Zacks Small-Cap Research

September 28, 2015

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Metastat Inc (MTST-OTC)

MTST: Lab Receives State License, Last Major Step Before CLIA Certification

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	07/06/2015
Current Price (09/28/15)	$0.35
Target Price	**$0.75**

OUTLOOK

MTST, in collaboration with some of the leading cancer research institutions, discovered the critical roll that the Mena protein appears to play in cancer metastasis. MetaSite Breast and MenaCalc Breast, in late stage development, identify the presence of Mena and tumor microenvironments which have been shown in clinical studies to be associated with cancer metastasis. Performance looks to be superior to already commercialized metastatic-risk based diagnostics. MTST hopes to launch their breast cancer tests in 2016. MenaCalc is a platform technology which MTST hopes to exploit and launch follow-on tests for cancers of the lung (positive clinical data just reported), prostate and colon.

SUMMARY DATA

52-Week High	**$0.86**
52-Week Low	**$0.20**
One-Year Return (%)	**-59.21**
Beta	**0.36**
Average Daily Volume (sh)	**39,257**
Shares Outstanding (mil)	**28**
Market Capitalization ($mil)	**$10**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**9**
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 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**N/A**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(in 000s of $)

	Q1 (May)	Q2 (Aug)	Q3 (Nov)	Q4 (Feb)	Year (Feb)
2015	0 A	0 A	0 A	0 A	0 A
2016	0 A	0 E	0 E	0 E	0 E
2017					1,467 E
2018					5,893 E

Earnings per Share

	Q1 (May)	Q2 (Aug)	Q3 (Nov)	Q4 (Feb)	Year (Feb)
2015	-$0.06 A	-$0.07 A	-$0.05 A	-$0.05 A	-$0.33 A
2016	-$0.08 A	-$0.06 E	-$0.08 E	-$0.09 E	-$0.31 E
2017					-$0.25 E
2018					-$0.19 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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MTST Receives State Lab License, CLIA Cert Should Be Next. Follows Positive Test Results
This morning (9/28) MTST announced that they have received Massachusetts state licensure for their Boston-based pathology lab. This is the last major step before receiving CLIA certification from CMS. The state license is issued following a survey (i.e. – inspection) by the Massachusetts State Department of Health and allows for the company to begin processing tissue samples.

The state licensure follows on the heels of studies validating the performance and accuracy of MTST's fully automated MetaSite Breast assay. In late August MTST announced the automated (i.e. – to-be commercialized) MetaSite Breast assay showed greater than 97% analytical precision as compared to results of the Rohan et al study. As a reminder, the Rohan et al study, which included 481 patients with breast cancer, showed a highly statistically significant (95% C.I., p=0.004) association between risk of metastasis and MetaSite score in women with ER-positive/HER2-negative breast cancer. This represented a 2.7x increase in the odds of metastasis for women with a high risk score compared to those with a low risk score. In addition, for every increase of 10 MetaSites, there was a 1.16x increase in the risk of metastasis in this sub-population.

Additional confirmation of the accuracy and performance of the automated assay came just last week when MTST announced topline results from an independent study which again showed that MetaSite score was significantly associated with risk of distant metastasis in women with ER-positive/HER2-negative breast cancer. The data, which also confirmed results from Rohan et al, met its primary endpoint and not only showed MetaSite score was significantly and directly associated with increased risk of distant metastasis for both high versus low MetaSite scores (OR = 3.4; 95%CI = 2.8-4.1; P=0.0002), it also showed statistically significant association of risk of cancer metastasis between low and intermediate scores (OR=3.24; 95%CI = 2.6-3.9; P=0.0006).

