

**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, 2022
- 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 (I.R.S. Employer  
Incorporation or Organization) 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 effectiveness 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 \$153,482,658.

The number of shares outstanding of the registrant's common stock on May 20, 2022 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 2022 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 potential strategic options (and the Company’s exploration thereof) and statements regarding our drug candidates and technologies (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, 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 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 product candidates; 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 strategic initiatives; 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 Company’s process to evaluate strategic options; the terms, timing, structure, benefits and costs of any strategic transaction and whether any transaction will be consummated at all; the impact of any strategic transaction on the Company; the outcomes of any litigation, regulatory proceedings, inquiries or investigations to which the Company may be subject; the ability to obtain financing or third-party approvals for a transaction as needed; the severity, duration, and economic impact of the COVID-19 pandemic; our ability to achieve the intended benefits of our strategic initiatives; that certain 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, additional analyses of existing data and results that may lead to a discontinuation of trials; 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 or analyses and may not support further clinical development; and 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; the ability of TYME to maintain compliance with Nasdaq listing standards; 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](http://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

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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 2022 Form 10-K, we have used terms which are defined below:

AE	Adverse event	GMP	Good manufacturing practices
ANDA	Abbreviated New Drug Application	HIPAA	Health Insurance Portability and Accountability Act of 1996
APIs	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	HHS	United States Department of Health and Human Services
CARES	Coronavirus Aid, Relief, and Economic Security	IEC	Independent Ethics Committee
CBR	Clinical benefit rate	IND	Investigational New Drug
CCPA	California Consumer Privacy Act	IIT	Investigator Initiated Trial
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.	IP	Intellectual Property
cGMP	Current good manufacturing practice	IRB	Institutional Review Board
CMBTs	Cancer metabolism-based therapies	KOLs	Key opinion leaders
CMC	Chemistry, manufacturing and controls	LLC	Limited Liability Company
CMOs	Contract Manufacturing Organizations	MAA	Marketing Authorization Application
CMS	Centers for Medicare & Medicaid Services	MOA	Mechanism of action
COSO	Committee of Sponsoring Organizations of the Treadway Commission	mOS	Median overall survival
CR	Complete responses	mPDAC	Metastatic pancreatic ductal adenocarcinoma
CRO	Contract/Clinical Research Organization	MPS	Methoxsalen, phenytoin, and sirolimus
CT	Computerized Tomography	M2PS	Melanin, melanotan II, phenytoin, and sirolimus
CTC	Circulating Tumor Cell	NDA	New Drug Application
DCR	Disease control rate	NOL	Net Operating Loss
DMC	Data Monitoring Committee	ORR	Objective response rate
DO1	Division of Oncology 1	OS	Overall Survival
DO2	Division of Oncology 2	PanCAN	Pancreatic Cancer Action Network
DOR	Duration of response	PCAOB	Public Company Accounting Oversight Board
DSMB	Data Safety Monitoring Board	PFS	Progression free survival
ECOG PS	Eastern Cooperative Oncology Group Performance Status	PHSA	Public Health Service Act
EEA	European Economic Area	PI	Principal Investigator
EMA	European Medicines Agency	PR	Partial responses
EORTC	European Organisation for Research and Treatment of Cancer	PSA	Prostate specific antigen

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EPS	Earnings Per Share	R&D	Research and Development
ESG	Environmental, social and governance	RCT	Randomized Clinical Trial
ETASU	Elements to assure safe use	RECIST	Response Evaluation Criteria In Solid Tumors
EU	European Union	REMS	Risk evaluation mitigation strategies
FASB	Financial Accounting Standards Board	rPFS	Radiographic progression-free survival
FCPA	Foreign Corrupt Practices Act	ROU	Right-of-use
FDA	Food and Drug Administration	SAEs	Serious adverse events
FDAMA	Food and Drug Administration Modernization Act of 1997	SD	Stable disease
FDCA	Federal Food, Drug, and Cosmetic Act	SEC	U.S. Security and Exchange Commission
FIH	First in Human	SOX	Sarbanes-Oxley Act of 2002
FTE	Full time equivalent	SPA	Securities Purchase Agreement
GAAP	Generally Accepted Accounting Principles	UK	United Kingdom
GCP	Good clinical practices	US	United States
GDPR	General Data Protection Regulation	USPTO	United States Patent and Trademark Office
GLP	Good laboratory practices		

## 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.
- We may be unable to regain and maintain compliance with Nasdaq continued listing requirements, which could cause our common stock to be delisted from Nasdaq.
- 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 two principal areas. We are currently participating in the advancement of clinical trials for 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.

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- 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 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.
- Our exploration of strategic options may not achieve its intended benefits and could 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.

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## PART I

### ITEM 1. BUSINESS

#### Executive Summary of Our Business

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

The Company is currently focused on developing its novel compound, SM-88, as well as further evaluating its preclinical pipeline of novel CMBTTM programs, and TYME-19 as a potential therapeutic for SARS CoV-2 diseases. The Company believes that early clinical results demonstrated by SM-88 in multiple advanced cancers, including breast, sarcomas, pancreatic, and prostate, reinforce the potential of its emerging CMBT™ pipeline.

#### Exploration of Strategic Options and Diversification

On March 29, 2022, we announced that the Board of Directors of the Company (the "Board") had decided to explore potential strategic options to enhance stockholder value and engaged outside financial and legal advisors to assist with that process.

The Company continues to believe there are additional opportunities that could enhance value for TYME stockholders, notwithstanding its announcement, in January 2022, of the discontinuation of a randomized Phase II/III trial of SM-88 in combination with MPS for patients with metastatic pancreatic cancer, the most advanced clinical trial studying SM-88, upon learning that the trial sponsor terminated the study arm due to futility. TYME believes that being well-capitalized affords it the ability to consider a wide range of strategic options and is conducting a formal evaluation process with its financial advisor Moelis & Company LLC.

The Strategic Planning Committee of the Board, which is led by TYME Board Member Timothy C. Tyson, who possesses over 35 years of biotechnology and pharmaceutical industry experience, including multiple M&A transactions, is acting as Transaction Committee in connection with this process. There can be no assurance that this process will result in any such transaction. The Company does not undertake any obligation to provide any updates with respect to these matters except as required by applicable law.

#### Our Pipeline

PROGRAM	INDICATION	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
<b>ONCOLOGY</b>					
<b>SM-88</b> Oral	Breast Cancer (HR+/HER2-)				
	Metastatic Sarcomas				
<b>SM-88i</b> Injectable	Multiple Oncology Indications (Alternative Formulation)				
<b>TYME-18</b> Intra-tumoral	Solid Tumors				
<b>TYME-T<sup>3</sup></b> Tumor Targeting Technology	Solid Tumors				
<b>VIRAL</b>					
<b>TYME-19</b> Oral	COVID-19				

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### **Ongoing 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 HR+/HER2-. This represents approximately 68% of the annual breast cancer diagnosis in the US each year. According to estimates from Data Monitor and Syneos Health based on data published in 2020, 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 who have failed or progressed after receiving two hormonal agents and a CDK4/6 inhibitor to receive SM-88 with MPS without additional cancer therapies. The primary endpoint of this trial is ORR, with secondary endpoints including DOR, CBR at >24 weeks, PFS, and safety. The trial is being 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 began in 2021 with the first patient dosed in September. We plan to provide an update on the OASIS breast cancer study during the first half of calendar year 2023.

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 (each discussed below under “Completed Studies”), 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 Phase II Trial in sarcoma

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 that had not progressed on prior therapy. The primary objectives are to measure ORR and PFS. Secondary objectives include DOR, OS, CBR using RECIST, and incidence of treatment-emergent AEs. The Joseph Ahmed Foundation is sponsoring this trial, which is being conducted by Principal Investigator Dr. Chawla at the Sarcoma Oncology Center in Santa Monica, CA. We anticipate that the trial enrollment will continue through the end of calendar year 2022.

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 (each discussed below under “Completed Studies”). 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 13,500 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.

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### Preclinical Pipeline Programs

#### SM-88 MOA and Biomarker Research

The Company has begun a comprehensive translational preclinical program. We have engaged Evotec, a leading global research and development company, to aid in the execution of these activities, and we are also incorporating several complementary academic collaborations into this multi-faceted program. The overall goal of these activities is to potentially identify actionable biomarkers of sensitivity and activity to SM-88 in various cancers, complementary combination drugs strategies for SM-88, and other cancer metabolism targets that could benefit from 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 that it is likely to last through this fiscal year and into future periods.

#### Georgetown Collaboration – Breast Cancer

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 is examining the effects of SM-88 and MPS in various breast cancer models in culture and animal models. The project is exploring 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.

#### Mayo Collaboration – Pancreatic Cancer

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.

#### SM-88 Injectable

TYME has been developing an injectable form of SM-88 as an additional potential administration for the therapy. This formulation is a distinct drug substance to oral SM-88, however the active product is ultimately the same as the oral formulation. The company is working with Evotec to conduct detailed pharmacokinetics and pharmacodynamics of this agent, as well as comprehensive *in vivo* xenograft studies in animals to determine the optimal dosing and composition of the product. These studies will also include detailed computational analysis of transcriptional, biological, and immune related markers from these studies in order to identify potential biomarkers that may aid in the direction of eventual clinical development. We anticipate much of this work to be complete in the calendar year 2022. The company, working with various contractors, has also begun a manufacturing campaign of GMP grade drug product for potential clinical use. We have completed the initial formulation stages of the program and anticipate we would be able to complete this campaign during the first half of calendar year 2023.

#### TYME-18 and TYME-19

TYME-18 is a CMBT<sup>TM</sup> compound under development that is delivered intratumorally. TYME-18 leverages a member of the bile acid family to create a potential treatment for inoperable tumors. Preliminary observations of the local administration of TYME-18, a combination of a proprietary surfactant system and natural sulfonic acid, suggested its potential as an important regulator of energy metabolism that may impede the ability of tumors to increase in size, which, in addition to its lytic functionality, could prove useful in difficult-to-treat cancers. The Company is assessing development priorities to determine if additional advancement of this program is warranted at this time.

TYME-19 is an oral synthetic member of the bile acid family. The Company also uses bile acids in its anti-cancer drug candidate, TYME-18. Because of its expertise in bile acids and their effects, the Company was able to identify TYME-19 as a well-characterized bile acid with potential antiviral properties. Bile acids have primarily been used for liver disease; however, like all steroids, they are messenger molecules that modulate a number of diverse critical cellular processes. Bile acids can modulate lipid and glucose metabolism and can remediate dysregulated protein

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folding, with potentially therapeutic effects on cardiovascular, neurologic, immune, and other metabolic systems. Some agents in this class have also previously shown antiviral properties.

The Company has retained virology experts at Evotec to assess the mechanisms of TYME-19. Evotec is a global drug development company that has the capability to access the multiple existing and emerging variants of the COVID-19 virus. TYME and Evotec are testing the ability of TYME-19 to interrupt the cellular pathways commonly used by viruses to produce viral proteins as well as cellular responses to viral infection that cause local inflammation. Prolonged inflammation from SARS-CoV-2 can lead to some of the severe outcomes experienced by infected patients. We expect the work by Evotec will provide us with information allowing us to assess the potential path forward for the program.

### Tumor Targeting Technology

TYME has developed a technology (“Tumor Targeting Technology”) by which the tyrosine isomer L metyrosine (L- $\alpha$ -methylparatyrosine) can be fused with a second therapeutic agent in a manner that creates a fusion compound that may allow targeted accumulation of the treatment by the cancer cells in a novel manner. The Company is assessing potential development paths for this technology.

### **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 mOS of 29.8 months, median PFS of 13 months, and a 33% ORR. The ORR consisted of four CRs and six PRs, based on RECIST. In addition, 57% of patients (17/30) achieved RECIST 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 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 mOS 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 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 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

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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 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 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.

### TYME-88 Pancreatic Trial Reported Results

In April 2022 we reported on the final results of our TYME-88-Panc trial, a multicenter, prospective open-label phase II/III RCT of oral SM-88 plus methoxsalen, phenytoin, and sirolimus (MPS) in patients with mPDAC who had failed at least one prior line of therapy. (TYME-88-Panc Part 1) Study subjects received either 460 or 920 mg PO daily of SM-88 plus oral MPS. Patients in both arms of the study received the same dose of oral MPS. The primary endpoint of the trial was objective response rate (RECIST 1.1).

On March 12, 2019, the last trial subject was enrolled and as of September 1, 2021, 49 subjects had been randomized to either the 460 (n = 26) or 920 mg (n = 23) dose of SM-88, with 37 subjects deemed evaluable after completing at least one 28-day cycle of treatment and having a minimum of 23 days on treatment. Of the evaluable patients, five had failed one prior line of therapy, 18 patients had failed two prior lines and 14 patients had failed three or more prior lines. Twenty of these patients (54.0%) had received FOLFIRINOX in the first line.

