Zacks Small-Cap Research

August 11, 2015
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GenSpera, Inc. (GNSZ - OTC)

GNSZ: Looking For A Partnership Deal in the Second Half of 2015…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	06/08/2015
Current Price (08/11/15)	$0.72
Target Price	**$1.25**

UPDATE

GenSpera recently filed form 10-Q with financial results for the second quarter of 2015 and also provided a business update. In July 2015, the company raised $2.5 million, which should fund operations through the end of 2015.

The company is in active discussions to enter a corporate partnership for moving mipsagargin into the next clinical trial in liver cancer. A partnership should also provide the company with non-dilutive capital to extend their cash runway. Given the innovative nature of mipsagargin, we feel it's a matter of "if" not "when" for GenSpera to sign a partnership deal.

SUMMARY DATA

52-Week High	**$1.02**
52-Week Low	**$0.58**
One-Year Return (%)	**4.35**
Beta	**-1.50**
Average Daily Volume (sh)	**16,711**
Shares Outstanding (mil)	**37**
Market Capitalization ($mil)	**$27**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**1**
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 2013 Estimate	**N/A**
P/E using 2014 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	-$0.07 A	-$0.06 A	-$0.05 A	-$0.05 A	-$0.23 A
2015	-$0.06 A	-$0.05 A	-$0.06 E	-$0.06 E	-$0.22 E
2016					-$0.20 E
2017					-$0.19 E

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WHAT'S NEW

Financial Update

On August 6, 2015, GenSpera, Inc. (GNSZ) filed form 10-Q with financial results for the second quarter of 2015. As expected, the company did not report any revenues. Net loss for the quarter was $1.5 million, or $0.05 per share, and consisted of $0.6 million in R&D and $0.9 million in G&A expenses. Cash burn for the quarter was approximately $1.3 million and the company exited the second quarter of 2015 with $0.1 million in cash. On July 6, 2015, the company announced it raised $2.5 million in gross proceeds in a private placement with institutional investors through the sale of 3,571,430 shares at $0.70 per share. In connection with the private placement, the investors got 3,571,430 series D warrants with an exercise price of $0.85 and 3,571,430 series E warrants with an exercise price of $0.70. The series D warrants expire in five years while the series E warrants expire in 18 months. We now estimate that the company should have sufficient funds through the end of 2015, but the company will need to raise cash soon or sign a partnership that could bring in capital through an upfront payment.

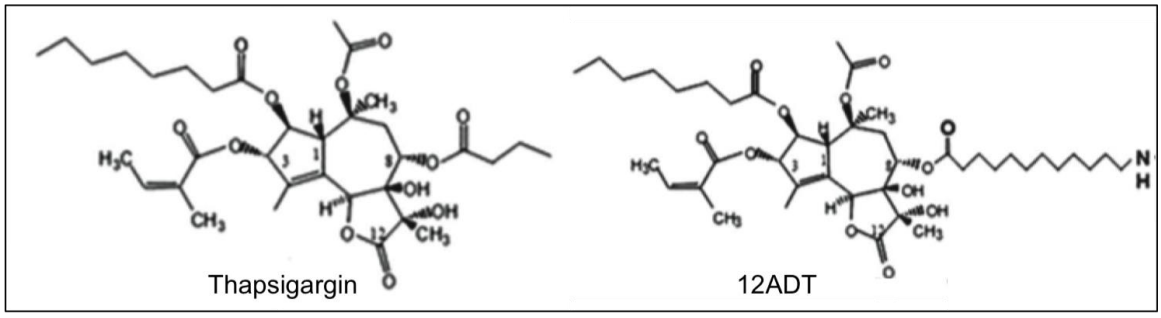
Business Update

GenSpera is focused on the targeted delivery of a novel anti-cancer agent specifically to cancerous tissue, thus mitigating systemic adverse effects that are typical with standard chemotherapeutic agents. The novel cytotoxic agent is thapsigargin, which is derived from the plant *Thapsia garganica* that grows wild in the Mediterranean region. Thapsigargin is a potent inhibitor of the intracellular sarcoplasmic/endoplasmic reticulum calcium adenosine triphosphastase (SERCA) pump protein, consequently causing calcium levels to rise significantly and trigger apoptosis (cell death).

The company has announced that its focus over the next 12-18 months will be on: 1) the upcoming liver cancer clinical trial, which will probably involve a development partner; 2) the ongoing Phase 2 clinical trial in glioblastoma; 3) partnering discussions with a larger pharmaceutical company. The company's previously planned clinical trial in prostate cancer has been postponed until the second quarter of 2016 while the planned clinical trial in renal cell carcinoma (RCC) has been suspended indefinitely. We view the delay in both the prostate and RCC clinical trials as prudent given the company's currently limited financial resources.

