

FY2020 ANNUAL REPORT

TYME TO CONQUER ADVANCED CANCERS

TYME 

Tyme Technologies

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

TYME is advancing proprietary

Cancer Metabolism-Based Therapies (CMBTs™)

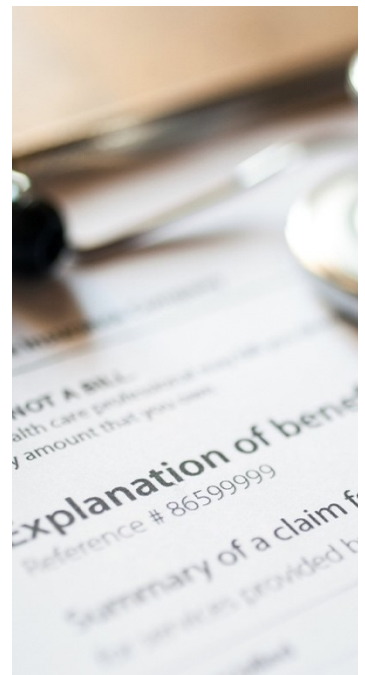
for difficult-to-treat cancers

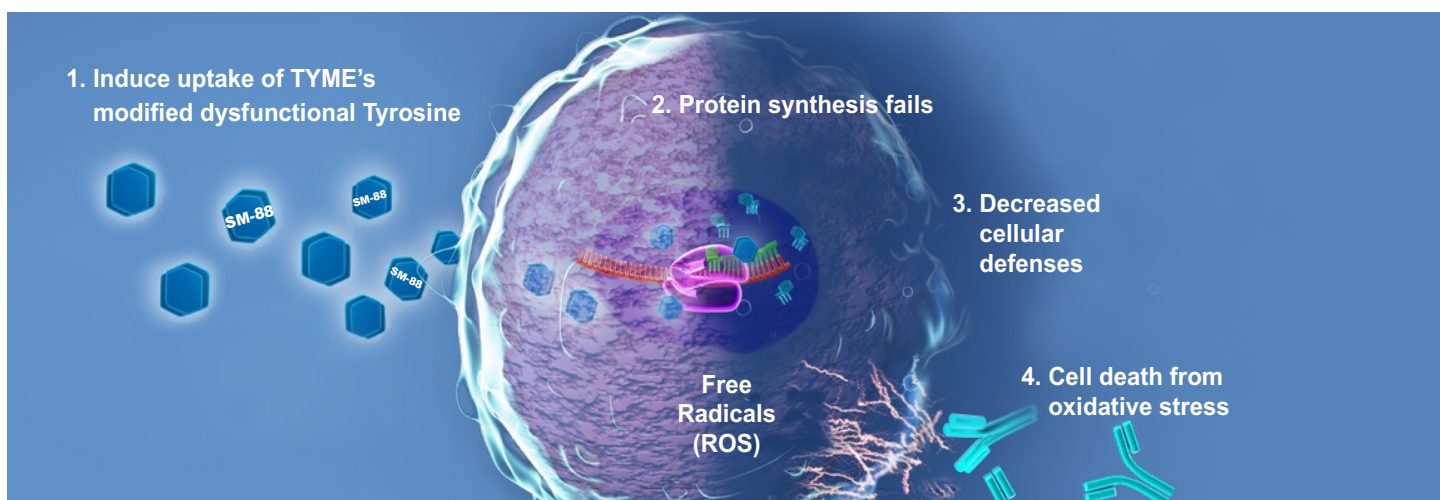


Committed to Improving the Lives of Patients with Advanced Cancers

While cancer survival rates have improved steadily since the 1970s, much more progress is needed. This year alone, cancer will strike nearly 1.8 million Americans and an estimated 18.1 million people worldwide. And because close to 610,000 people in the United States, and nearly 9.6 million worldwide are expected to die of cancer this year, TYME and its employees are working relentlessly to discover, develop and deliver innovative disease-altering medicines. Our goal is to transform certain advanced and difficult-to-treat cancers into diseases that are either curable or that can be managed as chronic conditions so that cancer patients can lead longer and better-quality lives.