The DCR, OS, and PFS did not differ significantly between the two dose levels. Stable disease was achieved in nine of 37 patients (DCR, 24.3%), and there were no complete or partial responses. In the intent to treat population of 49 patients, the mOS was 3.4 months (95% CI: 2.7- 4.9 months). Those treated in the second line had a mOS of 8.1 months and a median PFS of 3.8 months. Survival was higher for patients with stable disease than those with progressive disease (any line; median OS: 10.6 months compared to 3.9 months;  $p = 0.01$ ).

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Quality of life, as measured by QOL scores as reflected in completed EORTC quality of life questionnaires (the EORTC QLQ-C30 questionnaire) was maintained or improved in 24 of 37 evaluable patients (65%) and trended in favor of the 920 mg SM-88 dose (p=ns). The SM-88 with oral MPS was well tolerated; only a single patient (1/49) experienced related grade 3 and 4 SAEs on treatment, which consisted of Grade 3 abdominal pain and Grade 4 hypotension, each of which eventually resolved.

Although the Company completed and reports the results of Part 1 of this trial, as discussed below under “-Discontinuing Programs - TYME-88-PANC (Part 2) (third-line Metastatic Pancreatic Cancer)”, the Company decided to stop enrollment in this trial and has begun the process of closing down the remaining Part 2 of this trial.

### **Discontinuing Programs**

#### Precision Promise Trial- SM-88 with MPS as 2<sup>nd</sup> line therapy in metastatic pancreatic cancer

In October 2018 the Company partnered with PanCAN to study SM-88 in an adaptive randomized Phase II/III trial with registration intent known as Precision PromiseSM. The objective of Precision Promise is to expedite the study and approval of promising therapies for pancreatic cancer by bringing multiple stakeholders together, including academic, industry and regulatory entities. The trial, began in early 2020, SM-88 (with the conditioning agents MPS) was being studied as monotherapy in a treatment arm for patients who have failed one prior line of chemotherapy.

On January 26, 2022, the Company announced the discontinuation of SM-88 with MPS in the Precision Promise trial in metastatic pancreatic ductal adenocarcinoma (“mPDAC”) upon learning from PanCAN, the trial sponsor, that it terminated the arm due to futility compared to the control of standard of care chemotherapy in second-line mPDAC. Based on the information provided by PanCAN, the OS for SM-88 with MPS in monotherapy was lower compared to standard of care chemotherapies with either Gemcitabine and Abraxane or modified FOLFIRINOX. As of March 31, 2022, remaining estimated costs to close out the trial have been expensed.

#### 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 appeared it was likely to complete enrollment in a similar timeline to the second-line Precision Promise pancreatic cancer trial. There was also a higher than expected dropout of patients randomized to the chemotherapy control arm, which could have potentially impacted the interpretative and regulatory utility of the data.

Following the strategic review discussed above, 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 and includes tumor biopsy and biomarker analyses that align with the Company’s overall strategic focus on identifying targeted therapies.

Therefore, the Company decided to stop enrollment and begin the process of closing down the trial. Patients currently on therapy are allowed to continue treatment until progression or unacceptable toxicity. The closing of this trial is expected to require several months to complete. During the year ended March 31, 2022, the Company expensed \$723,000 of estimated closeout costs. The trial’s remaining ongoing expense to the Company is approximately \$400,000 and is expected to be incurred over the five months following March 31, 2022.

### **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,

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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 and Georgetown University. 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.

### **Portfolio Development Strategy and Key Product Properties**

In the first half of calendar year 2021, the Company undertook a comprehensive strategic review with the goal of aligning the Company's development plans with core strategic goals. Key elements of our strategy to achieve this goal were to:

- **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.**
- **Continue to invest in our technology platform and expand the breadth and depth of our IP portfolio.**
- **Build a balanced portfolio of proprietary and partnered programs.**

By leveraging our confidence in SM-88's ability to disrupt key aspects of cancer's unique metabolism, our intention is to create an innovative therapeutic program with SM-88 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 healthy 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

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- **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.

Some outcomes aimed to be achieved in this pipeline review process were to: 1) assure the current clinical programs were optimally aligned with both the current data for SM-88 and were in areas that were clinically and strategically relevant to the company, 2) identify any key gaps in preclinical or mechanism information that would optimally guide the clinical development of SM-88, and 3) assess the appropriate capital commitment to each of these areas in order to improve the potential to achieve the long-term development and strategic goals of the company. The Company’s current strategy, including ongoing studies, the Preclinical Pipeline Program and diversification efforts, have been developed based on the key takeaways from the strategic review, as well as on subsequent developments.

## **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 fields of cancer and viral infection 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 270 patent applications granted 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, and also a new potential treatment of COVID-19. 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.

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

### **Competition**

Our business strategy is intended to effectively position SM-88 and our pipeline 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 and our pipeline.

## 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 GLP. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product 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

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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 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. Additionally, as with an existing number of previously approved oncology products, the FDA will likely require us

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to educate health care providers and patients about the proper use and administration of our drug candidates and obtain FDA approval to market.

As of March 31, 2022, 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 divisions within the Office of Oncologic Diseases that oversee our ongoing trials, the DO1 and the DO2. 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 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 upon the request of an applicant and based on 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 the 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 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

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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 and social media. Failure to comply with these regulations can result in significant penalties, including the issuance of untitled and 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, may require a 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

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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.

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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 APIs 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 European 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 the 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 registered and inspected manufacturer of this drug. We believe this 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

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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, 2022, we had a total of 13 employees, all full-time and all located in the United States. Of this total workforce, 6 FTE employees were engaged in or directly supported our research and development activities and 7 FTE employees perform general and administrative functions. The roles of certain employees 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.

We are committed to a work environment that is welcoming, inclusive and encouraging, and we believe that we can be at our best when we bring together diverse teams with different perspectives, experiences and ideas. In furtherance of our commitment to diversity and inclusion, and diverse perspectives on our Board and among our employees, our Corporate Governance Guidelines provide that, when evaluating candidates for nominations as new directors, the pool of candidates from which the nominating and governance committee of the Board recommends nominees will include qualified persons who reflect diverse backgrounds, including both underrepresented people of color and different genders, and if any third party search firm is used, it will be specifically instructed to include such candidates.

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.

Throughout the COVID-19 pandemic, many of our employees have worked remotely. In June 2021, our employees returned to the Company's office in-person from time to time while also continuing to work remotely and being permitted to fully "work-from-home" if preferred, and we have relaxed our travel restrictions. For in-office work, we implemented a number of significant safety measures based on current guidelines recommended by the Centers for Disease Control.

### **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

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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](http://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

On October 18, 2019, TYME entered into an Open Market Sale Agreement<sup>SM</sup> (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”). Under the Sale Agreement the minimum share sales price (“Floor Price”) shall not be less than \$1.00 without Jefferies prior written consent. 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. We have not sold any securities pursuant to the Jefferies ATM during fiscal year 2022 or into fiscal year 2023.

#### 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.

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### 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 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.

### 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](http://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](http://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 former Chief Science Officer and current director, owned approximately 12.2% of our outstanding common stock as of March 31, 2022. Additionally, Michael Demurjian, our former Chief Operating Officer, also owned approximately 13.8% of our outstanding common stock as of March 31, 2022. 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.

The Company entered into voting agreements with Messrs. Hoffman and Demurjian on March 24, 2022 and April 18, 2022 respectively. Mr. Hoffman agreed to vote all shares of TYME common stock beneficially owned by him in accordance with the Board's recommendation with respect to any matter presented to the stockholders for a period of one year and Mr. Demurjian agreed to do so for a period of two years from the date of the agreement.

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 agreed that all IP he had developed during his employment with us that related 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 is subject to significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. Some of the factors that may cause the market price of our common stock to fluctuate include, but are not limited to:

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- results and timing of our clinical trials and clinical trials of our competitors' products;
- the failure or discontinuation of clinical trials in which our product candidates are being studied or of any of our development programs;
- limitations on the availability of acceptable-quality clinical supplies 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, capital commitments or strategic reviews;
- 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, military conflicts 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.

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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 \$0.28 to \$2.02 between April 1, 2021 and March 31, 2022, 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, 2022, the average daily trading volume for our common stock was approximately 2,883,757 shares. In addition, the price of our common stock has been volatile. Our common stock had a closing price of \$1.87 on April 1, 2021, and ended fiscal year 2022 at a closing price of \$0.35. During the fiscal year 2022, our common stock had a low closing price of \$0.28, which occurred on March 14, 2022 and March 15, 2022, and had a high closing price of \$1.87, which occurred on April 1, 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.

***We may be unable to regain and maintain compliance with Nasdaq continued listing requirements, which could cause our common stock to be delisted from Nasdaq. This could result in the lack of a market for our common stock, cause a decrease in the value of an investment in us, and adversely affect our business, financial condition, and results of operations.***

Our common stock is currently listed on The Nasdaq Capital Market. To maintain the listing of our common stock on The Nasdaq Capital Market, we are required to meet certain listing requirements, including, among others, a minimum closing bid price of \$1.00 per share. On December 22, 2021, the Company received notice from Nasdaq that the closing bid price for our common stock had been below \$1.00 per share for the previous 30 consecutive business days, and that we are therefore not in compliance with the minimum bid price requirement for continued inclusion on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2) (“Rule 5550(a)(2)”). Nasdaq’s notice has no immediate effect on the listing or trading of our common stock on The Nasdaq Capital Market.

The notice indicates that we will have 180 calendar days, until June 20, 2022, to regain compliance with this requirement. We can regain compliance with the \$1.00 minimum bid listing requirement if the closing bid price of our common stock is at least \$1.00 per share for a minimum of ten (10) consecutive business days during the 180-day compliance period.

If the Company does not regain compliance during the initial compliance period, we may be eligible for an additional 180 day period to regain compliance. To qualify, we would be required to meet the continued listing requirement for market value of our publicly held shares and all other Nasdaq initial listing standards, with the exception of the minimum bid price requirement under Rule 5550(a)(2), and we would need to provide written notice to Nasdaq of our intention to cure the deficiency during the second compliance period. If it appears to Nasdaq that we will not be able to cure the deficiency, or if we are otherwise not eligible, we expect that Nasdaq will notify us that our common stock will be subject to delisting. We will have the right to appeal a determination to delist our common stock, and our common stock would remain listed on The Nasdaq Capital Market until the completion of the appeal process.

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A delisting of our common stock could negatively impact us by, among other things, reducing the liquidity and market price of our common stock and reducing the number of investors willing to hold or acquire shares, which would further restrict our ability to obtain equity financing. A suspension or delisting could also adversely affect our reputation, our relationships with our business partners and suppliers, which would have a material, adverse impact on our business, operating results and financial condition. In addition, a suspension or delisting would impair our ability to raise additional capital through equity or debt financing as well as our ability to attract and retain employees by means of equity compensation.

As of the date hereof, we had not regained compliance with Rule 5550(a)(2). While the Company intends to seek an additional period beyond June 20, 2022 to regain compliance and to regain compliance during such additional compliance period, there can be no assurance that we will be able to do so, or to maintain compliance with any other Nasdaq continued listing requirement.

***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 5,750,000 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

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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 by-laws 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.

Additionally, our by-laws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) will be the exclusive forum for actions or proceedings for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a breach of fiduciary duty owed to the Company or its stockholders; (iii) any action asserting a claim against us arising under the Delaware General Corporation Law, the Company’s certificate of incorporation, or the Company’s by-laws; or (iv) any action asserting a claim against the Company that is governed by the internal affairs doctrine. Our by-laws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended.

***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.*

We continue to monitor the effect of the novel strain of coronavirus, COVID-19, which has spread worldwide and has caused significant disruptions due to the pandemic and efforts to mitigate it. We may continue to experience disruptions because of the COVID-19 pandemic that could impact our business. These disruptions may be made more likely to occur or may be exacerbated the longer the crisis continues:

In particular, 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, data analysis, dissemination of product information and regulatory review 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.

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Although many pandemic-related restrictions have been loosened, COVID-19 continues to evolve and counter measures have also changed and been re-imposed from time to time. Should this continue or should government countermeasures become more restrictive, our business operations, results of operations and financial condition may further be affected as follows:

- The continuation of the coronavirus pandemic may adversely impact our operations and 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.
- Our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our clinical trials and research and development operations, if our third party suppliers are adversely impacted.
- Our business may experience a material economic effect due to the additional work and resource demands for our employees and vendors.
- Our ability to file on a routine and timely basis our periodic reports or other filings under federal securities or other laws and regulations may be adversely impacted.
- Our business may experience a material economic effect. Our ability to access capital either at all or on favorable terms may be reduced. 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. 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. Management will continue to monitor the situation closely and implement business continuity and emergency response plans as needed.

