SM-88 and any other drug product we may develop.

We have limited experience with completing large-scale or pivotal Phase II or III clinical trials, obtaining FDA approvals or commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability or could result in delays or the failure to obtain required regulatory approval of our products.

Although some members of our management team have experience in creating, seeking approval and marketing various products, our operations to date have been limited to financing and staffing our Company, developing our technology platform, SM-88, TYME-19 and our other drug candidates, conducting our small-scale completed Phase

I or Phase II clinical trials for our drug candidates, and initiating or partnering to initiate pivotal trials for SM-88. We have initiated our commercialization strategy and marketing plan. Accordingly, as a company, we have not have experience completing a large-scale or pivotal clinical trial (whether Phase II, III, or otherwise), obtaining marketing approval, manufacturing product on a commercial scale or conducting sales and marketing activities. If a product candidate is approved, we will need to transition from a company with a research and development focus to a company capable of supporting successful commercial activities. We may not be successful in any step in such a transition. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

Moreover, this lack of experience could result in delays in obtaining necessary regulatory approvals, both in conducting clinical trials and final marketing approvals; additional costs; and the possibility that approvals will not be obtained due to the failure to comply with the regulatory approval process. Such delays, costs and/or failure would likely adversely affect our business, financial condition and results of operations and could possibly cause us to cease our operations in their entirety.

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

The timing and length of our clinical trials depends in part on the speed at which we can identify and recruit patients to participate in clinical trials of our product candidates. We currently have multiple clinical trials pending for SM-88 including our Phase II OASIS trial, with patient enrollment expected to begin in the third quarter of calendar year 2021. Difficulties with enrollment or finding eligible patients and retaining them may cause delays in current and future clinical trials. If patients are unwilling or unable to participate or remain in our clinical trials due to any negative publicity in the industry, interest in trials for other third-party product candidates, or for other reasons, including fears or restrictions related to the COVID-19 pandemic, our clinical trials could be delayed or terminated.

We or our clinical trial sites may not be able to identify, recruit, enroll and retain enough patients, or those with the required or desired characteristics in a clinical trial, to complete our clinical trials in a timely manner. Patient enrollment is affected by factors including the design of clinical trial protocols, size of patient populations, eligibility criteria, proximity and availability of clinical trial sites, perceived risks and benefits of the product candidate under study, and other factors. If we have difficulty enrolling and retaining enough patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which could have an adverse effect on our business. For example, due in part to the COVID-19 pandemic, we experienced slower-than-expected enrollment in our TYME-88-Panc trial, which we have since discontinued.

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

All our current drug candidates are in clinical development. We conducted several Phase I or Phase II trials for SM-88. We have also partnered with PanCAN to study SM-88 in an adaptive randomized Phase II/III trial with registration intent known as Precision Promise. In June 2021, we announced our Phase II OASIS trial research collaboration with a research investigator at Georgetown University, to examine the effects of SM-88 in breast cancer. The successful completion of these and future trials will be subject to numerous factors that can cause interruptions or delays, many of which may be beyond our control. Should we experience any interruption or delay, our plans and expected future revenue could be adversely affected and could result in our inability to continue our operations.

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

- slower than expected rate of subject recruitment and enrollment;
- slower than projected IRB or Independent Ethics Committee (“IEC”) review and approval;
- the Data Monitoring Committee (“DMC”) for a clinical trial requires the clinical trial be delayed or stopped or requests major or minor modifications to the clinical trial;

- failure of subjects to complete their full participation in clinical trial or return for post-treatment follow-up, which we have experienced in the TYME-88-Panc trial;
- unforeseen safety issues, including severe or unexpected drug-related adverse effects experienced by subjects, including the possibility of death;
- lack of drug candidate efficacy during the clinical trials;
- poor trial design for one or more of our clinical trials;
- withdrawal of participation by a Principal Investigator ("PI") in one or more of our clinical trials;
- withdrawal of participation by one of our Clinical Research Organizations ("CRO");
- inability or unwillingness of subjects or clinical investigators to comply with clinical trial procedures;
- resolution of data discrepancies;
- inadequate CRO management and/or monitoring in one or more of our clinical trials;
- the need to repeat, reconstruct or terminate a clinical trial due to inconclusive or negative results or unforeseen complications in testing; and
- a request by the FDA to suspend or terminate our current drug development programs.

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

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

Any failure or significant delay in clinical and regulatory development plans for current or future drug candidates would likely adversely affect our ability to obtain regulatory approval for the drug and would diminish our ability to generate revenue.

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

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

Clinical failure can occur at any stage of clinical development and the outcome of early clinical trials may not be predictive of the success of later clinical trials. Additionally, interim results of a clinical trial do not necessarily

predict final trial results. In addition, nonclinical and clinical data are often susceptible to varying interpretations and analyses. In this regard, many companies that have believed their drug performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products from regulatory organizations. Furthermore, changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application.

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

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

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

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

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

There is always the possibility that none of our drug candidates gain regulatory approval if they do not achieve their primary endpoints in its clinical trials, and other factors, such as product safety or nonclinical registration requirements, may prevent such drug candidates from gaining regulatory approval even if it achieves its primary endpoints. The FDA, the EMA or other global regulatory authorities may disagree with our trial design and/or our interpretation of data from nonclinical and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a drug even after reviewing and providing comments or advice on a protocol for a clinical trial. In addition, any of these regulatory authorities may also approve a drug for fewer or more limited

indications than requested or may grant approval that is contingent on the performance of costly post-marketing clinical trials. Further, the FDA, the EMA or other non-U.S. regulatory authorities may not accept the labeling claims that we believe would be necessary or desirable for the successful commercialization of our drug candidates.

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

We are conducting a range of preclinical experiments with external CROs and academic partners to more fully understand and illustrate the mechanism of action of SM-88 in oncology and we have recently determined to expand our activity in this area through a biomarker initiative. However it is unknown if the impact of SM-88 on processes studied in cultured cells or animal models would be replicated in humans or provide a clinical benefit. The FDA is interested in understanding the general biologic properties of SM-88, and there is a risk that the results produced by our planned preclinical activities might not satisfy their requirements to support a regulatory approval. Therefore, additional activity may be required to address the FDA's questions, or we might not be able to effectively address these questions.

In addition to SM-88, we are researching other drug platforms, such as TYME-18 and TYME-19. Before we can commence human clinical trials for a product candidate, we must complete extensive preclinical testing. Preclinical development is highly speculative and carries a high risk of failure. Preclinical studies and early-stage clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics, to understand the side effects of product candidates at various doses and schedules, and may not advance to later-stage clinical trials. Furthermore, the results of preclinical studies and early-stage clinical trials may not be predictive of the future results of later-stage, large scale efficacy clinical trials.

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

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

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

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

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

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

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

The FDA has broad discretion whether or not to grant fast track or breakthrough designation, which are further discussed under the captions "Fast Track Program" and "Breakthrough Therapy Approvals" in Item 1 of this Annual Report on Form 10-K. Accordingly, even if we believe SM-88 or any other drug candidate meets the criteria for fast track or breakthrough designation, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of fast track or breakthrough designation for a drug candidate may not result in a faster development process, review or approval compared to drug candidates considered for approval under conventional FDA procedures and, in any event, does not assure ultimate approval by the FDA. The FDA may even withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Further, in connection with fast track designation, we may be required to provide government regulators with additional manufacturing and production information, some of which we may not be able to provide in a timely manner and to the extent required by such regulators.

Although we have obtained orphan drug designation from the FDA for SM-88 as a potential treatment for patients with pancreatic cancer, we may be unable to obtain orphan drug designation for any other drug candidate we may develop. If our competitors instead can obtain orphan drug exclusivity for their products in the same indications of any other drug candidate we may develop, we may be at a competitive disadvantage and may not be able to have our products approved by the applicable regulatory authority for a significant period of time, if at all. In addition, we may not be able to fully benefit from the associated marketing exclusivity of SM-88's orphan drug designation or for any other drug we develop that is granted that designation.

As further described under the captions "Orphan Drug Designation" in Item 1 of this Annual Report on Form 10-K, regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. In July 2020, the Company received from the FDA orphan drug designation for SM-88 as a potential treatment for patients with pancreatic cancer. Nonetheless, SM-88, or any other drug candidate we may develop that receives orphan drug designation, may not have market exclusivity in particular markets. There is no assurance we will be able to receive orphan drug designation for any other drug candidate we are developing or may develop. Associated marketing exclusivity for SM-88 or another drug candidate for which we may receive orphan drug designation may not effectively protect it from competition because that exclusivity can be suspended under certain circumstances. Further, the granting of a request for orphan drug designation does not alter the standard regulatory requirements and process for obtaining marketing approval.

SM-88, TYME-18, TYME-19 or any other drug product we may develop may have serious adverse, undesirable or unacceptable side effects, which may delay or prevent marketing approval. If such side effects are identified during the development of a product candidate we may develop or following such candidate's approval, if any, we may need to abandon our development of such product candidate, the commercial profile of any approved label may be limited and/or we may be subject to other significant negative consequences following marketing approval, if any.

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

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

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

If SM-88 or our other product candidates receives marketing approval and it is later identified as undesirable or has unacceptable side effects, we are at risk for the following actions:

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

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

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval and commercialization of our product candidates and may affect the prices we obtain. Our successful commercialization will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement and pricing policies.

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

In the United States, there have been a number of proposals for increased federal and state government regulation of, or involvement in, the pricing and/or purchasing of drugs. For example, the Prescription Drug Price Relief Act, introduced in the Senate in January 2019, would require the HHS Secretary to assure that Americans do not pay more for prescription drugs than the median price of five countries (Canada, UK, France, Germany and Japan). There have also been state legislative efforts to address drug costs, which generally have focused on increasing transparency about drug costs and limiting drug prices. Some such legislation has been subject to legal challenges.

In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Medicare Modernization Act") established the Medicare Part D program and provided authority for limiting the number of drugs that will be covered in any therapeutic class thereunder. The Medicare Modernization Act, including its cost reduction initiatives, could limit the coverage and reimbursement rate that we receive for any of our approved products. Private payors may follow Medicare coverage policies and payment limitations in setting their own reimbursement rates resulting in similar limits in payments from private payors.

Further, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, adopted in March 2010 (together, the "Health Care Reform Law"), is a far-reaching law intended to broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The law has continued the downward pressure on the pricing of medical items and services, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs. Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the Health Care Reform Law, which are further described in this section, and we expect there will be additional challenges and amendments to the Health Care Reform Law in the future.

Other legislative changes have been proposed and adopted since the Health Care Reform Law was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2% per fiscal year through 2030 due to subsequent legislative amendments to the statute, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic, unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers (including hospitals and cancer treatment centers), and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, in response to the COVID-19 pandemic, the Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed into law in March 2020. The CARES Act is aimed at providing emergency assistance and health care for individuals, families and businesses affected by the COVID-19 pandemic and generally supporting the U.S. economy. The effects of the COVID-19 pandemic may introduce temporary or permanent healthcare reform measures, which could have negative financial implications on our business.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and

state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration. On November 20, 2020, the Centers for Medicare & Medicaid Services ("CMS") issued an interim final rule implementing the Trump administration's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the U.S. District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. In addition, there have been and continue to be similar initiatives at the state level to reduce drug costs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of SM-88 or our other existing or future product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

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

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

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

candidates, if approved. In markets outside of the United States and European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

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

We currently have very limited marketing, sales or distribution infrastructure. If we are unable to develop full sales, marketing and distribution capabilities on our own or through collaborations or if we fail to achieve adequate pricing and/or reimbursement, we will not be successful in commercializing our candidates.

We currently have very limited marketing, sales and distribution capabilities because our lead drug candidate, SM-88, is still in clinical development and initial trials and our other drug candidates are only in the initial stages of development. If any of our drug candidates is approved, we intend either to have established a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our drug or to have outsourced this function or portions, to one or more experienced third parties. Either of these options is expensive and time-consuming. Some of these costs may be incurred well in advance of any regulatory approvals for such drug candidate. In addition, we may not be able to hire a sales force that is sufficient in size or has adequate expertise in the medical markets that we intend to target. Any failure or delay in the development of our internal sales, marketing and distribution capabilities or to outsource these functions, in whole or part, would adversely affect the commercialization of our products.

To the extent that we enter into collaborative agreements for marketing, sales and/or distribution, our revenue may be lower than if we directly marketed and sold an approved drug product. For example, as further discussed in Item 1 of this Annual Report on Form 10-K, under the Co-Promote, Eagle will receive 15% of the net sales of all SM-88 products in the U.S. during the term of the agreement. In addition, any revenue we receive will depend in whole or in part upon the efforts and success of these third-party collaborators, which are likely not to be entirely within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize SM-88 or other drug candidates. If we are not successful in commercializing our drug candidates, either on our own or through collaborations with one or more third parties, our future revenues will suffer, we may incur significant and additional losses and we may be forced to curtail operations. These factors would have an adverse effect on our share price.

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

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

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

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

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

The commercial success of our drug candidates will depend upon its acceptance among physicians, patients and the overall medical community. The degree of market acceptance of the drug candidates we develop will depend on a number of factors, which include, but are not limited to:

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

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

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

As is likely to be common with any other product candidate we may develop, the process of manufacturing SM-88, TYME-18 and TYME-19 is complex, highly regulated and subject to several risks, which include, but are not limited to the following risks:

- We do not have experience in manufacturing our drug candidates in bulk quantity or at commercial scale. We plan to contract with external manufacturers to develop a larger scale process for manufacturing SM-88 in parallel with our involvement in Phase II/III trials of SM-88. We expect

to do the same for our other current drug candidates. We may not succeed in the scaling up of our process or we may need a larger manufacturing process for our drug candidates than what we have planned. Any changes to our manufacturing processes may result in the need to obtain additional regulatory approvals. Difficulties in achieving commercial-scale production or the need for additional regulatory approvals could delay the development and regulatory approval of our drug candidates and ultimately affect our success.

- The process of manufacturing drugs, such as SM-88, is extremely susceptible to loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in drug characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, drug defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our drug candidates or in the manufacturing facilities in which any of our drug candidates is made, such manufacturing facilities may need to be closed for an extended time to investigate and remedy the contamination.
- A shortage of drug product and/or the agents used with our drug candidates.
- The manufacturing facilities in which our drug candidates are made could have delays in manufacturing due to delays created by other sponsor company drug manufacturing runs, which could affect our manufacturing runs.
- An unforeseen increase in ingredients procurement or other manufacturing costs.
- An unforeseen production shortage resulting from any events, including interruptions to business operations and supply chain disruption as a result of widespread health crises, such as the COVID-19 pandemic, affecting raw material and or intermediate supply or manufacturing capabilities abroad and domestic.
- The manufacturing facilities in which our drug candidates are made could be adversely affected by equipment failures, labor shortages, labor strikes, natural disasters, widespread disease and other public health crises, including COVID-19, power failures, lack of phone or internet services, riots, crime, act of foreign enemies, war, nationalization, government sanction, blockage, embargo, any extraordinary event or circumstance beyond control and numerous other factors.
- We and our manufacturing partners must comply with applicable cGMP and local and state regulations and guidelines. Compliance with cGMP can be time consuming and expensive. Further, cGMP may not be flexible in situations where business pressures would normally call for immediate ingenuity. We or our manufacturing partners may encounter difficulties in achieving quality controls and quality assurance and may experience shortages in qualified personnel. We and our manufacturing partners will be subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm compliance with applicable regulatory requirements. Any failure to follow cGMPs or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging or storage of our drug candidates that result from a failure at the facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our drug candidates. This could lead to significant delays in the availability of our drug for clinical trials or the termination or clinical hold on a trial or the delay or prevention of a filing or approval of marketing applications for our drug candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our drug candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we and/or our manufacturing partners are not able to maintain regulatory compliance, we may not be permitted to market our drug candidates and/or may be subject to drug recalls, seizures, injunctions or criminal prosecution.

- Any adverse developments affecting manufacturing operations for our drug candidates, if approved for marketing by the FDA, may result in shipment delays, inventory shortages, lot inspection failures, drug withdrawals or recalls or other interruptions in the supply of our drug candidates. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet regulator-approved manufacturing specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.
- Drug products that have been produced and stored for later use may degrade, become contaminated or suffer other quality defects, which could cause the affected products to no longer be suitable for its intended use in clinical trials or other development activities. If the defective drug cannot be replaced in a timely fashion, we may incur significant delays in our development programs that could adversely affect the value of our drug candidates.
- As further described under the caption "Manufacturing" in Item 1 of this Annual Report on Form 10-K, SM-88 drug substance is being manufactured by a FDA-approved third party and to date that manufacturer is our sole supplier of this drug substance. We believe that replacement for this supplier, in the event it becomes necessary, is not impossible, but would cause us to lose time that could otherwise be devoted to development. Currently, we do not have an arrangement in place for a secondary supplier for this drug substance.
- Third parties may hold IP rights that impact, restrict or inhibit manufacturing or sale of a commercial version of any of our drug candidates.

The drug candidates that we may develop will face significant competition and, if competitors develop and market products that are more effective, safer or less expensive than our drug, our commercial opportunity will be negatively impacted.

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

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

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient or are less expensive than our drug candidates. Our competitors also may obtain FDA, EU or other non-U.S. regulatory approval for their products more rapidly than we may, which could result in our competitors establishing a strong market position before we are able to enter the market. If third parties obtain regulatory approval for their products before we do, such products may change the treatment landscape for our product candidates and affect our ability to successfully launch and commercialize any products for which we receive regulatory approval. Even if our drug candidates achieve

marketing approval, they may be priced at a significant premium over competitive products, if any have been approved by then, resulting in our product's reduced competitiveness. In addition, the costs and restrictions effected by the Health Care Reform Law may impact our competitiveness or availability opportunity.

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

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

In addition, generic therapies, as further discussed under the caption "Competition" in Item 1 of this Report, are typically sold at lower prices than branded therapies and are generally preferred by hospital formularies and managed care providers of health services. We anticipate that, if approved, our product candidates will face increasing competition in the form of generic versions of branded products of competitors, including those that have lost or will lose their patent exclusivity. In the future, we may face additional competition from a generic form of our own candidates when the patents covering them begin to expire, or earlier if the patents are successfully challenged. If we are unable to demonstrate to physicians and payers that the key differentiating features of our product candidates translate to overall clinical benefit or lower cost of care, we may not be able to compete with generic alternatives.

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

We face an inherent risk of drug liability lawsuits related to the testing of SM-88, TYME-18, TYME-19 and any other product candidate we may develop that is intended to treat seriously ill patients. In addition, we face risk of liability lawsuits if our drug candidates is approved by regulatory authorities and introduced commercially. Drug liability claims may be brought against us or our collaborators, if any, by subjects enrolled in our clinical trials, patients, health care providers or others using, administering or selling drug products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities. Regardless of their merit or eventual outcome, liability claims may result in, but are not limited to:

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

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

We hold clinical trial insurance for our ongoing clinical trials. We also intend to obtain drug liability insurance coverage at appropriate levels for our operations, which will vary as the level of our operations vary during our growth from a R&D company to a company manufacturing and/or marketing drugs to the public. Our current and planned insurance coverage may not be adequate to cover all liabilities that we may incur. We also may need to increase our insurance coverage when we begin the commercialization of SM-88, TYME-18 or TYME-19. Insurance coverage can be expensive for pharmaceutical products and candidates. As a result, we may be unable to obtain or maintain sufficient liability insurance at a reasonable cost to protect us against losses, which could have a material adverse effect on our business. A successful drug liability claim or series of claims brought against us, particularly if judgments exceed any insurance coverage we may have, could decrease our cash resources and adversely affect our business, financial condition and results of operations and could possibly cause us to cease our operations in their entirety.

Risks Related to our Financial Condition and Need for Additional Capital

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

We are a clinical-stage pharmaceutical company with a limited operating history. We have incurred significant losses since our inception. As of March 31, 2021, our accumulated deficit was $136,794,015. Our losses have resulted principally from expenses incurred in the discovery and development of SM-88 and from general and administrative expenses incurred while building our business infrastructure. We expect to continue to incur losses for the near future. Furthermore, we expect these losses to increase as we continue our research and development of and seek regulatory approval for our drug candidates and any other product candidates we may develop, prepare for and begin to commercialize our drug candidates or any other regulatory-approved products and add infrastructure and personnel to support our drug development efforts and operations as a public company. The net losses and negative cash flows from operations incurred to date, together with expected future losses, have had and likely will continue to have, an adverse effect on our stockholders' equity and working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

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

- completing research and clinical development of our drug candidates, including successful completion of required clinical trials;
- obtaining marketing approval for our drug candidates;
- developing a sustainable and scalable manufacturing process for our drug candidates and maintaining supply and manufacturing relationships with third parties that can conduct the process and provide adequate (in amount and quality) drugs to support clinical development and the market demand for our drug candidates, if approved;
- launching and commercializing our drug candidates, either directly or with a collaborator or distributor;

- establishing sales, marketing and distribution capabilities in the United States and in other markets, such as the EU;
- obtaining market acceptance of our drug candidates as a viable treatment option;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

These factors would likely be applicable to any other product candidate we may develop. Even if a product candidate that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercialization. Because of the numerous risks and uncertainties with drug development, we are unable to accurately predict the timing or amount of increased expenses and when or if we will be able to achieve profitability. For example, our expenses could increase if the FDA or EMA require us to conduct supplemental clinical trials not included in our current development plan or if there are any delays in completing our planned clinical trials or in the development of our drug candidates or any other drug product we may pursue. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to realize revenue or become or remain profitable could depress our market value and could impair our ability to raise capital, expand our business, develop other product candidates or continue our operations. A decline in the value of our shares could also cause investors in our common stock (or other securities we may issue in the future) to lose all or part of their investment.