Thapsigargin as an Anti-Cancer Agent

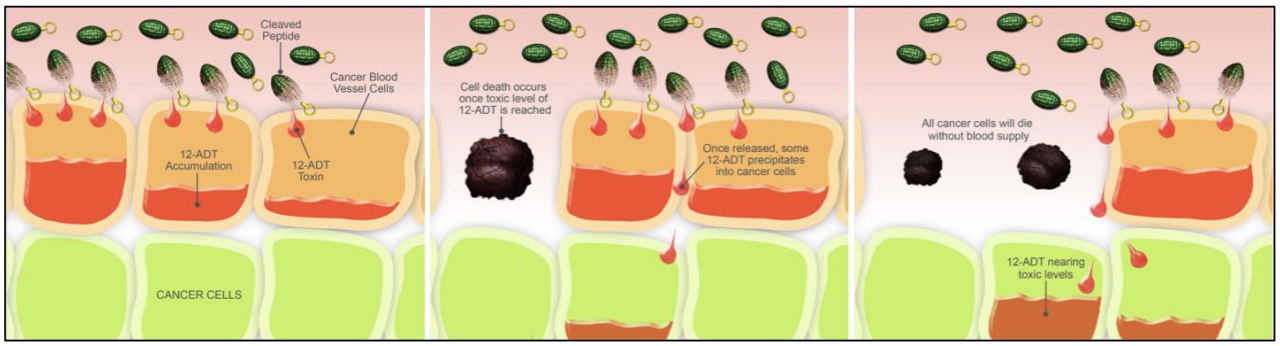
Unlike traditional chemotherapeutic agents, which are somewhat selective based on the blockage of pathways that are required for rapid proliferation, thapsigargin inhibits the SERCA pump, which is required for both quiescent as well as proliferating cells. Thus, there is no selectivity with thapsigargin between benign and cancerous cells and systemic administration of thapsigargin is highly toxic (Denmeade *et al*., 1993). To overcome this limitation, a protease-activated prodrug strategy was developed whereby a chemically modified derivative of thapsigargin (12ADT) was produced and coupled to a protease-specific peptide carrier (Denmeade *et al*., 1998). 12ADT was shown to retain the cytotoxicity of thapsigargin while allowing the easy coupling of different peptides (Jakobsen *et al*., 2001).



Source: Denmeade *et al*., 2012

In order to target 12ADT to different types of cancers, specific enzymes that are found in high levels in tumors relative to other tissues in the body are identified and a peptide is designed that is recognized predominantly by that enzyme. The peptide is then covalently linked to 12ADT to create a prodrug, with the end result being that the

prodrug can safely travel through the body without eliciting harmful side effects and 12ADT is only liberated in the presence of tumor specific enzymes. This is akin to a hand grenade, where the peptide acts as the "pin" and 12ADT is the "bomb". When the "pin" is removed, the insoluble 12ADT immediately enters the nearby cancer cells, and after sufficient quantities of 12ADT have accumulated, the cell dies. This is depicted in the following graphic.



Source: GenSpera, Inc.

The company's lead compound, mipsagargin, harbors a peptide that is recognized by prostate specific membrane antigen (PSMA), an enzyme that is expressed in the vasculature of almost all solid tumors.

Mipsagargin Phase 2 Clinical Results in Hepatocellular Carcinoma…

GenSpera tested mipsagargin in a multi-site, single arm Phase 2 clinical trial in 25 hepatocellular carcinoma (HCC) patients with advanced stage liver disease who had failed first line treatment with sorafenib (NCT01777594). Eighteen of the 25 patients were Child Pugh A while seven were Child Pugh B, which is indicative of more advanced liver disease. Nineteen patients were dosed with 40 mg/m^2 on days 1, 2 and 3, of a 28-day cycle while six patients were treated with 40 mg/m^2 on day 1 and 66 mg/m^2 on days 2 and 3 of a 28-day cycle.

The results from the study showed that mipsagargin was well tolerated, with the most frequently occurring grade ≥ 2 adverse events being increased creatinine (n=8, 32%), fatigue (n=7, 28%), and increased ALT and AST (n=6, 24%). Notably, typical side effects of standard chemotherapeutic agents such as severe nausea, vomiting, diarrhea, and hair loss were not seen in the study. In addition, there were no immunosuppressive side effects seen with treatment, which means the drug could potentially be paired with an immunotherapy. There were five serious adverse events that were determined to be mipsagargin-related: 3 patients had acute renal failure or acute renal injury, 1 patient had congestive cardiac failure, and 1 patient experience grade 3 chest pain. The company has stated that the effect on the kidney is dose dependent, non-cumulative, and 100% rapidly reversible if the patient increases their water intake. The following table gives the final results from the study.