***Our proprietary lead drug product, SM-88, is in clinical development in two principal areas. We are currently participating in the advancement of clinical trials for 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 whether our lead drug candidate for the treatment of cancer, SM-88, will prove safe and effective for use in humans or if it 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 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 an 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;

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- 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 cancers 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 indications for use 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

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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 had experience completing a large-scale or pivotal clinical trial (whether Phase II, III, or otherwise), obtaining marketing approval, manufacturing product on a commercial scale or conducting sales and marketing activities. 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. SM-88 is currently being studied in two investigator-initiated clinical trials, including the Phase II OASIS trial for SM-88 in patients with metastatic HR+/HER2- breast cancer, for which patient enrollment commenced in 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 COVID-19, 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 and Phase II trials for SM-88. We are collaborating with Georgetown University to support a Phase II trial, OASIS, to study effects of SM-88 in breast cancer. SM-88 is also being studied in an open label Phase II investigator-sponsored trial, HoPES, to study SM-88 therapy in sarcoma. 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. For example, we also partnered with PanCAN to study SM-88 in an adaptive randomized Phase II/III trial with registration intent known as Precision Promise. In January 2022, we announced the discontinuation of the Precision Promise trial upon learning that the trial sponsor had discontinued the SM-88 arm due to futility. Should we experience any interruption, delay, or discontinuation of our current trials, 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, which include, but are not limited to the following:

- slower than expected rate of subject recruitment and enrollment;
- slower than projected IRB or IEC review and approval;

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- the DMC or Data Safety Monitoring Board (“DSMB”) 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 PI in one or more of our clinical trials;
- withdrawal of participation by one of our CROs;
- 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.

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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. For example, despite promising results in prior trials in pancreatic cancer, the Phase II/III trial with registrational intent, Precision Promise, was discontinued due to futility in January 2022. 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

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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 proposed labeling or 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 have recently expanded 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. 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 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.

***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

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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 or to the extent required by such regulators, in particular because we are using contract manufacturers.

***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, however, we do not currently have any active clinical trials in 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

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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 can 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 have generally 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 of 2021, introduced in the Senate in March 2021, 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

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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 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.

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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

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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 would expect to contract with external manufacturers to develop a larger scale process for manufacturing SM-88 in parallel with our involvement in any larger-scale trials of SM-88

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should we pursue participation in such trials. 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 worldwide economic and political disruptions including the impacts of military conflict between Russia and Ukraine, and widespread health crises, such as the COVID-19 pandemic, affecting raw material and or intermediate supply or manufacturing capabilities abroad and domestically.
- The manufacturing facilities in which our drug candidates are made could be adversely affected by equipment failures, labor shortages, labor strikes, extreme weather events and other 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.

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- 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 registered and inspected 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 anti-cancer 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 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 anti-cancer 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

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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 generic or biosimilar products if and when they become available.

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 and that 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.

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Adverse results, side effects of 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.

If any of our drug candidates is approved for commercial sale, we will be highly dependent upon consumer perception and the safety, effectiveness 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, 2022, our accumulated deficit was \$160,420,062. 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;

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- 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

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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;
- 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 are also engaged in 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, but the trial sponsor terminated the SM-88 arm of the trial due to futility, as described below under the heading “Discontinued Programs.” 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 are collaborating with Georgetown University to support a 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

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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. Further, 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 or other supply chain disruptions, 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

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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

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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 ANDA filers or may settle such litigation on unfavorable terms;

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- 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**

***Our exploration of strategic options may not achieve its intended benefits and could have a material impact on our business, results of operations and financial condition.***

In early calendar year 2022, we completed a strategic review to evaluate the Company's opportunities and implemented several initiatives related to our clinical trials, resource allocations and development strategy. The Company is currently conducting a formal evaluation process with its financial advisor Moelis & Company LLC. As part of this process, we may consider pursuing strategic options, such as mergers, acquisitions, divestitures, joint ventures, partnerships and collaborations. We cannot be certain when or if any type of transaction will occur. Any strategic option involves risks and uncertainties, and we cannot guarantee that any completed or potential transaction or other strategic option, if identified, evaluated and consummated, will provide greater value to our stockholders than that reflected in our current stock price. In addition, the process of negotiating any corporate transaction could be time-consuming and disruptive, and any transaction would be dependent on a number of factors that are beyond our control, including, among other things, regulatory or other approvals, the availability of financing to potential buyers on reasonable terms, market conditions, industry trends and the interest of third parties in our business. We also could incur substantial expenses associated with identifying and evaluating potential strategic alternatives, including those related to employee retention payments, equity compensation, severance pay and legal, accounting and financial advisory fees. Moreover, this process could divert our resources and require significant management time and attention that would otherwise be available for ongoing development of our business. It also could disrupt our relationships with third-party collaborators, impair our ability to recruit and retain key personnel, increase our costs, and lead to legal disputes in connection with this process or any resulting transaction. Any of these factors could have an adverse effect on our business and financial condition.

***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 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. We do not currently maintain "key person" insurance on any of our executives or employees. While we may, in the future, seek to obtain key person insurance, 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 the insured's services.

Recruiting and retaining qualified scientific, clinical, administrative, operations, manufacturing and sales and marketing personnel will also be critical to our success. An overall tightening and increasingly competitive labor market has been observed in the U.S. employment market generally, especially in response to the COVID-19 pandemic. Specific to the biotechnology industry, there is significant demand and competition for the highly specialized talent that we require. 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,

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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.

Until March 21, 2022, our drug discovery process and development program had been led by Steve Hoffman, our former chief science officer and former chief executive officer. Mr. Hoffman continues to serve as a member of our Board. As chief science officer, he had been instrumental in providing scientific, technical and business expertise. Development of SM-88 will continue without Mr. Hoffman's direct contributions, but future development of SM-88 and all other drug products in our pipeline may be adversely affected without his continued active involvement.

We are highly reliant on our executives, but certain of them, including 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, 2022, we had 13 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, economic and political disruptions including the impacts of military conflict between Russia and Ukraine and other natural or human-caused 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.

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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, such as the current conflict between Ukraine and Russia, 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.

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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 remains 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, 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. The threat of these types of lawsuits is particularly pronounced in the biotechnology and pharmaceuticals industry. 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

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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

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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

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- 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

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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,

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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. On June 17, 2021, the Supreme Court ruled that the plaintiffs (consisting of the state of Texas, as well as other states and individuals) did not have proper standing and accordingly vacated the Fifth Circuit’s decision and instructed the district court to dismiss the case. As a result, the Affordable Care Act will remain in its current form for the foreseeable future, but we cannot predict when, or whether, additional challenges may arise and what the outcome of such challenge may be. The Biden administration has also introduced various measures in 2021 focusing on healthcare and drug pricing. 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. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which, in relevant part, eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug’s average manufacturer price, for single source drugs and innovator multiple source drugs, beginning January 1, 2024. In July 2021, the Biden administration released an executive order entitled, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response, HHS released a “Comprehensive Plan for Addressing High Drug Prices” that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions that HHS can take to advance these principles. In November 2021, President Biden announced the “Prescription Drug Pricing Plan” as part of the Build Back Better Act (H.R. 5376) passed by the House of Representatives on November 19, 2021, which aims to lower prescription drug pricing by, among other things, allowing Medicare to negotiate prices for certain high-price prescription drugs covered under Medicare Part D and Part B after the drugs have been on the market for a certain number of years and imposing tax penalties on drug manufacturers that refuse to negotiate pricing with Medicare or increase drug prices “faster than inflation.” If passed, this bill could have a substantial impact on our business, particularly when we have commercially available products on the U.S. market, if ever.

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,

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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

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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

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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

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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 untitled or 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.

### ***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 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.

Additionally, there continues to be public interest and increased legislative pressure related to public companies' 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. Beginning with our 2022 Proxy Statement, we will be required to publicly disclose consistent, transparent diversity statistics regarding our Board and, in subsequent years, we will be required to have, or disclose why we do not have, a minimum of two diverse board members.

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 May 25, 2022 were:

	Title and Business Experience	Age
Richard Cunningham	Mr. Cunningham has served as Chief Executive Officer since November 2020.	51
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.	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.	48
Barbara C. Galaini	Ms. Galaini has served as our Principal Accounting Officer since August 2018 and our Corporate Controller since April 2018.	64
Frank Porfido	Mr. Porfido has served as our Chief Financial Officer since June 14, 2021.	58
Jan Van Tornout	Mr. Tornout has served as our acting Chief Medical Officer since April 1, 2021.	66

## PART II

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

#### ***Public market for our common stock***

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

The closing price of TYME stock as of May 20, 2022 was \$0.27.

#### **Holders; Shares Outstanding**

We had a total of 172,206,894 shares of our common stock outstanding on May 20, 2022, 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, 2022,” which is incorporated herein by this reference.

#### **Share Repurchases**

During the twelve months ended March 31, 2022, we did not repurchase any shares of common stock.

### **ITEM 6. [RESERVED]**

Not applicable.

**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 CMBTs that are intended to be effective across a broad range of solid tumors and hematologic cancers, while also maintaining patients' quality of life through relatively low toxicity profiles. Unlike targeted therapies that attempt to regulate specific mutations within cancer, the Company's therapeutic approach is designed to take advantage of a cancer cell's innate metabolic requirements to cause cancer cell death through oxidative stress and exposure to the body's natural immune system.

The Company is currently focused on developing its novel compound, SM-88, as well as further evaluating its preclinical pipeline of novel CMBTTM programs, and TYME 19 as a potential therapeutic for SARS Co V-2 diseases. The Company is also exploring options to further diversify its product candidate pipeline. The Company believes that early clinical results demonstrated by SM-88 in multiple advanced cancers, including breast, sarcomas, pancreatic, and prostate, reinforce the potential of our emerging CMBT™ pipeline.

**Exploration of Strategic Options and Diversification**

On March 29, 2022, we announced that the Board of Directors of the Company (the “Board”) had decided to explore potential strategic options to enhance stockholder value and engaged outside financial and legal advisors to assist with that process.

The Company continues to believe there are additional opportunities that could enhance value for TYME stockholders, notwithstanding its announcement, in January 2022, of the discontinuation of a randomized Phase II/III trial of SM-88 in combination with MPS for patients with metastatic pancreatic cancer, the most advanced clinical trial studying SM-88, upon learning that the trial sponsor terminated the study arm due to futility. TYME believes that being well-capitalized affords it the ability to consider a wide range of strategic options and is conducting a formal evaluation process with its financial advisor Moelis & Company LLC.

The Strategic Planning Committee of the Board, which is led by TYME Board Member Timothy C. Tyson, who possesses over 35 years of biotechnology and pharmaceutical industry experience, including multiple M&A transactions, is acting as Transaction Committee in connection with this process. There can be no assurance that this process will result in any such transaction. The Company does not undertake any obligation to provide any updates with respect to these matters except as required by applicable law.

**Strategic Review**

In the first half of calendar year 2021, the Company undertook a comprehensive strategic review with the goal of aligning the Company's development plans with core strategic goals.

The strategic review was extensive and involved internal and external assessments by industry experts, KOLs and advisors with considerable experience in the various areas we sought to probe and explore.

The strategic review process resulted in several key takeaways including, but not limited to:

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- broad activity across 15 cancer types as seen in the First in Human study and Compassionate Use program and confirmation of strong IP portfolio provides us extra development opportunities, for which focus is critical;
- the second-line Precision Promise trial was the priority in pancreatic cancer;
- breast cancer is a priority indication for development as part of pipeline diversification beyond pancreatic cancer;
- there is a need to refine our understanding of the MOA and identify biomarkers to enhance targeting of patient populations; and
- the rapidly changing COVID-19 landscape requires a reevaluation of the market potential and development pathway for TYME-19.

The Company's current strategy, including ongoing studies, the Preclinical Pipeline Programs and diversification efforts, has been developed based on the takeaways from the strategic review, as well as on subsequent developments. Key elements of the Company's strategy include to (i) successfully advance the development of SM-88 across a broad range of cancers, (ii) work towards identifying actionable biomarkers for patient selection or treatment response to SM-88, (iii) continue to invest in our technology platform and expand the breadth and depth of our IP portfolio, and (iv) build a balanced portfolio of proprietary and partnered programs. For more information about our strategy, see Item 1. Business— “Portfolio Development Strategy and Key Product Properties.”

