Zacks Small-Cap Research

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Brian Marckx, CFA
bmarckx@zacks.com
Ph (312) 265-9474

scr.zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

Metastat Inc (MTST-OTC)

MTST: MenaCalc Study Data Published in BioMed Central Cancer

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	07/06/2015
Current Price (09/04/15)	$0.32
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	**$0.20**
One-Year Return (%)	**-40.76**
Beta	**0.36**
Average Daily Volume (sh)	**31,530**
Shares Outstanding (mil)	**28**
Market Capitalization ($mil)	**$9**
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	-$0.08 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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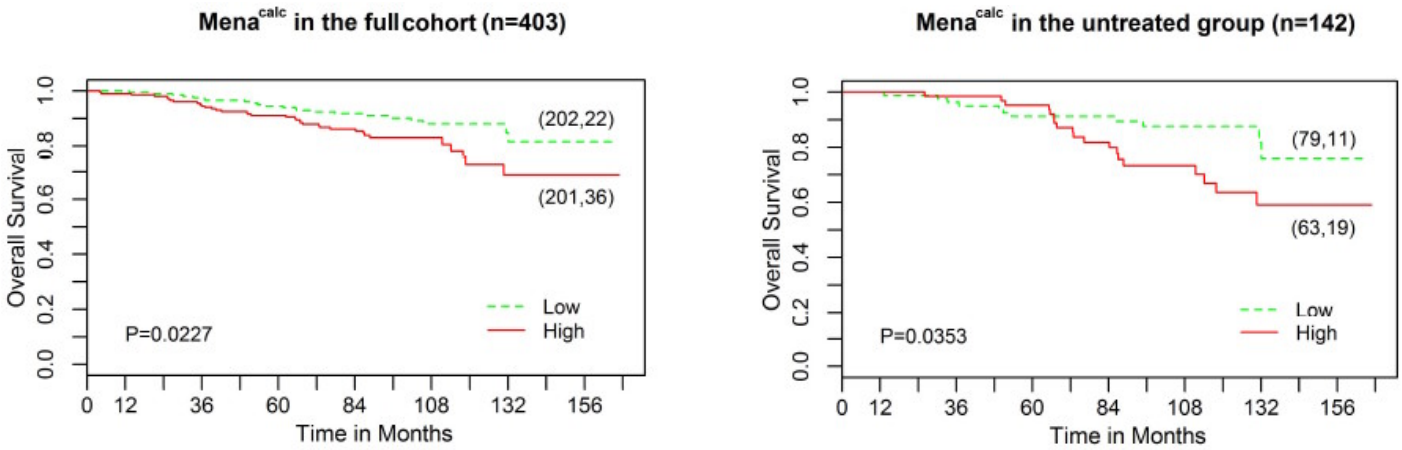
WHAT's NEW…..

MenaCalc ANN Study Published in BioMed Central Cancer
A manuscript of the MenaCalc 403-patient axillary node-negative study was published in the current issue of BioMed Central Cancer. The study, titled *Mena^{calc} , a Quantitative Method of Metastasis Assessment, as a Prognostic Marker for Axillary Node-Negative Breast Cancer*, assessed MenaCalc as a predictor of survival in patients with axillary node-negative (ANN) breast cancer. Axillary lymph nodes are located in the armpit which is typically the first place where breast cancer will spread. ANN means that the cancer has not spread to the lymph nodes which generally relates to a more favorable prognosis. Tumor samples were obtained from eight Toronto hospitals where patients were treated from 1987 to 1993. Of the 403 patients, 332 had no lymphatic invasion while 70 did (data was missing on 1). Subgroups including treatment (chemo and/or hormone therapy, n=261)) versus non-treatment (n=142) and molecular subtype; luminal, basal and HER2, were also included in the analysis.