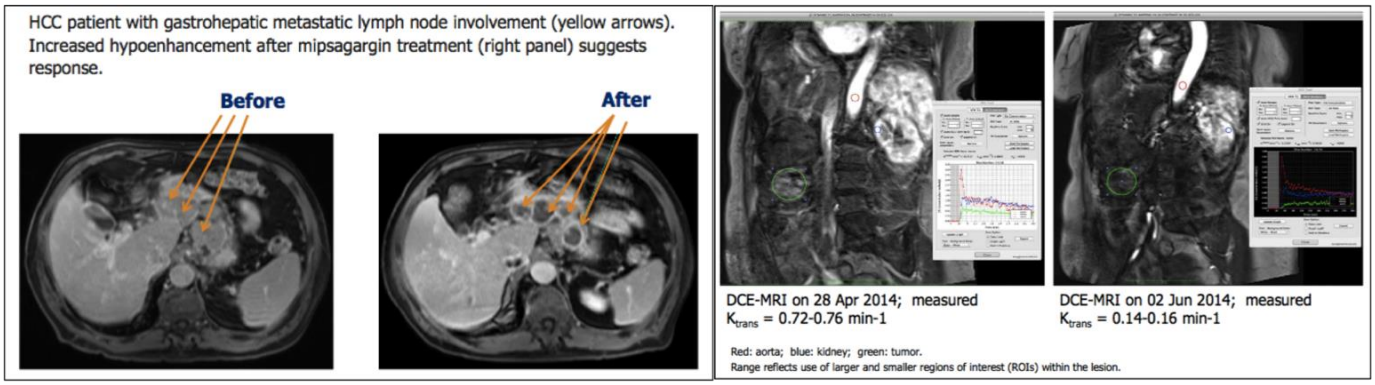
Number of Cycles (n=25 patients)	**75 total (average 3 per pt; range 1 - 9) 63 cycles at 40/40/40 12 cycles at 40/66.8/66.8**
Evaluable for Response (EE Population)	**19 patients (76%)**
Best Response (EE Population)	**CR + PR 0 pts SD 12 pts (63%)**
SD ≥ 5 cycles	**6 pts (24%)**
TTP (EE Population)	**134 days* (4.5 months; 95% CI: 58.0, NE)****
OS (EE Population)	**205 days (6.8 months; 95% CI: 138, NE)*****
PFS (EE Population)	**129 days (4.3 months; 95% CI: 58.0, 205.0)******

Source: GenSpera, Inc.

Some may look at a treatment with no complete responses (CR) or partial responses (PR) and think that it is not effective. Liver cancer is unique in that it is quite rare to see tumor regression due to the advanced nature of liver disease and cirrhosis outside of the cancer that exists in most HCC patients, particularly those patients who are Child-Pugh B or C. At the 2015 Noble Financial Conference, GenSpera CEO Dr. Craig Dionne stated that the company believes mipsagargin kills the tumor cells, which are then being replaced with scar tissue, thus on standard imaging there doesn't appear to be a change in size where the tumor was located.

To better understand whether mipsagargin is having an anti-tumor effect, the company performed dynamic contrast enhanced magnetic resonance imaging (DCE-MRI), which allows for analysis of the vascular blood flow within the tumor. The DCE-MRI data demonstrated substantially decreased blood flow in the tumors, indicative of a

pharmacodynamic proof-of-concept for the mechanism of action of mipsagargin. The following images show DCE-MRI images taken from two HCC patients before and after treatment with mipsagargin. The images on the left shows metastatic lymph nodes, which after treatment appear to show a "necrotic hole" where there does not appear to be cancer present. However, since the size of the "hole" did not change, the patient is graded as having stable disease even though all cancer cells may be gone. The images on the right are DCE-MRI scans that show decreased vascular enhancement, indicative of the cancer no longer being present.



Source: GenSpera, Inc. *Source*: GenSpera, Inc.

Mipsagargin Development Plan in HCC

GenSpera recently received the final report and full data set from the Clinical Research Organization that conducted the HCC Phase 2 trial. With the full data set, the company can now conduct more definitive discussions with potential corporate partners that they had previously engaged. The plan is to move into a large, international Phase 3 trial after a partnership agreement is signed, however the company is also prepared to initiate the Phase 3 trial alone.