### Ongoing Studies

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

We are collaborating with Georgetown University to support a Phase II trial, OASIS, for SM-88 in patients with metastatic breast cancer who have HR+ and HER2- disease (“HR+/HER2-“). This represents approximately 68% of the annual breast cancer diagnose 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 HR+/ HER2- breast cancer after treatment with a CDK4/6 inhibitor. This trial is designed as a two-stage trial, enrolling up to 50 patients who have failed or progressed after receiving two hormonal agents and a CDK4/6 inhibitor to receive SM-88 with MPS without additional cancer therapies. The primary endpoint of this trial is ORR, with secondary endpoints including DOR, CBR at >24 weeks, PFS, and safety. The trial is being 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 began in 2021 with the first patient dosed in September. We plan to provide an update on the OASIS breast cancer study during the first half of calendar year 2023.

#### HoPES Phase II Trial in sarcoma

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 DOR, OS, CBR using RECIST, and incidence of treatment-emergent AEs. The Joseph Ahmed Foundation is sponsoring this trial, which is being conducted by Principal Investigator Dr. Chawla at the Sarcoma Oncology Center in Santa Monica, CA. We anticipate that the trial enrollment will continue through the end of calendar year 2022.

### Preclinical Pipeline Programs

#### SM-88 MOA and Biomarker Research

The Company has begun a comprehensive translational preclinical program. We have engaged Evotec, a leading global research and development company to aid in the execution of these activities, and we are also incorporating several complementary academic collaborations into this multi-faceted program. The overall goal of these activities is to potentially identify actionable biomarkers of sensitivity and activity to SM-88 in various cancers,

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complementary combination drugs strategies for SM-88, and other cancer metabolism targets that could benefit from 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 that it is likely to last through this fiscal year and into future periods.

### TYME-18 and TYME-19

TYME-18 is a CMBTTM compound under development that is delivered intratumorally. TYME-18 leverages a member of the bile acid family to create a potential treatment for inoperable tumors. Preliminary observations of the local administration of TYME-18, a combination of a proprietary surfactant system and natural sulfonic acid, suggested its potential as an important regulator of energy metabolism that may impede the ability of tumors to increase in size, which, in addition to its lytic functionality, could prove useful in difficult-to-treat cancers. The Company is assessing development priorities to determine if additional advancement of this program is warranted at this time.

TYME-19 is an oral synthetic member of the bile acid family. The Company also uses bile acids in its anti-cancer drug candidate, TYME-18. Because of its expertise in bile acids and their effects, the Company was able to identify TYME-19 as a well-characterized bile acid with potential antiviral properties. Bile acids have primarily been used for liver disease; however, like all steroids, they are messenger molecules that modulate a number of diverse critical cellular processes. Bile acids can modulate lipid and glucose metabolism and can remediate dysregulated protein folding, with potentially therapeutic effects on cardiovascular, neurologic, immune, and other metabolic systems. Some agents in this class have also previously shown antiviral properties. In *in vitro* preclinical testing, TYME-19 prevented COVID-19 viral replication at doses without meaningful cytotoxicity to the treated cells. Previous independent preclinical research has also shown select bile acids may have had broad antiviral activity.

The Company has retained virology experts at Evotec to assess the mechanisms of TYME-19. Evotec is a global drug development company that has the capability to access the multiple existing and emerging variants of the COVID-19 virus. TYME and Evotec are testing the ability of TYME-19 to interrupt the cellular pathways commonly used by viruses to produce viral proteins as well as cellular responses to viral infection that cause local inflammation. Prolonged inflammation from SARS-CoV-2 can lead to some of the severe outcomes experienced by infected patients. We expect the work by Evotec will provide us with information allowing us to assess the potential path forward for the program.

### Tumor Targeting Technology

TYME has developed a technology (“Tumor Targeting Technology”) by which the tyrosine isomer L metyrosine (L- $\alpha$ -methylparatyrosine) can be fused with a second therapeutic agent in a manner that creates a fusion compound that may allow targeted accumulation of the treatment by the cancer cells in a novel manner. The Company is assessing potential development paths for this technology.

### **Discontinuing Programs**

#### Precision Promise Trial- SM-88 with MPS as 2nd line therapy in metastatic pancreatic cancer

In October 2018 the Company partnered with PanCAN to study SM-88 in an adaptive randomized Phase II/III trial with registration intent known as Precision PromiseSM. The objective of Precision Promise is to expedite the study and approval of promising therapies for pancreatic cancer by bringing multiple stakeholders together, including academic, industry and regulatory entities. The trial, began in early 2020, SM-88 (with the conditioning agents MPS) is being studied as monotherapy in a treatment arm for patients who have failed one prior line of chemotherapy.

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On January 26, 2022, the Company announced the discontinuation of SM-88 with MPS in the Precision Promise trial in mPDAC upon learning from PanCAN, the trial sponsor, that it terminated the arm due to futility compared to the control of standard of care chemotherapy in second-line mPDAC. Based on the information provided by PanCAN, the OS for SM-88 with MPS in monotherapy was lower compared to standard of care chemotherapies with either Gemcitabine and Abraxane or modified FOLFIRINOX. As of March 31, 2022, remaining estimated costs to close out the trial have been expensed.

### *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 the strategic review discussed above, 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 which offers treatment options to patients earlier in their disease and includes tumor biopsy and biomarker analyses that aligns with the Company's overall strategic focus on targeted identifying therapies.

Therefore, the Company decided to stop enrollment and begin the process of closing down the trial. Patients currently on therapy are allowed to continue treatment until progression or unacceptable toxicity. The closing of this trial may require several months to complete. During the year ended March 31, 2022, the Company expensed \$723,000 of estimated closeout costs. The trial's remaining ongoing expense to the Company is approximately \$400,000, and is expected to be incurred over the five months following March 31, 2022.

### ***COVID-19 Update***

In March 2020, the World Health Organization categorized 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 continue to closely monitor the impact of COVID-19 on all aspects of our business, our clinical trials, and the safety of patients as the situation continues to evolve. We will continue to work closely with our clinical trial sites during the pandemic and are committed to working with them 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, by continuing to provide a fully "work-from-home" option. Although we have operated in the COVID-19 environment for approximately two years, there remains substantial uncertainty about the extent to which COVID-19 will impact 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 and 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**

#### Nasdaq Notice

On December 22, 2021, the Company received notice from The Nasdaq Stock Market ("Nasdaq") that the closing bid price for our common stock had been below \$1.00 per share for the previous 30 consecutive business days, and

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that we are therefore not in compliance with the minimum bid price requirement for continued inclusion on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2). Nasdaq's notice has no immediate effect on the listing or trading of our common stock. The Company can regain compliance with the \$1.00 minimum bid listing requirement if the closing bid price of our common stock is at least \$1.00 per share for a minimum of ten (10) consecutive business days. We are actively monitoring the minimum bid price of our common stock and are considering available options to regain compliance, including potentially seeking stockholder approval to amend our certificate of incorporation to effectuate a reverse stock split and exploring strategic options, as well as diversification initiatives as described above.

### **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 CROs, 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

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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, 2022, the Company had gross U.S. federal net operating loss carryforwards of approximately \$119.1 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, 2022, the Company had gross federal research and development tax credit carryforwards of \$5.9 million available to reduce future tax liabilities, which will begin to expire at various dates starting in 2030. As of March 31, 2022, 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 \$890,000 and \$559,000 at March 31, 2022 and 2021, 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, 2022. 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, using a blend of the Company's expected volatility and those of similar companies, 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 8, 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.

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

### **Results of Operations**

#### Year ended March 31, 2022 Compared to Year Ended March 31, 2021

Net loss for the year ended March 31, 2022 was \$23,626,000 or \$0.14 per share compared to \$28,979,000 or \$0.22 per share for the year ended March 31, 2021. The decrease in the net loss compared to the prior year was due to the non-cash favorable variance of \$5,722,000 in the change in fair value of the warrant liability and decreased operating costs, offset by \$2,229,000 prior years gain on the warrant exchange. The decrease in operating costs for the current year of \$1,703,000 related to decreased research and development costs of \$3,264,000 and decreased general and administrative costs of \$554,000, partially offset by \$2,115,000 increased severance expenses, explained below under “Operating Expenses.”

Cash used in operating activities for the year ended March 31, 2022 was \$21,243,000 compared to \$23,564,000 for the year ended March 31, 2021. 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 \$22,981,000 or \$0.13 per share for the year ended March 31, 2022 compared to \$23,836,000 or \$0.18 per share for the year ended March 31, 2021. 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, 2022 and March 31, 2021, 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, 2022, operating costs and expenses totaled \$25,514,000, compared to \$27,217,000 for the year ended March 31, 2021, representing a decrease of \$1,703,000. Operating costs and expenses by function were comprised of the following:

- Research and development expenses were \$13,445,000 for the year ended March 31, 2022, compared to \$16,709,000 for the year ended March 31, 2021, representing a decrease of \$3,264,000. 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 expenditures also included costs for pre-clinical studies on SM-88 MOA, biomarker identification and TYME-19. Research and development activities primarily consist of the following:
  - Study and consulting expenses were \$11,022,000 for the year ended March 31, 2022, compared to \$12,637,000 for the year ended March 31, 2021 representing a decrease of \$1,615,000 between the comparable periods. The decrease is mainly attributable to lower ongoing trial costs due to the discontinued TYME-88-Panc Part 2 third-line Metastatic Pancreatic Cancer and Precision Promise trials, partially offset by costs incurred related to the OASIS clinical trial as well as mechanism of action and biomarker preclinical studies.
  - Salary and salary related expenses for research and development personnel were \$1,846,000 for the year ended March 31, 2022, compared to \$2,693,000 for the year ended March 31, 2021, representing a decrease of \$847,000 between comparable periods, primarily due to lower headcount for roles currently outsourced to consultants.
  - Included in research and development expense for the year ended March 31, 2022 is \$577,000 of stock based compensation related to stock options granted to research and development personnel compared to \$1,379,000 for the year ended March 31, 2021,

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representing a decrease of \$802,000 between the comparable periods, primarily attributable to fully vested grants and cancellation/forfeiture of options.

- General and administrative expenses were \$9,632,000 for the year ended March 31, 2022, compared to \$10,186,000 for the year ended March 31, 2021, representing a decrease of \$554,000. The general and administrative expenses include:
  - Stock based compensation related to stock options granted was \$1,875,000 for the year ended March 31, 2022, compared to \$2,078,000 for the year ended March 31, 2021, representing a decrease of \$203,000, primarily attributable to fully vested grants and cancellation/forfeiture of options.
  - Legal, professional services, accounting and auditing expenses for the year ended March 31, 2022, were \$2,668,000, compared to \$3,150,000 for the year ended March 31, 2021, representing a decrease of \$482,000.
  - Salary and salary related expenses for non-research and development personnel were \$3,301,000 for the year ended March 31, 2022, compared to \$3,235,000 for the year ended March 31, 2021, representing an increase of \$66,000 between the comparable periods.
  - Other general and administrative expenses for the year ended March 31, 2022 were \$1,788,000, compared to \$1,723,000 for the year ended March 31, 2021, an increase of \$65,000.
- Severance expense was \$2,437,000 for the year ended March 31, 2022, compared to \$322,000 for the year ended March 31, 2021, representing an increase of \$2,115,000 which primarily represents severance expense attributable to the Release Agreement, dated March 24, 2022, pursuant to which the Chief Science Officer resigned and received a lump sum severance payment of \$2.1 million that would have been payable under his employment agreement. Severance expense for the year ended March 31 2021 included amounts related to the Separation and General Release Agreement entered into with its Chief Medical Officer for separation of employment as of March 31, 2021, classified in salary and salary related expenses for research and development personnel in prior year.

### *Other Income/Expenses*

For the year ended March 31, 2022, the Company had \$1,807,000 non-cash income relating to the change in fair value of the warrant liability during the period compared to \$3,915,000 of non-cash expense for the year ended March 31, 2021, resulting in a \$5,722,000 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, 2022, the Company incurred \$70,000 of interest expense as compared to \$97,000 in the year ended March 31, 2021 primarily related to the amortization of severance payable discount.

Investment and interest income for the year ended March 31, 2022 was \$151,000 as compared to \$22,000 in the year ended March 31, 2021, due to the establishment of our investment portfolio.

### *Income Tax*

Our effective income tax rate for the years ended March 31, 2022 and 2021 was zero percent.

