Zacks Small-Cap Research

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Tyme, Inc. (TYMI - OTC)

TYMI: Unique Anti-Cancer Treatment Set For a Phase 2 Study in Metastatic Breast Cancer Patients in 2H 2015…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	04/20/2015
Current Price (08/18/15)	$8.00
Target Price	**$12.00**

FULL UPDATE

On August 14, 2015, Tyme, Inc. filed form 10-Q with financial results for the second quarter of 2015.

Tyme is set to file an IND and initiate a Phase 2 clinical trial to test the company's lead candidate, SM-88, in 80-120 patients with metastatic breast cancer. The IND is likely to be filed during 3Q15 with the Phase 2 clinical trial initiating before the end of 2015.

The company obtained impressive data from a Phase 1 clinical trial of SM-88 in 30 patients with late-stage, metastatic cancer. If those results can be replicated in the upcoming Phase 2 trial, SM-88 has blockbuster potential.

SUMMARY DATA

52-Week High	**$8.50**
52-Week Low	**$6.25**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**473**
Shares Outstanding (mil)	**86**
Market Capitalization ($mil)	**$731**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	0 A	0 A	0 A	0 A	0 A
2015	0 A	0 A	0 E	0 E	0 E
2016					0 E
2017					0 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014					
2015	-$0.08 A	-$0.02 A	-$0.03 E	-$0.03 E	-$0.15 E
2016					-$0.11 E
2017					-$0.10 E

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WHAT'S NEW

Financial Update

On August 14, 2015, Tyme, Inc. (NASDAQ: TYMI) filed Form 10-Q with financial results for the first quarter of 2015. As expected, the company did not have any revenues in the quarter. Net loss for the second quarter of 2015 was $1.8 million, and consisted of $0.8 million in R&D expense, $1.0 million in G&A expense. Actual cash burn for the quarter was $1.6 million.

The company exited the first quarter of 2015 with approximately $3.0 million in cash and cash equivalents. We estimate that this will be enough to fund the company through the end of 2015. In connection with the March 5, 2015 private placement, the company was given a promissory note (PPO note) for $2.5 million. The PPO note was originally secured by the escrow of 5,000,000 shares of company common stock. The PPO note was amended on June 5, 2015, whereby half of the note was paid in cash ($1.25 million) and the maturity date was extended to July 6, 2015. Upon payment of half of the note, 2,500,000 shares of common stock were released from escrow. A second amendment to the PPO note was made on July 26, 2015 where the maturity date of the remaining $1.25 million was extended to five business days following written evidence to the maker of the PPO note that an Investigational New Drug (IND) application for SM-88 has been submitted to the U.S. Food and Drug Administration (FDA). We anticipate the IND being filed during the third quarter of 2015.

Tyme Strengthens Scientific Advisory Board

On June 16, 2015, Tyme announced the appointment of Dr. Guiseppe Del Priore to the company's Medical Advisory Board. Dr. Del Priore is a gynecological oncologist and the National Director of the Gynecological Oncology Southeastern Regional Director at Cancer Treatment Centers of America (CTCA). Prior to joining CTCA, Dr. Del Priore was Professor and Director of Gynecologic Oncology at the Indiana University School of Medicine in Indianapolis. Before that, he was the Director of Gynecologic Oncology at New York Downtown Hospital. Dr. Del Priore earned his Doctor of Medicine with Distinction in Research from State University of New York Downstate Medical Center in Brooklyn, NY. *U.S. News and World Report* named Dr. Del Priore one of its "Best Doctors" in 2011 and 2012.

Business Update

Tyme is developing SM-88, a drug cocktail that takes a novel approach to treat intractable, aggressive, metastatic forms of cancer that have proven refractory to traditional strategies, including radiation, surgery, chemotherapy, and targeted therapeutics aimed at known receptor pathways. The company is focused on exploiting the aberrant metabolic characteristics of cancer cells that make them susceptible to subtle shifts in nutrient availability to which normal cells are impervious. Below we provide background on SM-88, the results of the proof-of-concept Phase 1 clinical trial, and what the Phase 2 clinical trial may look like.