Before beginning the Phase 3 trial, the company will need to conduct a small Phase 1/2 clinical trial in East Asian patients, as they will make up the majority of patients in the global Phase 3 trial. This will likely be a dosing and pharmacokinetic study that should start before the end of 2015 and be completed within nine months. The global Phase 3 study could then initiate after the completion of the East Asian study, which we estimate would be the second half of 2016.

Phase 2 Clinical Trial of Mipsagargin in Glioblastoma Multiforme

In Febrary, 2014, GenSpera initiated a Phase 2 clinical trial of mipsagargin in patients with glioblastoma multiforme (GBM) at the University of California, San Diego Moores Cancer Center, which is funding the trial, and is being led by Dr. David Piccioni and Dr. Santosh Kesari. The study is a two-stage, single-arm, open-label study designed to evaluate the activity, safety, and central nervous system (CNS) exposure of mipsagargin in up to 34 patients with recurrent or progressive GBM. After enrolling the first 12 patients, the study has now advanced to the second stage, where enrollment will continue up to 34 patients total, indicating that the first cohort of patients exhibited potential signs of efficacy and that mipsagargin was well-tolerated. We estimate that the trial will complete in the first half of 2016.

On June 17, 2015, GenSpera announced that Dr. Kesari had received an RO-1 grant from the U.S. Food and Drug Administration (FDA) to support the on-going Phase 2 clinical trial and preclinical research to gain insight into the mechanism of action and identification of biomarkers to aid in clinical development of mipsagargin. On July 28, 2015, the company announced an abstract about the ongoing Phase 2 clinical trial was accepted for presentation at the Society for Neuro-Oncology's 20th Annual Scientific Meeting from Nov. 19-22, 2015.

Valuation and Conclusion

With a market cap of only $25 million, we feel the market does not fully appreciate the potential for GenSpera's core technology of the use of thapsigargin-containing prodrugs as cancer therapeutics. An investment in GenSpera has been substantially de-risked due to the proof-of-concept data generated from the Phase 2 clinical trial of mipsagargin in HCC patients. Two important conclusions from this trial are: 1) Mipsagargin is safe, as exemplified by the low occurrence of adverse events and the lack of "typical" side effects associated with traditional chemotherapy such as severe nausea, vomiting, diarrhea, and immunosuppression; and 2) Mipsagargin works as

intended, which was shown by the DCE-MRI data indicating substantially decreased blood flow to the tumors, meaning that mipsagargin is being specifically targeted to the cells that express PSMA (e.g., the tumor vasculature).

At this point, the most important thing the company could do is sign a corporate partnership deal so that there is more clarity as far as the next liver cancer clinical trial is concerned. The company only has enough money to get through the end of 2015, thus getting a partnership deal signed within the next 5 months that supplies the company with a fresh infusion of non-dilutive capital (from an upfront payment) would go a long way in increasing investor confidence, as the lack of a partnership is currently the greatest drag on the stock price. Given the innovative nature of mipsagargin and proven efficacy in the Phase 2 clinical trial, we feel that a partnership deal is not a matter of "if" but "when". GenSpera CEO Dr. Craig Dionne recently stated "GenSpera has been actively engaged in this partnering process for over two years since the beginning of Phase II clinical trials in liver cancer." With discussions having been going on for so long we are confident that a deal will get done before the end of 2015, which could be a major catalyst for the stock price in the near term.

…Valuation Methodology…

We value GenSpera using a probability-adjusted discounted cash flow model that takes into account potential revenues from the sale of mipsagargin in HCC and GBM, as these two programs are the furthest along in development. We estimate that for HCC, a Phase 3 trial will commence in 2016, an NDA will be filed in 2018, and approval of mipsagargin will occur in 2019. For GBM, we estimate a Phase 3 trial commencing in 2017, with an NDA filing in 2019 and approval in 2020. We model for peak revenues of $600 million in GBM and $2 billion in HCC. For both indications we model for GenSpera to partner mipsagargin and receive a 15% royalty on net sales. We think the shares are worth $1.25.

PROJECTED FINANCIALS

GenSpera, Inc.
Income Statement

GenSpera, Inc.	2014 A	Q1 A	Q2 A	Q3 E	Q4 E	2015 E	2016 E	2017 E
Mipsagargin (HCC)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Mipsagargin (GBM)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
MIpsagargin (Prostate Cancer)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Mipsagargin (Kidney Cancer)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Grants & Collaborative Revenue	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$3.691	$0.815	$0.610	$1.100	$1.200	$3.725	$5.500	$6.300
General & Administrative	$3.307	$1.028	$0.921	$1.200	$1.300	$4.449	$4.500	$5.000
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($6.998)	($1.843)	($1.531)	($2.300)	($2.500)	($8.174)	($10.0)	($11.3)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.004	$0.0	($0.0)	$0.0	$0.0	$0.0	($0.1)	($0.1)
Pre-Tax Income	($7.0)	($1.8)	($1.5)	($2.3)	($2.5)	($8.2)	($10.1)	($11.4)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($7.0)**	**($1.8)**	**($1.5)**	**($2.3)**	**($2.5)**	**($8.2)**	**($10.1)**	**($11.4)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.23)**	**($0.06)**	**($0.05)**	**($0.06)**	**($0.06)**	**($0.22)**	**($0.20)**	**($0.19)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	30.413	33.300	33.548	39.000	41.000	36.712	50.000	60.000