Validation of the accuracy of the automated test is a major milestone as this is the test that is expected to be commercialized. This should also bode well for eventual CLIA certification (Kaiser validation study will be used to support CLIA certification) – which the company anticipates could happen in Q1 2016. MTST continues to conduct additional validation studies (including to predict response to chemotherapy) with data from the following various studies expected;

- Kaiser cohort MetaSite replication study: topline data expected Q4 2015. This will be used to support CLIA certification
    - Replicate findings of Rohan et al
    - Primary endpoint is direct association between risk of distant metastasis and MetaSite score in ER+/HER2- patients

- Kaiser cohort MetaSite/MenaCalc combined: topline data expected Q1 2016
    - Define product specs and risk cut-points for combined MetaSite/MenaCalc score as compared to MetaSite score and/or MenaCalc score
    - Define the assay or assays to be used in subsequent validation studies
    - Primary endpoint is direct assoc. between risk of distant metastasis and MetaSite/MenaCalc score in ER+/HER2-, triple negative and/or HER2+ invasive breast cancer patients

- ECOG 2197 cohort validation study: topline data expected Q1 2016. This is the pivotal clinical validation study for MetaStat in early stage breast cancer
    - Compare MetaSite/MenaCalc scores with Oncotype DX's "recurrence score"
    - Primary endpoint is direct assoc. between risk of distant metastasis and MetaSite/MenaCalc score in ER+/HER2-, triple negative and/or HER2+ invasive breast cancer patients

- Chemo-predictive study: topline data expected Q2 2016
    - Evaluate ability of MenaCal/MetaSite Breast to predict response of adding adjuvant chemotherapy to hormonal therapy in ER+ patients
    - Primary endpoint is direct association between risk classification and benefit from chemotherapy comparing Kaplan-Meier survival curves of treatment with tamoxifen alone versus treatment with combo of tamoxifen and adjuvant chemotherapy for all patients and high, medium and low risk cohorts

The company continues to expect initial commercialization to happen next year.

Additional Operational Progress
In addition to the recent positive study results using the automated assay, the company has made other operational progress. This includes bringing on Dr. Bruce Zetter to the Scientific and Clinical Advisory Board and appointing Dr. Michael Donovan (MD and PhD) as Chief Medical Officer. Both individuals are highly seasoned in cancer diagnostics and related research and should provide invaluable resources to help MTST guide their clinical programs.

Dr. Zetter is the Charles Nowiszewski Professor in the Departments of Cell Biology and Surgery at Harvard Medical School. Per MTST's press release, he is an internationally recognized leader in cancer research, tumor progression, cancer diagnosis, cancer metastasis, and tumor angiogenesis.

Dr. Donovan had previously been the Chief Medical Officer of Exosome Diagnostics, Inc and Chief Scientific Officer for Aureon Biosciences. Per MTST's press release, he is board-certified in anatomic and clinical pathology and pediatric pathology with extensive experience in designing and implementing clinical studies. He has spearheaded the utilization of multiplex tissue and fluid-based assays and coupled mathematic applications to produce clinically relevant diagnostic/predictive/prognostic outcome models for a variety of tumor types and disease states. Dr. Donovan also serves as a Professor of Experimental Pathology and Director of the Biorepository and Pathology core at the Icahn School of Medicine at Mt. Sinai, New York City, New York.

MTST has also raised additional capital to help fund the various clinical studies. This includes the sale of $1.2M of non-convertible debt (1yr, 8%) in late July.

VALUATION / RECOMMENDATION

Ballparking initial launch in mid/late calendar 2016…
MTST has indicated that they hope to have their initial breast assay(s) commercialized in the U.S. market sometime in calendar 2016 with the launch and roll-out supported by the existing positive clinical data as well as more data from the newly initiated studies. Prerequisite for the launch will be completing any necessary build-out and regulatory/accreditation requirements of their lab in order to meet CLIA compliance - this is expected to be wrapped up in calendar Q1 2016. With Massachusetts state licensure coming in September, MTST has cleared the last major hurdle prior to receiving CLIA certification. The company will also need to line up initial distribution/sales infrastructure and will also likely be looking to raise additional capital to fund ongoing operations including R&D/clinical trial activities as well as any pre-launch preparations.

