Zacks Small-Cap Research

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GeoVax Labs Inc. (GOVX-OTC)

GOVX: Balance sheet relatively strong, Positive data reported for GOVX-B11 Phase I trial, on track to advance its HIV vaccine programs--Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	01/15/2013
Current Price (03/17/14)	$0.38
Twelve- Month Target Price	**$1.50**

OUTLOOK

GOVX is a unique developer for both preventive and therapeutic HIV vaccines. The Company's preventive HIV vaccine is among the only 5 candidates out of more than 90 vaccines entering HVTN Phase I testing chosen to progress to Phase II clinical trials.

Both HIV/AIDS vaccine and treatment markets are huge and GOVX has the potential to be a key player in the two markets. Management will continue to create shareholder value by generating new clinical data, bringing in government support and partnership.

We believe valuation is attractive with the potential for substantial returns.

SUMMARY DATA

52-Week High	**$0.89**
52-Week Low	**$0.37**
One-Year Return (%)	**-37.71**
Beta	**2.04**
Average Daily Volume (sh)	**70,740**
Shares Outstanding (mil)	**24**
Market Capitalization ($mil)	**$9**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**36.8**
Insider Ownership (%)	**7**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**10.5**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2012 Estimate	**N/A**
P/E using 2013 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	0.80 A	0.44 A	1.00 A	0.18 A	2.42 A
2014					2.00 E
2015					2.50 E
2016					7.50 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.03 A	-$0.02 A	-$0.01 A	-$0.04 A	-$0.11 A
2014	-$0.03 E	-$0.03 E	-$0.03 E	-$0.04 E	-$0.13 E
2015					-$0.15 E
2016					-$0.10 E

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

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WHAT'S NEW

GeoVax Exited 2013 with Relatively Strong Balance Sheet

On Mar 5, 2014，GeoVax announced its financial results for the year ended December 31, 2013 and provided corporate update.

For the fiscal year ending Dec 31, 2013, GeoVax generated grant revenues of $2.4 million. This compares to $2.7 million of grant revenue reported in 2012. The company also reported approximately $822,000 in unused grant funds available for use as of December 31, 2013.

R&D expenses were $2.9 million in 2013, compared with $3.0 million in 2012. G&A expenses were $1.8 million for each of 2013 and 2012, respectively.

Net loss for 2013 was $2.3 million ($0.11 per share) compared to net loss of $2.1 million ($0.12 per share) for 2012.

At December 31, 2013, GeoVax held $2.5 million in cash, compared to $1.0 million at December 31, 2012. There was no debt on its balance sheet as of December 31, 2013. The company's balance sheet is relatively strong in our view. Current cash balance, together with our projected cash inflow, can last through the 1Q2015.

Positive Results for Phase I HIV Therapeutic Vaccine GOVX-B11 Announced

On Jan 13, 2014, GeoVax announced preliminary top-line results from **GV-TH-01**, a **Phase I** clinical trial investigating the ability of the Company's unadjuvanted DNA/MVA vaccine GOVX-B11 vaccine to control HIV infections in patients who initiated antiretroviral drug treatment within 18 months of seroconversion.

GV-TH-01 is an open label Phase I treatment interruption trial investigating the safety and immunogenicity of the Company's novel DNA/MVA vaccine in **9 HIV-infected patients** who had initiated drug treatment within 18 months of seroconversion and had stably controlled virus for at least 6 months. Patients were vaccinated with two DNA inoculations followed by two MVA inoculations at intervals of two months. Eight weeks following the last inoculation, patients suspended drug therapy for a 12 week period. Vaccinated patients' ability to control the time and temporal height of re-emergent virus in the absence of drugs was then observed. Drug treatment was re-instituted after 12 weeks, and trial participants were observed for an additional 6 months.

The **primary endpoint** of this study is to evaluate the safety of GOVX-B11 in HIV-positive patients with well-controlled infections who are being treated with oral HIV medications. A **secondary objective** is to evaluate the immunogenicity of the GOVX-B11 vaccine during the vaccination phase of the trial. An **exploratory objective** of the study is to evaluate the ability of the vaccinated patient to control re-emergent virus during a 12-week drug treatment interruption period.

Excellent safety was observed throughout the trial, with none of the participants needing to reinstate antiretroviral drugs during the treatment interruption phase of the trial.