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

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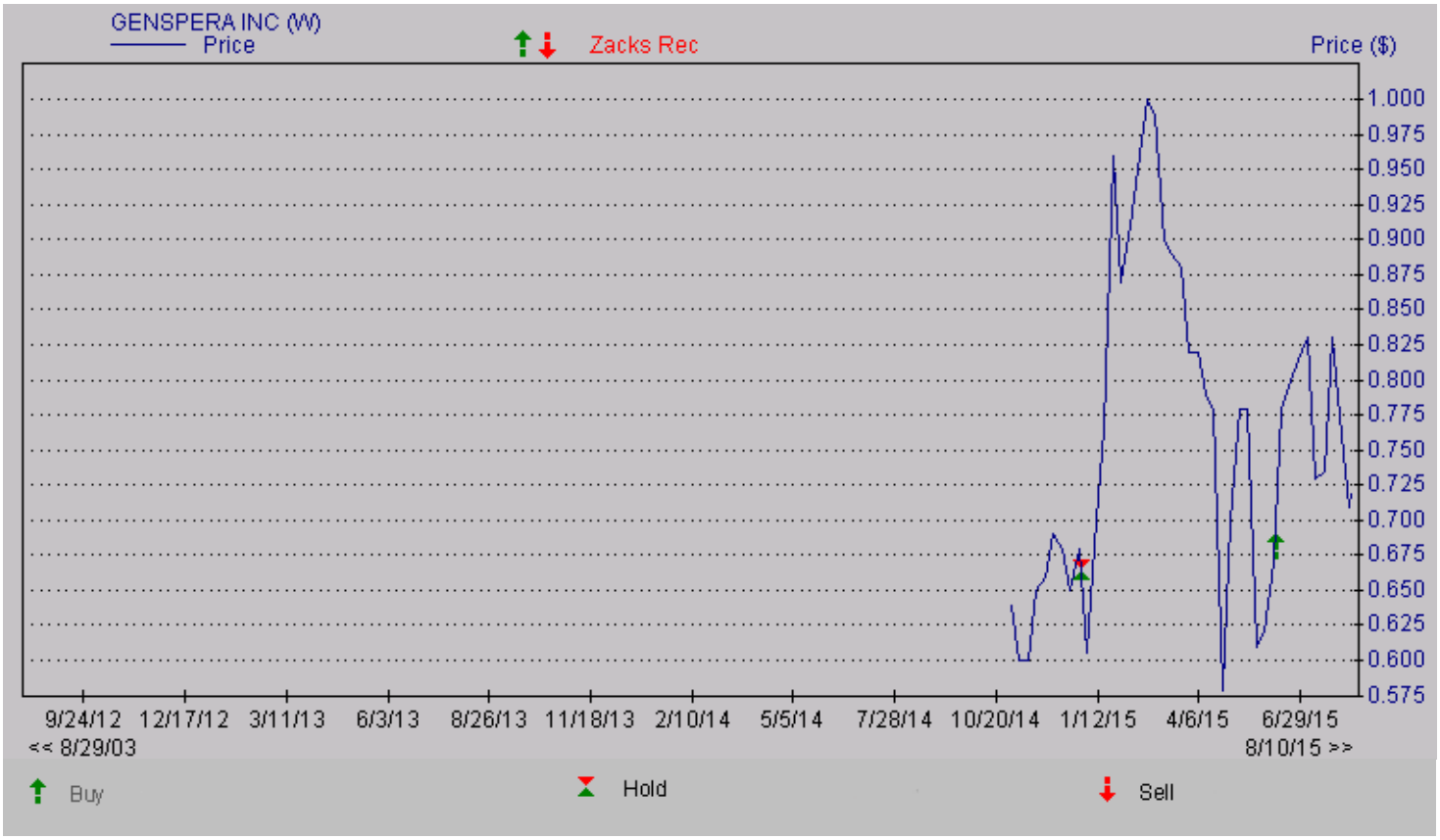

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