Today, many cancers are treated with complex regimens and supportive care that are burdensome to the healthcare system and often difficult for patients to endure. At TYME, we are applying the latest advances in the field of cancer metabolism to develop novel cancer metabolism-based therapies (CMBTs™) that target the mechanisms of disease at their source, and thereby create significantly improved outcomes for patients.





Changing the Course of Disease – By Targeting the Source

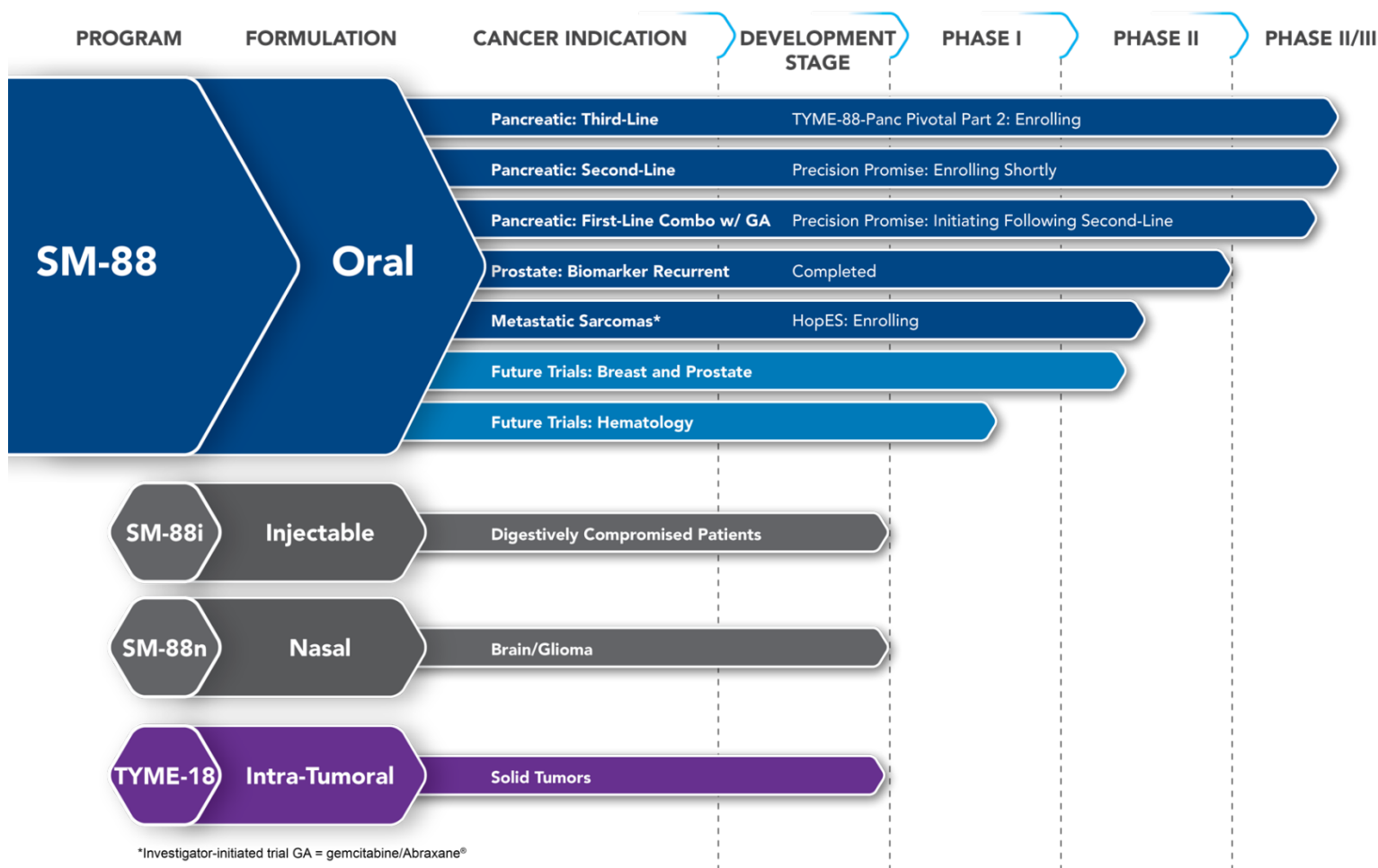
There are few things that cause patients more fear and uncertainty than a cancer diagnosis. Our mission at TYME is to develop innovative, transformational therapies that create better overall outcomes for patients and reduce the burden on healthcare resources. CMBT compounds, our proprietary class of novel cancer metabolism-based investigational therapies, address the underlying causes of the disease that they treat, and not just the symptoms, potentially through multiple mechanisms of action.