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

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

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

- the effect of competing products that may limit market penetration of our drug candidates;
- the amount and timing of revenues, if any, we receive from commercial sales of our 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 product candidates, technologies, future revenue streams or research programs and/or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, as we expect to do, the ownership interests of our then existing stockholders could be diluted and the terms of these securities may include liquidation or other preferences that adversely affect stockholders' rights.

While we regularly consider options and opportunities to raise additional capital and obtain financing and will continue to seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all, and our negotiating position in capital generating efforts may worsen as existing resources are used. Additionally, if we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences, which are not favorable to us or our stockholders. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates or future revenue streams or have to grant licenses on terms that are not favorable to us. For example, as described under the heading "Collaboration with Eagle" in Item 1 of this Annual Report on Form 10-K, under the Co-Promote, Eagle will receive 15% of the net sales of all SM-88 products in the U.S. during the term of the agreement. The transactions with Eagle are further discussed under the heading "Collaboration with Eagle" in Item 1 of this Annual Report on Form 10-K. In addition, general market conditions, as well as market conditions for companies in our financial and business position, as well as the ongoing issues arising from the COVID-19 pandemic, may make it difficult for us to seek financing from the capital markets, and the terms of any financing may adversely affect the holdings or the rights of our stockholders. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, our business, operating results, financial condition and prospects could be materially and adversely affected, and we may be unable to continue our operations.

We may expend our limited resources to pursue approval of our drug candidates to treat certain indications that may not be the most profitable or do not have the greatest likelihood of success.

Because we have limited financial and managerial resources, we currently are focusing our research programs on SM-88 for the treatment of specified cancer therapies and on the pre-clinical development of TYME-19. We have also recently implemented a biomarker initiative in an effort to better inform our development activities and areas of focus. As a result of our limited returns, we may forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential. Our resource allocation

decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. For example, in June 2021, we announced the discontinuation of our TYME-88-Panc trial. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products.

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

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

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

Risks Related to our Reliance on Third Parties

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

We currently rely on, and will likely continue to rely on, third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators to study our product candidates in clinical trials. We may independently conduct future clinical trials for any drug product we may develop, including SM-88, but will continue to collaborate with such parties to study SM-88 in their clinical trials of SM-88 or other drug candidates. This strategy necessarily relies upon clinical data and other results obtained by third parties that may ultimately prove to be inaccurate or unreliable. For example, we partnered with PanCAN to study SM-88 in its adaptive randomized Phase II/III trial with registration intent known as Precision Promise. Also, HopES is a Phase II investigator-initiated trial evaluating SM-88 monotherapy in late-stage sarcomas, under the direction of principal investigator Dr. Sant Chawla and in collaboration with The Joseph Ahmed Foundation. We recently announced partnership with Georgetown University for our clinical trial evaluating SM-88 in breast cancer. Our reliance on these third parties for clinical development activities reduces our control over these activities, relieves us of certain rights we otherwise would have and puts us at risk for the acts or omissions of these third parties, but it does not relieve us of our responsibilities. For example, the FDA requires us to comply with standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of subjects in clinical trials are protected even though we are not in control of these processes. If the third-party data and results we rely upon prove to be inaccurate, unreliable or not applicable to our product candidates or future product candidate, we could make inaccurate assumptions and conclusions about our product candidates and our research and development efforts could be compromised. These third parties also may have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our drug candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our drug candidates.

In addition, if any of our relationships with third-party CROs or site management organizations terminate, we may not be able to enter into arrangements with alternative CROs or site management organizations or to do so on commercially reasonable terms. Switching or adding additional CROs or site management organizations involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO or site management organization commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we carefully manage our relationships with our

CROs or site management organizations, there can be no assurance that we will not encounter similar challenges or delays in the future. Forces beyond our control, including the impacts of COVID-19, could disrupt the ability of our third-party CROs, site management organizations, clinical data management organizations, medical institutions and clinical investigators to conduct our preclinical studies and our clinical trials for our product candidates and for any future product candidate.

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

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

We currently have limited experience in and we do not own facilities for, clinical-scale manufacturing of SM-88, TYME-18 and TYME-19, and we expect to rely upon third-party contract manufacturing organizations to manufacture and supply drug for our clinical trials. However, we may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including the possible breach of the manufacturing agreement by the third party or the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. In addition, the manufacture of pharmaceutical products in compliance with the FDA's cGMP requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, quality control, including drug stability, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced cGMP requirements and other federal and state regulatory requirements and foreign regulations. If our manufacturers were to encounter any of these difficulties or otherwise fail to comply with their obligations to us or under applicable regulations, it would jeopardize our ability to supply investigational drug for our clinical trials. Any delay or interruption in the supply of clinical trial materials, including as a result of restrictions put in place because of the COVID-19 pandemic, could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical development programs and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the ongoing trials.

All manufacturers used to formulate the components of our drug candidates must comply with cGMP requirements, which are enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance and the documentation and maintenance of records. Manufacturers of our product candidates may be unable to comply with cGMP requirements and/or with other FDA, state and foreign regulatory requirements. The FDA or similar foreign regulatory agencies may also implement new standards at any time or change their interpretation and enforcement of existing standards for the manufacture, packaging or testing of drug products. We have little control over our manufacturers' compliance with these regulations and standards and a failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in drug approval, drug seizure or recall or withdrawal of a drug approval. If the safety of any drug supplied is compromised due to a manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize SM-88 and as a result, may be held liable for any injuries sustained. Any of these factors could cause a delay of clinical trial completion, regulatory submission, approval or commercialization of our drug candidates, increase our costs or impair our reputation.

We currently rely on third party suppliers for our drug candidates, including for the components of MPS used with SM-88. Supplies are obtained through limited term supply agreements under individual purchase orders. At this time, no supply agreements in place exceed 18 months. Although we believe alternative sources of supplies exist, the number of third-party suppliers with the necessary manufacturing and regulatory expertise and facilities is limited, could be more expensive and it could take a significant amount of time to source, any of which would adversely affect our business. New suppliers would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable IP laws to the method of manufacturing the drug

candidate. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party IP rights could result in a significant interruption of supplies and could require the new manufacturer(s) to bear significant additional costs which may be passed on to us.

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

Because we rely on third parties to assist in the research, development and manufacture of SM-88, TYME-18 and TYME-19, and may do so with any other product candidate we may develop, we must, at times, share trade secrets with such third parties. We will seek to protect our proprietary technology in part by initially entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees and third-party contractors prior to disclosing any proprietary information. These agreements typically limit the rights of third parties to use or disclose our confidential information, which include our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets could become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's independent discovery of our trade secrets or other unauthorized use or disclosure could impair our competitive position and could have a material adverse effect on our business.

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

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

As described under the heading "Collaboration with Eagle" in Item 1 of this Annual Report on Form 10-K, we entered into a co-promotion agreement with Eagle Pharmaceuticals, whereby Eagle agreed to provide sales representatives to cover 25% of the Company's sales force requirements and will receive 15% of the net sales of all SM-88 products in the U.S. during the term of the agreement. TYME remains responsible for the remaining promotional effort. The co-promotion of SM-88 in the United States will be supervised by a joint sales operations committee composed of representatives from the Company and Eagle. Under the agreement, the Company will remain responsible for clinical development and commercial strategy and for the costs of seeking regulatory approval, manufacturing and distribution of SM-88. TYME has the ability to purchase back the Eagle 15% share of the net U.S. sales for $200 million.

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

proceedings we may have with Eagle in the future could delay development programs, distract management from other business activities and generate substantial expense.

We may in the future enter into additional license or collaboration arrangements with other third parties with respect to our drug candidates that may place the development or promotion of our product candidates partially or entirely outside of our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us, and could be subject to similar types of risks as described above. In particular, we expect to seek partners for activities related to our TYME-18 and TYME-19 product candidates. 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 our drug candidates 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 our drug candidates, repeat or conduct new clinical trials or require a new formulation of our drug candidates;
- 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 our drug candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our IP rights or may use our IP or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our IP or proprietary information or expose us to potential liability;
- collaborators may not aggressively or adequately pursue litigation against Abbreviated New Drug Application (“ANDA”) filers or may settle such litigation on unfavorable terms;
- collaborations may be terminated, sometimes at-will, without penalty;
- collaborators may own or co-own IP covering our products that results from our collaborating with them and, in such cases, we would not have the exclusive right to commercialize such IP;

- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws and could result in civil or criminal proceedings; and

- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our drug candidates or any other product candidate we may

develop or results in costly litigation or arbitration that diverts management attention and resources.

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

Risks Related to the Operation of our Company

We recently completed a comprehensive review of our development strategy and product candidate portfolio, which may result in additional changes to certain development programs, may not achieve its intended benefits and could have a material impact on our business, results of operations and financial condition.

In connection with our new CEO recently joining the Company, we undertook a strategic review of our development strategy and product candidate portfolio. As described under the heading "Strategic Review" in Part I. Item 1 of this Annual Report on Form 10-K, we are in the process of implementing several initiatives as a result of this review, which relate to our clinical trials, resource allocations and development strategy. Moreover, additional changes to certain development programs may be required as we continue to implement these development strategies. We believe the resulting changes will be beneficial to us and our stockholders in the long-term; however, there can be no assurance that these initiatives will produce their anticipated benefits or any benefits at all. If we do not successfully implement this development strategy, or our development strategy is ultimately unsuccessful, our business, financial condition, results of operations and prospects could be adversely affected.

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

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

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

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

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

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

As of March 31, 2021, we had 17 full-time employees. Over the next several years, we expect to experience significant growth in the number of our employees and the scope of our operations. To manage our anticipated future growth, including the potential development of new products, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and recruit and train additional qualified personnel. Future growth would impose significant added responsibilities on management. Due to our limited financial resources and the limited experience of our management team in managing a life sciences company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Some members of our current management have limited experience in managing a company that had the life sciences research and development and operational growth we anticipate for our Company. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

Our operations could be subject to equipment failures, labor shortages, labor strikes, earthquakes, power shortages, telecommunications failures, floods, hurricanes, typhoons, fires, extreme weather conditions, terrorist activities, medical epidemics, riots, crime, acts of foreign enemies, war, nationalization, government sanction, blockage, embargo, widespread public health crises, and other natural or manmade disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and could increase our costs and expenses.

Our current and future, third-party collaborators, future partners, supplies, CROs and investigational sites are or will be, located throughout the United States or internationally and may be located near major high-risk terrorist targets, earthquake faults, flood and fire zones. The ultimate impact on us, our significant partners and suppliers as well as our and their general infrastructures being located near major high-risk terrorist targets, earthquake faults, flood and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major terrorist attack, earthquake, fire, flood or other natural or manmade disaster.

Our business is also subject to risks associated with conducting international business. If we conduct clinical trials outside of the United States, or pursue and/or obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business. Some of our third-party collaborators, future partners, suppliers, CROs and investigational sites could be located outside the United States. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. We may not obtain foreign regulatory approvals for our product candidates on a timely basis, if at all. Accordingly, our future success could be harmed by a variety of factors, which include, but are not limited to:

- economic weakness, including inflation or political instability in particular non-U.S. economies and markets;
- differing regulatory requirements for drug approvals in non-U.S. countries;
- differing, and in some cases, more stringent data protection requirements in non-U.S. countries, such as the EU General Data Protection Regulation;
- potentially reduced protection for IP rights;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates and currency controls;

- changes in a specific country's or region's political or economic environment;
- trade protection measures, import/export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, widespread public health crises or pandemics, such as COVID-19, and related government responses, or natural disasters including earthquakes, typhoons, floods and fires.

We may seek approvals of our product candidates in the EU and United Kingdom. On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the EU, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the EU, the United Kingdom was subject to a transition period until December 31, 2020 (the "Transition Period") during which EU rules continued to apply. A trade and cooperation agreement (the "Trade and Cooperation Agreement"), which outlines the future trading relationship between the United Kingdom and the EU, was agreed upon in December 2020.

The Trade and Cooperation Agreement provides details on how some aspects of the United Kingdom's and EU's relationship will operate going forwards, however, there are still many uncertainties. Brexit has already and may continue to adversely affect European and/or worldwide regulatory conditions and increase regulatory complexities. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations in Europe, including those related to the pricing of prescription pharmaceuticals, as the United Kingdom determines which EU laws to replicate or replace, which could impair our ability to transact business in the EU and the United Kingdom in the future, if we elect to seek regulatory approval and commercialize any of our products there, if approved. The impact of Brexit on the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the EU is uncertain, and could prevent or delay us from commercializing our product candidates in the United Kingdom or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or EU for our product candidates.

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

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

In addition, in the past, including as recently as 2020 as result of the COVID-19 pandemic, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. Any lawsuit brought against us by one or more of our stockholders, could result in substantial

costs to defend the lawsuit, divert the time and attention of our management, result in substantial monetary judgments or settlement costs and harm our reputation, any of which could seriously harm our business.

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

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

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

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

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

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

Risks Related to Intellectual Property

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

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

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

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

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

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or drugs in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the patent claims of our owned or licensed patents being narrowed, invalidated or held unenforceable and may cost significant time and resources to defend. This could limit our ability to stop or prevent us from stopping others from using or commercializing similar or

identical technology and drugs or limit the duration of the patent protection of our technology and drugs. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting use of our drug might expire before or shortly after any drug candidate is commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to our drug products or otherwise provide us with a competitive advantage. Furthermore, changes to patent laws could diminish the value of patents in general, thereby impairing our ability to protect our rights in our product candidates.

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

Filing, prosecuting and defending patents for our drug candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in countries where we have not obtained patent protection to develop their own drugs and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as in the United States. These products may compete with our drug products in countries where we do not have any issued patents and our patent claims or other IP rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending IP rights in foreign countries. The legal systems of a number of countries, particularly a number of developing countries, do not favor the enforcement of patents and other IP protection, including those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights. Even if we do secure patents in foreign jurisdictions, the legal systems in certain of those countries might require us, as examples, to do business through an entity that is partially owned by a local investor, or to grant license rights to local partners in a manner not required by the jurisdictions in which we currently operate. Additionally, governmental actions, such as the potential waiver of intellectual property protection or imposition of compulsory licenses related to COVID-19 vaccines, or other potential waivers of intellectual property during emergencies, if applicable to any of our product candidates could harm our ability to successfully and profitably commercialize our product candidates. Requirements such as the foregoing could limit our ability to fully exploit and in the future monetize our product candidates and patents, as well as placing potential additional difficulties on our enforcement efforts in those jurisdictions. Further, the initiation of proceedings to enforce or protect our patent rights in foreign countries could result in substantial cost and divert our efforts and attention from other aspects of our business.

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

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

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

Competitors or other third parties may infringe or otherwise violate our patents, trademarks, copyrights or other IP. To counter infringement or unauthorized use, we or our licensees may be required to file infringement claims, which can be expensive and time-consuming. For example, if we need to file patent infringement lawsuits in the future against manufacturers of generic pharmaceuticals that have filed ANDAs with the FDA seeking approval to manufacture and sell generic versions of our drug candidates, we anticipate that the prosecution of such lawsuits will require a significant amount of time and attention from our chief executive officer, chief science officer and other senior executives. In addition, in a patent infringement proceeding, a court may decide that our patent is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in the litigation or proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Such a result could limit our ability to prevent others from using or commercializing similar or identical technology and drugs, limit our ability to prevent others from launching generic versions of our drug products and could limit the duration of patent protection for our

products, all of which could have a material adverse effect on our business. A successful challenge to our patents could reduce or eliminate our right to receive royalties. Furthermore, because of the substantial amount of discovery required in connection with IP litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation.

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

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

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

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

- we or our collaborators may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our drugs or processes do not infringe those third parties' patents;
- if our competitors file patent applications that claim technology also claimed by us or our licensors or collaborators, we or our licensors or collaborators may be required to participate in interference or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third-party with a dominant patent position;
- if third parties initiate litigation claiming that our processes or products infringe their patent or other IP rights, we and our licensors or collaborators will need to defend against such proceedings; and
- if a license to necessary drug technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other IP rights and/or that we breached our obligations under the license agreement and we and our collaborators would need to defend against such proceedings.

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

The pharmaceutical and biotechnology industries have produced a significant number of patents and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts and the interpretation is not always uniform or predictable. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent or that the patent claims are invalid. We may not be able to do this because proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing

of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our drug candidates to market and be precluded from manufacturing or selling one or more of our drug products.

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

- patent litigation and other proceedings initiated by or against us may also absorb significant management time;
- if proceedings are initiated by or against the Company to determine the priority of invention, they could jeopardize our patent rights and potentially provide a third-party with a dominant patent position;
- if third parties initiate litigation claiming that our processes or products infringe their patent or other IP rights, we and our licensors or collaborators will need to defend against such proceedings; and
- if a license to necessary drug technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other IP rights and/or that we breached our obligations under the license agreement and we and our collaborators would need to defend against such proceedings.

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

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

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

In addition to our patented technology, we rely upon trade secrets, including unpatented know-how, technology and other proprietary information to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our current and future employees, as well as our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. However, while it is our policy to require our employees and contractors who may be involved in the conception or development of IP to execute such agreements, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops IP that we regard as our own. In addition, it is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. While to our knowledge the confidentiality of our trade secrets has not been compromised, if the employees, consultants or collaborators that are parties to these agreements breach or violate the terms of these agreements, we may not have

adequate remedies for any such breach or violation and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could be disclosed, misappropriated or otherwise become known or be independently discovered by our competitors. In addition, IP laws in foreign countries may not protect our IP to the same extent as the laws of the United States. If our trade secrets are disclosed or misappropriated, it would harm our ability to protect our rights and adversely affect our business.

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

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

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

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

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

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

copyrights or other IP may be ineffective and could result in substantial costs and a diversion of resources and could adversely affect our financial condition or results of operations.

Risks Related to Government Regulations and Agencies

Health care reform measures could hinder or prevent the commercial success of our drug candidates.

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

- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, which include, among other things, new government investigative powers and enhanced penalties for non-compliance;
- expansion of eligibility criteria for Medicaid programs in certain states;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- an independent payment advisory board that will submit recommendations to Congress to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

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

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare, including initiatives designed to control or influence product pricing. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may, among other things, adversely affect:

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

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

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

Although Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the Health Care Reform Law have been signed into law. The federal Tax Cuts and Jobs Act of 2017, or the Tax Act, includes a provision that became effective on January 1, 2019 and repealed the tax-based shared responsibility payment imposed by the Health Care Reform Law on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which payment is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Health Care Reform Law-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the Health Care Reform Law, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On December 14, 2018, a Texas U.S. District Court judge ruled that the Health Care Reform Law is unconstitutional in its entirety because the individual mandate was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Health Care Reform Law are also invalid. The U.S. Supreme Court is currently reviewing the case, although it is unknown when a decision will be made. Further, although the U.S. Supreme Court has not yet ruled on the constitutionality of the Health Care Reform Law, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the Health Care Reform Law marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Health Care Reform Law. It is unclear how the Supreme Court ruling, other such litigation and the healthcare reform measures of the Biden administration will impact the Health Care Reform Law and our business.