Given the list of boxes that need to be checked off prior to initiating launch, we are modeling initial introduction of the breast cancer assays around mid-to-late calendar 2016. MTST hopes to establish substantial distribution reach at the outset by partnering with well established sales organizations and through relationship-building at the hospital and cancer center levels. We model approximately $1.5 million of revenue in fiscal 2017 (ending Feb 28, 2017), which represents about 2% of the low-hanging fruit addressable breast cancer market (i.e. - Oncotype DX "intermediate risk" market) and less than 1% of the total addressable breast cancer market.

Market share gains from low-hanging fruit, expanded label…
The second and third years on the market (fiscal 2018 and 2019) we model revenue of approximately $5.9M and $21.5M, which assumes deeper penetration of the (previously defined) low-hanging fruit opportunity but represents less than 9% penetration of the total addressable market in 2019. This compares to the $4.8M and $27M Oncotype DX generated in its second and third full years after launch. We further assume MTST realizes average pricing of about $1.1k per test, a significant discount (i.e. again, applying conservative assumptions) to Oncotype DX's ~$3.5k).

We think our somewhat more conservative approach is warranted given the relative dearth of competition to Oncotype DX following its launch in 2004 and the fact that Genomic Health had substantially more financial resources at the time (compared to MTST today) to support the roll-out. However, we also think MenaCalc/MetaSite Breast have the potential to be well received given the compelling clinical data to-date (which indicates potentially superior performance over Oncotype DX) as well as near-term data which could provide further insight into the utility of the technology and potentially demonstrate even greater benefit over Oncotype DX (possibly including in cancer subtypes which exclude competing tests).

MTST has indicated that they will continue to build their clinical database beyond the already planned studies and look to further broaden the indicated uses for the breast cancer assays (similar to what GHDX did with Oncotype DX following initial commercialization). We think an expanded breast cancer label, which could include additional cancer subtypes, survival independent of therapy and predictive of chemotherapy response (among others) would provide meaningful additional competitive benefits and could result in an acceleration in market share gains.

Follow-on launches in other cancers…
Following launch in breast cancer MTST hopes to bring one new assay to market in other cancers at a rate of one every 12 to 18 months. And while we think the bulk of the revenue opportunity lies with breast cancer, expanding the portfolio to include additional cancers offers meaningful market-expansion and scalability opportunities.

The positive clinical data presented in non-small cell lung cancer at AACR in April 2015 was the first major step towards commercialization of a lung cancer test, which is expected to be MTST's next product launch in the U.S. We currently model this to be a fiscal 2018 event. Importantly, while GHDX has Oncotype DX tests for cancers of the breast, prostate and colon, they do not for lung cancer. In addition, the Mena^{calc} Lung data demonstrated significant predictive ability in squamous cell. The lack of significant competition and the presence of a low-hanging fruit opportunity in SCC may present ripe conditions for a particularly receptive market for MetaStat's lung cancer assay.

Beyond lung cancer, visibility of the potential timing of introduction of tests in prostate and colorectal cancers is somewhat more cloudy, particularly given the lack of clinical data to be able to anchor to. However, as demonstrated in breast and lung cancer, patient samples have been readily available and these studies can be

completed fairly swiftly and cost-effectively. In the span of just over 3 years GHDX was able to bring three new tests to market. As such, we think it is reasonable MTST could have lung, prostate and colorectal cancer tests commercialized within the next five years, and potentially earlier (MTST is aiming for closer to 3 - 4 years). We more conservatively model launch of a prostate and colorectal cancer test in fiscal 2020 and 2021, respectively.

Value MTST at $0.75/share

We value MTST using a combination of 10-year DCF and P/S comparables. We model incremental revenue contribution to begin for tests in; NSCLC in 2018, prostate cancer in 2020 and colorectal cancer in 2021. However, the breast cancer assays remain the majority driver of revenue throughout the term of 10-year DCF. We model revenue to grow from $21.5M in 2019 to approximately $111M in 2025 (the ninth year on the market). For reference, GHDX generated almost $260M in revenue from their Oncotype DX franchise (the majority of which comes from their breast cancer assays) 9 years post-launch - which arguably indicates our model is conservative.