Our lead pipeline candidate, oral SM-88 (racemetyrosine), represents a new approach designed to selectively disrupt protein synthesis in cancers with confirmed clinical responses in 15 different cancer types, both solid and liquid tumors, observed across four separate studies. Importantly, a targeted mechanism of action has resulted in fewer than 2% of the approximately 180 patients treated with SM-88 experiencing serious adverse events related to SM-88.

Clinical results from the Part 1 portion of the TYME-88-Panc study, were presented at the European Society of Medical Oncology (ESMO) 21st World Congress on Gastrointestinal Cancer in Barcelona, Spain ([Poster](#)). The study demonstrated a median overall survival of 6.4 months in evaluable patients (N=38) with advanced pancreatic cancer. These survival results compare very favorably to the analysis of 19 prospective pancreatic cancer trials where the median reported survival after progressing on second-line therapy was 2.0 – 2.5 months based on reported historical trials.

In addition, a peer-reviewed study published in [Investigational New Drugs](#) reported that patients with advanced cancers, treated with SM-88 in use with methoxsalen, phenytoin and sirolimus, achieved a median overall survival of 29.8 months and median progression free survival (PFS) of 13 months without additional therapy. Remarkably, 33% of patients (10/30) achieved RECIST complete response (CR) and partial response (PR), with median time to best response of greater than 3 months. 57% of patients (17/30) achieved RECIST stable disease (SD) with a median duration of 11 months. For these patients, we believe the clinical benefit of SM-88 was truly meaningful.

Advancing Our Innovative Pipeline of Cancer Metabolism-Based Compounds (CMBTs™)



Next-generation Cancer Metabolism-Based Therapies Delivering Quality Outcomes for Better Healthcare

TYME continues to develop a strong pipeline of cancer metabolism-based therapies for advanced cancers. We are focusing on metastatic and hard-to-treat cancers for which current therapies are inadequate. We believe that targeting cancer's metabolism by disrupting protein synthesis and increasing oxidative stress has advantages over existing treatment approaches and may benefit patient's lives with improved efficacy and safety profile. Building on our growing knowledge of the biology behind cancer metabolism in solid and hematological cancers, we are investing in novel therapeutic approaches and discovering ways to attack the disease source through multiple mechanisms of actions, including inducing amino acid transport, disrupting critical protein synthesis, modulating autophagy, leveraging immunomodulation and inhibiting key intracellular pathways.

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



We are now enrolling patients in TYME-88-Panc, a pivotal trial with third-line pancreatic cancer to study our lead compound SM-88. Additionally, in partnership with the Pancreatic Cancer Action Network (PanCAN), patients with second-line pancreatic cancer are being enrolled into the PanCAN-sponsored adaptive randomized Phase II/III registration-intent trial known as Precision PromiseSM. We are also currently enrolling patients in a Phase II study evaluating SM-88 in high-risk sarcomas. We presented final SM-88 Phase II clinical data at ESMO 2019 showing encouraging clinical benefit in patients with bio-marker recurrent prostate cancer. To date, we believe SM-88 is one of the rare investigational compounds that has demonstrated confirmed responses across 15 different tumor types.

TYME-18 is a CMBT compound under preclinical development that is designed for intra-tumoral administration of difficult to treat tumors and leverages the acidic tumor microenvironment and signaling pathways to kill cancer cells. TYME-18 is distinct in composition, but like SM-88, targets susceptibilities of cancer that are related to its altered metabolism. Initial preclinical data for TYME-18 in animal tumor models demonstrate rapid and complete tumor regression, with no reported local or systemic toxicities. We continue our TYME-18 preclinical studies to advance proof-of-concept and IND-enabling activities.