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

If we fail to comply with healthcare and privacy laws and regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse patients' rights are, and other healthcare issues and will be, applicable to our business. We could be subject to healthcare fraud and abuse, privacy and security, and transparency regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include, but are not limited to:

- the federal healthcare program Anti-Kickback Statute, which prohibits knowingly and willfully offering, soliciting, receiving or providing any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce either the referral of an individual for or the purchase order, lease or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs, such as the Medicare and Medicaid programs;
- the federal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented, false or fraudulent claims for payment or approval or knowingly using false statements, to obtain payment from the federal government and which may apply to entities like us which provide coding and billing advice to customers;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") which created new federal criminal statutes that prohibit knowingly and willfully executing or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of or payment for, healthcare benefits, items or services relating to healthcare matters;
- the federal physician self-referral law, commonly known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services reimbursed by Medicare or Medicaid if the physician or a member of the physician's family has a financial relationship with the entity and which also prohibits the submission of any claims for reimbursement for designated health services furnished pursuant to a prohibited referral;
- the federal transparency requirements under the Health Care Reform Law, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the HHS information related to physician payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family members;
- HIPAA, the Health Information Technology for Economic and Clinical Health Act ("HITECH") and their respective implementing regulations, which govern the conduct of certain electronic healthcare transactions and are designed to protect the security and privacy of individual identifiable health information; and
- state, local and foreign law equivalents of each of the above federal laws, such as anti-kickback, false claims and transparency laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers; for example, California has recently passed the California Consumer Privacy Act (the "CCPA"), which we may become subject to in the future. The CCPA introduces strict compliance regulations on organizations doing business in California that collect personal information about California residents. The CCPA defines personal information broadly and allows for fines as well as a private right of action from individuals in relation to certain security breaches involving personal information. The CCPA is also prompting similar legislative developments in other U.S. states , which could lead to a series of overlapping but varying laws. These developments, as we become subject to such laws, are

likely to increase our compliance burden and our risk, including risks of regulatory fines, litigation and associated reputational harm. Further, as our operations expand, we may become subject to the EU General Data Protection Regulation ("GDPR"). The GDPR, together with the national legislation of the EU member states governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. It is unclear whether the transfer of personal information from the EU to the United Kingdom will continue to remain lawful under the GDPR in light of Brexit. Pursuant to a post-Brexit trade deal between the U.K. and the EU, transfers of personal information from the EEA to the U.K. are not considered restricted transfers under the GDPR for a period of up to four months from January 1, 2021 with a potential two-month extension. However, unless the EU Commission makes an adequacy finding with respect to the U.K. before the end of that period, the U.K. will be considered a "third country" under the GDPR and transfers of European personal information to the U.K. will require an adequacy mechanism to render such transfers lawful under the GDPR. Additionally, although U.K. privacy, data protection and data security laws are designed to be consistent with the GDPR, uncertainty remains regarding how data transfers to and from the U.K. will be regulated notwithstanding Brexit.

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

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

Changes in tax laws or regulations that are applied adversely to us may have a material adverse effect on our business, financial condition or results of operations.

New tax laws or regulations could be enacted at any time, and existing tax laws or regulations could be interpreted, modified or applied in a manner that is adverse to us, which could adversely affect our business and financial condition. For example, the Tax Act resulted in many significant changes to the U.S. tax laws, including changes in corporate tax rates, the utilization of our net operating loss carryforwards, or NOLs, and other deferred tax assets, the deductibility of expenses, and the taxation of foreign earnings. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified by future legislation. For example, The Coronavirus Aid, Relief, and Economic Security (CARES) Act modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, or any newly enacted federal tax legislation. The impact of changes under the Tax Act, the CARES Act, or future reform legislation could increase our future U.S. tax expense and could have a material adverse impact on our business and financial condition. We urge our stockholders to consult with their legal and tax advisors with respect to these legislations and the potential tax consequences of investing in or holding our common stock.

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

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

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

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

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

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

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

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

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

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. FDA review time and communications with the FDA may be delayed, prolonged and otherwise negatively impacted by the FDA's response to the COVID-19 pandemic. With many FDA staff working on COVID-19 activities, it is possible the FDA may need to reprioritize work in order to appropriately address the ongoing pandemic. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

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

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

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

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

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

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

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

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

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

If approved, the marketing for SM-88 or other drug candidates, will be limited to the specific approved cancer or antiviral indications, as applicable, and, if we want to expand the indications for which these drug candidates may be marketed, additional regulatory approvals will need to be obtained, which may not be granted.

In addition to other areas of regulatory oversight, we will also need to comply with a variety of laws and regulations concerning the advertising and promotion of our products. For instance, the FDA closely regulates the post-approval labeling, marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, product-specific risk evaluation mitigation strategies (REMS), industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. If we desire to market additional indications for our drug candidates, we will need to seek additional regulatory approvals requiring additional clinical trials to support the new indications, which would be time-consuming and expensive and may produce results that do not support regulatory approvals. If we do not obtain additional regulatory approvals, our ability to expand our business will be limited.

While physicians may choose to prescribe drugs for uses that are not described in a product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote products is limited to those indications that are specifically approved by the FDA, or similar regulatory authorities outside the United States. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in certain circumstances. Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict promotion by pharmaceutical companies on the subject of off-label use. If we are found to have promoted our products for off-label uses after FDA approval for the applicable indication(s) or to have engaged in inappropriate pre-approval promotion of any approved drug candidate, we may receive warning letters and become subject to significant liability, which would materially harm our business. The federal government and states' attorneys general have levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred and our reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use or engage in improper pre-approval promotion, we could be subject to FDA prohibitions on the sale or marketing of our products or significant fines and penalties and the imposition of these sanctions could also affect

our reputation and position within the industry.

Adverse results, side effects or injuries may happen and may lead to product liability claims. Liability claims could divert management's attention from our core business, be expensive to defend, result in sizable damage awards against us that may not be covered by liability insurance, and could harm our reputation in the marketplace among physicians and patients. Any of these events could harm our business and results of operations and cause our stock price to decline.

Additionally, as with an existing number of previously approved oncology products, the FDA will likely require us to educate health care providers and patients about the proper use and administration of our drug candidates and obtain FDA approval to market.

Being a public company is expensive and administratively burdensome.

As a public reporting company, we are subject to the information and reporting requirements of the Securities Act of 1933, as amended (the "Securities Act"), the Exchange Act and other federal securities laws, rules and regulations related thereto, including compliance with the Sarbanes-Oxley Act of 2002 ("SOX"). Complying with these laws and regulations requires the time and attention of our Board and management and increases our expenses. Among other things, we must:

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

The cost of preparing and filing annual, quarterly and current reports, proxy statements and other information with the SEC and furnishing annual reports containing audited financial statements to stockholders is expensive and much greater than that of a privately-held company. Compliance with these rules and regulations may require us to hire additional financial reporting, internal controls and other finance personnel and will involve significant regulatory, legal and accounting expenses and the attention of management, including as a result of changing laws, regulations and standards. There can be no assurance that we will be able to comply with the applicable regulations in a timely manner, if at all. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation. For example, Nasdaq's quantitative listing standards require, among other things, that listed companies maintain a minimum closing bid price of $1.00 per share. On October 20, 2020, the closing price of our common stock was approximately $0.99 per share, and while the closing price of our common stock rose to $1.03 per share on November 25, 2020, and has subsequently remained at or above the minimum closing bid price of $1.00 per share from November 25, 2020 through the date of this filing, it may in the future fall below the closing minimum bid price of $1.00 per share. Given the increased volatility and market reaction to the COVID-19 pandemic, we may be unable to maintain such a bid price and could face delisting proceedings.

Additionally, there continues to be public interest and increased legislative pressure related to public companies' environmental, social and governance ("ESG") activities. We risk negative stockholder reaction, including from proxy advisory services, as well as damage to our brand and reputation, if we do not act responsibly in a number of key areas, including diversity and inclusion, environmental stewardship, support for local communities, corporate governance and transparency and employing ESG strategies in our operations. A growing number of states are requiring organizations to report their board composition and/or mandating gender diversity, including New York and California. In December 2020, Nasdaq filed a proposal with the SEC to adopt new listing rules related to board

diversity and disclosure. If approved by the SEC, the new listing rules would, among other things, require all companies listed on Nasdaq's U.S. exchange to publicly disclose consistent, transparent diversity statistics regarding their board of directors.

In addition, being a public company makes it more expensive for us to obtain director and officer liability insurance. Premiums for director and officer insurance can vary substantially from year-to-year and have recently been increasing due to the growth in threatened and actual suits across public companies, which is even more pronounced in biotechnology. In the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain this coverage. These factors could also make it more difficult for us to attract and retain qualified executives and members of our Board, particularly directors willing to serve on our audit committee.

ITEM 1B. UNRESOLVED STAFF COMMENTS

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

ITEM 2. PROPERTIES

Our principal executive offices are located at 1 Pluckemin Way – Suite 103, Bedminster, NJ 07921 where we lease and occupy approximately 1,962 square feet of office space. We estimate our annual costs for this office at approximately $43,200 per year plus utilities and other expenses.

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

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ADDITIONAL ITEM. EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers and their positions as of June 10, 2021 were:

	Title and Business Experience	Age
Richard Cunningham	Mr. Cunningham has served as Chief Executive Officer since November 2020.	50
Steve Hoffman	Mr. Hoffman is Chairman of the Board and has served as Chief Science Officer since March 2015. Mr. Hoffman also served as Chief Executive Officer from March 2015 to November 2020 and as Chief Executive Officer of our wholly-owned subsidiary, Tyme, Inc. since its formation in July 2013, and a manager of our wholly-owned subsidiary, Luminant Biosciences, LLC, since its formation in September 2011 until its dissolution in October 2020. In such roles and continuing with his current position as Chairman of the Board and Chief Science Officer of the Company, he supervises the development of our product candidates.	58
Dr. Jonathan Eckard, PH.D.	Dr. Eckard has served as Chief Scientific Affairs Officer since August 2017 and assumed the role of Chief Business Officer in March 2019.	47
John Rothman, PH.D.	Mr. Rothman has served as Executive Vice President of Product Development since August 2020 and served as a consultant to the Company from March 2018 until August 2020.	72
James Biehl	Mr. Biehl has served as our Chief Legal Officer and Secretary since September 2018 and served on our Board from 2017 until September 2018.	57
Barbara C. Galaini	Ms. Galaini has served as our Principal Accounting Officer since August 2018 and our Corporate Controller since April 2018. In connection with the resignation of the Company's former President and Chief Financial Officer, Ms. Galaini, has been the acting Principal Financial Officer since September 30, 2020.	63

PART II

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

Public market for our common stock

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

The closing price of TYME stock as of June 7, 2021 was $1.63.

Holders; Shares Outstanding

We had a total of 172,206,894 shares of our common stock outstanding on June 7, 2021, held by approximately 170 stockholders of record. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in "street name" by brokers and other nominees.

Dividend Policy

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

Securities Authorized for Issuance Under Equity Compensation Plan

Reference is made to the information in Item 12 of this report under the caption "Equity Compensation Plans in effect as of March 31, 2021," which is incorporated herein by this reference.

Share Repurchases

During the twelve months ended March 31, 2021, we did not repurchase any shares of common stock.

ITEM 6. SELECTED FINANCIAL DATA

Reserved.

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

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

Overview

TYME is an emerging biotechnology company developing cancer metabolism-based therapies (CMBTs™) that are intended to be effective across a broad range of solid tumors and hematologic cancers, while also maintaining patients' quality of life through relatively low toxicity profiles. TYME's therapeutic approach is designed to take advantage of a cancer cell's innate metabolic requirements to cause cancer cell death. Our lead first-in-class CMBT compound is SM-88. Early clinical results demonstrated by SM-88 in multiple advanced cancers, including pancreatic, prostate, sarcomas and breast, reinforce the potential of our emerging CMBT pipeline. Moreover, we also believe our pipeline offers hope to patients for a new future in long-term management of advanced cancers.

Our lead clinical CMBT compound, SM-88, is an oral investigational modified proprietary tyrosine derivative that is hypothesized to interrupt the metabolic processes of cancer cells by breaking down the cells' key defenses and leading to cell death through oxidative stress and exposure to the body's natural immune system. To date, clinical trial data have shown that SM-88 has achieved confirmed tumor responses across 15 different cancers, both solid and liquid tumors, including pancreatic, lung, breast, prostate, sarcoma and lymphoma cancers with minimal drug related serious Grade 3 or higher adverse events, which we believe is rare for investigational compounds.

Strategic Review

In November 2020, TYME appointed Richie Cunningham as its new Chief Executive Officer. His initial priority was to build a management team better equipped to transition the Company to its next phase of growth. In January 2021, he commenced a comprehensive strategic review examining every facet of the Company. The goals of the review were to assess the Company's existing opportunities, explore untapped opportunities that may have been overlooked and maximize the efficiency of our capital expenditures in an effort to unlock TYME's full potential. In February 2021, Mr. Cunningham led an effort to raise $100 million in capital that we believe will provide significant runway for the Company to execute on its move-forward strategy.

The strategic review process encompassed an extensive review of internal and external resources, the design of and results from our preclinical and clinical trials, the likelihood of approval by the Food and Drug Administration ("FDA") or similar regulatory authorities outside the United States, the potential market for pipeline candidates, the costs and complexities of manufacturing to ensure a safe and sustainable supply of investigational compounds can be delivered to patients, the potential of competing products, the likelihood of any challenges to our intellectual property, regardless of merit, the ongoing and potential effects of COVID-19 or any future pandemics, and industry and market conditions generally. The review included internal and external assessments by industry experts, key opinion leaders ("KOLs") and advisors with considerable experience in the various areas we sought to probe and explore.

Ongoing Studies

The Company has partnered with Pancreatic Cancer Action Network ("PanCAN") to study SM-88 in an adaptive randomized Phase II/III trial with registration intent known as Precision Promise℠. The objective of Precision Promise is to expedite the study and approval of promising therapies for pancreatic cancer by bringing multiple stakeholders together, including academic, industry and regulatory entities. In this trial which began in early 2020,

SM-88 with MPS is being studied as monotherapy treatment arm for patients who have failed one prior line of chemotherapy. PanCAN is sponsoring Precision Promise and providing funding and other support. While TYME's SM-88 is included in the trial, we do not oversee, conduct or control the trial.

In early 2020, the open-label Phase 2 investigator sponsored trial of SM-88 therapy in sarcoma, HoPES, opened. This trial has two cohorts each expecting to enroll 12 patients. The first is SM-88 with MPS as salvage treatment in patients with mixed rare sarcomas, the other is SM-88 with MPS as maintenance treatment for patients with metastatic Ewing's sarcoma that had not progressed on prior therapy. The primary objectives are to measure ORR and PFS. Secondary objectives include duration of response, OS, CBR using RECIST, and incidence of treatment-emergent adverse events. The Joseph Ahmed Foundation is providing funding and patient support for this trial and the trial is being conducted by principal investigator Dr. Chawla at the Sarcoma Oncology Center in Santa Monica, CA.

In calendar year 2019, the Company presented final SM-88 prostate Phase II clinical data showing encouraging clinical benefit in patients with bio-marker recurrent prostate cancer, with the final results published in the peer-reviewed journal, *Investigational New Drugs*, on September 13, 2020.

Preclinical Pipeline Programs

TYME-19 is an oral synthetically produced member of the bile acid family that is being developed for the potential treatment of COVID-19. From the Company's metabolic understanding of bile acids, it was able to identify TYME-19 as a well characterized candidate and a potential treatment of corona viruses. A patent has been issued for TYME-19 for the treatment of COVID-19.

Bile acids can cellular modulate lipid and glucose metabolism and can remediate dysregulated protein folding, each that are relevant to viral infection of a host cell. Existing literature have shown that certain bile acids can have antiviral properties in a range of different viruses, including prior corona viruses.

Our initial preclinical in vitro experiments displayed effectiveness against COVID-19 infection and replication, and we will continue to conduct additional tests to support the potential utility of TYME-19 in the treatment of COVID-19 and disease variants. With the ever-changing dynamics of this disease area, the company's intent with this program is to prepare this agent for clinical testing, while learning from the ongoing work to identify an optimal clinical setting where TYME-19 could potentially offer clinical benefits, and for which there may be a sustainable market.

TYME-18 is a pre-clinical CMBT compound under development that is delivered intratumorally. TYME-18 is a combination of a proprietary surfactant system and natural sulfonic/bile acid that is designed to disrupt energy metabolism and have lytic function for potential treatment of inoperable tumors. TYME-18 is distinct in composition from SM-88. However, like SM-88, it aims to enhance the susceptibility of a cancer to the highly acidic and toxic tumor microenvironment, while minimizing the impact to normal tissues. In initial preclinical xenograft mouse studies, TYME-18 was able to completely resolve over 90 percent (11 of 12 mice) of established colorectal tumors within 12 days versus an average of over 600 percent growth in the control animals.

TYME-18 is currently in preclinical development, and as with TYME-19, we expect at the proper time, to identify a potential partner with a focus on surgical oncology to assist in the ongoing development of TYME-18.

Discontinuing Programs

TYME-88-PANC (Part 2) (third-line Metastatic Pancreatic Cancer)

In fiscal year 2020, we launched our pivotal study for SM-88 in the third-line treatment of pancreatic cancer through an amendment to our ongoing TYME-88-Panc trial (Part 2), with the first patient dosed in the third quarter of the fiscal year. As described previously, the COVID-19 pandemic significantly impacted enrollment of this trial such that it appears it is likely to complete enrollment in a similar timeline to the second-line Precision Promise pancreatic cancer trial. There has also been a higher than expected dropout of patients randomized to the chemotherapy control arm, which could potentially impact the interpretative and regulatory utility of the data.

Following a comprehensive strategic review, considering, in part, the timeline and regulatory utility for this trial compared to the parallel Precision Promise trial and concentration of investment in this specific cancer, management concluded that it would be best to focus on the second-line Precision Promise trial that offers treatment options to patients earlier in their disease. Furthermore, the trial includes tumor biopsy and biomarker analyses that aligns with the Company's overall strategic focus to identifying patients with the best chance of benefit from our therapies.

Therefore, the Company has decided to stop enrollment and begin the process of closing down the trial. Patients currently on therapy will be allowed to continue treatment until progression or unacceptable toxicity. The closing of this trial may require several months to complete, with anticipated close out costs to be $2 million to $3 million.

See "Recent Developments" below for a discussion of planned upcoming clinical and preclinical studies.

COVID-19 Update

In March 2020, the World Health Organization categorized the novel coronavirus (COVID-19) as a pandemic and the President of the United States declared the COVID-19 outbreak a national emergency. The COVID-19 pandemic, and actions taken by governments and others to reduce its spread, including travel restrictions, shutdowns of businesses deemed non-essential, and stay-at-home or similar orders, has negatively impacted the global economy, financial markets, and our industry and has disrupted day-to-day life and business operations. We are closely monitoring the impact of COVID-19 on all aspects of our business, our clinical trials, and the safety of patients, including as vaccines become more widely available, as jurisdictions begin to ease certain restrictions and as possible new outbreaks or virus variants emerge. We continue to work closely with our clinical trial sites during the pandemic. While all trials for SM-88 are still actively enrolling patients and we believe we have sufficient clinical supply to complete all of our trials, the COVID-19 pandemic has significantly impacted enrollment of our TYME-88-Panc pivotal trial. Enrollment has slowed primarily due to various reasons related to the pandemic, including but not limited to an overall decrease in cancer diagnoses, changes in patient treatment practices, changes in hospital or university policies, federal, state or local regulations, and prioritization of hospital resources toward pandemic efforts.

We are committed to working with the clinical trial sites to assure appropriate access for patients who are seeking clinical trial options for these advanced cancers for which the patients have limited or no other treatment options. We have also taken important steps to protect the health and welfare of our employees, consultants and board members, primarily by adapting to a fully "work-from-home" model since March 2020. The extent to which COVID-19 impacts our product candidates and business, including patients' willingness to participate and remain in clinical trials, the timing of meeting enrollment expectations, the ability of our third-party partners to remain operational and our access to capital markets and financing sources, however, depends on numerous evolving factors that are highly uncertain and cannot be accurately predicted, including those identified under "Risk Factors" in this report, many of which are beyond our control. Management continues to monitor the situation closely and intends to continue to adapt and implement process adjustments as needed.

Recent Developments

Appointment of Chief Financial Officer

On May 13, 2021, the Board of Directors of the Company (the "Board") appointed Frank L. Porfido as the new Chief Financial Officer of the Company, to be effective on the second business day following the filing of the Company's Annual Report on Form 10-K for the year ended March 31, 2021. Mr. Porfido brings over 25 years of strategic financial experience, including the pharmaceutical and biotechnology industries.

Upcoming Studies

OASIS (Metastatic HR+/HER2- Breast Cancer After CDK4/6 Inhibitors)

In June 2021, we announced an agreement with Georgetown University to support a Phase II trial for SM-88 in patients with metastatic breast cancer who have hormone receptor positive ("HR+") and human epidermal growth factor receptor 2 negative ("HER2-") disease ("HR+/HER2-"). This represents approximately 73% of the annual

breast cancer diagnoses in the US each year. According to estimates from Data Monitor and Syneos Health, there are approximately 150,000 metastatic breast cancer diagnoses in the US each year. According to Data Monitor, company reported sales figures, and Syneos Health analyses, the total 2019 U.S. market revenues for drug treatment for metastatic breast cancer were $7.7 billion.