Preliminary data have demonstrated that during the vaccination phase of the trial, enhanced CD8+ T cells were elicited in 8 of 9 patients and enhanced CD4+ T cell and antibody responses in 5 of 9 participants. Antibody responses were boosted in 4 of 9 participants. Analyses during the treatment interruption phase suggested that individuals with the best immune responses have lower levels of re-emergent virus. Preliminary analyses in the first 7 patients who completed the treatment interruption phase of the trial demonstrated expanded antiviral T cell and antibody responses associated with re-

emergent virus. There was a trend toward enhanced viral control in individuals with the best CD4+ and CD8+ T cell responses.
The Company expects to release **additional results** from this trial as final analyses are completed, and in conjunction with scientific presentations and publications.

Based on the results from GV-TH-01, GeoVax is formulating plans for a **follow-on Phase I** clinical trial investigating the treatment of HIV-positive individuals with its GM-CSF adjuvanted DNA/MVA vaccine **(GOVX-B21)** in combination with standard-of-care antiretroviral drug therapy. This proposed trial would involve more patients than the GV-TH-01 trial and, unlike GV-TH-01, would include a placebo control arm. The study design is also expected to more closely resemble the likely commercial therapeutic use of an HIV vaccine. The primary and secondary objectives of the study will be to evaluate the safety and immunogenicity of GOVX-B21. An exploratory objective will be to investigate the vaccine's effect on reducing HIV viral reservoirs as an indicator of the potential for an eventual cure.

The positive data from the Phase I trial of GOVX-B11 is another achievement for GeoVax. We are very pleased with the safety of the vaccine and its ability to enhance immune responses in infected and drug-treated patients. The opportunity for GOVX-B11/GOVX-B21 lies in its ability to **complement drug therapies**, which can control virus spread but not recognize and kill infected cells, with a vaccine response capable of recognizing and eradicating infected cells.

Preventive HIV Vaccine Update

GeoVax completed a **Phase IIa trial (HVTN 205) of GOVX-B11** in 2012 and initial results of this trial were presented in September 2012 at the AIDS Vaccine 2012 Conference in Boston. HVTN 205 confirmed the Phase I results, demonstrating an excellent safety profile and reproducible T cell and antibody immune responses.

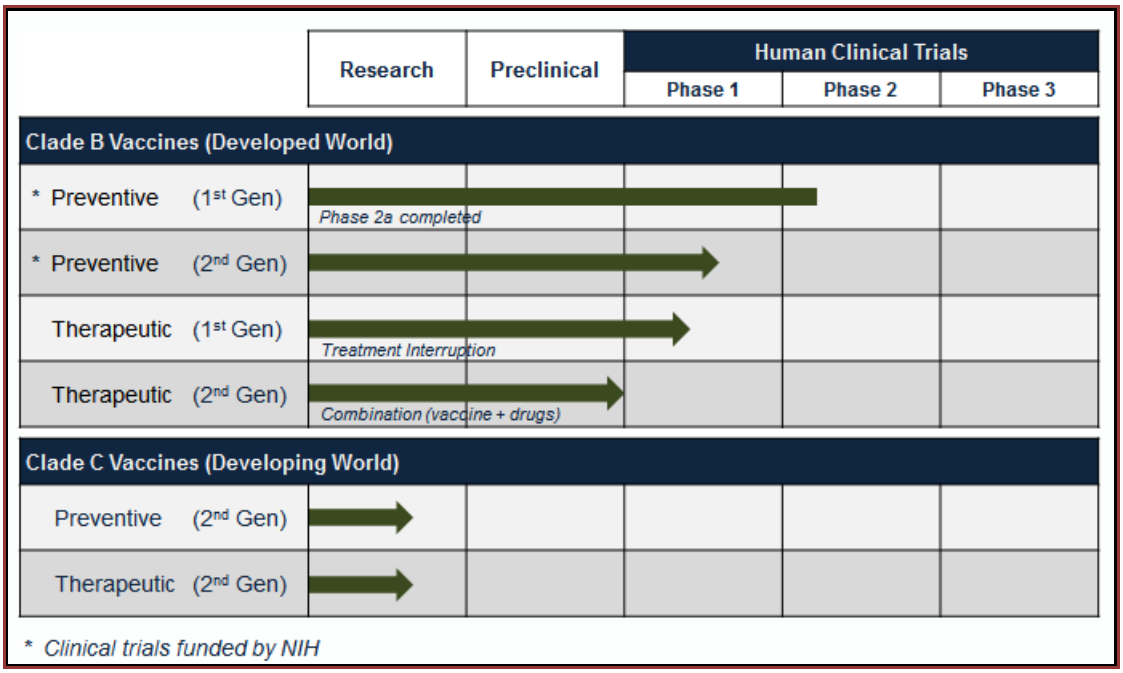
In October 2013, GeoVax reported additional clinical data from this study showing that, at six months after the final vaccination (the latest time point tested), gp140 IgG antibody response titers in the primary arm of the study had declined by less than 3-fold, with response rates only declining from 100% to 84%, indicating excellent durability of the antibody response. Additionally, HVTN 205 also showed that the antibody responses after vaccination had high affinity binding, a characteristic which has been associated with prevention of HIV infection in preclinical models. The results from HVTN 205 are published on-line in the Journal of Infectious Disease.