Background on SM-88

Tumor cells are metabolically distinct from normal cells as a direct result of the modulation of intracellular signaling pathways that are altered by different genes through mutation and/or increased expression. Altered signaling pathways not only enable cells to adapt to tumor cell metabolism, but several of these metabolic alterations are also essential for malignant transformation (DeBerardinis *et al.*, 2008). However, these altered signaling pathways also represent opportunities for therapeutic intervention, as a slight perturbation in nutrient availability is enough to send the cancer cell into distress. SM-88 is based on attacking various points of a cancer cell's unique metabolic profile, and – as opposed to most current cancer treatments that target one or two signaling pathways – it is designed to attack at least three separate metabolic pathways that render the cancer cell incapable of acquiring the necessary nutrients to rapidly divide. This ultimately pushes the cell into senescence or cell death.

Unlike most cancer treatments, which are developed by trained medical researchers and tested in animal models, SM-88 was developed by an engineer – Steve Hoffman (Tyme's current CEO) – who became interested in the manner by which electromagnetic radiation killed tumor cells. He scoured the medical literature in a way that was different from the approach typically taken by classically trained cancer investigators. In this approach, tumor cells were viewed to be vulnerable due to the aberrant nature of their metabolism, and mechanisms defined in the

literature were invoked both serially and in parallel to attack tumors using already developed agents. Also unusual was the conscious decision to eschew the use of any preclinical models to test the underlying assumptions in animals. Rather, based upon extensive reading and an effective understanding of the medical literature, a theoretical approach was developed to attack and kill tumor cells selectively while sparing normal cells; and this was then tested in people. Thus far results have been quite encouraging – all while sparing late-stage cancer patients the debilitating side effects associated with chemotherapy, most of which are directly linked to chemotherapy's lack of specificity (i.e., its targeting of any rapidly-proliferating cells).

SM-88 Proof-of-Concept Trial

In November 2011, Luminant Biosciences (the precursor company to Tyme) filed for approval of a clinical trial for SM-88 (then known as SMK) with the Institutional Review Board (IRB) of New York Downtown Hospital. The company enrolled 30 patients with advanced metastatic cancer in the single-center, open-label, proof-of-concept clinical trial. The purpose of the trial was to determine the safety, tolerability, and efficacy of SM-88 in subjects with advanced metastatic cancer. Additional exploratory endpoints were the assessment of progression free survival, objective response rate, duration of response, overall survival, and patient reported outcomes including health-related Quality-of-Life (QoL) and disease/treatment-related symptoms. Between January and December 2012, 30 subjects were enrolled into the study. The patient population was comprised of patients who failed all available anti-cancer treatments and had the following cancer types: 14 had breast cancer, four had non-small cell lung cancer, three had pancreatic cancer, two had prostate cancer, and one patient had each of small cell lung cancer, hepatic cancer, tongue cancer, appendix cancer, thyroid cancer, colon cancer, and a cancer of unknown origin.

Patients received one to 10 courses of therapy, with each course consisting of daily SM-88 administration, five days per week, for a total of six weeks. The therapy was well tolerated, with all drug related adverse events occurring within the first treatment cycle, with the exception of hyperpigmentation, which eventually occurred in all patients. Drug-related or possibly drug-related adverse events (AEs) were mild-to-moderate, self-limiting, and did not require interventional therapy.

During Cycle 1, 24 (80.0%) subjects experienced at least one AE that was considered by the investigator to be possibly, probably, or definitely related to SM-88. The majority of these AEs were fatigue, which was reported as related in 15 (50.0%) subjects. Other AEs reported as related to SM-88 in greater than 10% of subjects were hyperpigmentation (8 subjects, 26.7%) and pain (4 subjects, 13.3%). No serious adverse events (SAE) were reported during Cycle 1 and there were no subject discontinuations due to an AE. Most AEs of fatigue started within two weeks of the onset of treatment and had durations ranging from 1.5 to 3 weeks. Two of those events resolved within one day and approximately one-third were still ongoing at the end of treatment. Three of the events were reported as moderate in severity and the rest were mild. The following table lists all reported AEs.