The OASIS trial is an investigator-initiated prospective open-label Phase II trial evaluating the efficacy and safety of SM-88 with MPS for the treatment of metastatic hormone-receptor positive, HER2- breast cancer after treatment with a CDK4/6 inhibitor, this trial is designed as a two-stage trial, enrolling up to 50 patients to receive SM-88 with MPS without additional therapies in patients who have failed or progressed after receiving two hormonal agents and a CDK4/6 inhibitor. The primary endpoint of this trial is ORR, with secondary endpoints including duration of response ("DOR"), CBR at >24 weeks, PFS, and safety. The trial will be conducted at Georgetown University at a total of five sites within the Georgetown/MEDSTAR system located in Washington DC, Maryland, and New Jersey. Patient enrollment is expected to begin in the third quarter of calendar year 2021.

This trial is being conducted as a follow up to the encouraging anti-tumor efficacy observed from the initial trials of SM-88 in this specific patient sub-group. In the FIH study and Compassionate Use Program, several heavily pretreated metastatic HR+/HER2- breast cancer patients displayed tumor responses to SM-88, including several complete responses. This trial is aimed to further explore this signal, and will also collect cell-free DNA from patients from different time-points with a goal of better understanding potential biomarkers of response and other aspects of SM-88's mechanism of action. TYME has also established an academic collaboration with an investigator at Georgetown University to explore the mechanism of SM-88 and MPS, including models of CDK 4/6 resistance.

SM-88 Mechanism of Action and Biomarker Research

Following feedback from the recent strategic review, the company has begun a comprehensive translational preclinical program. This program will be multi-faceted incorporating Evotec, a leading global research and development company together with several complementary academic collaborations. The overall goal of these activities is to potentially identify actionable biomarkers of sensitivity and activity to SM-88 in various cancers, identifying potential complementary combination drugs strategies for SM-88, and potentially identify other cancer metabolism targets that could be targeted for treatment. Additionally, the company intends to incorporate liquid and tumor biopsies to future clinical trials to contribute to the biomarker identification. We anticipate this engagement will have several stages, and to last likely over at least this coming fiscal year and potentially beyond.

Critical Accounting Policies and Estimates and Recent Accounting Pronouncements

Critical accounting estimates are those made in accordance with generally accepted accounting principles in the United States of America ("GAAP") that involve a significant level of estimation and have had or are reasonably likely to have a material impact on the Company's financial condition or results of operations. In preparing these financial statements, management has used available information in forming its estimates, assumptions and judgments. Actual performance may differ from estimates and the Company's estimates may differ from those of other companies. While our significant accounting policies are more fully described in Note 2 to the Consolidated Financial Statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies and estimates are critical to the preparation of our financial statements. The financial information presented in this section is in conformity with GAAP.

Research and Development Expenses

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

Payments for these activities are based on the terms of the individual arrangements, which may differ from the patterns of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued expense.

Income Taxes

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

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

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

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

As of March 31, 2021, the Company had gross U.S. federal net operating loss carryforwards of approximately $95.8 million, which may be available to offset future income tax liabilities and will begin to expire at various dates starting in 2033. As of March 31, 2021, the Company had gross federal research and development tax credit carryforwards of $1.7 million available to reduce future tax liabilities, which will begin to expire at various dates starting in 2030. As of March 31, 2021, none of the Company's state net operating losses have value due to the apportionment rule in the states where state income tax returns are currently filed. We had unrecognized tax benefits of $559,000 and $318,000 at March 31, 2021 and 2020, respectively. Increases or decreases would not have an effect on the effective tax rate.

The Company files federal income tax returns in the United States, and various state jurisdictions. The federal and state income tax returns are generally subject to tax examinations for the period January 1, 2017 through March 31, 2021. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities to the extent utilized in a future period. In addition, we had no income tax related penalties or interest for periods presented in these consolidated financial statements. When and if we were to recognize interest and penalties related to unrecognized tax benefits, they would be reported in tax expense.

Stock-Based Compensation

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

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected term of the option, risk-free interest rates, the value of the common stock and expected dividend yield of the common stock. For awards subject to time-based vesting conditions, we recognize stock-based compensation expense equal to the

grant date fair value of stock options on a straight-line basis over the requisite service period, which is generally the vesting term. The Company accounts for forfeitures as they occur, rather than estimating forfeitures as of an award's grant date.

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

Derivative Warrant Liability

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

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

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

Results of Operations

Year ended March 31, 2021 Compared to Year Ended March 31, 2020

Net loss for the year ended March 31, 2021 was $28,979,000 or $0.22 per share compared to $22,001,000 or $0.19 per share for the year ended March 31, 2020. The increase in the net loss compared to the prior year was due to the non-cash expense variance of $7,560,000 in the fair value of the warrant liability, partially offset by non-cash gain of $2,229,000 on the warrant exchange and increased operating costs. The increase in operating costs for the current year of $1,457,000 related to increased research and development costs of $4,075,000, partially offset by $2,618,000 decrease in general and administrative costs as explained below under "Operating Expenses."

Cash used in operating activities for the year ended March 31, 2021 was $23,564,000 compared to $19,560,000 for the year ended March 31, 2020. See "Cash Flows" section below for further details.

Adjusted net loss, which excludes the change in fair value of warrant liability, amortization of employees, directors and consultants stock options and gain on warrant exchange, was $23,836,000 or $0.18 per share for the year ended March 31, 2021 compared to $19,560,000 or $0.17 per share for the year ended March 31, 2020. 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.

Revenue

During the years ended March 31, 2021 and March 31, 2020, we did not realize any revenues from operations. We do not anticipate recognizing any revenues until such time as one of our products has been approved for marketing by appropriate regulatory authorities or we enter into collaboration or licensing arrangements, none of which is anticipated to occur in the near future.

Operating Expenses

For the year ended March 31, 2021, operating costs and expenses totaled $27,217,000, compared to $25,760,000 for the year ended March 31, 2020, representing an increase of $1,457,000. Operating costs and expenses by function were comprised of the following:

- Research and development expenses were $17,031,000 for the year ended March 31, 2021, compared to $12,956,000 for the year ended March 31, 2020, representing an increase of $4,075,000. The majority of 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 $12,617,000 for the year ended March 31, 2021, compared to $7,713,000 for the year ended March 31, 2020 representing an increase of $4,904,000 between the comparable periods. The increase is mainly attributable to increased activity, including supply costs, related to Part 2 of our TYME-88-Panc trial and the Precision Promise Phase II/III trial.
  - Salary and salary related expenses for research and development personnel was $3,015,000 for the year ended March 31, 2021, compared to $2,697,000 for the year ended March 31, 2020, representing an increase of $318,000 between comparable periods, primarily due to costs associated with severance and shift of resources.
  - Included in research and development expense for the year ended March 31, 2021 is $1,379,000 of stock based compensation related to stock options granted to research and development personnel compared to $2,537,000 for the year ended March 31, 2020, representing a decrease of $1,158,000 between the comparable periods, primarily due to reduction in expense for fully amortized awards and forfeited awards partially offset by the amortization of expense related to options granted to employees during fiscal year 2021.
- General and administrative expenses were $10,186,000 for the year ended March 31, 2021, compared to $12,804,000 for the year ended March 31, 2020, representing a decrease of $2,618,000. The general and administrative expenses include:
  - Stock based compensation related to stock options granted was $2,078,000 for the year ended March 31, 2021, compared to $3,549,000 for the year ended March 31, 2020, representing a decrease of $1,471,000, primarily attributable to a reduction in expense for fully amortized awards and forfeited awards, partially offset by amortization of grants granted to employees, board members and consultants during fiscal year 2021.
  - Legal, professional services, accounting and auditing expenses for the year ended March 31, 2021, was $3,150,000, compared to $3,205,000 for the year ended March 31, 2020, representing a decrease of $55,000.
  - Salary and salary related expenses for non-research and development personnel was $3,235,000 for the year ended March 31, 2021, compared to $3,741,000 for the year ended March 31, 2020, representing a decrease of $506,000 between the comparable periods due to current year resignations and shifts in resources to research and development.
  - Other general and administrative expenses for the year ended March 31, 2021 was $1,723,000, compared to $2,309,000 for the year ended March 31, 2020, representing a decrease of $586,000 between the comparable periods due to lower costs in fiscal year 2021 related to warrant issuances, travel and office costs.

Other Income/Expenses

For the year ended March 31, 2021, the Company had $3,915,000 non-cash expense relating to the change in fair value of the warrant liability during the period compared to $3,645,000 of non-cash income for the year ended

March 31, 2020, resulting in a $7,560,000 variance between the periods. See Item 8, Note 7 for details regarding changes in the fair value of the warrant liability.

For the year ended March 31, 2021, the Company had a non-cash gain on warrant exchanges of $2,229,000 pursuant to the Share Exchange Agreements and the Warrant Exchange Agreement (See Historical Financings – Exchange Agreements below.)

For the year ended March 31, 2021, the Company incurred $97,000 of interest expense as compared to $114,000 in the year ended March 31, 2020 related to the severance and insurance note payables.

Interest income for the year ended March 31, 2021 was $22,000 as compared to $229,000 in the year ended March 31, 2020, due to lower interest rates on bank deposits.

Income Tax

Our effective income tax rate for the years ended March 31, 2021 and 2020 was zero percent.

Use of Non-GAAP Measures

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

Reconciliation of Net Loss to Adjusted Net Loss

	For the Year Ended March 31,	
	2021	2020
Net loss (GAAP)	$ (28,979,000)	$ (22,001,000)
Adjustments:		
Change in fair value of warrant liability	3,915,000	(3,645,000)
Gain on warrant exchange	(2,229,000)	—
Amortization of employees, directors and consultants stock options	3,457,000	6,086,000
Adjusted net loss (non-GAAP)	$ (23,836,000)	$ (19,560,000)

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

	For the Year Ended March 31,	
	2021	2020
Net loss per share (GAAP)	$ (0.22)	$ (0.19)
Adjustments:		
Change in fair value of warrant liability	0.03	(0.03)
Gain on warrant exchange	(0.02)	—
Amortization of employees, directors and consultants stock options	0.03	0.05
Adjusted basic and diluted net loss per share (non-GAAP)	$ (0.18)	$ (0.17)

The Non-GAAP Measures for the year ended March 31, 2021 and 2020 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 were 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 May 2020 Warrant issued as part of the warrant exchange as described under the subheading "Historical Financings" below was measured at fair value using a Black-Scholes 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 and the risk-free interest rate for the term of the warrant.

The warrant liability is revalued at each reporting period or upon exercise. Changes in fair value are recognized in the consolidated statements of operations and are excluded from adjusted net loss and adjusted net loss per share.

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

c) Gain on warrant exchange resulted from the difference in fair value of the warrants issued as part of the equity offering on April 2, 2019 before their exchange (as described under the subheading "Historical Financings" below) and the fair value of the common stock exchange shares and the May 2020 Warrant granted pursuant to the Share Exchange Agreements and the Warrant Exchange Agreement, respectively.

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

Liquidity and Capital Resources

Liquidity and Capital Requirements Outlook

On February 8, 2021, the Company closed on a registered direct offering of 40,000,000 shares of its common stock, par value $0.0001 per share, at a purchase price of $2.50 per share. The gross proceeds of the offering were $100 million, prior to deducting placement agent's fees and other offering expenses payable by TYME, which were approximately $6.2 million.

The Company intends to use the net proceeds of this offering for the development of our clinical and preclinical assets and for general corporate purposes, capital expenditures, working capital and general and administrative expenses. We may also use a portion of the net proceeds to acquire or invest in businesses, products and technologies that are complementary to our own, although we have no current plans, commitments or agreements with respect to any acquisitions. In addition, we may also use the proceeds, and may require additional capital, to engage in potential partnerships or collaborations. The Company's most significant funding needs are in connection with (i) participating in Precision Promise, an adaptive randomized Phase II/III trial with registration intent, which examines our lead compound SM-88 for patients with second-line pancreatic cancer, and closing out our Part 2 of TYME-88 pivotal trial (ii) conducting preclinical and clinical studies in connection with TYME-19, (iii) participating in an investigator-initiated clinical trial of SM-88 in sarcoma, (iv) participating in OASIS our recently announced investigator-initiated prospective open-label Phase II trial evaluating the efficacy and safety of SM-88

with MPS for the treatment of metastatic hormone-receptor positive, HER2- breast cancer after treatment with a CDK4/6 inhibitor, and (v) conducting preclinical biomarker and mechanism of action research of our lead clinical program SM-88 to potentially identify actionable biomarkers of sensitivity and activity to SM-88 in various cancers, identifying potential complementary combination drugs strategies for SM-88, and potentially identify other cancer metabolism targets that could be targeted for treatment, and (vi) conducting additional or related studies of other potential drug candidates, including TYME-18 and TYME-19. The greater scale of these trials is expected to lead to increased costs, including providing SM-88 for patient use. If we determine to move beyond the pre-clinical stage for any of our pre-clinical trials or if we pursue studies in other cancer types, our liquidity requirements will be increased.

Primarily as a result of its active clinical trials, as well new initiatives including participating in OASIS our investigator-initiated prospective open-label Phase II breast cancer trial, preclinical biomarker and mechanism of action research of SM-88 studies, and preclinical and clinical studies in connection with TYME-19, the Company currently anticipates that its quarterly cash usage, or “cash burn rate”, will range from $6.0 million to $8.0 million per quarter during fiscal 2022.

As of March 31, 2021, the Company had cash on hand of approximately $107.5 million and a working capital of approximately $104.0 million. In the first quarter of fiscal year 2022, the Company established an investment policy and invested approximately $80 million in a portfolio of highly liquid investments and marketable securities. The primary objectives of the Company’s policy are to preserve capital and diversify risk, while maintaining sufficient liquidity to meet cash flow requirements.

Management has concluded that substantial doubt does not exist regarding the Company’s ability to satisfy its obligations as they come due during the twelve-month period following the issuance of these financial statements. This conclusion is based on the Company’s assessment of qualitative and quantitative conditions and events, considered in aggregate as of the date of issuance of these financial statements that are known and reasonably knowable. Among other relevant conditions and events, including the ongoing COVID-19 pandemic and related government and economic reactions, the Company has considered its operational plans, liquidity sources, obligations due or expected funds necessary to maintain the Company’s operations, and potential adverse conditions or events as of the issuance date of these financial statements.

The Company has historically funded its operations primarily through equity offerings of its common stock. As a clinical-stage entity, without product revenues and ongoing needs to fund our clinical development activities and general operations, 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 and investment balances and a variety of other means, including potential issuances of debt or equity securities in public or private financings, option exercises, and partnerships and/or collaborations. The demand for the equity and debt of biopharmaceutical companies like ours is dependent upon many factors, including the general state of the financial markets. During times of extreme market volatility, capital may not be available on favorable terms, if at all. Our inability to obtain such additional capital could materially and adversely affect our business operations.

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

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

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

Historical Financings

As further described above under the heading "Liquidity and Capital Requirements Outlook", on February 8, 2021, the Company closed on a registered direct offering of 40,000,000 shares of its common stock.

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

On October 18, 2019, the Company entered into an Open Market Sale Agreement℠ (the "Sale Agreement") with Jefferies LLC ("Jefferies"), pursuant to which the Company may, from time to time, sell shares of Common Stock, having an aggregate offering price of up to $30 million through Jefferies, as the Company's sales agent (the "Jefferies ATM"). As indicated in an amendment to the Sale Agreement, the shares will be offered and sold by the Company pursuant to its currently effective Registration Statement on Form S-3, as amended (Reg. No. 333-245033). Any sales of Common Stock pursuant to the Sales Agreement will be made by methods deemed to be an "at-the-market offering" as defined in Rule 415 promulgated under the Securities Act. Jefferies will use commercially reasonable efforts to sell the shares from time to time, based on the instructions of the Company. The Company will pay Jefferies a commission rate of three percent (3%) of the gross proceeds from the sales of shares of Common Stock sold pursuant to the Sale Agreement. Under the Sale Agreement, the Company is not required to use the full available amount authorized and it may, by giving notice as specified in the Sale Agreement, terminate the Sale Agreement at any time. During the year ended March 31, 2021, the Company raised approximately $6.1 million in gross proceeds via the sale of 4,453,939 shares of common stock under the Jefferies ATM and incurred $0.3 million of related costs which offset such proceeds. During the year ended March 31, 2020, the Company raised approximately $1.7 million in gross proceeds via the sale of 1,361,315 shares of common stock under the Jefferies ATM and incurred $0.2 million of related costs which offset such proceeds. As of March 31, 2021, there remained approximately $22.2 million of availability in the Jefferies ATM.

Prior to the Jefferies ATM, the Company had a similar facility with Canaccord Genuity Inc. ("Canaccord") that was closed shortly prior the opening of the Jefferies ATM. On November 2, 2017, the Company had entered into an equity distribution agreement with Canaccord to commence an at-the-market offering that had an aggregate potential offering price up to $30 million (the "Canaccord ATM"). The Company raised a total of $12.1 million through the facility between November 2, 2017 and October 12, 2019, the effective date of the Canaccord ATM's termination.

On April 2, 2019, the Company closed on an underwritten registered offering of 8,000,000 shares of its common stock, par value $0.0001 per share ("Common Stock"), and warrants to purchase up to 8,000,000 shares of its common stock with an exercise price of $2.00 per share (the "April 2019 Warrants") at a combined purchase price of $1.50 per share of common stock and accompanying warrant. The net proceeds to the Company, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company, were approximately $11 million. The proceeds of the offering are being used for continued and new clinical trials, continued development of compounds, and other general corporate purposes. However, as further described under the subheading "Exchange Agreements" below, on May 20, 2020, the Company exchanged the April 2019 Warrants with their respective holders for shares of the Company's Common Stock or new warrants in reliance upon the exemption from registration provided by Section 3(a)(9) of the Securities Act of 1933, as amended. After such exchanges, the April 2019 Warrants no longer remained outstanding.

Exchange Agreements

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

Pursuant to exchange agreements (the "Share Exchange Agreements") with Holders of April 2019 Warrants to purchase 5,833,333 shares of Common Stock in the aggregate, the Company issued an aggregate of 2,406,250 shares of Common stock (the "Exchange Shares") in exchange for such April 2019 Warrants. Concurrently therewith, each such Holder executed and delivered to the Company a leak-out agreement (a "Share Leak-Out Agreement") that contains trading restrictions with respect to the Exchange Shares, which (i) for the first 90 days, prohibit any sales of Exchange Shares, (ii) for the subsequent 90 days, limit sales of Exchange Shares on any day to 2.5% of that day's trading volume of Common Stock, and (iii) prohibit new short positions or short sales on Common Stock for the combined 180 day period.

The Company also entered into an exchange agreement (the "Warrant Exchange Agreement") with another Holder of April 2019 Warrants to purchase 2,166,667 shares of Common Stock in the aggregate. Pursuant to the Warrant Exchange Agreement, the Company issued such Holder a new warrant (the "May 2020 Warrant") to purchase the same number of shares of Common Stock. The May 2020 Warrant has the same expiration date, April 2, 2024, as the April 2019 Warrants, but has an exercise price of $1.80 and does not include the price protection, anti-dilution provisions or other restrictions on Company action from the April 2019 Warrants. Concurrently therewith, such Holder executed and delivered to the Company a leak-out agreement that contains trading restrictions on sales of Common Stock issued upon exercise of the May 2020 Warrant that are substantially similar to the restrictions on Exchange Shares in the Share Leak-Out Agreement, provided that the leak-out restrictions will only apply to the first 893,750 shares of Common Stock issued pursuant to the May 2020 Warrant.

After such exchanges, the April 2019 Warrants no longer remained outstanding.

Cash Flows

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

	2021	2020
Net cash used in operating activities	$ (23,564,000)	$ (19,560,000)
Net cash used in investing activities	$ —	$ —
Net cash provided by financing activities	$ 104,380,000	$ 31,958,000

Operating Activities

Our cash used in operating activities in the year ended March 31, 2021 totaled $23.6 million which is the sum of (i) our net loss of $29.0 million, adjusted for non-cash expenses totaling $3.9 million related to change in fair value of the warrant liability and $3.5 million expense amortization of stock-based compensation, partially offset by $2.2 million non-cash gain on warrant exchange, and (ii) changes in operating assets and liabilities of $0.3 million.

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

Investing Activities

There were no investing activities in the years ended March 31, 2021 and March 31, 2020.

Financing Activities

During the year ended March 31, 2021, our finance activities mainly consisted of the following

- In February 2021, the Company raised $100 million in gross proceeds through a registered direct offering of 40,000,000 shares of its common stock, at a purchase price of $2.50 per share. The Company incurred $6.2 million of related costs which offset such proceeds.
- The Company raised approximately $6.1 million in gross proceeds via sale of 4,453,939 shares of Common Stock through the Jefferies ATM. The Company incurred $0.3 million of related costs which offset the proceeds. At March 31, 2021 there remained approximately $22.2 million of availability to sell shares through the Jefferies ATM.
- The Company raised $5.4 million through the exercise of the stock options.
- The Company made payments of $518,000 on the insurance note payable related to premiums for its Director and Officer liability insurance coverage.