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### *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**

	<b>For the Year Ended March 31,</b>	
	<b>2022</b>	<b>2021</b>
Net loss (GAAP)	\$ (23,626,000)	\$ (28,979,000)
Adjustments:		
Change in fair value of warrant liability	(1,807,000)	3,915,000
Gain on warrant exchange	—	(2,229,000)
Amortization of employees, directors and consultants stock options	2,452,000	3,457,000
Adjusted net loss (non-GAAP)	<u>\$ (22,981,000)</u>	<u>\$ (23,836,000)</u>

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

	<b>For the Year Ended March 31,</b>	
	<b>2022</b>	<b>2021</b>
Net loss per share (GAAP)	\$ (0.14)	\$ (0.22)
Adjustments:		
Change in fair value of warrant liability	(0.01)	0.03
Gain on warrant exchange	—	(0.02)
Amortization of employees, directors and consultants stock options	0.02	0.03
Adjusted basic and diluted net loss per share (non-GAAP)	<u>\$ (0.13)</u>	<u>\$ (0.18)</u>

The Non-GAAP Measures for the year ended March 31, 2022 and 2021 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.

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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 continue 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 to further diversify our product pipeline and are exploring various strategic options as described above. 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 the investigator-initiated HoPES clinical trial of SM-88 in sarcoma, (ii) participating in OASIS, our investigator-initiated prospective open-label Phase II trial, evaluating the efficacy and safety of SM-88 with MPS for the treatment of metastatic HR+, HER2- breast cancer after treatment, (iii) conducting preclinical studies of an injectable form of SM-88, (iv) conducting preclinical studies in connection with our other preclinical pipeline products, TYME-19, TYME-18 and Tumor Targeting Technology, and (v) conducting additional or related studies of other potential drug candidates. If we determine to move beyond the preclinical stage for any of our preclinical product candidates or if we pursue studies in other cancer types, our liquidity requirements will be increased. Additionally, if the Company completes a material transaction resulting from its strategic evaluation process, the Company will, among other potential payment obligations, be obligated to pay each of its executive officers a retention bonus within 20 days of such transaction.

Primarily as a result of its active clinical trials, including timing of enrollment, as well as other business developments, and based on its current operating plan, but not taking into consideration to the execution or completion of any transaction that may result from the evaluation of strategic options and diversification initiatives as described above, the Company currently anticipates that its quarterly cash operating expense will approximate \$4.0 million to \$6.0 million per quarter during fiscal year 2023. Management expects that the Company’s net cash usage or net “cash burn” will be less than its operating costs.

As of March 31, 2022, the Company had cash on hand of approximately \$13.7 million and a working capital of approximately \$71.5 million. In the first quarter of fiscal year 2022, the Company established an investment policy and invested approximately \$74.1 million in a portfolio of highly liquid investments and marketable securities. As of

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March 31, 2022 the Company had marketable securities of \$69.7 million and accrued interest of \$0.6 million classified in other current assets. The primary objectives of the Company's policy are to preserve capital and diversify risk, while maintaining sufficient liquidity to meet cash flow needs.

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 responses, 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 liquidity needs, we currently expect to use existing cash balances and marketable securities in the short term, and a variety of other means as longer term funding sources, 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 and biotechnology companies like ours is dependent upon many factors, including the general state of the financial markets. During times of extreme market volatility, capital may not be available on favorable terms, if at all. Our inability to obtain such additional capital could materially and adversely affect our business operations.

While we will continue to seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all, and our negotiating position in capital generating efforts may worsen as existing resources are used. Moreover, as discussed above, should the Company be unable to maintain compliance with Nasdaq listing requirements, our ability to raise funds and, therefore, our liquidity, could be negatively impacted. See Item 1A – Risk Factors for additional information.

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<sup>SM</sup> SM-88 registration arm; or (iii) U.S. 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.

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On October 18, 2019, the Company entered into an Open Market Sale AgreementSM which was amended on August 12, 2020 (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”). Under the Sale Agreement the minimum share sales price (“Floor Price”) shall not be less than \$1.00 without Jefferies prior written consent. 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 of 1933, as amended. 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, 2022, the Company did not raise any proceeds under the Jefferies ATM. 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. As of March 31, 2022, there remained approximately \$22.2 million of availability in the Jefferies ATM subject to the terms of the Sale Agreement.

### Exchange Agreements

In May 20, 2020, the Company entered into exchange agreements (the “Share Exchange Agreements”) with the Holders of the warrants issued in April 2019 (“the April 2019 Warrants”). Pursuant to 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 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 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:

	<b>2022</b>	<b>2021</b>
Net cash used in operating activities	\$ (21,243,000)	\$ (23,564,000)
Net cash used in investing activities	\$ (72,541,000)	\$ —
Net cash provided by financing activities	\$ 6,000	\$ 104,380,000

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### Operating Activities

Our cash used in operating activities in the year ended March 31, 2022 totaled \$21.2 million which is the sum of (i) our net loss of \$23.6 million, adjusted for \$2.5 million expense amortization of stock-based compensation and \$1.6 million net amortization of premiums and discounts on marketable securities, partially offset by \$1.8 million non-cash change in fair value of the warrant liability, and (ii) changes in operating assets and liabilities of \$0.1 million.

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.

### Investing Activities

During the year ended March 31, 2022, our investing activities consisted of the purchase of \$95.2 million of marketable securities and the receipt of approximately \$22.7 million of proceeds from maturities of marketable securities. There were no investing activities in the year ended March 31, 2021.

### Financing Activities

During the year ended March 31, 2022, our financing activities consisted of the receipt of \$6,000 in proceeds from the exercise of stock options.

During the year ended March 31, 2021, our finance activities consisted of the receipt of \$100 million gross proceeds from a registered direct offering of 40,000,000 shares of the Company's common stock, at a purchase price of \$2.50 per share net of \$6.2 million of related costs which offset such proceeds, \$6.1 million in gross proceeds via sale of 4,453,939 shares of common stock under the Jefferies ATM, net of \$0.3 million of related costs which partially offset such proceeds and \$5.4 million proceeds 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.

### **Seasonality**

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

### **Contractual Obligations and Commitments**

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. At March 31, 2022, the Company's obligations to contract service providers were \$0.2 million in the aggregate.

### **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. On January 26, 2022, the Company announced the discontinuation of SM-88 with MPS in the Precision Promise trial in mPDAC upon learning from PanCAN, the trial sponsor, that it terminated the arm due to futility compared to the control of standard of care chemotherapy in second-line mPDAC. As of March 31, 2022, remaining estimated costs to close out the trial have been expensed.

### **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

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clinical supply needs for the Company's ongoing trials and registration activity are approximately \$0.9 million and \$2.5 million, respectively, at March 31, 2022. The Company expects the timing of associated payments to predominately occur through fiscal year 2023.

### **Leases**

The Company leases office space in New Jersey. The New Jersey lease expires in February 2023. The Company's future minimum remaining lease payments for the New Jersey lease are approximately \$39,200 due in fiscal 2023.

### **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, 2022 and 2021, the related consolidated statements of operations, changes in stockholders’ equity, and cash flows for each of the two years in the period ended March 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended March 31, 2022, 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 matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

#### *Stock-based compensation*

As described further in Notes 7 and 12 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.

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.

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Our audit procedures related to stock-based compensation estimates include 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;
- 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

May 25, 2022

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

	March 31, 2022	March 31, 2021
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 13,738,931	\$ 107,516,420
Marketable securities	60,611,961	—
Prepaid clinical costs	480,623	987,470
Prepaid expenses and other current assets	4,064,770	1,152,970
Total current assets	78,896,285	109,656,860
Prepaid clinical costs, net of current portion	—	530,989
Operating lease right-of-use asset	38,229	75,471
Marketable securities	9,080,671	—
Total assets	<u>\$ 88,015,185</u>	<u>\$ 110,263,320</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable and other current liabilities (including \$153,000 and \$87,000 of related party accounts payable, respectively)	\$ 3,803,427	\$ 3,842,390
Severance payable	2,611,857	726,027
Accrued bonuses	933,082	1,040,710
Operating lease liability	37,332	34,658
Total current liabilities	<u>7,385,698</u>	<u>5,643,785</u>
Long-term liabilities		
Severance payable, net of current portion	421,575	850,709
Operating lease liability, net of current portion	—	41,256
Warrant liability	124,480	1,931,921
Total liabilities	<u>7,931,753</u>	<u>8,467,671</u>
Commitments and contingencies (See Note 9)		
Stockholders' equity		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized, 0 shares issued and outstanding	—	—
Common stock, \$0.0001 par value, 300,000,000 shares authorized, 172,206,894 issued and outstanding at March 31, 2022, and 300,000,000 authorized, 172,200,644 issued and outstanding at March 31, 2021	17,223	17,222
Additional paid in capital	241,030,535	238,572,442
Accumulated other comprehensive loss	(544,264)	—
Accumulated deficit	(160,420,062)	(136,794,015)
Total stockholders' equity	<u>80,083,432</u>	<u>101,795,649</u>
Total liabilities and stockholders' equity	<u>\$ 88,015,185</u>	<u>\$ 110,263,320</u>

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

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**Tyme Technologies, Inc. and Subsidiaries**  
**Consolidated Statements of Operations and Comprehensive Loss**

	Years Ended March 31,	
	2022	2021
<b>Operating expenses:</b>		
Research and development	\$ 13,444,101	\$ 16,709,649
General and administrative (including \$507,000 and \$517,000 of related party legal expenses, respectively)	9,632,103	10,185,537
Severance expense	2,437,379	321,825
Total operating expenses	25,513,583	27,217,011
Loss from operations	(25,513,583)	(27,217,011)
<b>Other income (expense):</b>		
Change in fair value of warrant liability	1,807,441	(3,915,393)
Gain on warrant exchange	—	2,228,697
Other income	150,339	22,077
Interest expense	(70,244)	(97,133)
Total other income (expense)	1,887,536	(1,761,752)
Loss before income taxes	(23,626,047)	(28,978,763)
Net loss	\$ (23,626,047)	\$ (28,978,763)
Basic and diluted loss per common share	\$ (0.14)	\$ (0.22)
Basic and diluted weighted average shares outstanding	172,206,534	134,250,722
<b>Statements of Comprehensive Loss</b>		
Net loss	\$ (23,626,047)	\$ (28,978,763)
Other comprehensive loss		
Unrealized loss on marketable securities, net of tax	(544,264)	—
Comprehensive loss	\$ (24,170,311)	\$ (28,978,763)

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, 2022 and 2021**

	Common Stock		Additional Paid-in capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance, March 31, 2020	<u>123,312,252</u>	<u>\$ 12,333</u>	<u>\$ 126,828,055</u>	<u>\$ (107,815,252)</u>	<u>\$ -</u>	<u>\$ 19,025,136</u>
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	<u>172,200,644</u>	<u>\$ 17,222</u>	<u>\$ 238,572,442</u>	<u>\$ (136,794,015)</u>	<u>\$ -</u>	<u>\$ 101,795,649</u>
Proceeds from the exercise of stock options	6,250	1	6,187	—	—	6,188
Stock based compensation	—	—	2,451,906	—	—	2,451,906
Unrealized gain (loss) on available-for-sale securities	—	—	—	—	(544,264)	(544,264)
Net loss	—	—	—	(23,626,047)	—	(23,626,047)
Balance, March 31, 2022	<u>172,206,894</u>	<u>\$ 17,223</u>	<u>\$ 241,030,535</u>	<u>\$ (160,420,062)</u>	<u>\$ (544,264)</u>	<u>\$ 80,083,432</u>

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

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

	Years Ended, March 31	
	2022	2021
<b>Cash flows from operating activities:</b>		
Net loss	\$ (23,626,047)	\$ (28,978,763)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	—	5,181
Amortization of employees, directors and consultants stock options	2,451,906	3,456,895
Change in fair value of warrant liability	(1,807,441)	3,915,393
Gain on warrant exchange	—	(2,228,697)
Net amortization of premiums and discounts on marketable securities	1,615,332	—
Loss on call redemption of marketable securities	1,416	—
Change in operating assets and liabilities:		
Prepaid clinical costs	1,037,836	144,528
Prepaid expenses and other assets	(2,224,512)	(171,021)
Operating lease right-of-use asset	37,242	150,269
Accounts payable and other current liabilities	(38,963)	1,015,088
Severance payable	1,456,696	(58,896)
Accrued bonuses	(107,628)	(760,269)
Operating lease liability	(38,582)	(54,186)
Net cash used in operating activities	<u>(21,242,745)</u>	<u>(23,564,478)</u>
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	(95,244,730)	—
Proceeds from maturities of marketable securities	22,703,798	—
Net cash used in investing activities	<u>(72,540,932)</u>	—
<b>Cash flows from financing activities:</b>		
Insurance note payments	—	(518,124)
Proceeds from registered offerings, net of issuance costs	—	99,547,283
Proceeds from exercise of stock options	6,188	5,351,323
Net cash provided by financing activities	<u>6,188</u>	<u>104,380,482</u>
Net (decrease) increase in cash	(93,777,489)	80,816,004
Cash and cash equivalents — beginning of year	107,516,420	26,700,416
Cash and cash equivalents — end of year	<u>\$ 13,738,931</u>	<u>\$ 107,516,420</u>
<b>Supplemental Cash Flow Information:</b>		
Cash paid for interest and income taxes are as follows:		
Interest	<u>\$ 70,244</u>	<u>\$ 97,133</u>
Income taxes	<u>\$ —</u>	<u>\$ —</u>
<b>Noncash investing and financing activities:</b>		
Cashless exchange of April 2019 Warrants to purchase 5,833,333 shares of common stock for 2,406,250 shares in May 2020.	<u>\$ —</u>	<u>\$ —</u>
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.	<u>\$ —</u>	<u>\$ —</u>
Operating lease right-of-use asset obtained in exchange for lease liabilities	<u>\$ —</u>	<u>\$ 75,439</u>

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

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### **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 CMBTs that are intended to be effective across a broad range of solid tumors and hematologic cancers, while also maintaining patients’ quality of life through relatively low toxicity profiles. Unlike targeted therapies that attempt to regulate specific mutations within cancer, the Company’s therapeutic approach is designed to take advantage of a cancer cell’s innate metabolic requirements to cause cancer cell death.