Adverse Events Reported in SMK Phase 1 Trial: 1st Course

Adverse Event	Number of Patients (30 treated)
Hyperpigmentation	8
Fatigue	15
Lethargy	1
Pain	4
Paresthesia (numbness & tingling)	1
Pigmentation change	2
Pruritus (itching)	1

Source: Tyme, Inc.

It is noteworthy that common side effects of chemotherapy – such as nausea, vomiting, various other gastrointestinal side effects (e.g., GI tract bleeding, constipation, etc.), hair loss, anemia, neutropenia, thrombocytopenia, immune system compromise, and neurotoxicity – were noticeably absent in this trial. The safety profile alone appeared to indicate that the therapy does not adversely impact normal physiological processes or harm normal cells or tissues. Long-term repeat dosing did not appear to increase the toxicity of the regimen, which is also a substantial differentiator compared to chemotherapy.

In this study, the most striking findings were on the level of tumor response and patient survival. The last assessment of tumor responses was performed on November 15, 2013 and at that time 25 of 30 treated subjects were evaluable according to the Response Evaluation Criteria In Solid Tumors (RECIST) classification guidelines (Therasse *et al*., 2000). The results are presented in the following table.

RECIST Results

Tumor Response	Number of Subjects n = 25
Complete Response	2 (8%)
Partial Response	3 (12%)
Stable Disease	18 (72%)
Progressive Disease	2 (8%)

Source: Tyme, Inc.

Evaluation of target lesions according to RECIST is defined by the following:

- ✓ Complete Response (CR): Disappearance of all target lesions
- ✓ Partial Response (PR): At least a 30% decrease in the sum of the longest diameter (LD) of target lesions, taking as reference the baseline sum LD
- ✓ Stable Disease (SD): Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference the smallest sum LD since the treatment started
- ✓ Progressive Disease (PD): At least a 20% increase in the sum of the LD of target lesions, taking as reference the smallest sum LD recorded since treatment started or appearance of ≥1 new lesions

Evaluation of non-target lesions according to RECIST is defined by the following:

- ✓ Complete Response (CR): Disappearance of all non-target lesions and normalizing of marker levels
- ✓ Incomplete Response/ Stable Disease (SD): Persistence of one or more non-target lesion(s) or/and maintenance of tumor marker level above the normal limits
- ✓ Progressive Disease (PD): Appearance of one or more new lesions and/or unequivocal progression of existing non-target lesions

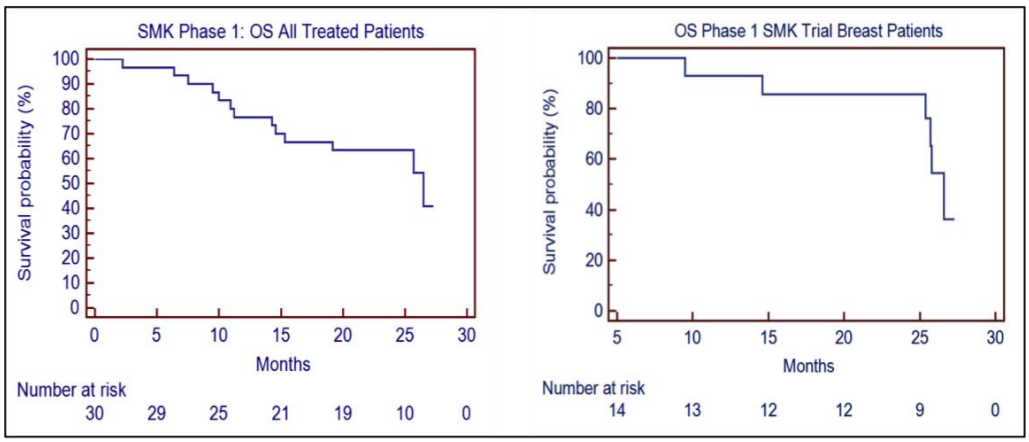
There are a number of ways to report clinical trial data for cancer therapies (Kogan *et al*., 2008). Objective response rate (ORR) is defined by the FDA as the "proportion of patients with a tumor size reduction of a predefined amount and for a minimum period of time", in other words CR + PR. For the SM-88 trial, there was an ORR of 20%. Perhaps the most striking piece of data from the SM-88 trial was the 72% of patients who achieved stable disease (SD). Interestingly, while most companies (and investors) focus on CR and ORR, a 2009 study from Japan in 602 patients with lung cancer showed very little difference in overall survival between those patients with CR/PR (16.1 months) compared to patients with SD (15.2 months) (Watanabe *et al*., 2009).