During December 2013, GeoVax reviewed preliminary results from an ongoing **Phase I trial (HVTN 094)** of its adjuvanted DNA/MVA vaccine **(GOVX-B21)** that co-expresses GM-CSF in the priming DNA vaccine. Based on excellent preclinical non-human primate data, this trial was originally initiated with the expectation that GOVX-B21 would be carried forward into Phase II testing by the HIV Vaccine Trials Network (HVTN), with support by the NIH. Comparison of data between HVTN 094 and HVTN 205 has not shown a significant benefit for adding the adjuvant to the vaccine for preventive use. Following an extensive review of preclinical and clinical data, GeoVax has decided to advance **GOVX-B11** to the next stage of clinical testing.

GeoVax is currently in planning discussions with the HVTN for the next stage of clinical trials, and several scenarios are being considered. While the GeoVax vaccine is currently the only vaccine being contemplated for efficacy trials for prevention of clade B HIV infection, the HVTN believes the best path forward may be to test a combination of **GOVX-B11 with a protein boost**. Protein boosts may augment antibody responses that can block virus infections (neutralizing antibody) and cause antibody dependent cellular cytotoxicity (ADCC antibody). Protein added to HIV vaccines have shown some success in other trials and the HVTN believes this to be the prudent and cost effective path forward for supporting large clinical trials. GeoVax expects the next clinical trial to begin during **2015** and to be fully funded by the NIH, with specific details of the study determined after further data analysis and input from the HVTN and NIH in mid-2014.

We think GeoVax has made great progress in its HIV/AIDS vaccine clinical programs. The recent failure of HVTN505, a 2500-patient Phase IIb trial conducted by the National Institutes of Allergy and Infectious Disease (NIAID), strengthened our confidence in GeoVax's vaccine technology. The vaccine studied in HVTN 505 used an adenovirus vector of genetic material from the HIV virus, similar to the vaccine used in the Merck trial (STEP/Phambili) that was halted in 2007. In contrast, GeoVax's boosting vaccine uses a poxvirus vector (modified vaccine Ankara) which has been associated with clinical success.

GeoVax has important near-term milestones, including the completion of two key **Phase I** clinical trials (one therapeutic and one preventive). Entering 2014, the company will continue to place emphasis in advancing its clinical progress. The company plans to initiate a second **Phase I** trial with its 2nd generation therapeutic vaccine in 2014. GeoVax should be entering into a **Phase II** trial with its preventive vaccine in 2015 (GOVX B11+protein boost). As other HIV vaccines have fallen by the wayside over the past several years, GeoVax continues to move forward with its unique approach to HIV prevention and treatment through effective vaccination.



Valuation and Recommendation

We maintain our Outperform rating on GeoVax and reiterate our 12-month price target of $1.50.

GeoVax has developed the technology for the development of both **preventive** and **therapeutic** HIV/AIDS vaccines. The Company's vaccine candidates have completed Phase IIa and will enter into Phase IIb clinical trials soon, which are the only HIV vaccines for America/Europe entering efficacy trial.

The Company has a modest cash burn rate ($4 to $5 million annually) due to generous government support. Down the road, we believe GeoVax will continue to seek non-dilutive government and non-government support for its HIV vaccine development. If the planned Phase II trial for preventive HIV vaccine proves to be positive, we believe it would be likely for the Company to find a partner from big pharma or biotech companies who seek to boost or enter into the anti-HIV/AIDS market.

GeoVax has a strong position in intellectual property. The excellent relationship with Emory University put the Company in a better position to get the most advanced vaccine technology in the first hand, therefore providing a sustainable growth engine for the Company.