The Company is currently focused on developing its novel compound, SM-88, its preclinical pipeline of novel CMBTTM programs, and TYME-19 as a potential therapeutic for SARS CoV-2 diseases. The Company believes that early clinical results demonstrated by SM-88 in multiple advanced cancers including breast, sarcomas, pancreatic, and prostate, reinforce the potential of its emerging CMBTTM pipeline.

#### Ongoing Studies

##### OASIS Trial in metastatic HR+/HER2- breast cancer

The Company is collaborating with Georgetown University to support a Phase II trial, OASIS, for SM-88 in patients with metastatic breast cancer who have HR+ and HER2- disease (“HR+/HER2-”). This represents approximately 68% of the annual breast cancer diagnoses 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 HR+/HER2- breast cancer after treatment with a CDK4/6 inhibitor. This trial is designed as a two-stage trial, enrolling up to 50 patients who have failed or progressed after receiving two hormonal agents and a CDK4/6 inhibitor to receive SM-88 with MPS without additional cancer therapies. The primary endpoint of this trial is ORR, with secondary endpoints including DOR, CBR at >24 weeks, PFS, and safety. The trial is being 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 began in 2021 with the first patient dosed in September.

##### HoPES Trial in sarcoma

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 DOR, OS, CBR using RECIST, and incidence of treatment-emergent AEs. The Joseph Ahmed Foundation is sponsoring this trial, which is being conducted by Principal Investigator Dr. Chawla at the Sarcoma Oncology Center in Santa Monica, CA.

#### Preclinical Pipeline Programs

The Company has begun a comprehensive translational preclinical program focused on SM-88 MOA and Biomarker Identification/Validation. We have engaged Evotec, a leading global research and development company, to aid in the execution of these activities and we are also incorporating several complementary academic collaborations into this multi-faceted program. The overall goal of these activities is to potentially identify actionable biomarkers of sensitivity and activity to SM-88 in various cancers, complementary combination drugs strategies for SM-88, and other cancer metabolism targets that could benefit from treatment.

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TYME-18 is a CMBTTM compound under development that is delivered intratumorally. TYME-18 leverages a member of the bile acid family to create a potential treatment for inoperable tumors. Preliminary observations of the local administration of TYME-18, a combination of a proprietary surfactant system and natural sulfonic acid, suggested its potential as an important regulator of energy metabolism that may impede the ability of tumors to increase in size, which, in addition to its lytic functionality, could prove useful in difficult-to-treat cancers. The Company is assessing development priorities to determine if additional advancement of this program is warranted at this time.

TYME-19 is an oral synthetic member of the bile acid family. The Company also uses bile acids in its anti-cancer drug candidate, TYME-18. Because of its expertise in bile acids and their effects, the Company was able to identify TYME-19 as a well-characterized bile acid with potential antiviral properties. Bile acids have primarily been used for liver disease; however, like all steroids, they are messenger molecules that modulate a number of diverse critical cellular processes. Bile acids can modulate lipid and glucose metabolism and can remediate dysregulated protein folding, with potentially therapeutic effects on cardiovascular, neurologic, immune, and other metabolic systems. Some agents in this class have also previously shown antiviral properties.

The Company has retained virology experts at Evotec to assess the MOAs of TYME-19 to assist the Company in assessing the path forward for the TYME-19 program. Evotec is a global drug development company with the capability to access the multiple existing and emerging variants of the COVID-19 virus. TYME and Evotec are testing the ability of TYME-19 to interrupt the cellular pathways commonly used by viruses to produce viral proteins as well as cellular responses to viral infection that cause local inflammation. Prolonged inflammation from SARS-CoV-2 can lead to some of the severe outcomes experienced by infected patients.

### Tumor Targeting Technology

TYME has developed a technology (“Tumor Targeting Technology”) by which the tyrosine isomer L metyrosine (L- $\alpha$ -methylparatyrosine) can be fused with a second therapeutic agent in a manner that creates a fusion compound that may allow targeted accumulation of the treatment by the cancer cells in a novel manner. The Company is assessing potential development paths forward for this technology.

### **Discontinuing Programs**

#### Precision Promise Trial- SM-88 with MPS as 2nd line therapy in metastatic pancreatic cancer

In October 2018 the Company partnered with PanCAN to study SM-88 in an adaptive randomized Phase II/III trial with registration intent known as Precision PromiseSM. The objective of Precision Promise is to expedite the study and approval of promising therapies for pancreatic cancer by bringing multiple stakeholders together, including academic, industry and regulatory entities. The trial began in early 2020, with SM-88 (with the conditioning agents MPS) being studied as monotherapy in a treatment arm for patients who have failed one prior line of chemotherapy.

On January 26, 2022, the Company announced the discontinuation of SM-88 with MPS in the Precision Promise trial in mPDAC upon learning from PanCAN, the trial sponsor, that it terminated the arm due to futility compared to the control of standard of care chemotherapy in second-line mPDAC. Based on the information provided by PanCAN, the OS for SM-88 with MPS in monotherapy was lower compared to standard of care chemotherapies with either Gemcitabine and Abraxane or modified FOLFIRINOX. As of March 31, 2022, remaining estimated costs to close out the trial have been expensed.

#### 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 was also a higher than expected dropout of patients randomized to the chemotherapy control arm, which could have potentially impacted the interpretative and regulatory utility of the data.

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Following the 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 which offers treatment options to patients earlier in their disease and includes tumor biopsy and biomarker analyses that align with the Company's overall strategic focus on identifying targeted therapies.

Therefore, the Company decided to stop enrollment and begin the process of closing down the trial. Patients currently on therapy are allowed to continue treatment until progression or unacceptable toxicity. The closing of this trial is expected to require several months to complete. During the year ended March 31, 2022, the Company expensed \$723,000 of estimated close out costs. The trial's remaining ongoing expense to the Company is approximately \$400,000 and is expected to be incurred over the five months following March 31, 2022.

### 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.

On October 18, 2019, TYME entered into an Open Market Sale AgreementSM (as amended, 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"). Under the Sale Agreement the minimum share sales price ("Floor Price") shall not be less than \$1.00 without Jefferies prior written consent. During the year ended March 31, 2022, the Company did not sell any shares through 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. At March 31, 2022, there remained approximately \$22.2 million of availability to sell shares through the Jefferies ATM subject to the terms of the Sale Agreement.

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, 2022, the Company had negative cash flow from operations of \$21.2 million and net loss of \$23.6 million, which included \$2.5 million non-cash equity compensation and \$1.6 million net amortization expense of premiums and discounts on marketable securities, offset by \$1.8 million income change in fair value of warrant liability. As of March 31, 2022, the Company had working capital of approximately \$71.5 million.

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

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

#### **Basis of Presentation**

The accompanying financial statements have been prepared in conformity with GAAP. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the ASC and ASU of the 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.

##### Reclassifications

Certain prior year amounts, primarily severance expense which was broken out to a separate line item on the Consolidated Statements of Operations and Comprehensive Loss, have been reclassified to conform to the current year presentation. These reclassifications have no effect on the previously reported net loss or cash flows.

##### Risks and Uncertainties

The Company is subject to those risks associated with any biotechnology 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*

The novel COVID-19 pandemic and actions taken by governments and others to reduce its spread, has negatively impacted the global economy, financial markets, and the Company's industry and has disrupted day-to-day life and business operations. Although we have operated within the COVID-19 environment for approximately two years, outbreaks of infections (including the spread of the new variants) continue to be experienced as conditions evolve and fluctuate around the world. The extent to which the continuing COVID-19 pandemic 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, depends on numerous evolving factors that are highly uncertain, cannot be accurately predicted, 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. Cash equivalents are stated at fair value. The Company's cash and cash equivalents consisted of \$13.7 million at March 31, 2022 and \$107.5 million at March 31, 2021.

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### Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentration of credit risk consist primarily of cash and marketable securities. 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 \$10.1 million at March 31, 2022 and \$107.3 million at March 31, 2021. 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.

### Marketable Securities

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.

All of the Company's marketable securities are debt securities and are classified as available-for-sale in accordance with the ASC Topic 320, "Investments - Debt and Equity Securities." Available for sale securities are carried at fair value and reported in cash equivalents and marketable securities. Marketable securities are further classified as short-term or long-term based on maturity dates and the Company's intent in line with its investment policy to hold the securities to scheduled maturity. Unrealized gains and losses on available-for-sale securities are excluded from net loss and reported in accumulated other comprehensive loss as a separate component of stockholders' equity. Other income includes interest, dividends, amortization of purchase premiums and discounts, gain and losses on sale (or redemptions) of securities and other-than-temporary declines in the fair value of securities, if any.

For individual debt securities classified as available-for-sale securities where there has been a decline in fair value below amortized cost, the Company determines whether the decline resulted from a credit loss or other factors. In making this assessment, the Company considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and adverse conditions specifically related to the security, among other factors. If this assessment indicates that a credit loss exists, the present value of cash flows expected to be collected from the security is compared to the amortized cost basis of the security. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for a credit loss is recorded on our consolidated balance sheet, limited by the amount that the fair value is less than the amortized cost basis. Impairment that has not been recorded through an allowance for credit losses is recorded through other comprehensive loss, net of applicable taxes.

### 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.

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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. Cash equivalents, marketable securities and the derivative warrant liability are recorded at fair value. See 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. As of March 31, 2022, prepaid expenses and other current assets includes \$1.1 million of prepaid insurance, \$0.6 million accrued interest receivable on marketable securities and a \$2.1 million deposit with our payroll vendor to satisfy the Chief Science Officer severance payment. As of March 31, 2021, prepaid expenses and other current assets includes \$1.0 million of prepaid insurance.

### Property and Equipment, Net

Property and equipment are recorded at cost and are depreciated on a straight-line basis over their estimated useful lives. The Company estimates a life of 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, 2022 and 2021, the Company determined that there were no triggering events requiring an impairment analysis.

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### 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 CROs, 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. The Company

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will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrant. The Company utilizes Level 3 fair value criteria to measure the fair value of the warrants.

As noted in Note 8, 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 or requires issuance of registered common shares upon exercise which cause the warrants to be treated as derivatives. Each warrant of this type is initially recorded at fair value on date of grant using the Monte Carlo simulation model 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.

### 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 12, 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 December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), 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 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 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. Prior U.S. GAAP delayed recognition of the full amount of credit losses until the loss was 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-

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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 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,	
	2022	2021
Basic and diluted net loss per common share calculation		
Net loss	\$ (23,626,047)	\$ (28,978,763)
Weighted average common shares outstanding — basic and diluted	172,206,534	134,250,722
Net loss per share of common stock — basic and diluted	\$ (0.14)	\$ (0.22)

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

Warrants issued in April 2019, discussed further in Note 8, participated 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 as results of operations was a loss for the period. In May 2020, these warrants were all exchanged for Common Stock or new warrants without such participation rights and are no longer outstanding (see Note 8).