In recent years a number of studies have been reporting the Disease Control Rate (DCR), which calculated by adding the ORR to the percent SD (ORR + SD). For the SM-88 trial, the DCR was 92%. The DCR was shown to be a more powerful predictor of survival than ORR in a lung cancer study (Lara *et al*., 2008) and in analysis of three separate breast cancer studies (Liu *et al*., 2011). It should be noted that the five of the 30 patients that were not evaluable were excluded not because they were deceased, in fact they are all still alive, but because of the strict criteria that must be met for inclusion that requires having a certain number of scans available for evaluation. The excluded patients were typically missing one of the necessary scans. If included in the last assessment, the five excluded patients included three complete responses and two partial responses. Including these patients in the final analysis lifts the ORR to 33% (10/30) and the DCR to 93% (28/30), results that are quite impressive for a group of patients with Stage IV cancer.

It is impossible to directly compare the data from the SM-88 study to those generated in other oncology trials with different experimental or approved therapies, particularly since there was no control arm in the SM-88 trial. However, it is interesting to compare the data to other studies in patients deemed refractory to at least one line of chemotherapy prior to study entry. In such settings, there are examples such as the following:

- Colorectal cancer: Erbitux (irinotecan-refractory patients): 10.5% PR, 35% SD (Saltz *et al*., 2004).
- Metastatic breast cancer: Tykerb + Herceptin: 10.3% ORR (O'Sullivan *et al*., 2014).
  Perjeta: 3.4% ORR (Zagouri *et al*., 2013).
- Non-small cell lung cancer: Erlotinib: 8.9% ORR (vs. <1% on placebo) (Shepherd *et al*., 2005).

Another intriguing aspect of the data from the first proof-of-concept clinical trial of SM-88 was the long-term survival of the patients from this study. As of June 2014, more than two years after the trial began, 17/30 patients were still alive and 8/14 breast cancer subjects remained alive. Accordingly, median survival had still not been reached either in the overall group or the cohort of patients with breast cancer. In an environment where next-generation therapeutics typically provide only a few extra months or weeks of survival benefit, an approach that seemingly adds years to patients' lives seems to be substantially differentiated. The charts below depict the Kaplan-Meier curves of this population.



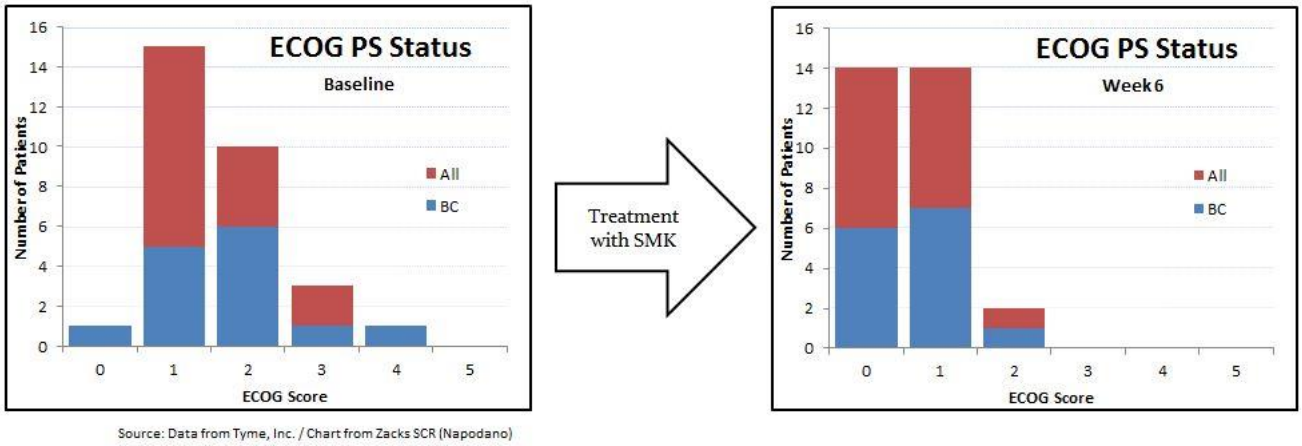
Source: Tyme, Inc.