Dear Stockholders:

In fiscal 2020, our fourth full year as a public company – TYME delivered extraordinary results culminating with the launch of our first pivotal trial that will evaluate SM-88 for patients with third-line pancreatic cancer, moving us one step closer to becoming a commercial enterprise. Our highest corporate priorities for 2020 were – to present our growing body of clinical data at major international medical meetings; initiate a pivotal study in third-line pancreatic cancer; advance PanCAN’s Precision PromiseSM adaptive randomized Phase II/III registration-intent trial for patients with pancreatic cancer using oral SM-88 in second-line monotherapy; expand clinical study program into sarcomas; secure capital resources that better position TYME to carry out its TYME-88-Panc pivotal trial; advance planning for clinical trials in metastatic breast, prostate and hematological cancers and continue developing pre-clinical and mechanism of action studies. We are proud that we were able to execute on all of these Fiscal Year 2020 corporate priorities.

We truly believe that our accomplishments demonstrate our leadership position in this emerging class of cancer metabolism-based therapies. The key to our success has been to follow the science, invest in great talent and create a culture where people can be the difference and truly impact the world of cancer.

Accelerating the Momentum

The launch of our first pivotal trial to evaluate SM-88 in third-line pancreatic cancer was not the only reason fiscal 2020 was an exceptional year for TYME. In fiscal 2020, we delivered on a number of important milestones and achievements creating multiple value drivers that position the company to create long-term growth and stockholder value.

- ◆ At the beginning of our fiscal year, TYME initiated a preclinical collaboration with NYU Langone to advance the study of SM-88 preclinical data.
- ◆ In July, TYME presented data at ESMO GI 2019 from the TYME-88-Panc Phase II study demonstrating encouraging overall survival trends in patients with advanced pancreatic cancer.
- ◆ In September, TYME presented positive circulating tumor cell and quality of life data from TYME-88-Panc Phase II study in patients with advanced pancreatic cancer at the AACR Special Conference on Pancreatic Cancer 2019.
- ◆ In September, TYME also presented final data at ESMO 2019 from SM-88 Phase II prostate cancer study demonstrating encouraging clinical benefit in patients with biomarker recurrent prostate cancer.
- ◆ In the fiscal third quarter, TYME-88-Panc pivotal trial started enrollment using oral SM-88 as a potential treatment for patients with third-line pancreatic cancer.

- At the start of our fiscal fourth quarter, TYME announced a strategic collaboration with Eagle Pharmaceuticals which entitled TYME to receive up to a total of \$40 million, which included \$20 million upfront and \$20 million in potential milestone payments.
- In January, PanCAN began opening sites in its Precision PromiseSM adaptive randomized Phase II/III registration-intent trial for patients with pancreatic cancer using oral SM-88 in second-line monotherapy.
- In January, The Joseph Ahmed Foundation started enrollment for the investigator-initiated HopES Sarcoma Phase II trial using TYME's oral SM-88 as maintenance monotherapy in patients with previously treated metastatic Ewing's sarcoma and salvage monotherapy in clinically advanced sarcomas.
- In June, TYME presented two abstracts highlighting preclinical data on SM-88 and TYME-18 at the American Association for Cancer Research 2020 Meeting from June 22 to June 24.

To continue to create value for patients and all stakeholders, our fiscal 2021 priorities are structured to broaden market opportunities across multiple metastatic cancers in our portfolio of cancer metabolism-based investigational compounds.

TYME BOARD OF DIRECTORS

"We have never been more optimistic about where our company is heading."



STEVEN HOFFMAN
Chairman of the Board,
Chief Executive Officer



DAVID CARBERRY
Director, Chairman of
Audit Committee



DON DEGOLYER
Director, Chairman of the
Compensation Committee



DOUGLAS A. MICHELS
Director, Chairman of the
Nominating and Corporate
Governance Committee



DR. GERALD H. SOKOL
Director



PAUL L. STURMAN
Director



TIMOTHY C. TYSON
Director

Executing the Plan

For fiscal 2021, our goal is clear: We have no higher priority than to successfully execute our TYME-88-Panc pivotal trial evaluating our lead CMBT candidate, oral SM-88, as a potential treatment for patients with third-line pancreatic cancer. After all, patients with metastatic pancreatic cancer have a very poor prognosis. For those 10,000 patients with pancreatic cancer actively seeking third-line treatment, there are currently no FDA-approved therapies and no oncology guideline recommendations for active therapy. We are excited about the potential of SM-88 as a first-in-class CMBT and are looking forward to evaluating this promising new approach for these patients in our pivotal study.