We assume gross margin grows from about 41% in the initial year of launch with relatively low production volumes to around 80% with improvement in reimbursement and laboratory/operating efficiencies. For reference, Oncotype DX gross margins are currently about 82%.

Using these inputs along with a 10% discount rate and 2% terminal growth rate, our 10-year DCF calculates fair value at approximately **$0.75/share**.

This valuation is supported with P/S comparables. Competitors NSTG and GHDX trade at 5.1x and 2.6x 2015 analysts' consensus revenue estimates. We apply the average (3.9x) to our estimated 2018 revenue of $5.9M and discount this back at 15%, which results in a per share value of approximately $0.70.

We value MTST at $0.75/share and recommend investors accumulate up to this level.

FINANCIAL MODEL

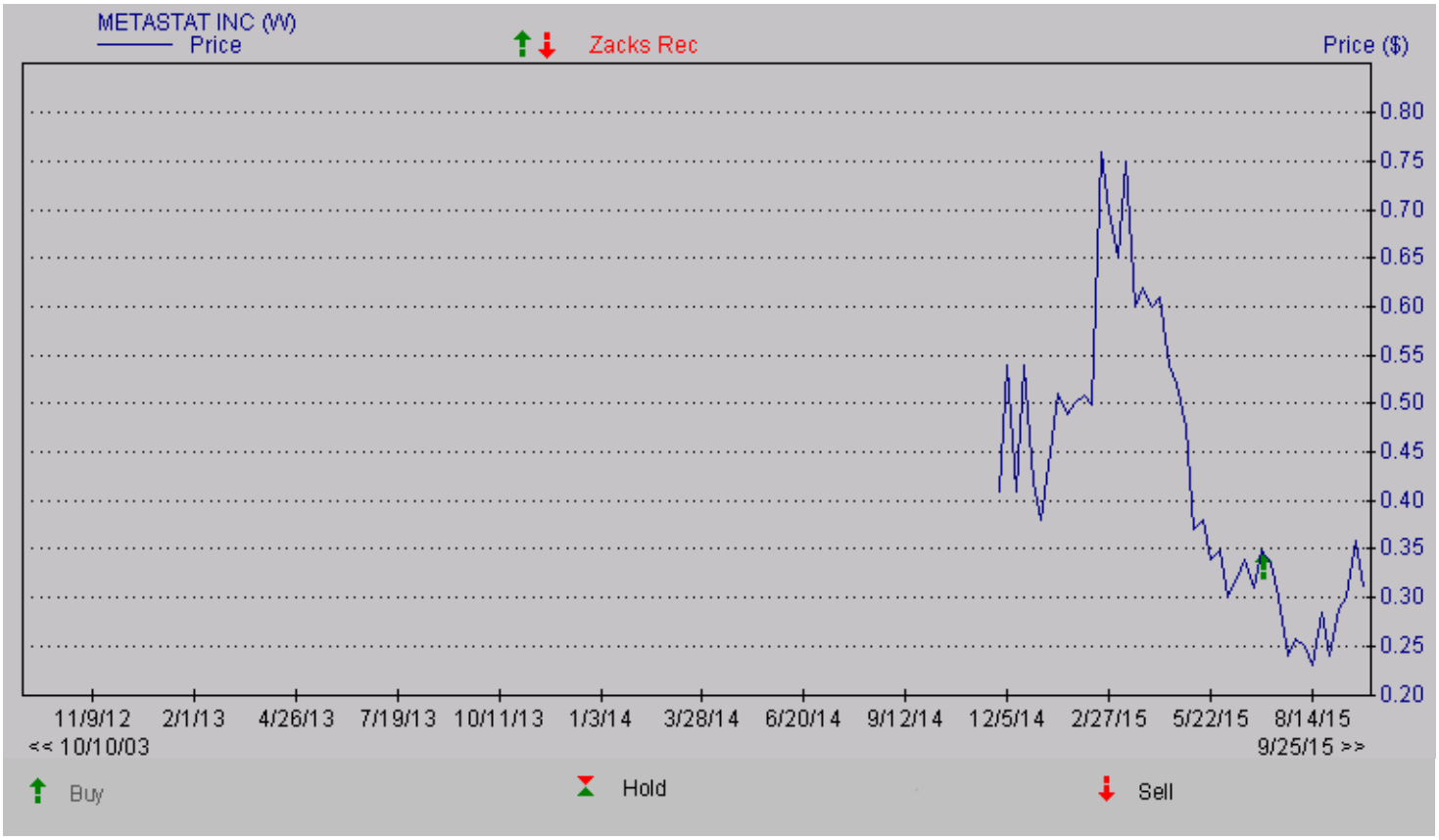
MetaStat, Inc.