While there is no current long-term follow-up data from this study available, it is worthwhile pointing out that even if the survival results had not improved at all from the last recorded time point, survival of >2.5 years for patients with Stage IV, disseminated disease that had been heavily pre-treated is unprecedented. The meager survival-promoting effects of currently-marketed anti-cancer agents is well-documented – a notable example is that of the Roche / Genentech drug Avastin® (bevacizumab), which has achieved the following survival results in various heavily pretreated, refractory patient populations:

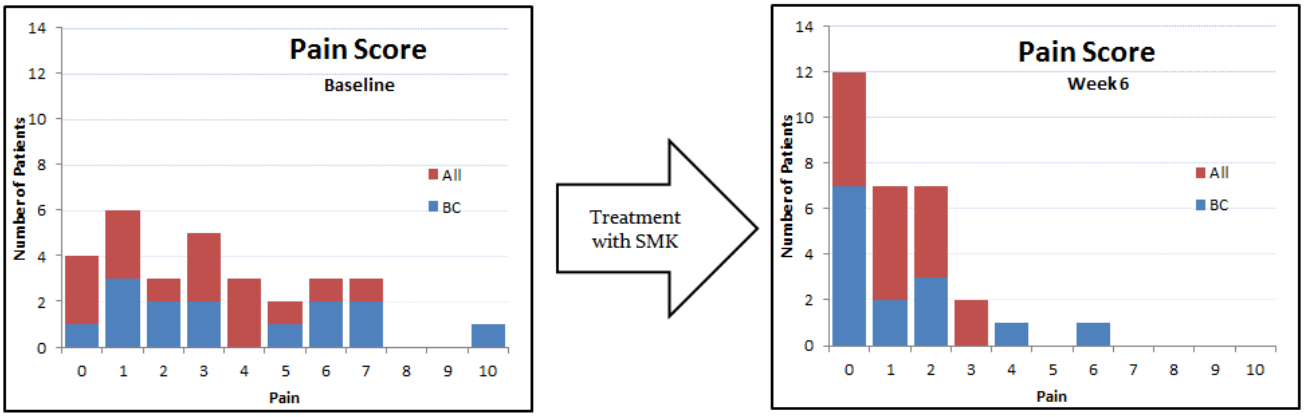
→ Advanced breast cancer: no survival benefit
→ Advanced cervical cancer: ↑ 3.7 months
→ Advanced colorectal cancer: ↑ 2.2 months
→ Advanced lung cancer: ↑ 4 months
→ Advanced glioblastoma: no survival benefit
→ Advanced renal cancer: no survival benefit

Avastin® has been associated with a litany of side effects, including potentially life-threatening blood clots in the lungs, hemorrhages, nausea, vomiting, diarrhea, headaches, dizziness, abdominal pain, and reduced white cell counts. The drug's cost is also a substantial drawback – currently, Avastin® costs over $50,000 per patient for only four to five months of therapy.

Virtually all patients manifested dramatic and rapid improvements in Eastern Cooperative Oncology Group (ECOG) performance status (PS), European Organization for the Research and Treatment of Cancer (EORTC) quality-of-life (QoL) measures, and self-reported pain scores during the first six-week course of treatment. These changes were rapid, dramatic, and durable in nature, as shown in the following charts for all treated patients and for just breast cancer (BC) patients. Once these improvements had occurred, they persisted. Only one patient in this trial entered with an ECOG PS of 0, and 14 patients had a PS of 0 after six weeks of therapy. It is worth noting that the patient with an ECOG PS of 4 improved to a PS of 1 during this time. A dramatic improvement in self-reported pain was seen in all patients. Four patients entered the trial with no pain, which improved to 12 patients by the end of the initial six weeks. The impact of SM-88 therapy on these outcome measures could be considered even more differentiating than the impact on survival, because there are virtually no therapeutic agents currently marketed to treat cancer that are capable of providing these kinds of benefits to patients.