Mena^{calc} scores were characterized as "high" if above the median and "low" if below the median and used to assess Mena^{calc} as a predictor of overall survival. The data showed that there was a significant association between high Mena^{calc} scores and increased risk of any-cause death (95% C.I., p=0.0199) in the full data set as well as in the non-treatment subgroup (95% C.I., p=0.0052). In addition, there was a trend towards (although not statistically significant) increased risk of all-cause death with high Mena^{calc} scores in all the three molecular subtype subgroups.

Statistically Significant Association With High Mena^{calc} Scores and Overall Survival in Full Cohort (L) and Untreated Subgroup (R)



SOURCE: Footnote[1]

This study, along with data from other unrelated studies of MenaCalc as well as MTST's MetaSite Breast assay, provides additional support for the company's technology as predictors of breast cancer metastasis and death as well as utility for making more informed treatment decisions.

Estimated Market for MTST's Breast Cancer Assays
Clinical data has shown a statistically significant association between MetaSite Breast scores and risk of metastasis in women with ER-positive/HER2-negative breast cancer. This represents approximately 60% of all breast cancer cases, or an annually diagnosed U.S. population of about 140k people. However, there may be an even lower-hanging fruit opportunity within this 140k person segment. Those being the 40%-45% of ER-positive/HER2-negative breast cancers which are diagnosed as "intermediate" risk by Genome Science's Oncotype DX test. This "intermediate" risk result may provide little to no "actionable" information and, therefore, this patient market (equal to 140k x 45% = **63k**) could be a particularly receptive market for MTST's tests.

Clinical data has shown a statistically significant association between high MenaCalc scores and risk of cancer death in node-positive/ER-negative breast cancer as well as risk of all-cause death in axillary node-negative breast

[1] Forse C. et al. *Mena^{calc} , a Quantitative Method of Metastasis Assessment, as a Prognostic Marker for Axillary Node-Negative Breast Cancer*. BMC Cancer (2015) 15:483

cancer (which relates to this recently published study in BMC Cancer). These patient populations are not being addressed by currently available gene panel tests (such as Oncotype DX), a market estimated at approximately 46k people.

So, in aggregate, MTST's addressable U.S. market is approximately 140k (MetaSite Breast/MenaCalc) + 46k MenaCalc = **186k** people, with a potential particularly receptive market of **63k** (~$73M). At an expected pricing/reimbursement of $1.1k - $1.2k per test, this aggregates to a potential market worth almost $300 million.

See our July 16th report on MTST for a more comprehensive background on MenaCalc and MetaSite Breast (including additional clinical trial data) as well as competition positioning of MTST's technology.

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 at least some of the preliminary 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 Q4 2015. They will also need to line up initial distribution/sales infrastructure. The company 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 4.9x and 3.0x 2015 analysts' consensus revenue estimates. We apply the average (4.0x) to our estimated 2018 revenue of $5.9M and discount this back at 15%, which results in a per share value of approximately $0.73.