Based on the current fundamentals of the Company, we believe current valuation is attractive. With a decent pipeline and mid-stage candidates, GeoVax is only valued at about $9 million in market cap. This is a huge discount in our view. We understand that HIV/AIDS vaccines have been tough to develop and that this is a high risk area for any biotech company especially for smaller ones with limited resources. However, we think GeoVax has done great job so far in the HIV/AIDS vaccine area and is well positioned to continue to create shareholder value down the road.

We see GeoVax as a risk reward opportunity with significant long term positive returns. Our price target of $1.50 represents a market cap of $33 million.

But Keep in Mind the Risks

Risk must be taken into account when investors add positions.

One major risk is **development/regulatory risk**. We remind investors that GeoVax's HIV/AIDS vaccines are still in mid-stage development and the Company still needs to navigate through the regulatory process in the US and around the world, which proves to be long and tough. When it comes to HIV/AIDS vaccine, investors should be aware that this has been a tough area to tackle considering the failed developments already.

Cash burn is still a concern. Although most of GeoVax's clinical trials have been supported by the government grants, there is no guarantee that the Company will continue to get enough support to continue late stage clinical studies. In such a case, the Company needs alternative financing measures, which include equity or debt financing. Current cash can only last through the 1Q15. We remind investors that equity financing will dilute existing shareholder base.

PROJECTED INCOME STATEMENT

	2013A (Dec)					2014E (Dec)					2015E (Dec)	2016E (Dec)	2017E (Dec)	2018E (Dec)
$ in million except per share data	Q1A	Q2A	Q3A	Q4A	FYA	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE	FYE
Grant revenue	$0.80	$0.44	$1.00	$0.18	$2.42	$0.50	$0.50	$0.50	$0.50	$2.00	$2.50	$2.50	$2.50	$2.50
Product Revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$5.00	$15.00	$25.00
Total Revenues	**$0.80**	**$0.44**	**$1.00**	**$0.18**	**$2.42**	**$0.50**	**$0.50**	**$0.50**	**$0.50**	**$2.00**	**$2.50**	**$7.50**	**$17.50**	**$27.50**
YOY Growth	-6.9%	-37.7%	57.0%	-62.0%	-9.0%	-37.3%	13.2%	-50.2%	185.3%	-17.3%	25.0%	200.0%	133.3%	57.1%
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Gross Income	**$0.80**	**$0.44**	**$1.00**	**$0.18**	**$2.42**	**$0.50**	**$0.50**	**$0.50**	**$0.50**	**$2.00**	**$2.50**	**$7.50**	**$17.50**	**$27.50**
Gross Margin	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
R&D	$0.88	$0.55	$0.88	$0.60	$2.92	$0.70	$0.85	$0.90	$1.00	$3.45	$5.00	$7.50	$9.00	$11.00
% R&D	110.7%	125.3%	87.5%	342.8%	120.6%	140.0%	170.0%	180.0%	200.0%	172.5%	200.0%	100.0%	51.4%	40.0%
SG&A	$0.61	$0.42	$0.32	$0.45	$1.79	$0.45	$0.50	$0.55	$0.60	$2.10	$2.80	$4.00	$7.50	$10.00
%SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($0.7)**	**($0.5)**	**($0.2)**	**($0.9)**	**($2.3)**	**($0.7)**	**($0.9)**	**($1.0)**	**($1.1)**	**($3.6)**	**($5.3)**	**($4.0)**	**$1.0**	**$6.5**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	5.71%	23.64%
Other Net	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	**($0.7)**	**($0.5)**	**($0.2)**	**($0.9)**	**($2.3)**	**($0.7)**	**($0.9)**	**($1.0)**	**($1.1)**	**($3.6)**	**($5.3)**	**($4.0)**	**$1.0**	**$6.5**
Income taxes(benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.5
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($0.7)**	**($0.5)**	**($0.2)**	**($0.9)**	**($2.3)**	**($0.7)**	**($0.9)**	**($1.0)**	**($1.1)**	**($3.6)**	**($5.3)**	**($4.0)**	**$1.0**	**$6.0**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	500.0%
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	5.7%	21.8%
Diluted Shares Out	20.2	21.1	21.7	21.9	21.2	23.8	24.5	30.0	31.0	27.3	35.0	40.0	45.0	50.0
Reported EPS	**($0.03)**	**($0.02)**	**($0.01)**	**($0.04)**	**($0.11)**	**($0.03)**	**($0.03)**	**($0.03)**	**($0.04)**	**($0.13)**	**($0.15)**	**($0.10)**	**$0.02**	**$0.12**
One time charge	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($0.7)**	**($0.5)**	**($0.2)**	**($0.9)**	**($2.3)**	**($0.7)**	**($0.9)**	**($1.0)**	**($1.1)**	**($3.6)**	**($5.3)**	**($4.0)**	**$1.0**	**$6.0**
Non GAAP EPS	**($0.03)**	**($0.02)**	**($0.01)**	**($0.04)**	**($0.11)**	**($0.03)**	**($0.03)**	**($0.03)**	**($0.04)**	**($0.13)**	**($0.15)**	**($0.10)**	**$0.02**	**$0.12**