Moreover, we are evaluating the clinical potential of SM-88 in other areas. Oral SM-88 is included in PanCAN's Precision PromiseSM adaptive randomized Phase II/III registration-intent trial as a second-line monotherapy for patients with pancreatic cancer. We are also enrolling in the HopES Sarcoma Phase II trial evaluating SM-88 in Ewing's- and high-risk sarcomas. We continue to maximize the potential of SM-88 by advancing our plans for new clinical programs into other tumor types where SM-88 has already demonstrated clinical promise such as, metastatic breast, recurrent prostate and hematological cancers.

Furthermore, we recently presented our preclinical data for SM-88 and Tyme-18 at the American Association for Cancer Research 2020 Virtual Meeting. We also plan to publish the final data from the Part 1 results of our TYME-88-Panc study. These events will guide our decisions and planning for a TYME-18 IND-enabling program. Our goal at TYME is to be one of the world's leading biotechnology companies addressing the high unmet medical needs for patients with advanced cancers.

We aspire to play a leading role in advancing the field of cancer metabolism where we can serve as a valuable resource for healthcare providers, their patients and advocates who hope for—and deserve—a better safer approach.

Securing the Future

We are making noteworthy progress across multiple areas of drug development. The major objective of our clinical-trial programs is to broaden our knowledge of the full potential of SM-88, and to evaluate and advance the promising potential of other innovative, proprietary new CMBT compounds. Our clinical-trial programs produced impressive results in fiscal 2020. Data from these studies were highlighted at multiple major international medical meetings by clinical investigators representing leading cancer research centers of excellence.

We will continue to make appropriate investments in our CMBT pipeline that have the potential to yield clinical results of the kind presented throughout fiscal 2020. We are encouraged by what we accomplished and are very excited about the opportunities that lie ahead.

Cultivating a Patient-Centric Culture

An important objective for fiscal 2020 was to advance planning for the transition of TYME into a commercial biotechnology company. To achieve this very important objective, it is paramount for us to continue to reinforce our corporate culture of putting patients first in all we do. Deeply embedded in the TYME culture are innovation, creativity, a “make-it-happen” philosophy and the development and empowerment of its people. The global face of TYME will be formed by people who genuinely have an opportunity to shape their own future and their own success. To the extent they are able to do so, our employees will directly influence the lives of cancer patients around the world and the success of TYME. We continue to engage with talented people to maximize the execution of our clinical, regulatory and commercial plans. We are now in the process of planning our commercial infrastructure to support the potential launch of SM-88. We are encouraged by the progress made thus far in building an agile organization designed to move quickly following potential regulatory approvals. We recognize that the many positive results achieved to date are the product of a determined, dedicated and accomplished team at TYME, our stakeholders and our partners. Therefore, we wish to acknowledge the invaluable counsel that Tommy Thompson contributed over the past several years as a trusted advisor and member of the board, and good friend to all of us at TYME.

**To all of you, we are grateful for your extraordinary
and unwavering support and dedication.**

Outlook to Fiscal 2021

The positive results across multiple milestones achieved in fiscal 2020 positioned TYME to have a pivotal trial in third-line pancreatic cancer; an adaptive randomized Phase II/III registration-intent trial for patients with second-line pancreatic cancer in partnership with PanCAN; a phase II trial for high-risk sarcomas; encouraging final data in Phase II biomarker recurrent prostate study; and capital resources in place, all of which may help serve as the engine of growth for the next five years. Each milestone that we accomplished strengthens our conviction in achieving our fiscal 2021 corporate goals and objectives toward improving the lives of patients with advanced cancers.

Summary

At TYME, we are excited by what has been accomplished and even more energized about what can be achieved over the next several years. We have quickly evolved our science from the conceptual to its practical application as we advance enrollment of patients in our SM-88 clinical trials. We continue to embark on new opportunities and build a model for sustainable growth by expanding our pipeline and broadening our clinical and regulatory plans. We are focused on the key success factors that validate our business model and lead to sustainable, long-term growth. We know what we do well, what our competitive advantages are, and how to leverage them to capture long-term value. We are very proud of all that we have been able to accomplish in a relatively short period of time - and we are just getting started. We could not have arrived at this point without the accomplished team we have in place and we thank each of them for their unwavering dedication towards advancing potentially life-changing therapies to people who are in need. We also could not have reached this point without the wonderful partnership with our clinical trial sites and the patients who have been participants in our clinical trials.