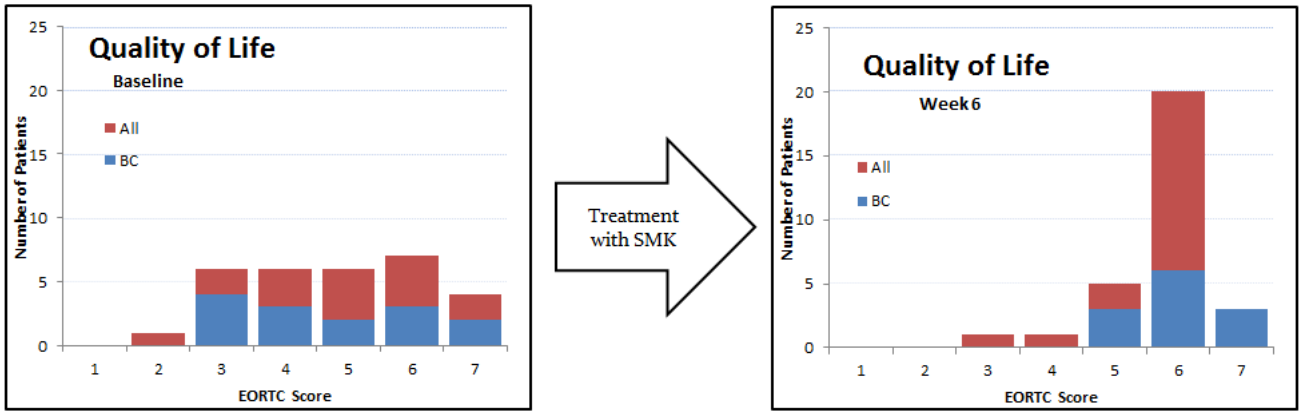


Source: Data from Tyme, Inc. / Chart from Zacks SCR (Napodano)



Source: Data from Tyme, Inc. / Chart from Zacks SCR (Napodano)

The EORTC QLQ C30 quality of life assessment tool incorporates nine multi-item scales, five functional scales (physical, role, cognitive, emotional, and social), three symptom scales (fatigue, pain, and nausea and vomiting), and a global health and quality-of-life scale. Unlike the pain and performance status scales in which low scores are good, the EORTC QoL goes from 0 = worst QoL to 7 = best QoL. Eleven of the 30 treated patients entered the study with excellent or near-excellent QoL ratings; by the end of the first six weeks, 23/30 patients fell into this category.



Source: Data from Tyme, Inc. / Chart from Zacks SCR (Napodano)

Anecdotal evidence of efficacy has also been gathered from additional patients, who were treated on a compassionate use basis. Among the more striking cases were:

(1) The report of an 18-year old male with Stage IV Ewing's sarcoma and bone metastases, who had previously been treated aggressively with surgery – including the removal of a kidney – to no avail, and who was also treated with various chemotherapeutic drugs (cyclophosphamide, vincristine, doxorubicin,

irinotecan, and temozolomide), without success and who was given weeks to live, yet who exhibited a dramatic response to SM-88 treatment and who is still alive roughly nine months post-SM-88 dosing;

(2) A 22-year old male with Stage IV non-Hodgkin's lymphoma (NHL), who was refractory to radiation, chemotherapy, and targeted therapy (brentuximab vedotin, known by the trade name Adcetris®) at the time of treatment with SM-88, who achieved a complete response after less than two months on treatment;

(3) A 56-year-old male with Stage IV prostate cancer, who experienced normalization of prostate-specific antigen (PSA) levels after only two weeks of treatment with SM-88. The compassionate access experience provides further evidence of the broad-spectrum activity achieved with this approach, as well as the activity across both solid and liquid tumor types.

In summary, SM-88 appears to be a safe and well-tolerated therapeutic regimen that induced unexpected increases in survival in a variety of Stage IV patients with many different tumor types, along with rapid and profound improvements in performance status, quality-of-life, and pain outcome measures in all treated patients. It is noteworthy that these responses occurred in "salvage" patients with fully disseminated Stage IV tumors who had failed all prior therapies – many of whom were referred by Memorial-Sloan Kettering Cancer Center (MSKCC) in New York City, as no approved treatment options remained for these patients.