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	$45.0	$8.0	$85.2	$244.0	$81.0	$207.0
Pre-Tax Income	($7,995.5)	($1,074.9)	($1,661.0)	($2,159.0)	($2,412.0)	($7,353.4)	($9,002.2)	($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)	($2,214.0)	($2,467.0)	($8,641.2)	($9,002.2)	($8,156.8)	($5,434.5)
YOY Growth	*53.5%*	*78.4%*	*-60.1%*	*57.3%*	*90.7%*	*4.9%*	*4.2%*	*-9.4%*	*-33.4%*
Net Margin	-	-	-	-	-	-	*-613.5%*	*-138.4%*	*-25.3%*
EPS	($0.33)	($0.08)	($0.06)	($0.08)	($0.08)	($0.31)	($0.25)	($0.19)	($0.10)
YOY Growth	*30.4%*	*42.1%*	*-63.6%*	*45.6%*	*69.5%*	*-7.5%*	*-19.1%*	*-21.7%*	*-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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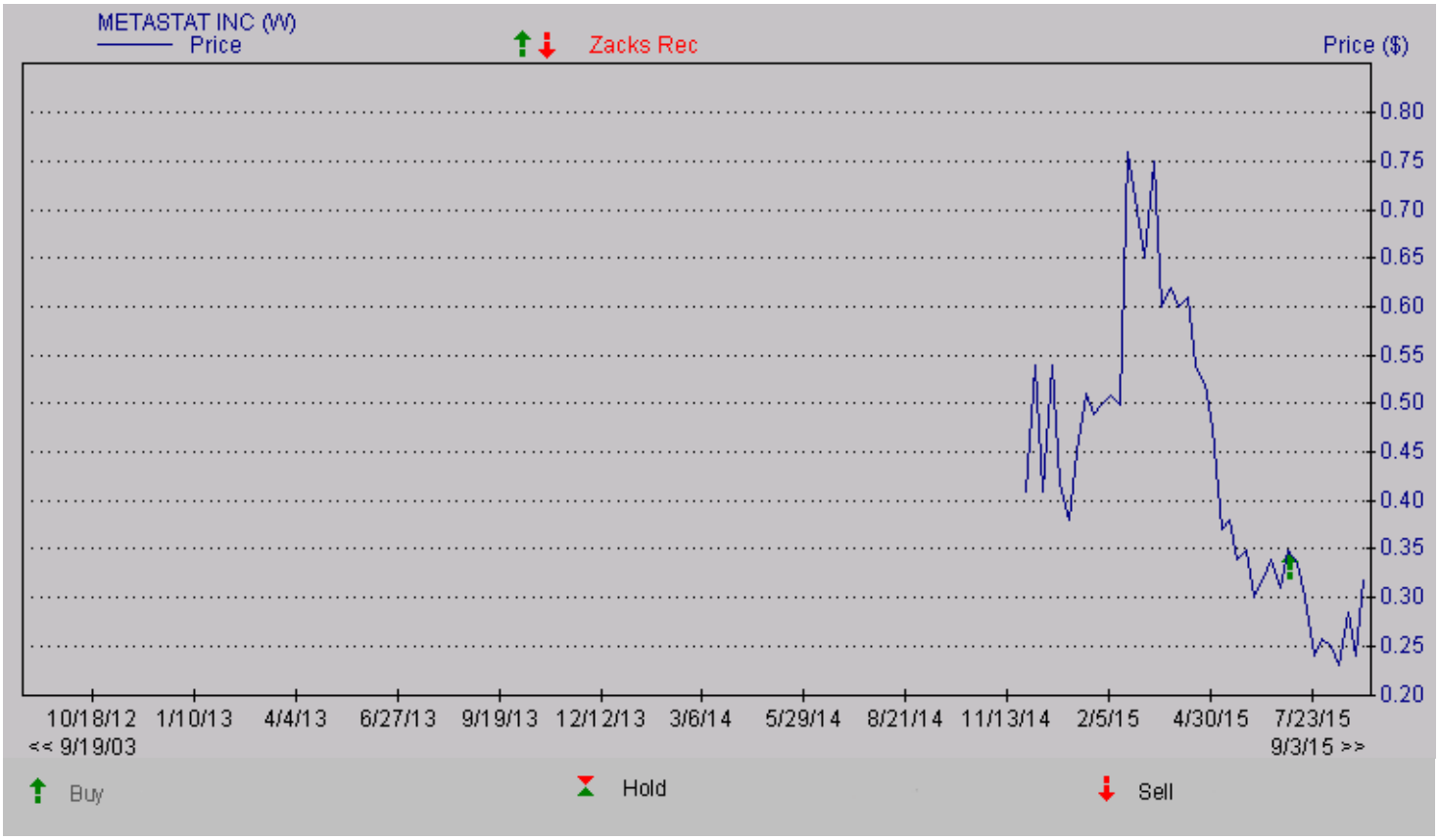
HISTORICAL ZACKS RECOMMENDATIONS



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