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The following outstanding securities at March 31, 2022 and 2021 have been excluded from the computation of diluted weighted average shares outstanding, as they would have been anti-dilutive:

	Year Ended March 31,	
	2022	2021
Stock options	14,504,271	12,588,068
Warrants	3,104,318	3,104,318
Total	<u>17,608,589</u>	<u>15,692,386</u>

### Note 4. Available-for-Sale-Securities.

The following table summarizes available-for-sale securities recorded in cash and cash equivalents or marketable securities as of March 31, 2022:

	March 31, 2022			
	Amortized cost	Gross Unrealized Gains	Gross Unrealized Loss	Fair Value
Money market funds	\$ 3,409,178	\$ —	\$ —	\$ 3,409,178
Corporate debt securities	32,831,174	—	(343,134)	32,488,040
Municipal debt securities	37,405,722	—	(201,130)	37,204,592
Total	<u>\$ 73,646,074</u>	<u>\$ —</u>	<u>\$ (544,264)</u>	<u>\$ 73,101,810</u>

The following table summarizes the classification of available-for-sale securities:

	March 31, 2022	March 31, 2021
Cash and cash equivalents	\$ 3,409,178	\$ —
Marketable securities	69,692,632	—
Total	<u>\$ 73,101,810</u>	<u>\$ —</u>

The following table summarizes our portfolio of available-for-sale securities by contractual maturity:

	Less than 12 months		12 months or Longer		Total	
	Fair Value	Net Unrealized Losses	Fair Value	Net Unrealized Losses	Fair Value	Net Unrealized Losses
Money market funds	\$ 3,409,178	\$ —	\$ —	\$ —	\$ 3,409,178	\$ —
Corporate debt securities	26,195,025	(227,300)	6,293,015	(115,834)	32,488,040	(343,134)
Municipal debt securities	34,416,936	(153,855)	2,787,656	(47,275)	37,204,592	(201,130)
Total	<u>\$ 64,021,139</u>	<u>\$ (381,155)</u>	<u>\$ 9,080,671</u>	<u>\$ (163,109)</u>	<u>\$ 73,101,810</u>	<u>\$ (544,264)</u>

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### **Note 5. Accounts Payable and Other Current Liabilities.**

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

	<u>March 31, 2022</u>	<u>March 31, 2021</u>
Legal	\$ 263,111	\$ 454,139
Consultant and professional services	300,051	176,957
Accounting and auditing	14,410	55,349
Research and development	2,776,594	2,657,202
Board of Directors and Scientific Advisory Board Compensation	418,389	435,594
Other	30,872	63,149
	<u>\$ 3,803,427</u>	<u>\$ 3,842,390</u>

### **Note 6. Severance Payable.**

The Company entered into a Release Agreement, dated March 24, 2022, pursuant to which the Chief Science Officer resigned and will receive severance that would be payable under his employment agreement in a lump sum payment of \$2.1 million. The Company also entered into Separation and General Release Agreement with three other employees. The agreements provide separation benefits which the Company recorded as severance expense.

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 \$3.0 million and \$1.6 million as of March 31, 2022 and March 31, 2021.

### **Note 7. Fair Value Measurements.**

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. 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, 2022 and March 31, 2021.

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

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>March 31, 2022</b>				
Financial assets				
Cash equivalents				
Money market funds	\$ 3,409,178	\$ 3,409,178	\$ —	\$ —
Marketable Securities				
Short-term				
Corporate debt securities	26,195,025	—	26,195,025	—
Municipal debt securities	34,416,936	—	34,416,936	—
Long-term				
Corporate debt securities	6,293,015	—	6,293,015	—
Municipal debt securities	2,787,656	—	2,787,656	—
	<u>\$ 73,101,810</u>	<u>\$ 3,409,178</u>	<u>\$ 69,692,632</u>	<u>\$ —</u>
Financial liability				
Warrant liability	<u>\$ 124,480</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 124,480</u>
<b>March 31, 2021</b>				
Warrant liability	<u>\$ 1,931,921</u>	<u>—</u>	<u>—</u>	<u>\$ 1,931,921</u>

Fair values of available-for-sale securities are generally based on prices obtained from commercial pricing services. The fair value of cash equivalents held in money market funds is determined based on "Level 1" inputs. Marketable securities classified as Level 2 within the valuation hierarchy consist of corporate debt securities and municipal debt securities. We estimate the fair values of these marketable securities by taking into consideration valuations obtained from third-party pricing sources. These pricing sources utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include market pricing based on real-time trade data for the same or similar securities, issuer credit spreads, benchmark yields, and other observable inputs.

The fair value measurement for the warrant issued in conjunction with the Exchange Agreements (see Note 8 for transaction details) (the "May 2020 Warrant") is based on significant inputs not observable in the market and is classified as Level 3 liability as of March 31, 2022 and March 31, 2021. The fair value of the May 2020 Warrant was determined using a Black Scholes model and included significant unobservable inputs such as volatility. The model also 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.

The following table details key inputs and assumptions used to estimate the fair value of the May 2020 Warrant as of March 31, 2022 and March 31, 2021 using a Black Scholes model:

	May 2020 Warrant March 31, 2022	May 2020 Warrant March 31, 2021
Stock price	\$ 0.35	\$ 1.78
Volatility	98%	78%
Remaining term (years)	2.01	3.01
Expected dividend yield	—	—
Risk-free rate	2.28%	0.35%

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

	<b>Warrant liability</b>
<b>Beginning balance, March 31, 2021</b>	<b>\$ 1,931,921</b>
Change in fair value of May 2020 Warrant liability	(1,807,441)
<b>Ending balance, March 31, 2022</b>	<b>\$ 124,480</b>

### **Note 8. Stockholders' Equity.**

#### Preferred Stock

The Company is authorized to issue up to 10,000,000 shares of preferred stock, each with a par value of \$0.0001. Shares of Company preferred stock may be issued from time to time in one or more series and/or classes, each of which will have such distinctive designation or title as shall be determined by the Company's Board 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.

In connection with the Release Agreement, dated March 24, 2022, the Company and Mr. Hoffman also entered into a Voting Agreement, pursuant to which Mr. Hoffman agreed to vote all shares of TYME common stock beneficially owned by him in accordance with the Board's recommendation with respect to any matter presented to the stockholders for a period of one year.

The Company and Michael Demurjian entered into a Voting Agreement, dated April 18, 2022, pursuant to which Mr. Demurjian agreed to vote all shares of TYME common stock beneficially owned by him in accordance with the board of directors of the Company's recommendation with respect to any matter presented to the Company's stockholders for a period of two years from the date of the agreement.

##### *Dividends*

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

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### *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.

### Exchange Agreements

On May 20, 2020, the Company entered into exchange agreements with holders (the “Holders”) of the warrants issued in April 2019 (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.

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. At May 20, 2020, the May 2020 Warrant was recorded at the fair value of \$1.7 million as determined using the Black Scholes model and 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 for the year ended March 31, 2022 of \$1.8 million income and for the period from May 20, 2020 through March 31, 2021 of \$0.3 million expense was recorded as a component of other income (expense) within the consolidated statement of operations.

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The following summarizes the common stock warrant activity for the years ended March 31, 2022 and March 31, 2021:

	<b>Warrant Shares of Common Stock</b>	<b>Weighted Average Exercise Price</b>
<b>Outstanding at March 31, 2020</b>	<b>8,937,651</b>	<b>\$ 2.31</b>
Granted	2,166,667	1.80
Exchanged	(8,000,000)	2.00
<b>Outstanding at March 31, 2021</b>	<b>3,104,318</b>	<b>\$ 2.77</b>
Granted	—	—
Exchanged	—	—
<b>Outstanding at March 31, 2022</b>	<b>3,104,318</b>	<b>\$ 2.77</b>

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.

At March 31, 2022 and March 31, 2021, 3,074,551 of common stock purchase warrants relating to securities purchase agreements were outstanding and exercisable.

<b>Issued</b>	<b>Classification</b>	<b>Warrants Outstanding</b>	<b>Exercise Price</b>	<b>Expiration</b>
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
May 2020	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. Under the Sale Agreement the minimum share sales price ("Floor Price") shall not be less than \$1.00 without Jefferies prior written consent. As indicated in an amendment, 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, as amended. 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.

The Company did not sell any shares through the Jefferies ATM during the year ended March 31, 2022. 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. At March 31, 2022, there remained approximately \$22.2 million of availability to sell shares through the Jefferies ATM subject to the terms of the Sale Agreement.

### 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

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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 9. Commitments and Contingencies.**

#### Contract Service Providers

In the course of the Company's normal business operations, it enters into agreements and arrangements with contract service providers to assist in the performance of its research and development and clinical research activities. At March 31, 2022, the Company's obligations to contract service providers were \$0.2 million in the aggregate.

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. On January 26, 2022, the Company announced the discontinuation of SM-88 with MPS in the Precision Promise trial in mPDAC upon learning from PanCAN, the trial sponsor, that it terminated the arm due to futility compared to the control of standard of care chemotherapy in second-line mPDAC. As of March 31, 2022, remaining estimated costs to close out the trial have been expensed.

#### 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 \$0.9 million and \$2.5 million, respectively at March 31, 2022.

#### 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.

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### **Note 10. 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 \$62,000 and \$165,000 for the years ended March 31, 2022 and 2021, respectively.

Operating lease 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, 2022, 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:

	<u>March 31, 2022</u>
Fiscal year 2023	\$ 39,240
Total remaining lease payments	39,240
Less: present value adjustment	(1,908)
Total operating lease liabilities	37,332
Less: current portion	37,332
Operating lease liabilities, net of current portion	\$ —

### **Note 11. 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 held the consulting role “Senior Counsel” with the Faegre Drinker until December 31, 2021. During the years ended March 31, 2022 and 2021, approximately \$0.5 million and \$0.6 million (\$0.1 million was capitalized into equity in prior year), respectively, have been incurred as legal expenses associated with Faegre Drinker, and the Company had approximately \$153,000 and \$87,000 in accounts payable and accrued expenses payable to Faegre Drinker at March 31, 2022 and March 31, 2021, respectively.

### **Note 12. 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, 2022, there were 7,223,029 shares available for grant under the 2015 Plan.

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On August 24, 2021 the stockholders approved the Amended and Restated 2016 Option Plan for Non-Employee Directors (the “2016 Director Plan”), which increased the total number of shares of Common Stock authorized and reserved for issuance the 2016 Director Plan by 3,000,000 shares to 5,750,000 shares. On August 24, 2021 the Board of Directors approved: (i) “Initial Grants” upon a director’s initial appointment to the Board consisting of an immediate stock option grant of 176,000 shares at fair market value and the shares will vest in equal quarterly increments over a three-year period from the date of grant; and (ii) “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 88,000 shares at fair market value and the shares will vest in equal quarterly increments over a one-year period from the date of grant. The Initial Grants and Annual Grants have a ten year term, subject to applicable termination or forfeiture provisions. As of March 31, 2022, there were 3,411,279 shares available for grant under the 2016 Director Plan.

### Stock Options

As of March 31, 2022, and 2021, there was approximately \$4.5 million and \$3.6 million, respectively, of total unrecognized compensation related to non-vested stock options. The cost is expected to be recognized over the remaining weighted average remaining amortization period of 2.8 years. During the years ended March 31, 2022 and 2021, the Company had stock compensation expense of \$2.5 million and \$3.5 million, respectively. For the year ended March 31, 2022, stock compensation expense is recognized as \$1.9 million in general and administrative expense, \$0.6 million in research and development expense. For the year ended March 31, 2021, stock compensation expense recognized was \$2.1 million in general and administrative expense and \$1.4 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,	
	2022	2021
Risk free interest rate	0.280% - 2.34%	0.174% - 0.527%
Expected volatility	95.39% - 105.37%	88.02% - 101.67%
Expected term	2.7 - 6.1 years	2.8 - 6.1 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, 2022:

	Number of Options	Weighted Average Exercise Price
Outstanding at March 31, 2021	12,588,068	\$ 2.92
Granted	3,862,388	1.30
Exercised	(6,250)	0.99
Cancelled/Forfeited	(1,939,935)	3.83
Outstanding at March 31, 2022	14,504,271	2.36
Options exercisable at March 31, 2022	9,329,798	\$ 2.99

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Weighted-average grant date fair value of options granted during the years ended March 31, 2022 and 2021 was \$1.00 and \$0.89, respectively.

During the year ended March 31, 2022, holders of options issued under the equity incentive plans exercised their right to acquire an aggregate of 6,250 shares of common stock at a weighted average exercise price of \$0.99 resulting in \$6,000 total proceeds to the Company. 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 resulting in \$5.4 million total proceeds to the Company.

Range of Exercise Price	Stock Options Outstanding				Stock Options Vested			
	Number Outstanding at March 31, 2022	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value	Number Vested at March 31, 2022	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value
\$0.29 - \$8.75	14,504,271	\$ 2.36	7	\$ 4,610	9,329,798	\$ 2.99	6	\$ —

The intrinsic value calculated as the excess of the market value as of March 31, 2022 over the exercise price of the options is \$4,610. The market value as of March 31, 2022 was \$0.35 as reported by the NASDAQ Capital Market. The total intrinsic value of options exercised during the year ended March 31, 2022 was \$3,500.