During the year ended March 31, 2020, our finance activities mainly consisted of the following:

- In April 2019, the Company raised $11.3 million after underwriting discounts and before offering expenses through an underwritten registered offering of 8,000,000 shares of our Common Stock, and 8,000,000 common stock purchase warrants.
- The Company raised approximately $1.7 million in gross proceeds via sale of 1,361,315 shares of Common Stock through the Jefferies ATM. The Company incurred $0.2 million of related costs which offset the proceeds.
- In January 2020, the Company raised $20 million before offering expenses through the Eagle SPA, pursuant to which the Company issued and sold to Eagle 10,000,000 shares of common stock, at a price of $2.00 per share.
- The Company made payments of $597,000 on the insurance note payable related to premiums for its Director and Officer liability insurance coverage.

Seasonality

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

Contractual Obligations and Commitments

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

Contract Service Providers

On April 1, 2020, the Company amended the Clinical Research Funding and Drug Supply Agreement dated October 9, 2018, with PanCAN, to enroll individuals diagnosed with pancreatic cancer in a platform style clinical research study. Stage 1 of the study was initiated in the fourth quarter of fiscal year 2020. After taking into consideration amounts already incurred, the remaining expense to the Company, which primarily consists of patient treatment costs, for Stage 1 is approximately $4.5 million, subject to enrollment adjustments, and is expected to be incurred over the next one and a half years.

Purchase Commitments

The Company has entered into contracts with manufacturers to supply certain components used in SM-88 in order to achieve favorable pricing on supplied products. These contracts have non-cancellable elements related to the scheduled deliveries of these products in future periods. Payments are made by us to the manufacturer when the products are delivered and of acceptable quality. The outstanding future contract obligations structured to match clinical supply needs for the Company’s ongoing trials and registration activity are approximately $0.7 million and

$3.2 million, respectively, at March 31, 2021. The Company expects the timing of associated payments to predominately occur through fiscal year 2022.

Leases

The Company leases office space in New Jersey. The New Jersey lease expires in February 2023. The Company's future minimum annual lease payments for the New Jersey lease are approximately $41,200 due in fiscal 2022 and $43,200 due in fiscal 2023.

Off-Balance Sheet Arrangements

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

ITEM 7A. QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined in Regulation S-K of the Securities Exchange Act of 1934, as amended, and are not required to provide the information under this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Tyme Technologies, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Tyme Technologies, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of March 31, 2021 and 2020, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended March 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of March 31, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended March 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Basis for opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical audit matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

Derivative Warrant Liability

As described further in notes 7 and 9 to the consolidated financial statements, the Company has derivative warrant liabilities that are recorded at fair value. The fair values rely on substantial use of estimates and were determined using the Monte Carlo and Black Scholes models, and included significant unobservable inputs, which consist of volatility and the probability of a fundamental transaction occurring. We identified derivative warrant liability valuation as a critical audit matter as auditing these elements required especially challenging auditor judgment and significant audit effort, including the need for specialized knowledge and skill in assessing these elements of the fair value determination.

The principal consideration for our determination that derivative warrant liability estimates are a critical audit matter is that the models used to determine the fair value include significant unobservable inputs, which were volatility and the probability of fundamental transactions occurring, which are subject to estimation uncertainty and require significant auditor subjectivity in evaluating those inputs and estimates. Volatility is based on a blend of the Company's expected volatility and those of similar companies. The probability of fundamental transactions

occurring is based on management's assessment over the timing of certain financing transactions.

Our audit procedures related to derivative warrant liability estimates included the following, among others:

a) We assessed the appropriateness of the similar companies used in the volatility calculation, recomputed expected volatility of the Company and volatility of the similar companies using the changes in the respective stock prices over the term, and with the assistance of our valuation professionals with specialized skills and knowledge, we assessed the methodology used in determining the volatility;
b) We assessed the reasonableness of management's process for developing the probability of fundamental transactions occurring for warrants valued using the Monte Carlo model;
c) We agreed the inputs to the key terms of the underlying agreements and read such agreements to assess the completeness of the inputs utilized;
d) We recomputed the fair value of each instrument using management's inputs and compared to the fair value calculated by management; and
e) With the assistance of our valuation professionals with specialized skills and knowledge, we evaluated the valuation methodologies utilized by management.

Stock-Based Compensation
As described further in notes 7 and 13 to the consolidated financial statements, the Company has stock-based compensation that is based on fair value measurements. We identified the computation of stock-based compensation as a critical audit matter because it relies on substantial use of estimates and were determined using the Black Scholes model, and included a significant unobservable input, volatility.
The principal consideration for our determination that stock-based compensation estimates is a critical audit matter is that the model used to determine the grant date fair value includes a significant unobservable input of volatility, which is subject to estimation uncertainty and requires significant auditor subjectivity in evaluating that input and estimate. Volatility is based on a blend of the Company's expected volatility and those of similar companies.

Our audit procedures related to stock-based compensation estimates included the following, among others:

a) We agreed the inputs of the grant date fair value calculation to the key terms of the underlying agreements and read such agreements to assess the completeness of the inputs utilized;
b) We assessed the appropriateness of the similar companies used in the volatility calculation, recomputed expected volatility of the Company and volatility of the similar companies using the changes in the respective stock prices over the term and with the assistance of our valuation professionals with specialized skills and knowledge, we assessed the methodology used in determining the volatility; and
c) We recomputed the fair value of each grant using management's inputs and compared to the fair value calculated by management.

/s/ GRANT THORNTON LLP

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

New York, New York
June 10, 2021

Tyme Technologies, Inc. and Subsidiaries
Consolidated Balance Sheets

	March 31, 2021	March 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 107,516,420	$ 26,700,416
Prepaid clinical costs	987,470	396,962
Prepaid expenses and other current assets	1,152,970	981,949
Total current assets	109,656,860	28,079,327
Property and equipment, net	—	5,181
Prepaid clinical costs, net of current portion	530,989	1,266,025
Operating lease right-of-use asset	75,471	150,301
Total assets	$ 110,263,320	$ 29,500,834
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and other current liabilities (including $87,000 and $73,000 of related party accounts payable, respectively)	$ 3,842,390	$ 2,827,302
Severance payable	726,027	380,722
Accrued bonuses	1,040,710	1,800,979
Insurance note payable	—	518,124
Operating lease liability	34,658	54,661
Total current liabilities	5,643,785	5,581,788
Long-term liabilities		
Severance payable, net of current portion	850,709	1,254,910
Operating lease liability, net of current portion	41,256	—
Warrant liability	1,931,921	3,639,000
Total liabilities	8,467,671	10,475,698
Commitments and contingencies (See Note 10)		
Stockholders' equity		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized, 0 shares issued and outstanding	—	—
Common stock, $0.0001 par value, 300,000,000 shares authorized, 172,200,644 issued and outstanding at March 31, 2021, and 300,000,000 authorized, 123,312,252 issued and outstanding at March 31, 2020	17,222	12,333
Additional paid in capital	238,572,442	126,828,055
Accumulated deficit	(136,794,015)	(107,815,252)
Total stockholders' equity	101,795,649	19,025,136
Total liabilities and stockholders' equity	$ 110,263,320	$ 29,500,834

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

Tyme Technologies, Inc. and Subsidiaries
Consolidated Statements of Operations

	Years Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	$ 17,031,474	$ 12,955,879
General and administrative (including $517,000 and $447,000 of related party legal expenses, respectively)	10,185,537	12,804,493
Total operating expenses	27,217,011	25,760,372
Loss from operations	(27,217,011)	(25,760,372)
Other income (expense):		
Change in fair value of warrant liability	(3,915,393)	3,644,601
Gain on warrant exchange	2,228,697	—
Interest income	22,077	229,458
Interest expense	(97,133)	(114,243)
Total other income (expenses)	(1,761,752)	3,759,816
Loss before income taxes	(28,978,763)	(22,000,556)
Net loss	$ (28,978,763)	$ (22,000,556)
Basic and diluted loss per common share	$ (0.22)	$ (0.19)
Basic and diluted weighted average shares outstanding	134,250,722	114,533,102

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

Tyme Technologies, Inc. and Subsidiaries
Consolidated Statements of Stockholders' Equity
For the Years Ended March 31, 2021 and 2020

	Common Stock		Additional Paid-in capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance, March 31, 2019	103,946,048	$ 10,397	$ 95,472,181	$ (85,814,696)	$ 9,667,882
Issuance of common stock from underwritten registered offering, net of associated expenses of $111,227 and warrants of $7,283,601	8,000,000	800	3,884,372	—	3,885,172
Cashless exercise of warrants	4,889	—	—	—	—
Issuance of common stock from at-the-market financing facility, net of associated expenses of $221,103	1,361,315	136	1,529,110	—	1,529,246
Issuance of common stock from securities purchase agreement, net of associated expenses of $142,281	10,000,000	1,000	19,856,719	—	19,857,719
Stock based compensation	—	—	6,085,673	—	6,085,673
Net loss	—	—	—	(22,000,556)	(22,000,556)
Balance, March 31, 2020	123,312,252	$ 12,333	$ 126,828,055	$ (107,815,252)	$ 19,025,136
Issuance of common stock from securities purchase agreement, net of associated expenses of $6,228,135	40,000,000	4,000	93,767,865	—	93,771,865
Issuance of common stock from at-the-market financing facility, net of associated expenses of $318,425	4,453,939	445	5,774,973	—	5,775,418
Proceeds from the exercise of stock options	2,028,203	203	5,351,120	—	5,351,323
Warrant to share exchange	2,406,250	241	3,393,534	—	3,393,775
Stock based compensation	—	—	3,456,895	—	3,456,895
Net loss	—	—	—	(28,978,763)	(28,978,763)
Balance, March 31, 2021	172,200,644	$ 17,222	$ 238,572,442	$ (136,794,015)	$ 101,795,649

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

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

	Years Ended, March 31	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (28,978,763)	$ (22,000,556)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	5,181	5,182
Amortization of employees, directors and consultants stock options	3,456,895	6,085,673
Change in fair value of warrant liability	3,915,393	(3,644,601)
Gain on warrant exchange	(2,228,697)	—
Change in operating assets and liabilities:		
Prepaid clinical costs	144,528	195,172
Prepaid expenses and other assets	(171,021)	538,073
Operating lease right-of-use asset	150,269	297,596
Accounts payable and other current liabilities	1,015,088	(865,006)
Severance payable	(58,896)	(428,242)
Accrued bonuses	(760,269)	305,731
Operating lease liability	(54,186)	(49,333)
Net cash used in operating activities	(23,564,478)	(19,560,311)
Cash flows from investing activities:		
Net cash used in investing activities	—	—
Cash flows from financing activities:		
Insurance note payments	(518,124)	(597,339)
Proceeds from registered offerings, net of issuance costs	99,547,283	32,555,738
Proceeds from exercise of stock options	5,351,323	—
Net cash provided by financing activities	104,380,482	31,958,399
Net increase in cash	80,816,004	12,398,088
Cash and cash equivalents — beginning of year	26,700,416	14,302,328
Cash and cash equivalents — end of year	$ 107,516,420	$ 26,700,416
Supplemental Cash Flow Information:		
Cash paid for interest and income taxes are as follows:		
Interest	$ 97,133	$ 114,243
Income taxes	$ —	$ —
Noncash investing and financing activities:		
Financing of insurance premiums	$ —	$ 518,124
Cashless exchange of April 2019 Warrants to purchase 5,833,333 shares of common stock for 2,406,250 shares in May 2020.	$ —	$ —
Cashless exchange of April 2019 Warrants to purchase 2,166,667 shares of common stock for May 2020 Warrant to purchase the same number of shares common stock.	$ —	$ —
Cashless exercise of 78,431 warrants for 4,889 shares in 2020	$ —	$ —
Operating lease right-of-use asset obtained in exchange for lease liabilities	$ 75,439	$ —

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

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

Note 1. Nature of Business

Tyme Technologies, Inc. is a Delaware corporation headquartered in Bedminster, New Jersey, with a wholly owned subsidiary, Tyme Inc. (together, "TYME" or the "Company"). The majority of the Company's research, development and other business activities are 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. TYME's therapeutic approach is designed to take advantage of a cancer cell's innate metabolic requirements to cause cancer cell death.
The Company's lead clinical CMBT compound, SM-88, is an oral investigational modified proprietary tyrosine derivative that is hypothesized to interrupt the metabolic processes of cancer cells by breaking down the cells' key defenses and leading to cell death through oxidative stress and exposure to the body's natural immune system. Clinical trial data have shown that SM-88 has achieved confirmed tumor responses across 15 different cancers, both solid and liquid tumors, including pancreatic, lung, breast, prostate, sarcoma and lymphoma cancers with minimal drug-related serious Grade 3 or higher adverse events, which the Company believes is rare for investigational compounds.

Ongoing Studies

The Company has partnered with Pancreatic Cancer Action Network ("PanCAN") to study SM-88 in an adaptive randomized Phase II/III trial with registration intent known as Precision Promise℠. The objective of Precision Promise is to expedite the study and approval of promising therapies for pancreatic cancer by bringing multiple stakeholders together, including academic, industry and regulatory entities. In this trial which began in early 2020, SM-88 with the conditioning agents methoxalen, phenytoin, and sirolimus ("MPS") is being studied as monotherapy treatment arm for patients who have failed one prior line of chemotherapy. PanCAN is sponsoring Precision Promise and providing funding and other support. While TYME's SM-88 is included in the trial, we do not oversee, conduct or control the trial.

In early 2020, the open-label Phase 2 investigator sponsored trial of SM-88 therapy in sarcoma, HoPES, opened. This trial has two cohorts each expecting to enroll 12 patients. The first is SM-88 with MPS as salvage treatment in patients with mixed rare sarcomas, and the other is SM-88 with MPS as maintenance treatment for patients with metastatic Ewing's sarcoma who had not progressed on prior therapy. The primary objectives are to measure ORR and PFS. Secondary objectives include duration of response, OS, CBR using RECIST, and incidence of treatment-emergent adverse events. The Joseph Ahmed Foundation is providing funding and patient support for this trial and the trial is being conducted by principal investigator Dr. Chawla at the Sarcoma Oncology Center in Santa Monica, CA.

We also recently announced an agreement with Georgetown University to support a Phase II trial, OASIS, for SM-88 in patients with metastatic breast cancer who have hormone receptor positive ("HR+") and human epidermal growth factor receptor 2 negative ("HER2-") disease ("HR+/HER2-"). This represents approximately 73% of the annual breast cancer diagnosis in the US each year.

The OASIS trial is an investigator-initiated prospective open-label Phase II trial evaluating the efficacy and safety of SM-88 with MPS for the treatment of metastatic hormone-receptor positive, HER2- breast cancer after treatment with a CDK4/6 inhibitor. This trial is designed as a two-stage trial, enrolling up to 50 patients to receive SM-88 with MPS without additional therapies in patients who have failed or progressed after receiving two hormonal agents and a CDK4/6 inhibitor. The primary endpoint of this trial is ORR, with secondary endpoints including duration of response ("DOR"), clinical benefit rate ("CBR") at >24 weeks, progression free survival ("PFS"), and safety. The trial will be conducted at Georgetown University at a total of five sites within the Georgetown/MEDSTAR system located in Washington DC, Maryland, and New Jersey. Patient enrollment is expected to begin in the third quarter of calendar year 2021.

In calendar year 2019, the Company presented final SM-88 prostate Phase II clinical data showing encouraging clinical benefit in patients with bio-marker recurrent prostate cancer, with the final results published in the peer-reviewed journal, *Investigational New Drugs*, on September 13, 2020.

Preclinical Pipeline Programs

TYME-19 is an oral synthetically produced member of the bile acid family that is being developed for the potential treatment of COVID-19. From the Company's metabolic understanding of bile acids, it was able to identify TYME-19 as a well characterized candidate and a potential treatment of corona viruses. A patent has been issued for TYME-19 for the treatment of COVID-19.

Bile acids can cellular modulate lipid and glucose metabolism and can remediate dysregulated protein folding, each that are relevant to viral infection of a host cell. Existing literature has shown that certain bile acids can have antiviral properties in a range of different viruses, including prior corona viruses.

Our initial preclinical in vitro experiments displayed effectiveness against COVID-19 infection and replication, and we continue to conduct additional tests to support the potential utility of TYME-19 in the treatment of COVID-19 and disease variants. With the ever-changing dynamics of this disease area, the company's intent with this program is to prepare this agent for clinical testing, while learning from the ongoing work in an effort to identify an optimal clinical setting where TYME-19 could potentially offer clinical benefits, and for which there may be a sustainable market.

TYME-18 is a pre-clinical CMBT compound under development that is delivered intratumorally. TYME-18 is a combination of a proprietary surfactant system and natural sulfonic/bile acid that is designed to disrupt energy metabolism and have lytic function for potential treatment of inoperable tumors. TYME-18 is distinct in composition from SM-88. However, like SM-88, it aims to enhance the susceptibility of a cancer to the highly acidic and toxic tumor microenvironment, while minimizing the impact to normal tissues. In initial preclinical xenograft mouse studies, TYME-18 was able to completely resolve over 90 percent (11 of 12 mice) of established colorectal tumors within 12 days versus an average of over 600 percent growth in the control animals.

TYME-18 is currently in preclinical development, and as with TYME-19, we expect at the proper time, to identify a potential partner with a focus on surgical oncology to assist in the ongoing development of TYME-18.

Discontinuing Programs

TYME-88-PANC (Part 2) (third-line Metastatic Pancreatic Cancer)

In fiscal year 2020, we launched our pivotal study for SM-88 in the third-line treatment of pancreatic cancer through an amendment to our ongoing TYME-88-Panc trial (Part 2), with the first patient dosed in the third quarter of the fiscal year. As described previously, the COVID-19 pandemic significantly impacted enrollment of this trial such that it appears it is likely to complete enrollment in a similar timeline to the second-line Precision Promise pancreatic cancer trial. There has also been a higher than expected dropout of patients randomized to the chemotherapy control arm, which could potentially impact the interpretative and regulatory utility of the data.

Following a comprehensive strategic review, considering, in part, the timeline and regulatory utility for this trial compared to the parallel Precision Promise trial and concentration of investment in this specific cancer, management concluded that it would be best to focus on the second-line Precision Promise trial that offers treatment options to patients earlier in their disease. Furthermore, the trial includes tumor biopsy and biomarker analyses that aligns with the Company's overall strategic focus to identifying patients with the best chance of benefit from our therapies.

Therefore, the Company has decided to stop enrollment and begin the process of closing down the trial. Patients currently on therapy will be allowed to continue treatment until progression or unacceptable toxicity. The closing of this trial may require several months to complete, with anticipated close out costs to be $2 million to $3 million.

Liquidity

The consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has historically funded its operations primarily through equity offerings.

In February 2021, the Company raised $100 million in gross proceeds through a registered direct offering of 40,000,000 shares of its common stock, at a purchase price of $2.50 per share. The Company incurred $6.2 million of related costs which offset such proceeds.

On January 7, 2020, the Company entered into a Securities Purchase Agreement with Eagle Pharmaceuticals, ("Eagle"), pursuant to which the Company raised $20,000,000 through the issuance and sale to Eagle of 10,000,000 shares of common stock, at a price of $2.00 per share.

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

On October 18, 2019, TYME entered into an Open Market Sale Agreement℠ (the "Sale Agreement") with Jefferies LLC ("Jefferies") as sales agent, pursuant to which the Company may, from time to time, sell shares of Common Stock through Jefferies having an aggregate offering price of up to $30.0 million (the "Jefferies ATM"). In the year ended March 31, 2021, the Company raised approximately $6.1 million in aggregate gross proceeds before commissions and expenses through the Sale Agreement and paid commissions and expenses of $0.3 million. In the year ended March 31, 2020, the Company raised approximately $1.7 million in aggregate gross proceeds before commissions and expenses through the Sale Agreement and paid commissions and expenses of $0.2 million. At March 31, 2021, there remained approximately $22.2 million of availability to sell shares through the Jefferies ATM.

The proceeds of the aforementioned offerings are being used by the Company for continued clinical studies, drug commercialization and development activities and other general corporate and operating expenses.

For the year ended March 31, 2021, the Company had negative cash flow from operations of $23.6 million and net loss of $29.0 million, which included non-cash expenses of $3.9 million related to the change in fair value of warrant liability and $3.5 million non-cash equity compensation, partially offset by non-cash gain on warrant exchange of $2.2 million. As of March 31, 2021, the Company had working capital of approximately $104.0 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 financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Significant Accounting Policies

Principles of Consolidation

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

Risks and Uncertainties

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

Current Economic Conditions

In March 2020, the World Health Organization categorized the novel coronavirus (COVID-19) as a pandemic and the President of the United States declared the COVID-19 outbreak a national emergency. The COVID-19 pandemic, and actions taken by governments and others to reduce its spread, including travel restrictions, shutdowns of businesses deemed non-essential, and stay-at-home or similar orders, has negatively impacted the global economy, financial markets, and the Company's industry and has disrupted day-to-day life and business operations. Even as certain restrictions have been lifted, new processes implemented and vaccines are distributed and administered, the Company believes that the current economic conditions are likely to continue to have a negative impact for the foreseeable future, and the extent to which they may impact the Company's operations, liquidity and financial condition remains uncertain and may be significant.

Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of expenses during the reporting period. Significant items subject to such estimation include the calculation of the stock-based compensation and warrant valuation. Actual results could differ from such estimates.

Cash and Cash Equivalents

The Company considers all highly-liquid investments that have maturities of three months or less when acquired to be cash equivalents. At March 31, 2021 and 2020, the Company did not have any cash equivalents. The Company's cash and cash equivalents consisted of $107.5 million at March 31, 2021 and $26.7 million at March 31, 2020.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentration of credit risk consist primarily of cash. Cash is deposited with major banks and, at times, such balances with any one financial institution may be in excess of FDIC insurance limits. The Company exceeded the FDIC limit of $250,000 by $107.3 million at March 31, 2021 and $26.4 million at March 31, 2020. Although the Company has exceeded the federally insured limit, it has not incurred losses related to these deposits. Management monitors the Company's accounts with these institutions to minimize credit risk.

In the first quarter of fiscal year 2022, the Company established an investment policy and invested in a portfolio of highly liquid investments and marketable securities. The primary objectives of the Company's policy are to preserve capital and diversify risk, while maintaining sufficient liquidity to meet cash flow requirements.

Fair Value of Financial Instruments

The Company records certain financial assets and liabilities at fair value in accordance with the provisions of ASC Topic 820, Fair Value Measurements and Disclosures. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

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

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

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

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

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

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

An adjustment to the pricing method used within either Level 1 or Level 2 inputs could generate a fair value measurement that effectively falls in a lower level in the hierarchy.

The carrying amounts of the Company's financial instruments, including cash, accounts payable and other current liabilities approximates fair value given their short-term nature. The fair value of the severance payable approximates the carrying value, which represents the present value of future severance payments. The fair value of warrant liability is discussed in Note 7.

Prepaid Expenses and Other Current Assets

Prepaid expenses represent expenditures made in advance of when the economic benefit of the cost will be realized, and which will be expensed in future periods with the passage of time. Prepaid expenses and other current assets includes $1.0 million and $0.8 million of prepaid insurance as of March 31, 2021 and 2020, respectively.

Property and Equipment, Net

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

Impairment of Long-Lived Assets

The Company assesses the recoverability of its long-lived assets, which include fixed assets and operating lease right of use assets, whenever significant events or changes in circumstances indicate impairment may have occurred. If indicators of impairment exist, projected future undiscounted cash flows associated with the asset are compared to its carrying amount to determine whether the asset's value is recoverable. Any resulting impairment is recorded as a reduction in the carrying value of the related asset in excess of fair value and a charge to operating results. For the years ended March 31, 2021 and 2020, the Company determined that there were no triggering events requiring an impairment analysis.

Research and Development

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

Income Taxes

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

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

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

The calculation of tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations in various jurisdictions. ASC 740 "Income Taxes" states that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits. When and if the Company were to recognize interest and penalties related to unrecognized tax benefits, they would be reported in tax expense.

Segment Information

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

Derivative Warrant Liability

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

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

Basic and Diluted Loss Per Share

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

Stock-based Compensation

The Company follows the authoritative guidance for accounting for stock-based compensation in ASC 718, Compensation-Stock Compensation. The guidance requires that stock-based payment transactions be recognized in the financial statements based on their fair value at the grant date and recognized as compensation expense over the vesting period as services are being provided. (See Note 13, Equity Incentive Plan.)

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected term of the option, risk-free interest rates, the value of the common stock and expected dividend yield of the common stock. For awards subject to time-based vesting conditions, the Company recognizes stock-based compensation expense equal to the grant date fair value of stock options on a straight-line basis over the requisite service period, which is generally the vesting term. The Company accounts for forfeitures as they occur. The Company adopted ASU 2018-07 and, as such, the fair value options granted to non-employees is estimated at the date of grant only.

Recently Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which modifies the disclosure requirements on fair value in Topic 820. Under this ASU, certain disclosure requirements for fair value measurements are eliminated, amended or added. The guidance is effective for the Company's fiscal year and interim periods within those fiscal years beginning after December 15, 2019. The Company has adopted ASU 2018-13 using a prospective method effective April 1, 2020. The adoption of this ASU did not have a material effect on the Company's financial statements and related disclosures. See Note 7.

Recent Accounting Pronouncements Not Yet Adopted

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), as part as part of its overall simplification initiative to reduce costs and complexity of applying accounting standards while maintaining or improving the usefulness of the information provided to users of financial statements. Amendments include removal of certain exceptions to the general principles of ASC 740, *Income Taxes* and simplification in several other areas such as accounting for a franchise tax (or similar tax) that is partially based on income. ASU 2019-12 is effective for public business entities for annual reporting periods beginning after December 15, 2020, and interim periods within those reporting periods. The Company does not expect the adoption of this standard to have a material impact on its consolidated financial statements and disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13") and has since modified the standard with several ASUs (collectively, "Topic 326"). Topic 326 requires companies to present a financial asset (or a group of financial assets) measured at amortized cost and available for sale debt securities net of the amounts expected to be collected. Currently, U.S. GAAP delays recognition of the full amount of credit losses until the loss is probable of occurring. Under this ASU, the income statement will reflect an entity's current estimate of all expected credit losses. The measurement of expected credit losses will be based upon historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down of the security. Early adoption is permitted. The guidance is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company adopted the pronouncement as of April 1, 2021 and the adoption of this standard did not have a material impact on its consolidated financial statements and disclosures.

In August 2020, the FASB issued ASU No. 2020-06, Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40). ASU No. 2020-06 eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, the new guidance modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted earnings per share ("EPS") computation.

The amendments in ASU No. 2020-06 are effective for public business entities that meet the definition of an SEC filer, excluding entities eligible to be smaller reporting companies as defined by the SEC, for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. FASB also specified that an entity should adopt the guidance as of the beginning of its annual fiscal year and is not permitted to adopt the guidance in an interim period. The Company adopted the pronouncement as of April 1, 2021 and the adoption of this standard did not have a material impact on its consolidated financial statements and disclosures.

Note 3. Net Loss Per Common Share.

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

	Year Ended March 31,	
	2021	**2020**
Basic and diluted net loss per common share calculation		
Net loss	$ (28,978,763)	$ (22,000,556)
Weighted average common shares outstanding — basic and diluted	134,250,722	114,533,102
Net loss per share of common stock — basic and diluted	$ (0.22)	$ (0.19)

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

Warrants issued in April 2019, discussed further in Note 9, 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 were, when outstanding, considered to participate with common stock in the earnings of the Company and, therefore, the Company calculates basic and diluted EPS using the two-class method. Under the two-class method, net income for the period is allocated between common stockholders and participating securities according to dividends declared and participation rights in undistributed earnings. No income was allocated to the warrants for the year ended March 31, 2021 and 2020 as results of operations was a loss for these periods. In May 2020, these warrants were all exchanged for Common Stock or new warrants without such participation rights and are no longer outstanding (see Note 9).

The following outstanding securities at March 31, 2021 and 2020 have been excluded from the computation of diluted weighted average shares outstanding, as they would have been anti-dilutive:

	Year Ended March 31,	
	2021	2020
Stock options	12,588,068	11,815,982
Warrants	3,104,318	8,937,651
Total	15,692,386	20,753,633

Note 4. Property and Equipment, Net.

Property and equipment, net consisted of the following:

	March 31, 2021	March 31, 2020
Machinery and equipment	$ 37,007	$ 37,007
Less: accumulated depreciation	37,007	31,826
	$ -	$ 5,181

Depreciation expense was $5,181 and $5,182 for the years ended March 31, 2021 and 2020, respectively.

Note 5. Accounts Payable and Other Current Liabilities.

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

	March 31, 2021	March 31, 2020
Legal	$ 454,139	$ 199,671
Consultant and professional services	176,957	109,504
Accounting and auditing	55,349	118,837
Research and development	2,657,202	1,863,355
Board of Directors and Scientific Advisory Board Compensation	435,594	484,750
Other	63,149	51,185
	$ 3,842,390	$ 2,827,302

Note 6. Severance Payable.

In April 2021, the Company entered into a Separation and General Release Agreement related to the separation of employment of its Chief Medical Officer as of March 31, 2021. The agreement provides for separation benefits which the Company recorded as severance expense for the year ended March 31, 2021. On March 15, 2019 the Company entered into a Release Agreement related to the separation of employment of their Chief Operating Officer, which 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 aggregate severance liability payable was $1.6 million as of March 31, 2021 and March 31, 2020.

Note 7. Fair Value Measurements.

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

The Company had no material re-measurements of fair value with respect to financial assets and liabilities, during the periods presented, other than those assets and liabilities that are measured at fair value on a recurring basis.

The Company has segregated all financial assets and liabilities that are measured at fair value on a recurring basis into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date in the table below. The fair value measurement for the warrants issued in connection with the issuance of Common Stock from the underwritten registered offering that closed on April 2, 2019 (the "April 2019 Warrants") and the warrant issued in conjunction with the Exchange Agreements (see Note 9 for transaction details) (the "May 2020 Warrant") are based on significant inputs not observable in the market and are classified as Level 3 as of March 31, 2021 and March 31, 2020.

The fair value of the April 2019 Warrants was determined using a Monte Carlo simulation model and included significant unobservable inputs including volatility and the probability of fundamental transactions occurring (see Note 9 for further discussion of the issuance of common stock from an underwritten registered offering). The fair value of the May 2020 Warrant was determined using the Black Scholes model and included significant unobservable inputs such as volatility. Both models incorporated several observable assumptions at each valuation date including: the price of the Company's common stock on the date of valuation, the remaining contractual term of the warrant and the risk free interest rate over the term. Transfers are calculated on values as of the transfer date. There were no transfers between Levels 1, 2 and 3 during the years ended March 31, 2021 and March 31, 2020.
The following table details key inputs and assumptions used to estimate the fair value of the May 2020 Warrant as of March 31, 2021 using a Black Sholes model and April 2019 Warrants liability as of March 31, 2020 using the Monte Carlo simulation models:

	May 2020 Warrant	April 2019 Warrants
	March 31, 2021	March 31, 2020
Stock price	$ 1.78	$ 1.10
Volatility	78%	60%
Remaining term (years)	3.01	4.01
Expected dividend yield	—	—
Risk-free rate	0.35%	0.33%

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

Description	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
March 31, 2021				
Warrant liability	$ 1,931,921	—	—	$ 1,931,921
March 31, 2020				
Warrant liability	$ 3,639,000	—	—	$ 3,639,000

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

	March 31, 2021
Beginning balance, March 31, 2020	$ 3,639,000
Change in fair value of April 2019 Warrant liability before May 20, 2020 Warrant Exchange	3,661,000
Less: fair value of April 2019 Warrants as of May 20, 2020	(7,300,000)
Plus: fair value of May 2020 Warrant as of May 20, 2020	1,677,528
Change in fair value of May 2020 Warrant liability from May 20, 2020 to March 31, 2021	254,393
Ending balance, March 2021	$ 1,931,921

Note 8. Debt.

Insurance Note Payable

During the year ended March 31, 2020, the Company entered into a short-term financing arrangement with its insurance carrier related to payment of premium for its Director and Officer liability insurance coverage totaling $0.5 million for the policy year ending on March 18, 2021. As of March 31, 2020, there remained a balance of $0.5 million, recorded to Insurance note payable on the accompanying consolidated balance sheets. The new policy commenced on March 19, 2021 and did not have a similar financing arrangement.

Note 9. Stockholders' Equity.

Preferred Stock

The Company is authorized to issue up to 10,000,000 shares of preferred stock, each with a par value of $0.0001. Shares of Company preferred stock may be issued from time to time in one or more series and/or classes, each of which will have such distinctive designation or title as shall be determined by the Company's Board prior to the issuance of any shares of such series or class. The Company preferred stock will have such voting powers, full or limited or no voting powers and such preferences and relative, participating, optional or other special rights and such qualifications, limitations or restrictions thereof, as shall be stated in such resolution or resolutions providing for the issue of such series or class of Company preferred stock as may be adopted from time to time by the Company's Board prior to the issuance of any shares thereof.

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

Common Stock

Voting

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

Dividends

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

Liquidation

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

April 2019 - Registered Offering

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

As part of the offering, the investors received warrants to purchase up to 8,000,000 shares of the Company's Common Stock at an exercise price of $2.00 per share (the "April 2019 Warrants").

The April 2019 Warrants, prior to the exchange, discussed below, participated with Common Stock on a one-for-one basis for distribution dividends or other assets of the Company.

Exchange Agreements

On May 20, 2020, the Company entered into exchange agreements with holders (the "Holders") of the April 2019 Warrants. The April 2019 Warrants were offered and issued pursuant to the Company's previous shelf registration statement on Form S-3 (File No. 333-211489).

Pursuant to exchange agreements (the "Share Exchange Agreements") with Holders of the April 2019 Warrants to purchase 5,833,333 shares of Common Stock in the aggregate, the Company issued an aggregate of 2,406,250 shares of common stock (the "Exchange Shares") in exchange for such April 2019 Warrants. Concurrently therewith, each such Holder executed and delivered to the Company a leak-out agreement (a "Share Leak-Out Agreement") that contained trading restrictions with respect to the Exchange Shares, which (i) for the first 90 days, prohibit any sales of Exchange Shares, (ii) for the subsequent 90 days, limit sales of Exchange Shares on any day to 2.5% of that day's trading volume of Common Stock, and (iii) prohibit new short positions or short sales on Common Stock for the combined 180 day period.

The Company also entered into an exchange agreement (the "Warrant Exchange Agreement") with another Holder of April 2019 Warrants to purchase 2,166,667 shares of Common Stock in the aggregate. Pursuant to the Warrant Exchange Agreement, the Company issued such Holder a new warrant (the "May 2020 Warrant") to purchase the same number of shares of Common Stock. The May 2020 Warrant has the same expiration date, April 2, 2024, as the April 2019 Warrants, but has an exercise price of $1.80 and does not include the price protection, anti-dilution provisions or other restrictions on Company action from the April 2019 Warrants. Concurrently therewith, such Holder executed and delivered to the Company a leak-out agreement that contained trading restrictions on sales of Common Stock issued upon exercise of the May 2020 Warrant that are substantially similar to the restrictions on Exchange Shares in the Share Leak-Out Agreement, provided that the leak-out restrictions will only apply to the first 893,750 shares of Common Stock issued pursuant to the May 2020 Warrant.

The April 2019 Warrants were remeasured as of May 20, 2020, before the exchange, using the Monte Carlo pricing simulation resulting in a fair value of approximately $7.3 million, and the change in fair value from March 31, 2020 to the fair value before the exchange of approximately $3.7 million expense was recorded as a component of other income (expense) within the consolidated statement of operations for the year ended March 31, 2021. The key assumptions in applying the Monte Carlo simulation model were as follows: $1.70 stock price, 73% volatility, 3.87 years remaining term, 0.28% risk free rate and the probability of fundamental transactions occurring. The change in fair value of the April 2019 Warrants was $3.6 million in income for the year ended March 31, 2020 and recorded as a component of other income (expense) within the consolidated statement of operations.

At May 20, 2020, the fair value of the 2,406,250 shares issued under the Share Exchange Agreements was approximately $3.4 million, which resulted in a gain on exchange of approximately $1.9 million.

The exercise price of the May 2020 Warrant is subject to adjustment upon the occurrence of specific events, including stock dividends, stock splits, combinations and reclassifications of the Company's Common Stock.

The Company determined that the May 2020 Warrant should be recorded as a derivative liability on the consolidated balance sheet due to the May 2020 Warrant's contractual provisions requiring issuance of registered common shares upon exercise. As of the issuance date of May 20, 2020, the May 2020 Warrant was recorded at the fair value of $1.7 million as determined using the Black Scholes model. The change in fair value before and after the exchange of $0.3 million was recorded as a gain on warrant exchange as a component of other income (expense) within the consolidated statement of operations. The key assumptions in applying the Black Scholes model were as follows: $1.64 stock price, 73% volatility, 3.87 years remaining term, 0.27% risk free rate and 7% discount for lack of marketability. The change in fair value of the May 2020 Warrant from May 20, 2020 through March 31, 2021 of $0.3 million expense was recorded as a component of other income (expense) within the condensed consolidated statement of operations.

The following summarizes the common stock warrant activity for the years ended March 31, 2021 and March 31, 2020:

	Warrant Shares of Common Stock	Weighted Average Exercise Price
Outstanding at March 31, 2019	4,499,603	$ 3.42
Granted	8,000,000	2.00
Exercised	(78,431)	3.00
Expired	(3,483,521)	3.00
Outstanding at March 31, 2020	8,937,651	$ 2.31
Granted	2,166,667	1.80
Exchanged	(8,000,000)	2.00
Outstanding at March 31, 2021	**3,104,318**	**$ 2.77**

In May 2020, April 2019 Warrants to purchase 5,833,333 shares of common stock were exchanged on a cashless basis for 2,406,250 shares and April 2019 Warrants to purchase 2,166,667 of common stock were exchanged for a May 2020 Warrant to purchase the same number of shares. During the year ended March 31, 2020. 78,431 warrants were exercised on a cashless basis resulting in the issuance of 4,889 shares.

At March 31, 2021 and March 31, 2020, 3,074,551 and 8,907,884,respectively, of common stock purchase warrants relating to securities purchase agreements were outstanding and exercisable.

Issued	Classification	Warrants Outstanding	Exercise Price	Expiration
December 2015	Equity	446,500	$ 5.00	December 2025
February 2016	Equity	461,384	$ 5.00	February 2026
July 2016	Equity	29,767	$ 5.00	June 2026
April 2019	Liability	2,166,667	$ 1.80	April 2024

At-the-Market Financing Facility

On October 18, 2019, the Company entered into the Sale Agreement with Jefferies, pursuant to which the Company may, from time to time, sell shares of Common Stock, having an aggregate offering price of up to $30 million through Jefferies, as the Company's sales agent (the "Jefferies ATM"). As indicated in an amendment to the Sale Agreement, the shares will be offered and sold by the Company pursuant to its currently effective Registration Statement on Form S-3, as amended (Reg. No. 333-245033). Any sales of Common Stock pursuant to the Sales Agreement will be made by methods deemed to be an "at-the-market offering" as defined in Rule 415 promulgated under the Securities Act. Jefferies will use commercially reasonable efforts to sell the shares from time to time, based on the instructions of the Company. The Company will pay Jefferies a commission rate of three percent (3%) of the gross proceeds from the sales of shares of Common Stock sold pursuant to the Sale Agreement. Under the Sale Agreement, the Company is not required to use the full available amount authorized and it may, by giving notice as specified in the Sale Agreement, terminate the Sale Agreement at any time.

During the year ended March 31, 2021, the Company raised approximately $6.1 million of gross proceeds via sale of 4,453,939 shares of Common Stock under the Jefferies ATM and incurred $0.3 million of related costs which offset the proceeds. During the year ended March 31, 2020, the Company raised approximately $1.7 million in gross proceeds via sale of 1,361,315 shares of Common Stock and incurred $0.2 million of related costs which offset the proceeds. At March 31, 2021, there remained approximately $22.2 million of availability to sell shares through the Jefferies ATM.

Securities Purchase Agreement

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

Registered Direct Offering

On February 8, 2021, the Company closed on its registered direct offering with several healthcare-focused institutional and other institutional investors (the "Purchasers"), pursuant to which the Company sold to the Purchasers, in a registered direct offering, an aggregate of 40,000,000 shares (the "Shares") of common stock, $0.0001 par value per share. The Shares were sold at a purchase price of $2.50 per share for aggregate gross proceeds to the Company of $100 million, prior to deducting placement agent's fees and other offering expenses payable by TYME. The Company incurred $6.2 million of related costs which offset such proceeds. The Shares were offered by the Company pursuant to an effective shelf registration statement on Form S-3, which was originally filed with the Securities and Exchange Commission on August 12, 2020 and was declared effective on September 2, 2020 (Reg. No. 333-245033). H.C. Wainwright & Co. acted as the exclusive placement agent for the offering.

Note 10. Commitments and Contingencies.

Contract Service Providers

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

On April 1, 2020, the Company amended the Clinical Research Funding and Drug Supply Agreement, dated October 9, 2018, with PanCAN, to enroll individuals diagnosed with pancreatic cancer in a platform style clinical research study. Stage 1 of the study was initiated in the fourth quarter of fiscal year 2020. As of March 31, 2021, after taking into consideration amounts already incurred, the remaining expense to the Company for Stage 1, which primarily consists of patient treatment costs, is approximately $4.5 million, subject to enrollment adjustments, and is expected to be incurred over the next one and a half 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 outstanding future contract obligations structured to match clinical supply needs for the Company's ongoing trials and registration activity are approximately $0.7 million and $3.2 million, respectively at March 31, 2021.