	2015 A	Q1 A	Q2 E	Q3 E	Q4 E	2016 E	2017 E	2018 E	2019 E
Breast Cancer									
Addressable market penetration	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.68%	2.38%	8.71%
Revenue	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$1,467.3**	**$5,136.0**	**$18,910.8**
NSCLC									
Addressable market penetration	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.69%	2.36%
Revenue	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.0**	**$756.8**	**$2,551.6**
Prostate Cancer									
Addressable market penetration	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Revenue	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.0**	**$0.0**	**$0.0**
Colorectal Cancer									
Addressable market penetration	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Revenue	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.0**	**$0.0**	**$0.0**
Total Revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1,467.3	$5,892.8	$21,462.5
YOY Growth	-	-	-	-	-	-	-	*301.6%*	*264.2%*
Cost of Revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$865.7	$2,710.7	$7,082.6
Gross Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$601.6	$3,182.1	$14,379.9
Gross Margin	-	-	-	-	-	-	*41.0%*	*54.0%*	*67.0%*
SG&A	$3,524.9	$948.9	$995.0	$1,121.0	$1,115.0	$4,179.9	$5,167.8	$7,041.8	$14,959.4
%SG&A	-	-	-	-	-	-	*352.2%*	*119.5%*	*69.7%*
R&D	$1,266.2	$219.3	$587.0	$993.0	$1,289.0	$3,088.3	$4,192.0	$4,216.0	$4,648.0
%R&D	-	-	-	-	-	-	*285.7%*	*71.5%*	*21.7%*
Operating Income	($4,791.1)	($1,168.2)	($1,582.0)	($2,114.0)	($2,404.0)	($7,268.2)	($8,758.2)	($8,075.8)	($5,227.5)
Operating Margin	-	-	-	-	-	-	*-596.9%*	*-137.0%*	*-24.4%*
Total Other (Inc) / Exp	$3,204.4	($93.3)	$79.0	$69.0	$32.0	$133.2	$292.0	$81.0	$207.0
Pre-Tax Income	($7,995.5)	($1,074.9)	($1,661.0)	($2,183.0)	($2,436.0)	($7,401.4)	($9,050.2)	($8,156.8)	($5,434.5)
Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($8,237.5)	($2,197.7)	($1,716.0)	($2,238.0)	($2,491.0)	($8,689.2)	($9,050.2)	($8,156.8)	($5,434.5)
YOY Growth	*53.5%*	*78.4%*	*-60.1%*	*59.0%*	*92.5%*	*5.5%*	*4.2%*	*-9.9%*	*-33.4%*
Net Margin	-	-	-	-	-	-	*-616.8%*	*-138.4%*	*-25.3%*
EPS	($0.33)	($0.08)	($0.06)	($0.08)	($0.09)	($0.31)	($0.25)	($0.19)	($0.10)
YOY Growth	*30.4%*	*42.1%*	*-63.6%*	*47.2%*	*71.2%*	*-7.0%*	*-19.1%*	*-22.1%*	*-46.6%*
Diluted Shares O/S	24,929	27,139	28,005	28,840	29,082	28,266	36,410	42,130	52,545

Brian Marckx, CFA

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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- 26.2%, Hold/Neutral- 54.1%, Sell/Underperform – 16.8%. Data is as of midnight on the business day immediately prior to this publication.