Phase 2 Development Plan

The company is planning to file an Investigational New Drug (IND) application with the FDA for SM-88 such that a Phase 2 clinical trial can be initiated. The IND should be filed during the third quarter of 2015. The trial will be a single-arm, open label trial. There are likely to be 10-20 clinical sites involved and the plan is to enroll 80-120 patients. All of the patients will have metastatic breast cancer that is refractory to more than one prior treatment. There will be no selection for patients based on receptor status, thus the trial will enroll patients who are positive or negative for estrogen receptor (ER), progesterone receptor (PR), and HER2.

Patients with metastatic breast cancer represent a very difficult cohort to treat, as the disease is considered incurable once it metastasizes and therapeutic goals are palliative in nature. The median overall survival for patients with metastatic breast cancer is 2-4 years (Chung *et al*., 2003); however, those statistics are for women who are previously untreated. Those with refractory metastatic breast cancer have a much worse prognosis as they have a median overall survival of 8-9 months (Pontiggia *et al*., 1995). While less than 10% of newly diagnosed patients (out of a total of approximately 230,000) will present with locally advanced or metastatic disease (Bernard-Marty *et al*., 2004), approximately 25% of patients diagnosed at earlier stages will relapse with metastatic disease (Metastatic Breast Cancer Network).

Once initiated, we anticipate that the Phase 2 trial will enroll patients fairly quickly, as there are no further treatment options for patients with refractory metastatic breast cancer and the trial is going to take place at between 10 and 20 clinical centers in the U.S. If the company can get the IND filed during the third quarter of 2015, then the clinical trial is likely to begin in the fourth quarter of 2015. Given an expected survival of 8-9 months for the patients, by the end of 2016 we should have a fairly clear understanding of whether SM-88 is prolonging overall survival.