Legal Proceedings

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

Note 11. Leases.

The Company has a lease for office space in New Jersey, which expires in February 2023.

Total Company rent expense, including short term rentals, was approximately $165,000 and $313,000 for the years ended March 31, 2021 and 2020, respectively.

Operating lease right-of-use ("ROU") assets and liabilities on the consolidated balance sheet represents the present value of the remaining lease payments over the remaining lease terms. ROU assets also include any initial direct costs incurred and any lease payments made at or before the lease commencement date, less lease incentives received. Payments for additional monthly fees to cover the Company's share of certain facility expenses are not included in operating lease ROU assets and liabilities. The Company used its estimated incremental borrowing rate of 11.0% to calculate the present value of its lease payments, as the implicit rate in the lease was not readily determinable.

As of March 31, 2021, the future minimum lease payments under non-cancellable operating lease agreements for which the Company has recognized operating lease ROU assets and lease liabilities were as follows:

	March 31, 2021
Fiscal year 2022	$ 41,202
Fiscal year 2023	43,164
Total remaining lease payments	84,366
Less: present value adjustment	(8,452)
Total operating lease liabilities	75,914
Less: current portion	(34,658)
Operating lease liabilities, net of current portion	$ 41,256

Note 12. Related Party Transactions.

Legal

Faegre Drinker Biddle & Reath ("Faegre Drinker"), formerly Drinker Biddle & Reath LLP ("DBR"), has provided legal services to the Company. The Company's Chief Legal Officer and Corporate Secretary holds the consulting role "Senior Counsel" with the Faegre Drinker. During the years ended March 31, 2021 and 2020, approximately $0.6 million and $0.9 million (of which $0.1 million and $0.5 million was capitalized into equity), respectively, have been incurred as legal expenses associated with Faegre Drinker, and the Company had approximately $87,000 and $73,000 in accounts payable and accrued expenses payable to Faegre Drinker at March 31, 2021 and March 31, 2020, respectively.

Note 13. Equity Incentive Plan.

On March 5, 2015, the Company's Board adopted and the Company's stockholders approved, the Company's 2015 Equity Incentive Plan (the "2015 Plan"). Awards under the 2015 Plan may include, but need not be limited to, one or more of the following: options, stock appreciation rights, restricted stock, performance grants, stock bonuses, and any other type of award deemed by the administrator to be consistent with the purposes of the 2015 Plan. The exercise price of all options awarded under the 2015 Plan must be no less than 100% of the fair market value of the Company common stock as determined on the date of the grant and have a term of no greater than ten years from the date of grant. In February 2018, the 2015 Plan was amended making available 12.5% of shares of common stock issued and outstanding. As of March 31, 2021, there were 2,485,717 shares available for grant under the 2015 Plan.

On August 23, 2018 the stockholders approved the Amended and Restated 2016 Stock Option Plan for Non-Employee Directors (the "2016 Director Plan"), which: (i) increased the total number of shares of Common Stock authorized and reserved for issuance under the 2016 Director Plan by 2,000,000 shares to 2,750,000 shares: (ii) made "Initial Grants" upon a director's initial appointment to the Board consisting of an immediate stock option grant of 100,000 shares at fair market value; and (iii) made "Annual Grants" for members who continue in service as members of the Board subsequent to each annual meeting of stockholders occurring subsequent to an Initial Grant, an annual stock option grant of 50,000 shares at fair market value. The Initial Grants and Annual Grants have a ten year term, subject to applicable termination or forfeiture provisions, and vest in equal quarterly increments over a one-year period from the date of grant. As of March 31, 2021, there were 889,167 shares available for grant under the 2016 Director Plan.

Stock Options

As of March 31, 2021, and 2020, there was approximately $3.6 million and $4.2 million, respectively, of total unrecognized compensation related to non-vested stock options. The cost is expected to be recognized over the remaining weighted average remaining amortization period of 2.8 years. During the years ended March 31, 2021 and 2020, the Company had stock compensation expense of $3.5 million and $6.1 million, respectively. For the year ended March 31, 2021, stock compensation expense is recognized as $2.1 million in general and administrative expense, $1.4 million in research and development expense. For the year ended March 31, 2020, stock compensation expense recognized was $3.6 million in general and administrative expense and $2.5 million in research and development expense.

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 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 a blend of the Company's expected volatility and those 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 "plain-vanilla" method as allowed under SAB No. 110 and ASU 2018-7.

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

	Year Ended March 31,	
	2021	2020
Risk free interest rate	0.174% - 0.527%	0.304% - 2.38%
Expected volatility	88.02% - 101.67%	71.65% - 78.95%
Expected term	2.8 - 6.1 years	2.5 - 6 years
Dividend yield	0.0%	0.0%

The following is a summary of the activity of the Company's stock options under the 2015 Plan and 2016 Director Plan as of March 31, 2021:

	Number of Options	Weighted Average Exercise Price
Outstanding at March 31, 2020	11,815,982	$ 3.43
Granted	5,568,000	1.24
Exercised	(2,028,203)	2.64
Cancelled/Forfeited	(2,767,711)	1.93
Outstanding at March 31, 2021	12,588,068	2.92
Options exercisable at March 31, 2021	8,232,897	$ 3.77

Weighted-average grant date fair value of options granted during the years ended March 31, 2021 and 2020 was $0.89 and $0.96, respectively.

During the year ended March 31, 2021, holders of options issued under the equity incentive plans exercised their rights to acquire an aggregate of 2,028,203 shares of common stock at a weighted average exercise price of $2.64. The total proceeds to the Company from these option exercises were $5.4 million. There were no option exercises during the year ended March 31, 2020.

	Stock Options Outstanding				Stock Options Vested			
Range of Exercise Price	Number Outstanding at March 31, 2021	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value	Number Vested at March 31, 2021	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value
$0.95 - $8.75	12,588,068	$ 2.92	7.33	$ 3,295,837	8,232,897	$ 3.77	6.46	$ 1,002,042

The intrinsic value calculated as the excess of the market value as of March 31, 2021 over the exercise price of the options is $3.3 million. The market value as of March 31, 2021 was $1.78 as reported by the NASDAQ Capital Market. The total intrinsic value of options exercised during the year ended March 31, 2021 was $1.7 million.

	Options	Weighted Average Grant Date Fair Value Per Share
Non-vested options at March 31, 2020	3,591,507	$ 1.36
Granted	5,568,000	0.89
Vested	(2,920,332)	1.27
Cancelled/Forfeited	(1,884,004)	1.13
Non-vested options at March 31, 2021	4,355,171	$ 0.91

The fair value of options vested during the years ended March 31, 2021 and 2020 was $3.7 million and $6.0 million, respectively.

Note 14. Income Taxes.

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

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

The Company's loss before income taxes was $29.0 million and $22.0 million for the years ended March 31, 2021 and 2020, respectively, and was generated entirely in the United States. Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets are comprised of the following:

	March 31,	
	2021	2020
Net operating loss carryforward	$ 20,123,621	$ 14,562,024
Research and development credit carryforward	1,164,895	1,804,233
Orphan Drug Credit	2,002,559	—
Stock options - NQSOs	5,267,351	5,877,971
Accruals and other temporary differences	595,418	825,696
Gross deferred tax assets	29,153,844	23,069,924
Deferred tax valuation allowance	(29,153,844)	(23,069,924)
Net deferred taxes	$ —	$ —

Based on the Company's history of operating losses since inception and consideration of available positive and negative evidence, the Company has concluded that it is not more likely than not that the benefit of its deferred tax assets will be realized. Accordingly, the Company continues to maintain a full valuation allowance against its net deferred tax assets as of March 31, 2021. The valuation allowance increased by $6.1 million for the year ended March 31, 2021 primarily due to the increase in the net operating loss carryforward and Orphan Drug credit.

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

	Year Ended March 31,	
	2021	2020
U.S. statutory income tax rate	21.00%	21.0%
Permanent differences	(0.02)%	3.30%
Tax credit carryforwards	4.70%	4.40%
Valuation allowance	(20.98)%	(28.70)%
Stock compensation	(3.41)%	—
Warrants	(1.29)%	—
Effective tax rate	—%	—%

As of March 31, 2021, the Company had gross U.S. federal net operating loss carryforwards of approximately $95.8 million, which may be available to offset future income tax liabilities and will begin to expire at various dates starting in 2033. As of March 31, 2021, none of the Company's state net operating losses have value due to the apportionment rule in the states where state income tax returns are currently filed. As permitted under the Protecting Americans Against Tax Hikes Act, which allows the Research and Development tax credit to be applied to Form 941 quarterly payroll tax returns, the Company reduced payroll taxes by $177 thousand and $170 thousand for the years ended March 31, 2021 and March 31, 2020, respectively. As of March 31, 2021, the Company had gross federal research and development tax credit carryforwards of $1.7 million, available to reduce future tax liabilities which will begin to expire at various dates starting in 2030.

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

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

	Year Ended March 31,	
	2021	2020
Gross unrecognized tax benefits at beginning of year	$ 318,394	$ 126,838
Increases (decreases) for tax positions in prior period	(99,063)	70,293
Increase for tax positions in current period	339,631	121,263
Gross unrecognized tax benefits at end of year	$ 558,962	$ 318,394

As of March 31, 2021, the Company had $559,000 of unrecognized tax benefits, which were offset with the net operating loss and valuation allowance on the consolidated balance sheets. None of the gross unrecognized tax benefits would affect the effective tax rate at March 31, 2021, if recognized. In addition, the Company did not record any penalties or interest related to uncertain tax positions for the periods presented in these consolidated financial statements. The Company does not have any positions for which it is reasonably possible that there will be significant increase or decrease in the amounts of unrecognized tax benefits within twelve months of the reporting date.

The Company files income tax returns in the United States, and various state jurisdictions. The federal and state income tax returns are generally subject to tax examinations for the period January 1, 2017 through March 31, 2021. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities to the extent utilized in a future period.

Note 15. Subsequent Events.

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

TYME-88-PANC (third-line Metastatic Pancreatic Cancer)

In June 2021, following a comprehensive strategic review, the Company announced that it has decided to stop enrollment of the TYME-88-PANC (third-line Metastatic Pancreatic Cancer) trial, and begin the process of closing down the trial. As previously disclosed, the COVID-19 pandemic significantly impacted enrollment of this trial such that it appears it is likely to complete enrollment in a similar timeline to the second-line Precision Promise pancreatic cancer trial. There has also been a significantly higher than expected dropout of patients randomized to the chemotherapy control arm, which could potentially impact the interpretative and regulatory utility of the data. Patients currently on therapy will be allowed to continue treatment until progression or unacceptable toxicity. The estimated costs to close the trial are $2.0 million to $3.0 million and are expected to extend into fiscal year 2023.

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

There were no disagreements with Grant Thornton LLP.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of the Company that are designed to ensure that information required to be disclosed by the Company in the reports that the Company files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that the Company files or submits under the Exchange Act is accumulated and communicated to the Company's management, including our principal executive and principal financial officer, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer and Principal Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) under the Exchange Act, as of the end of the period covered by this Annual Report on Form 10-K. Based on such evaluation, our Chief Executive Officer and Principal Financial Officer have concluded that as of March 31, 2021, our disclosure controls and procedures were effective.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined under Rule 13a-15(f) under the Exchange Act.

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and the board of directors of the Company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

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

Management assessed the effectiveness of our internal control over financial reporting as of March 31, 2021. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control—Integrated Framework issued in 2013. Based on the evaluation of our internal control over financial reporting as of March 31, 2021, our Chief Executive Officer and Principal Financial Officer concluded that as of such date, our internal control over financial reporting was effective.

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

Changes in Internal Control Over Financial Reporting

There have been no changes in the Company's internal control over financial reporting that occurred during the quarter ended March 31, 2021 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

Directors

Set forth below are the names of and certain information as of June 10, 2021 regarding our Board of Directors:

Name	Age	Position(s) with the Company/Principal Occupation	Date Elected to Our Board of Directors
Steve Hoffman	58	Director, Chief Science Officer of the Company	March 5, 2015*
Dr. Gerald Sokol	78	Director/Chief of Radiation Oncology, University of South Florida's Tampa General Hospital	March 10, 2015
Timothy C. Tyson	69	Director/Chairman and Chief Executive Officer, TriRx Pharmaceutical Services LLC	March 10, 2015
Paul Sturman	60	Director/Chief Executive Officer, Nature's Bounty Co.	March 2, 2017
David Carberry	68	Director/Former Chief Financial Officer of Excellis Health Solutions, LLC (Retired)	March 30, 2017
Donald W. DeGolyer	60	Director/Former Chief Executive Officer, Vertice Pharma LLC	May 24, 2018
Douglas A. Michels	64	Director/Former President and CEO OraSure Technologies	October 1, 2018
Richard Cunningham	50	Director, Chief Executive Officer of the Company	November 24, 2020

* Mr. Hoffman served as director of Tyme, Inc. (or Tyme, our subsidiary) since its formation on July 26, 2013 and served as director of the Company since the completion of a merger on March 5, 2015 whereby we acquired our current clinical-stage pharmaceutical business.

Executive Officers

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

Other Information

Other information required by this Item 10 is incorporated by reference to, and will be contained in, our definitive proxy statement, which will be filed within 120 days after March 31, 2021.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 is incorporated by reference to, and will be contained in, our definitive proxy statement, which will be filed within 120 days after March 31, 2021.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item 12 is incorporated by reference to, and will be contained in, our definitive proxy statement, which will be filed within 120 days after March 31, 2021.

The following table provides certain information with respect to all of our equity compensation plans in effect as of March 31, 2021:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights		Weighted Average Exercise Price	Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (3)
Equity compensation plans approved by stockholders prior to March 31, 2021	12,588,068	(1)	$ 2.92	3,374,884
Equity compensation plans not approved by stockholders prior to March 31, 2021	29,767	(2)	$ 5.00	—
Total Equity	12,617,835		$ 2.92	3,374,884

(1) Includes 12,588,068 shares of our common stock issuable under option awards made prior to March 31, 2021 under our 2015 Equity Incentive Plan and our 2016 Director Plan, each approved by stockholders; these option awards carry a weighted average exercise price of $2.92 per share. For a description of the terms of the 2015 Equity Incentive Plan and 2016 Director Plan, please see Note 13 to the consolidated financial statements presented elsewhere herein.

(2) Includes 29,767 shares of our common stock issuable upon the exercise of certain warrants to purchase common stock as of March 31, 2021 at a weighted average exercise price $5.00 per share; the warrants described in this sentence are limited to warrants issued in return for goods or services provided and do not include warrants issued in connection with capital raising transactions, consistent with applicable SEC disclosure obligations.

(3) Includes 3,374,884 shares of our common stock issuable under awards eligible to be made (and not outstanding) as of March 31, 2021 under our 2015 Equity Incentive Plan and 2016 Director Plan.

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

The information required by this Item 13 is incorporated by reference to, and will be contained in, our definitive proxy statement, which will be filed within 120 days after March 31, 2021.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item 13 is incorporated by reference to, and will be contained in, our definitive proxy statement, which will be filed within 120 days after March 31, 2021.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) DOCUMENTS FILED AS PART OF THIS REPORT

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

1. FINANCIAL STATEMENTS AND SUPPLEMENTAL DATA

(b) EXHIBITS

See Exhibit Index.

ITEM 16. FORM 10-K SUMMARY

Omitted at the company's option.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Tyme Technologies, Inc. (Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K, filed with the SEC on September 19, 2014.)
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Tyme Technologies, Inc., effective April 2, 2018 (Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K, filed with the SEC on April 2, 2018.)
3.3	Certificate of Designation of Series A Convertible Preferred Stock, dated January 7, 2020. (Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K, filed with the SEC on January 8, 2020.)
3.4	Amended and Restated By-Laws of Tyme Technologies, Inc., effective April 2, 2018. (Incorporated by reference to Exhibit 3.2 to our Current Report on Form 8-K, filed with the SEC on April 2, 2018.)
4.1	Form of Warrant Certificate, dated as of February 2, 2016. (Incorporated by reference to Exhibit A to the Form of Securities Purchase Agreement, dated as of February 2, 2016, filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on February 8, 2016.)
4.2	Form of Warrant Certificate, dated as of December 18, 2015, between Tyme Technologies, Inc. and the purchaser parties thereto. (Incorporated by reference to Exhibit A to the Form of Securities Purchase Agreement, dated as of December 18, 2015, filed as Exhibit 99.1 to our Current Report on Form 8-K, filed with the SEC on December 30, 2015.)
4.3	Registration Rights Agreement, dated January 7, 2020, between the Company and Eagle. (Incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K, filed with the SEC on January 8, 2020.)
4.4	Form of New Warrant, dated May 20, 2020. (Incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K, filed with the SEC on May 20, 2020.)
4.5	Description of Common Stock, dated as of June 12, 2019. (Incorporated by reference to Exhibit 4.6 to our Annual Report on Form 10-K, filed with the SEC on June 12, 2019.)
10.1	License Agreement, dated as of July 9, 2014, between Steven Hoffman and Tyme Inc. (Incorporated by reference to Exhibit 10.11 to our Current Report on Form 8-K, filed with the SEC on March 11, 2015.)
10.2	Open Market Sale Agreement, dated as of October 18, 2019, by and between Tyme Technologies, Inc. and Jefferies LLC. (Incorporated by reference to Exhibit 1.1 to our Current Report on Form 8-K, filed with the SEC on October 18, 2019.)
10.3	Amendment No. 1, dated August 12, 2020, to the Open Market Sale Agreement, dated as of October 18, 2019, by and between Tyme Technologies, Inc. and Jefferies LLC. (Incorporated by reference to Exhibit 1.2 to our Current Report on Form 8-K, filed with the SEC on August 12, 2020.)
10.4†	2015 Equity Incentive Plan of Tyme Technologies, Inc. (Incorporated by reference to Exhibit 10.8 to our Current Report on Form 8-K, filed with the SEC on March 11, 2015.)
10.5†	Amendment No. 1 to the Tyme Technologies, Inc. 2015 Incentive Plan, effective May 6, 2016. (Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q, filed with the SEC on August 9, 2016.)
10.6†	Amendment No. 2 to the Tyme Technologies, Inc. 2015 Incentive Plan, effective February 5, 2018. (Incorporated by reference to Exhibit 99.1 to our Current Report on Form 8-K, filed with the SEC on April 2, 2018.)

10.7†	Form of Nonqualified Stock Option Agreement under the Tyme Technologies, Inc. 2015 Equity Incentive Plan. (Incorporated by reference to Exhibit 99.3 to our Current Report on Form 8-K, filed with the SEC on April 2, 2018.)
10.8†	Form of Amendment to Nonqualified Stock Option Agreement under the Tyme Technologies, Inc. 2015 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.6 to our Quarterly Report on Form 10-Q, filed with the SEC on July 31, 2018.)
10.9†	Form of Stock Option Agreement under the Tyme Technologies, Inc. 2015 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.7 to our Quarterly Report on Form 10-Q, filed with the SEC on July 31, 2018.)
10.10†	Amended and Restated 2016 Stock Option Plan for Non-Employee Directors, effective May 24, 2018. (Incorporated by reference to Exhibit 99.1 to our Current Report on Form 8-K, filed with the SEC on May 29, 2018.)
10.11†	Form of Contingent Nonqualified Stock Option Agreement under the Tyme Technologies, Inc. 2016 Stock Option Plan for Non-Employee Directors. (Incorporated by reference to Exhibit 99.2 to our Current Report on Form 8-K, filed with the SEC on May 29, 2018.)
10.12†	Form of Nonqualified Stock Option Agreement under the Tyme Technologies, Inc. 2016 Stock Option Plan for Non-Employee Directors. (Incorporated by reference to Exhibit 10.11 to our Annual Report on Form 10-K, filed with the SEC on June 12, 2019.)
10.13†	Employment Agreement, dated as of March 5, 2015, between Tyme Technologies, Inc. and Michael Demurjian. (Incorporated by reference to Exhibit 10.13 to our Current Report on Form 8-K, filed with the SEC on March 11, 2015.)
10.14†	Release Agreement, dated as of March 15, 2019, between Tyme Technologies, Inc. and Michael Demurjian. (Incorporated by reference to Exhibit 10.14 to our Annual Report on Form 10-K, filed with the SEC on June 12, 2019.)
10.15†	Letter Agreement, dated as of September 10, 2018, between Tyme Technologies, Inc. and James Biehl, (Incorporated by reference to Exhibit 10.19 to our Annual Report on Form 10-K, filed with the SEC on June 12, 2019.)
10.16†	Letter Agreement, dated November 24, 2020, by and between Richard Cunningham and Tyme Technologies, Inc. (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q filed with the SEC on February 3, 2021.)****
10.17†	Letter Agreement, dated November 24, 2020, by and between Steve Hoffman and Tyme Technologies, Inc. (Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q filed with the SEC on February 3, 2021.)****
10.18†*	Separation and General Release Agreement, effective March 31, 2021, by and between Giuseppe Del Priore and Tyme Technologies, Inc.
10.19†	Securities Purchase Agreement, dated January 7, 2020, between the Company and Eagle Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on January 8, 2020.)***
10.20†	Co-Promotion Agreement with Eagle Pharmaceuticals, Inc., dated January 7, 2020. (Incorporated by reference to Exhibit 10.20 to our Annual Report on Form 10-K, filed with the SEC on May 22, 2020.)
10.21	Form of Share Exchange Agreement, dated May 20, 2020. (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on May 20, 2020.)
10.22	Form of Warrant Exchange Agreement, dated May 20, 2020. (Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K, filed with the SEC on May 20, 2020.)