As TYME grows, we have rigorous and robust discussions about how to build on the character and culture of our company—remaining bold and determined, willing to take smart and appropriate risks and focused on applying our expertise to benefit patients diagnosed with cancer. Every day, TYME employees are thinking about what we can do better, how we can further expand on and improve our unique value proposition. We understand the importance of our work for those in need and we expect fiscal 2021 to be a year filled with progress to that end. We are on a path towards offering a novel approach for how difficult-to-treat cancers are combatted in the future.

**TYME is creating
a bold new future
for all of its stakeholders.**

TYME CORPORATE INFORMATION

TYME CORPORATE HEADQUARTERS

1 Pluckemin Way, Suite 103
Bedminster, NJ 07921
(212) 461-2315
TYMEinc.com

TRANSFER AGENT

Continental Stock Transfer and Trust Company
1 State Street, 30th Floor
New York, NY 10004-1561

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Grant Thornton
1250 Connecticut Ave. NW, Suite 400
Washington, DC 20036-3531

FORM 10-K

Copies of the Form 10-K for the fiscal year ended March 31, 2020 may be obtained by stockholders without charge upon written inquiry to the Corporate Secretary at TYME headquarters.

VIRTUAL ANNUAL MEETING

The annual meeting of stockholders of Tyme Technologies, Inc. will be held on Thursday, August 20, 2020 at 11:00 A.M. Eastern Time.

Stockholders will not be able to attend the 2020 Annual Meeting in-person at a physical location. However, the virtual 2020 Annual Meeting will provide stockholders of record as of the close of business on July 01, 2020, the ability to participate, vote their shares and ask questions during the meeting via audio webcast.

To be admitted to the virtual 2020 Annual Meeting, shareholders should visit <https://www.cstproxy.com/tymeinc/2020> and enter the 12-digit control number included on your Important Notice Regarding the Availability of Proxy Materials, on your proxy card, or on the instructions that accompanied your proxy materials.

SECURITY HOLDER INFORMATION

TYME common stock is traded on the NASDAQ CM (Nasdaq Capital Market). NASDAQ Symbol: TYME.

Anyone wishing more information about TYME should direct their inquiries to:

Tyme Technologies, Inc.
Investor Relations
1 Pluckemin Way, Suite 103
Bedminster, NJ 07921

investorrelations@tymeinc.com

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In addition to historical information, this Annual Report (the "Report"), including our Annual Report on Form 10-K for the fiscal year ending March 31, 2020 (the "Form 10-K") and the letter to our stockholders that are included in this Report, contains statements relating to events, developments or results that we expect or anticipate may occur in the future. These statements are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the United States Private Securities Litigation Reform Act of 1995. These forward-looking statements, which may include, without limitation, statements regarding our future results of operations and financial position, our business strategy and plans and our objectives for future operations, statements regarding our drug candidates (including SM-88 and TYME- 18) and their clinical potential and non-toxic safety profiles, our drug development plans and strategies, ongoing and planned clinical trials, preliminary data results and the therapeutic design and mechanisms of our drug candidates, are made on the basis of management's current views, assumptions, expectations or projections with respect to future events. 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. Any forward-looking statement is not a guarantee of future performance, levels of activity, achievements or events and actual results, performance or achievements could differ materially from those contained in the forward-looking statement. These statements speak only as of the date they were made, and we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. In the case of the letter to our stockholders included in this Report, the forward-looking statements are current only as of the date on which we mailed this Annual Report and, in the case of the Form 10-K, the forward-looking statements are current only as of the date on which we filed the Form 10-K with the Securities and Exchange Commission. We operate in a changing environment where new risks emerge from time to time and it is not possible for us to predict all risks that may affect us. The forward-looking statements, as well as our prospects as a whole, are subject to risks and uncertainties, including those set forth in the Risk Factors detailed in Item 1A of Part I of our Form 10-K, that could cause actual results, performance or achievements to differ materially from those set forth in the forward-looking statements.

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