Conclusion and Recommendation

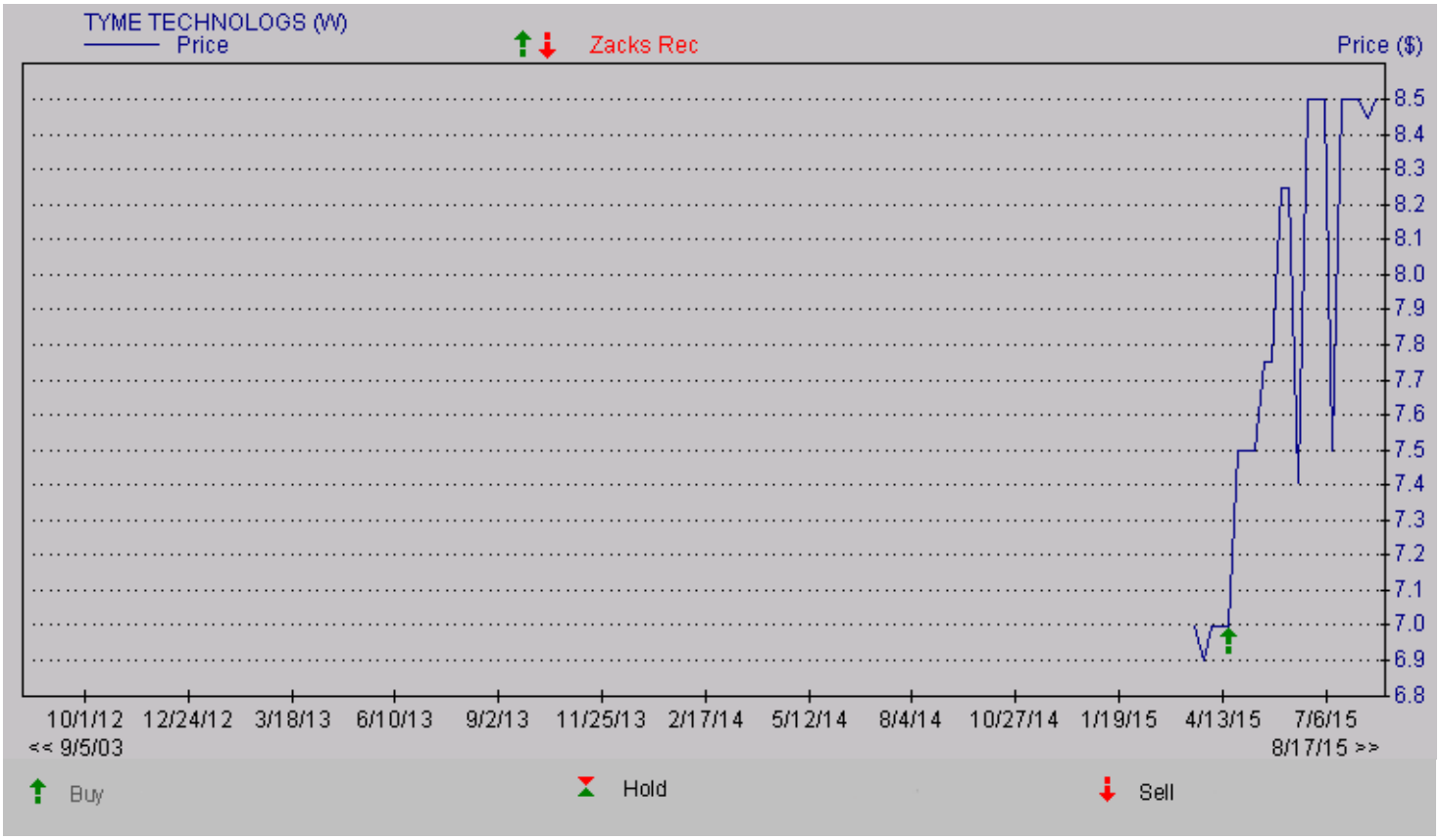
We have chosen to model potential sales of SM-88 solely in late-stage, metastatic breast cancer patients. However, based on what appears to be a broad applicability across multiple tumor types this analysis may ultimately be too restrictive if the results seen in the Phase 1 trial are replicated in a larger clinical trial. The possibility of broader applicability into other types of cancer – e.g., renal cell carcinoma, Ewing's sarcoma, lymphomas and leukemias – could represent sources of upside to our estimates. No revenue from an expanded access program is assumed, which may be conservative – companies like Pharmion and Celgene generated tens of millions of dollars from such programs prior to the actual formal approval of several of their anti-cancer drugs. We estimate peak revenues in the U.S. and E.U. of approximately $3.3 and $3.0 billion, respectively (with a 15% royalty generated through a partnership on sales in the E.U.). We think the shares are worth approximately $12 and we are maintaining a 'Buy' rating.

Tyme, Inc.
Income Statement

Tyme, Inc.	2014 A	Q1 A	Q2 A	Q3 E	Q4 E	2015 E	2016 E
SM-88 (Breast Cancer)	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-
Grants & Collaborative Revenue	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-
Research & Development	$0.8	$0.5	$0.8	$0.6	$0.7	$2.6	$3.0
General & Administrative	$1.8	$1.6	$1.0	$1.7	$1.7	$5.9	$7.5
Other Expenses	$0	$0	$0	$0	$0	$0	$0
Operating Income	($2.6)	($2.1)	($1.8)	($2.3)	($2.4)	($8.5)	($10.5)
Operating Margin	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($0.1)	($3.5)	$0.0	($0.1)	($0.1)	($3.7)	($0.1)
Pre-Tax Income	($2.7)	($5.6)	($1.8)	($2.4)	($2.5)	($12.3)	($10.6)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($2.661)**	**($5.6)**	**($1.8)**	**($2.4)**	**($2.5)**	**($12.3)**	**($10.6)**
Net Margin	-	-	-	-	-	-	-
Reported EPS	**($1,330)**	**($0.08)**	**($0.02)**	**($0.03)**	**($0.03)**	**($0.15)**	**($0.11)**
YOY Growth	-	-	-	-	-	-	-
Basic Shares Outstanding	0.0	73.4	86.0	88.0	90.0	84.4	100.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

HISTORICAL ZACKS RECOMMENDATIONS



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Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters.
Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 28.1%, Hold/Neutral- 54.0%, Sell/Underperform – 14.9%. Data is as of midnight on the business day immediately prior to this publication.