Source: Company filings and Zacks Research estimates

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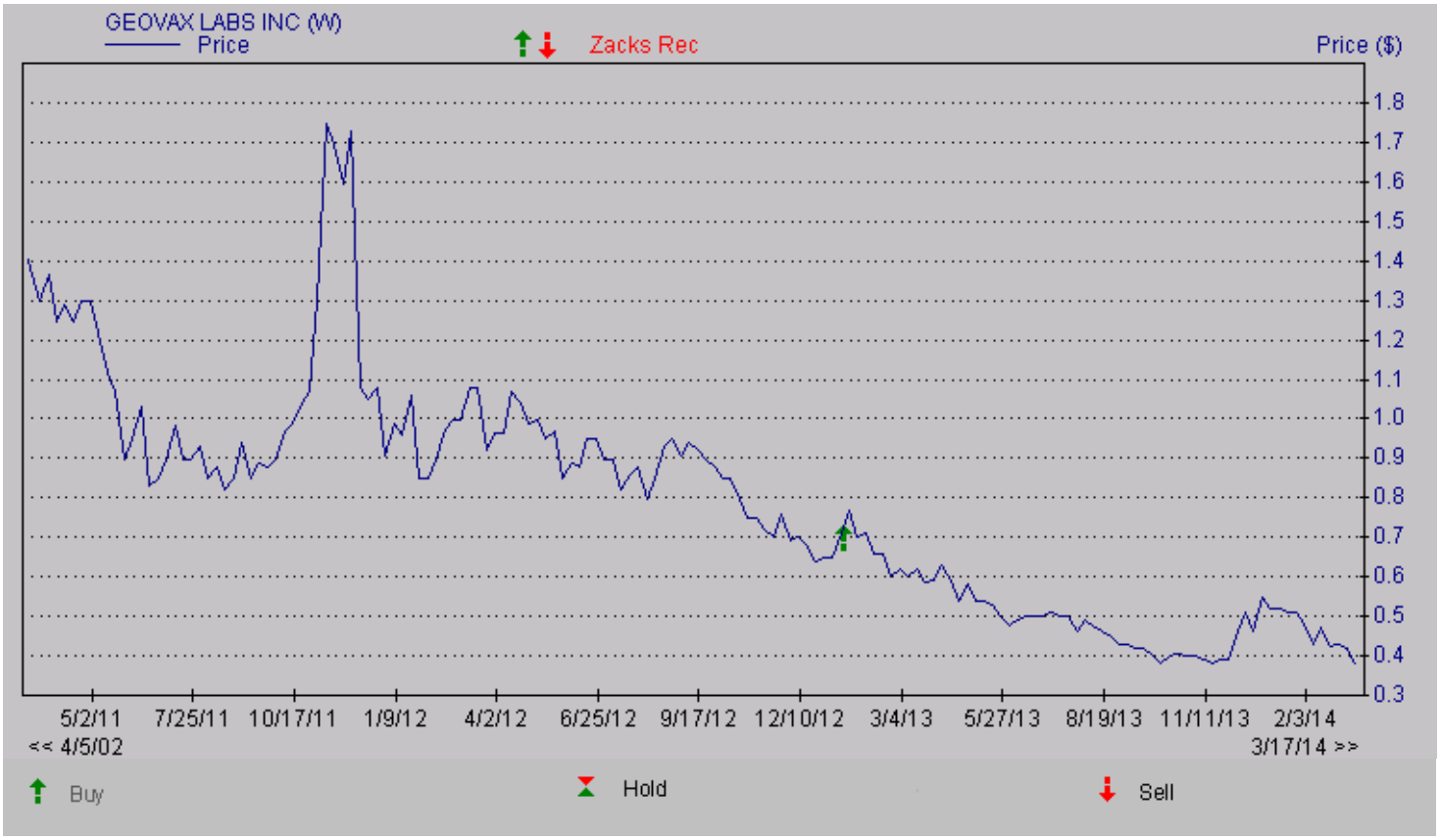

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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over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

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