	Options	Weighted Average Grant Date Fair Value	
		Per Share	
Non-vested options at March 31, 2021	4,355,171	\$	0.91
Granted	3,862,388		1.00
Vested	(446,522)		0.95
Cancelled/Forfeited	(2,596,564)		0.99
Non-vested options at March 31, 2022	<u>5,174,473</u>	\$	0.93

The fair value of options vested during the years ended March 31, 2022 and 2021 was \$2.6 million and \$3.7 million, respectively.

### **Note 13. 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 \$23.6 million and \$29.0 million for the years ended March 31, 2022 and 2021, 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,	
	2022	2021
Net operating loss carryforward	\$ 27,564,077	\$ 20,123,621
Research and development credit carryforward	884,130	1,164,895
Orphan Drug Credit	4,157,360	2,002,559
Stock options - NQSOs	4,765,662	5,267,351
Accruals and other temporary differences	662,754	595,418
Gross deferred tax assets	38,033,983	29,153,844
Deferred tax valuation allowance	(38,033,983)	(29,153,844)
Net deferred taxes	<u>\$ —</u>	<u>\$ —</u>

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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, 2022. The valuation allowance increased by \$8.9 million for the year ended March 31, 2022 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,	
	2022	2021
U.S. statutory income tax rate	21.00%	21.00%
State taxes, net of federal benefit	11.59%	—
Permanent differences	—	(0.02)%
Tax credit carryforwards	7.93%	4.70%
Valuation allowance	(37.08)%	(20.98)%
Stock compensation	(5.05)%	(3.41)%
Warrants	1.61%	(1.29)%
Effective tax rate	—%	—%

As of March 31, 2022, the Company had gross U.S. federal net operating loss carryforwards of approximately \$119.1 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, 2022, 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 \$120 thousand and \$177 thousand for the years ended March 31, 2022 and March 31, 2021, respectively. As of March 31, 2022, the Company had gross federal research and development tax credit carryforwards of \$5.9 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 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,	
	2022	2021
Gross unrecognized tax benefits at beginning of year	\$ 558,962	\$ 318,394
Increases (decreases) for tax positions in prior period	—	(99,063)
Increase for tax positions in current period	330,712	339,631
Gross unrecognized tax benefits at end of year	<u>\$ 889,674</u>	<u>\$ 558,962</u>

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As of March 31, 2022, the Company had \$890,000 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, 2022, 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, 2022. 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.

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

There were no disagreements with Grant Thornton LLP.

**ITEM 9A. CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

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

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) under the Exchange Act, as of the end of the period covered by this Annual Report on Form 10-K. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of March 31, 2022, 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, 2022. 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, 2022, our Chief Executive Officer and Chief Financial Officer concluded that as of such date, our internal control over financial reporting was effective.

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

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**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, 2022 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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**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 May 25, 2021 regarding our Board of Directors:

Name	Age	Position(s) with the Company/Principal Occupation	Date Elected to Our Board of Directors
Steve Hoffman	59	Director	March 5, 2015*
Dr. Gerald Sokol	79	Director/Chief of Radiation Oncology, University of South Florida's Tampa General Hospital	March 10, 2015
Timothy C. Tyson	70	Director/Chairman and Chief Executive Officer, TriRx Pharmaceutical Services LLC	March 10, 2015
David Carberry	69	Director/Former Chief Financial Officer of Excellis Health Solutions, LLC (Retired)	March 30, 2017
Donald W. DeGolyer	61	Director/Former Chief Executive Officer, Vertice Pharma LLC	May 24, 2018
Douglas A. Michels	65	Director/Former President and CEO OraSure Technologies	October 1, 2018
Richard Cunningham	51	Director, Chief Executive Officer of the Company	November 24, 2020
Christine D. Baker	56	Director/Chief Operating Officer of Hookipa Pharma	March 21, 2022

\* 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, 2022.

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### **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, 2022.

### **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, 2022.

The following table provides certain information with respect to all of our equity compensation plans in effect as of March 31, 2022:

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, 2022	14,504,271 (1)	\$ 2.36	10,634,308
Equity compensation plans not approved by stockholders prior to March 31, 2022	29,767 (2)	\$ 5.00	—
<b>Total Equity</b>	<b>14,534,038</b>	<b>\$ 2.92</b>	<b>10,634,308</b>

- (1) Includes 14,504,271 shares of our common stock issuable under option awards made prior to March 31, 2022 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 \$2.36 per share. For a description of the terms of the 2015 Equity Incentive Plan and 2016 Director Plan, please see Note 12 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, 2022 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 10,634,308 shares of our common stock issuable under awards eligible to be made (and not outstanding) as of March 31, 2022 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, 2022.

### **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, 2022.

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**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**

<a href="#"><u>Report of Independent Registered Public Accounting Firm</u></a> (Grant Thornton LLP, Iselin, New York, PCAOB #248)	88
<a href="#"><u>Consolidated Balance Sheets as of March 31, 2022 and March 31, 2021</u></a>	90
<a href="#"><u>Consolidated Statements of Operations and Comprehensive Loss for the years ended March 31, 2022 and 2021</u></a>	91
<a href="#"><u>Consolidated Statements of Stockholders' Equity for the years ended March 31, 2022 and 2021</u></a>	92
<a href="#"><u>Consolidated Statements of Cash Flows for the years ended March 31, 2022 and 2021</u></a>	93
<a href="#"><u>Notes to Consolidated Financial Statements as of March 31, 2022 and 2021</u></a>	94

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### (b) EXHIBITS

See Exhibit Index.

#### ITEM 16. FORM 10-K SUMMARY

Omitted at the company's option.

Exhibit Number	Description
3.1	<a href="#"><u>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.)</u></a>
3.2	<a href="#"><u>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.)</u></a>
3.3	<a href="#"><u>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.)</u></a>
3.4	<a href="#"><u>Amended and Restated By-Laws of Tyme Technologies, Inc., effective April 25, 2022. (Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K, filed with the SEC on April 29, 2022.)</u></a>
4.1	<a href="#"><u>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.)</u></a>
4.2	<a href="#"><u>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.)</u></a>
4.3	<a href="#"><u>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.)</u></a>
4.4	<a href="#"><u>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.)</u></a>
4.5	<a href="#"><u>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.)</u></a>
10.1	<a href="#"><u>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.)</u></a>
10.2	<a href="#"><u>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.)</u></a>
10.3	<a href="#"><u>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.)</u></a>
10.4†	<a href="#"><u>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.)</u></a>
10.5†	<a href="#"><u>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.)</u></a>
10.6†	<a href="#"><u>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.)</u></a>

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- 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 August 24, 2021.](#) [\(Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on August 26, 2021.\)](#)
- 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† [Form of Nonqualified Stock Option Agreement, adopted on April 22, 2022, under the Tyme Technologies, Inc. 2015 Equity Incentive Plan.](#) [\(Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on April 29, 2022.\)](#)
- 10.14† [Employment Agreement, dated as of March 5, 2015, between Tyme Technologies, Inc. and Michael Demurjian.](#) [\(Incorporated by reference to Exhibit 10.13 to our Current Report on Form 8-K, filed with the SEC on March 11, 2015.\)](#)
- 10.15† [Release Agreement, dated as of March 15, 2019, between Tyme Technologies, Inc. and Michael Demurjian.](#) [\(Incorporated by reference to Exhibit 10.14 to our Annual Report on Form 10-K, filed with the SEC on June 12, 2019.\)](#)
- 10.16† [Letter Agreement, dated as of September 10, 2018, between Tyme Technologies, Inc. and James Biehl.](#) [\(Incorporated by reference to Exhibit 10.19 to our Annual Report on Form 10-K, filed with the SEC on June 12, 2019.\)](#)
- 10.17† [Letter Agreement, dated November 24, 2020, by and between Richard Cunningham and Tyme Technologies, Inc.](#) [\(Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q filed with the SEC on February 3, 2021.\)\\*\\*\\*\\*](#)
- 10.18† [Letter Agreement, dated November 24, 2020, by and between Steve Hoffman and Tyme Technologies, Inc.](#) [\(Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q filed with the SEC on February 3, 2021.\)\\*\\*\\*\\*](#)
- 10.19†\* [Release Agreement, effective March 24, 2022, by and between Steve Hoffman and Tyme Technologies, Inc.](#)
- 10.20\* [Voting Agreement, effective March 24, 2022, by and between Steve Hoffman and Tyme Technologies, Inc.](#)
- 10.21† [Separation and General Release Agreement, effective March 31, 2021, by and between Giuseppe Del Priore and Tyme Technologies, Inc.](#) [\(incorporated by reference to Exhibit 10.18 to our Current Report on Form 10-K filed with the SEC on June 10, 2021.\)](#)
- 10.22\* [Voting Agreement, effective April 18, 2022, by and between Michael Demurjian and Tyme Technologies, Inc.](#) \*\*\*\*
- 10.23†\* [Amendment to Release Agreement, effective April 18, 2022, by and between Michael Demurjian and Tyme Technologies, Inc.](#)

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10.24†	<a href="#">Amended Letter Agreement, dated July 30, 2018, by and between Jonathan Eckard and Tyme Technologies, Inc. (incorporated by reference to Exhibit 10.4 to our Quarterly Report on Form 10-Q, filed with the SEC on July 31, 2018.)</a>
10.25†*	<a href="#">Letter Agreement, dated May 11, 2021, by and between Frank Porfido and Tyme Technologies, Inc.****</a>
10.26†	<a href="#">Form of Retention Agreement between Tyme Technologies, Inc. and certain executive officers (including James Biehl, Richard Cunningham, Jonathan Eckard, Barbara Galaini and Frank Porfido) (incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K filed with the SEC on April 29, 2022.)</a>
10.27†	<a href="#">Form of Indemnification Agreement between Tyme Technologies, Inc. and its individual directors and officers (incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed with the SEC on April 29, 2022.)</a>
10.28†	<a href="#">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.)***</a>
10.29†	<a href="#">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.)</a>
10.30	<a href="#">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.)</a>
10.31	<a href="#">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.)</a>
10.32	<a href="#">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.)</a>
10.33	<a href="#">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.)</a>
10.34	<a href="#">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.)</a>
21.1*	<a href="#">List of Subsidiaries.</a>
23.1*	<a href="#">Consent of Independent Registered Public Accounting Firm.</a>
24.1*	<a href="#">Power of Attorney (Included in Signature Page of Form 10-K).</a>
31.1*	<a href="#">Rule 13(a)-14(a)/15(d)-14(a) Certification of Principal Executive Officer.</a>
31.2*	<a href="#">Rule 13(a)-14(a)/15(d)-14(a) Certifications of Principal Financial Officer.</a>
32.1**	<a href="#">Rule 1350 Certifications.</a>
101.INS*	Inline XBRL Instance Document.
101.SCH*	Inline XBRL Schema Document.
101.CAL*	Inline XBRL Calculation Linkbase Document.
101.DEF*	Inline XBRL Definition Linkbase Document.
101.LAB*	Inline XBRL Label Linkbase Document.
101.PRE*	Inline XBRL Presentation Linkbase Document.
104	Cover Page Interactive Data File, formatted in Inline XBRL (contained in Exhibit 101.INS)

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- † 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.

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**SIGNATURES**

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

Dated: May 25, 2022

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 Frank Porfido 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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<u>/s/ Richard Cunningham</u> Richard Cunningham	Chief Executive Officer and Director (Principal Executive Officer)	May 25, 2022
<u>/s/ Barbara C. Galaini</u> Barbara C. Galaini	Corporate Controller (Principal Accounting Officer)	May 25, 2022
<u>/s/ Frank Porfido</u> Frank Porfido	Chief Financial Officer (Principal Financial Officer)	May 25, 2022
<u>/s/ Steve Hoffman</u> Steve Hoffman	Director	May 25, 2022
<u>/s/ Gerald Sokol</u> Gerald Sokol	Director	May 25, 2022
<u>/s/ David Carberry</u> David Carberry	Director	May 25, 2022
<u>/s/ Timothy C. Tyson</u> Timothy C. Tyson	Director	May 25, 2022
<u>/s/ Douglas A. Michels</u> Douglas A. Michels	Director	May 25, 2022
<u>/s/ Donald W. DeGolyer</u> Donald W. DeGolyer	Director	May 25, 2022
<u>/s/ Christine D. Baker</u> Christine D. Baker	Director	May 25, 2022