10.23	Form of Share Leak-Out Agreement, dated May 20, 2020. (Incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K, filed with the SEC on May 20, 2020.)
10.24	Form of Warrant Leak-Out Agreement, dated May 20, 2020. (Incorporated by reference to Exhibit 10.4 to our Current Report on Form 8-K, filed with the SEC on May 20, 2020.)
10.25	Form of Securities Purchase Agreement, dated February 4, 2021. (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on February 5, 2021.)
21.1*	List of Subsidiaries.
23.1*	Consent of Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (Included in Signature Page of Form 10-K).
31.1*	Rule 13(a)-14(a)/15(d)-14(a) Certification of Principal Executive Officer.
31.2*	Rule 13(a)-14(a)/15(d)-14(a) Certifications of Principal Financial Officer.
32.1**	Rule 1350 Certifications.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Schema Document.
101.CAL*	XBRL Calculation Linkbase Document.
101.DEF*	XBRL Definition Linkbase Document.
101.LAB*	XBRL Label Linkbase Document.
101.PRE*	XBRL Presentation Linkbase Document.

† Management contract or compensatory plan or arrangement
* Filed herewith
** Furnished herewith
*** Certain exhibits have been omitted and the Company agrees to furnish supplementally to the SEC a copy of any omitted exhibits upon request.
**** The personal addresses of the counterparties has been redacted from each of these exhibits.

SIGNATURES

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

Dated: June 10, 2021

TYME TECHNOLOGIES, INC.

By: /s/ Richard Cunningham
Richard Cunningham
Chief Executive Officer
(Principal Executive Officer)

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

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

Signature	Title	Date
/s/ Richard Cunningham Richard Cunningham	Chief Executive Officer and Director (Principal Executive Officer)	June 10, 2021
/s/ Barbara C. Galaini Barbara C. Galaini	Corporate Controller (Principal Financial and Accounting Officer)	June 10, 2021
/s/ Steve Hoffman Steve Hoffman	Chief Science Officer and Director	June 10, 2021
/s/ Gerald Sokol Gerald Sokol	Director	June 10, 2021
/s/ Paul L. Sturman Paul L. Sturman	Director	June 10, 2021
/s/ David Carberry David Carberry	Director	June 10, 2021
/s/ Timothy C. Tyson Timothy C. Tyson	Director	June 10, 2021
/s/ Douglas A. Michels Douglas A. Michels	Director	June 10, 2021
/s/ Donald W. DeGolyer Donald W. DeGolyer	Director	June 10, 2021

EXHIBIT 10.18

C O N F I D E N T I A L

SEPARATION AND GENERAL RELEASE AGREEMENT

This SEPARATION AND GENERAL RELEASE AGREEMENT ("Agreement") is made and entered into by and between Tyme Technologies, Inc. (the "Company") and Giuseppe Del Priore ("Employee"). Employee and the Company shall be referred to herein as the "Parties" or, each separately, a "Party."

WHEREAS, Employee is employed by the Company;

WHEREAS, the Parties have agreed that Employee's employment with the Company shall end on the Separation Date (as defined below); and

WHEREAS, Employee and the Company wish to agree on matters relating to the end of Employee's employment with the Company, on the terms set forth herein.

NOW, THEREFORE, for good and valuable consideration, receipt of which is hereby acknowledged, and fully intending to be legally bound hereby, Employee and the Company AGREE as follows:

1. Separation Date. Employee's employment with the Company shall permanently and irrevocably conclude as of March 31, 2021 (the "Separation Date"). As of the Separation Date, Employee shall be deemed to have relinquished and resigned from all titles and positions of any nature that Employee holds or has ever held with the Company, its affiliates and subsidiaries, or any other entity with respect to which the Company has requested Employee to perform services, to the extent Employee ever held such titles and positions. Employee will be paid all compensation due with respect to the pay period that includes the Separation Date in the same manner as Employee's salary was paid prior to the Separation Date.

2. Separation Benefits. In consideration of this Agreement, if Employee signs this Agreement within the 14-day consideration period described in Section 16 below, and provided that Employee does not breach this Agreement, the Company shall provide the following separation benefits:

a. The Company shall provide, as severance pay, three hundred eighteen thousand, seven-hundred and fifty dollars ($318,750) (the "Severance Payment"), paid in installments over a period of nine (9) months (the "Severance Period") at the same times and in the same manner as Employee's base salary was paid prior to the Separation Date. Notwithstanding the foregoing, in no event shall the Company commence making the Severance Payment prior to Employee's execution of this Agreement. Any missed installments of the Severance Payment shall be made on the first pay date that occurs at least five business days after Employee's execution of this Agreement. You agree that the additional compensation to be paid under this Agreement is due solely from the Company and that Insperity has no obligation to pay the additional compensation, even though the payment may be processed through Insperity.

b. Provided that Employee timely elects to continue his (and, to the extent applicable, his spouse and dependents') participation in the health plan in which Employee participated prior to the Separation Date pursuant to the Consolidated Omnibus Budget Reconciliation Act ("COBRA Coverage"), the Company will, during the Severance Period, continue to pay the portion of Employee's premium cost for health insurance benefits at the same rate as for active employees of the Company (such monthly Company premium contribution amount, the "Company Contribution Amount"). Following the end of the Severance Period, Employee may continue to participate in the Company's health plan as permitted by the terms of that plan and applicable law; provided, however, that any such continued participation shall be at Employee's sole cost. Notwithstanding the foregoing, in the event that Employee becomes covered under another employer's group health plan before the end of the Severance Period, the Company shall have no obligation to pay the Company Contribution Amount during the period that Employee is covered.

3. Return of Documents and Things.

a. Within five days after the complete execution of this agreement, Employee shall send to the Company any and all Company property, records, papers, emails, documents and writings, in whatever form (including electronic form), in Employee's possession, custody, or control, including all such materials contained on Employee's personal phone, laptop, computer and other electronic devices. Employee understands and agrees that the Company may inspect Employee's personal electronic devices for the purposes of obtaining and removing any Company property contained thereon, and upon the Company's written request he agrees to provide same to the Company.

b. To return Company property that is in electronic form (including all Company documents and materials stored on Employee's personal devices), the Company will provide a secure file transfer link for Employee's use. To return any other Company property in physical form, please request a shipping label from Barbara Galaini at the Company.

4. Representations and Warranties. Employee acknowledges, represents and warrants that, other than the payments described in Section 2 above, Employee has received payment in full of all of the compensation, benefits and/or payments of any kind due to Employee from the Company and its affiliates and subsidiaries (or any of them), including all wages, bonuses, equity, stock options, expense reimbursements, payments to benefit plans, and any other payment under a plan, program, practice, promise, or arrangement of the Company and its subsidiaries and affiliates. Employee understands and agrees that, except as provided herein, Employee is not entitled to any additional compensation or benefits from the Company or any of the other Released Parties (as defined below), including severance or separation payments.

5. Release.

a. In consideration of the promises contained herein and intending to be legally bound, Employee, for Employee, Employee's heirs, executors, administrators, successors, assigns, and legal and personal representatives, hereby unconditionally and irrevocably remises, releases, and forever discharges the Company and Insperity PEO Services, L.P. ("Insperity"); each of their subsidiaries, investors, and any other affiliated or related entities; and each of all such entities' respective current and former officers, directors, shareholders, benefit plans, members, agents, employees, and attorneys
(collectively, the "Released Parties") from any and all claims, causes of action, liabilities, obligations, controversies, damages, lawsuits, debts, demands, costs, charges and/or expenses (including attorneys' fees and costs) of any nature whatsoever, asserted or unasserted, known or unknown, suspected or unsuspected, that Employee ever had, now has or hereafter may have against the Company, Insperity or any of the other Released Parties that arose at any time regarding any matter up to and including the date Employee executes this Agreement. Without in any way limiting the generality of the foregoing, Employee specifically acknowledges and agrees that the claims released herein include, to the maximum extent permitted by law, (i) all discrimination, retaliation, whistleblower, and wrongful termination claims; (ii) all claims arising under any federal, state or local statute, ordinance, or regulation, including but not limited to the Age Discrimination in Employment Act, as amended by the Older Workers Benefit Protection Act, the Americans with Disabilities Act, the Family and Medical Leave Act, Title VII of the Civil Rights Act, the Employee Retirement Income Security Act, the New York State Human Rights Law, the New York State Labor Law (including but not limited to payment of wages, discrimination, retaliation, and failure to comply with the New York State Worker Adjustment and Retraining Notification Act), Section 125 of New York's Workers' Compensation Law, the New York State Civil Rights Law, and the New York State Corrections Law, the New York City Human Rights Law, and the New York City Earned Safe and Sick Time Act, and any other employee-protective law of any jurisdiction that may apply, each as amended; (iii) all claims arising under any agreement or contract ; (iv) all claims arising under any common law, including any claims for breach of any implied or express contract, wrongful discharge, constructive discharge, defamation, unjust enrichment, or negligent or intentional infliction of emotional distress; and (v) all claims arising out of or relating in any way to Employee's employment with the Released Parties, the termination of that employment, Employee's compensation arrangements or equity holdings, and all attorneys' fees and costs. Notwithstanding the foregoing, Employee does not release the Released Parties from any claims that may arise
(x) under this Agreement or (y) after the date of Employee's execution of this Agreement.

b. Subject to Section 17 below, Employee agrees to the fullest extent permitted by law that neither Employee nor any person or entity on Employee's behalf shall commence, maintain or prosecute any lawsuit, complaint, action or proceeding of any kind against the Released Parties with respect to any claim or potential claim that is released by Sections 5(a) above.

6. No Other Claims or Proceedings. Employee warrants, covenants, and represents that Employee has not heretofore assigned or transferred or purported to assign or transfer to any person any of the claims released in this Agreement. Employee also warrants, covenants, and represents that, as of the date of Employee's execution of this Agreement, neither Employee nor anyone acting on Employee's behalf has made or filed any lawsuit, complaint, charge, action or proceeding against any Released Party with any federal, state, or local court, agency or authority, or any other regulatory authority.

7. Non-Disparagement. Employee confirms that, subject to Section 17 below, Employee shall not, at any time in the future, disparage or otherwise make statements, electronic, oral or written, that would adversely affect the reputation of the Company or any of the other Released Parties, including to actual or potential customers of the Company or its affiliates, Company vendors or other business partners, the press, or on social media. Notwithstanding the foregoing, this Section shall not prohibit Employee from making truthful statements as required by applicable law (e.g., in response to a subpoena or where otherwise compelled to testify).

8. Confidentiality. Except as otherwise required by applicable law and subject to Section 17 below, Employee shall keep the existence and terms of this Agreement strictly confidential, and Employee shall not disclose the terms or any information concerning this Agreement to any person or entity, except that Employee may disclose the terms of this Agreement to Employee's immediate family members and Employee's current or future attorneys, accountants, tax advisors, and outplacement counselors (if any), each of whom shall have first agreed to be bound by this confidentiality provision.

9. Confidentiality of Business Information. Employee acknowledges and agrees that, during Employee's employment with the Company, Employee had access to and became acquainted with Confidential Information (as defined below). Employee covenants and agrees that Employee will not at any time, except as required by law (*e.g.*, in response to a lawful subpoena or order of a court of competent jurisdiction), directly or indirectly, use, disclose to any third party, or make available to any third party any Confidential Information. "Confidential Information" means all of the confidential, trade secret, and proprietary information of the Company, including but not limited to know-how, ideas, business plans, pricing information, the identity of and any information concerning customers and suppliers, scientific information and data, production methods and sources, marketing and sales information, information received from others that any member of the Company is obligated to treat as confidential, and any other technical, operating, clinical, financial and other business information that has commercial value, relating to any member of the Company, its business, potential business, operations or finances, or the business of the Company's customers, which Employee has acquired or developed knowledge of in the course of Employee's dealing with the Company.

10. Non-Solicitation. Employee agrees that for twelve (12) months following the Separation Date, Employee shall not, directly or indirectly, alone or in combination with any other firm, partnership, company, corporation or person, (a) employ, offer employment to, or otherwise attempt to hire, as an employee, consultant, independent contractor or otherwise, any individual who is employed or engaged by the Company or had been engaged or employed by the Company during the immediately prior three months (or assist any other individual or entity to take any such action); (b) solicit, persuade or encourage any individual who is employed or

engaged by the Company to terminate Employee's employment with or engagement by the Company (or assist any other individual or entity to take any such action); (c) solicit or attempt to solicit competitive business from, or any competitive business relationship with, any client, investor or strategic partner of the Company with whom Employee had contact, or about which Employee had Confidential Information, during and because of Employee's employment with the Company; or (d) otherwise adversely influence or alter, or attempt to adversely influence or alter any relationship between the Company and any client, investor or strategic partner of the Company, as applicable.

11. Breach. Upon Employee's breach of this Agreement, including Sections 3 (return of documents and things), 4 (representations and warranties), 7 (non-disparagement), 8 (confidentiality), 9 (confidentiality of business information), 10 (non-solicitation), or 13 (cooperation), in addition to such other remedies as may be available at law or in equity, (a) the Company shall be entitled to cease immediately, without further obligation, providing the Severance Payment, to the extent not yet completed, and (b) Employee shall repay the Company the full amount of those portions of the Severance Payment already provided to Employee, in all cases with this Agreement otherwise remaining in full force and effect.

12. Non-Admission. Employee agrees that the payments made and other consideration received pursuant to this Agreement are not to be construed as an admission of legal liability by the Company and that no person or entity shall utilize this Agreement or the consideration received pursuant to this Agreement as evidence of any admission of liability or obligation.

13. Cooperation. At all times in the future, Employee shall cooperate with the Company in any administrative or other matters with which Employee was involved while employed by the Company, and in any internal investigation, administrative, regulatory or judicial proceeding or any dispute with a third party. Employee's cooperation may include being available to the Company upon reasonable notice for interviews and factual investigations, appearing at the Company's request to give testimony without requiring service of a subpoena or other legal process, volunteering to the Company pertinent information, and turning over to the Company all relevant documents which are or may come into Employee's possession. Employee understands that in the event the Company asks for Employee's cooperation in accordance with this provision, the Company will reimburse Employee for reasonable expenses incurred by Employee in providing such cooperation.

14. Taxes. All payments referenced in this Agreement shall be less all tax and other authorized deductions and withholdings, and the Company shall have the power to withhold from (and thereby reduce) any payments due to Employee under this Agreement.

15. Knowing and Voluntary Waiver. Employee acknowledges that Employee has carefully reviewed this Agreement and that Employee enters into it knowingly and voluntarily. Employee understands and acknowledges that the release provided in this Agreement is in exchange for consideration that is in addition to anything to which Employee is already entitled and that, by this Section, the Company has advised Employee to consult with an attorney of
Employee's choosing prior to executing this Agreement. Employee acknowledges that neither the Company, Insperity, their affiliates and subsidiaries, nor any of their employees,

representatives or attorneys have made any representations or promises concerning the terms or effects of this Agreement other than those contained herein.

16. Consideration Period. Employee acknowledges that Employee has been given a period of at least 14 days within which to consider the Agreement, and the Parties agree that any changes to any prior draft of this Agreement, whether material or immaterial, have not re-started the running of this period.

17. Non-Interference. For clarity, the Company confirms that nothing in this Agreement – including in the Confidentiality, Non-Disparagement, and Release Sections – is intended to prevent, impede or interfere with Employee's right, without notice to the Company, to (a) file a charge or complaint with any agency which enforces anti-discrimination, workplace safety, securities, or other laws; (b) communicate with, cooperate with or provide truthful information to any governmental agency, or participate in any government investigation; (c) testify truthfully in any court or administrative proceeding; or (d) receive and retain any monetary award from a government administered whistleblower award program for providing information directly to a government agency. However, Employee understands that by signing this Agreement, Employee has waived any and all rights to recover any money from the Company or any other Released Parties, other than the Severance Payment and other benefits described in Section 2 above.

18. Options. With respect to Employee's outstanding stock options to acquire shares of capital stock in or issued by the Company (the "Options"), Employee acknowledges and agrees that the terms of Employee's Nonqualified Option Agreement by and between Employee and the Company (the "Option Agreement") and the Company's 2015 Equity Incentive Plan (the "Equity Plan") shall govern the treatment of such Options. For the avoidance of doubt, any Options that are unvested as of the Separation Date shall be immediately forfeited as of the Separation Date, and Employee's rights in such unvested Options shall thereupon lapse and expire.

19. Interpretation and Governing Law. This Agreement will be governed by and construed according to the laws of the State of New Jersey. The Parties irrevocably hereby submit to the exclusive jurisdiction and venue of the state and federal courts located within New Jersey in any action or proceeding brought with respect to or in connection with this Agreement. Each Party hereby waives any objection based on forum non conveniens and waives any objection to venue of any action instituted hereunder in such courts.

20. Headings/Counterparts. The headings of the sections in this Agreement are for convenience only and shall not be deemed to control or affect the meaning or construction of any of the provisions of this Agreement. This Agreement may be executed in two or more counterparts, and facsimile or emailed signature pages shall be treated the same as those with original signatures.

21. Entire Agreement; Amendments. This Agreement constitutes the entire agreement between Employee and the Company with respect to the subject matter hereof, and they supersede all prior or contemporaneous agreements or understandings; provided, however that all post-separation obligations applicable to Employee, including as set forth in the Equity

Plan, the Option Agreement remain in full force and effect. Amendments to this Agreement shall not be effective unless they are in writing signed by Employee and the Chief Executive Officer of the Company. No waiver by any Party at any time of any breach by the other Party shall be deemed a waiver of similar or dissimilar provisions or conditions at the same or at any prior or subsequent time. No waiver of any provision of this Agreement shall be implied from any course of dealing between or among the Parties or from any failure by any Party to assert its rights hereunder on any occasion or series of occasions.

BY SIGNING THIS AGREEMENT, GIUSEPPE DEL PRIORE ACKNOWLEDGES THAT HE DOES SO VOLUNTARILY AFTER CAREFULLY READING AND FULLY UNDERSTANDING EACH PROVISION AND ALL OF THE EFFECTS OF THIS AGREEMENT, WHICH INCLUDES A RELEASE OF KNOWN AND UNKNOWN CLAIMS AND RESTRICTS FUTURE LEGAL ACTION AGAINST TYME TECHNOLOGIES, INC AND OTHER RELEASED PARTIES.

IN WITNESS WHEREOF, and intending to be legally bound hereby, the Parties have executed this Agreement.

GIUSEPPE DEL PRIORE	**TYME TECHNOLOGIES, INC.**
/s/ Giuseppe Del Priore/ Date: 4/12/2021	By:/s/ Richard Cunningham/ Date: 4/12/2021 Name: Richard Cunningham Title: CEO

EXHIBIT 21.1

List of Subsidiaries

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

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated June 10, 2021, with respect to the consolidated financial statements included in the Annual Report of Tyme Technologies, Inc. on Form 10-K for the year ended March 31, 2021. We consent to the incorporation by reference of said report in the Registration Statements of Tyme Technologies, Inc. on Forms S-3 (File No. 333-229104 and No. 333-245033) and on Forms S-8 (File No. 333-219856, No. 333-227077, No. 333-236259, and No. 333-255253).

/s/ Grant Thornton LLP
New York, New York

June 10, 2021

EXHIBIT 31.1

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

I, Richard Cunningham, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: June 10, 2021

/s/ Richard Cunningham

Richard Cunningham
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

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

I, Barbara Galaini, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: June 10, 2021

/s/ Barbara Galaini

Barbara Galaini
Corporate Controller
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 32.1

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

In connection with the Annual Report on Form 10-K of Tyme Technologies, Inc. (the "Company") for the twelve-month period ended March 31, 2021, to which this certification is being filed as of the date hereof as an exhibit thereto (the "Report"), I, Richard Cunningham, Chief Executive Officer of the Company, and I, Barbara Galaini, Corporate Controller of the Company, each certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(a) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (15 U.S.C. 78m or 78*o*(d)); and

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

Date: June 10, 2021

/s/ Richard Cunningham
Richard Cunningham
Chief Executive Officer
(Principal Executive Officer)

/s/ Barbara Galaini
Barbara Galaini
Corporate Controller
(Principal Financial Officer and Principal Accounting Officer)

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