Zacks Small-Cap Research

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# GeoVax Labs Inc. (GOVX-OTC)

**GOVX:** exited 3Q13 with reasonable balance sheet, 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 (11/12/13) | $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** | **$0.80** |
| **52-Week Low** | **$0.37** |
| **One-Year Return (%)** | **-44.93** |
| **Beta** | **1.63** |
| **Average Daily Volume (sh)** | **25,960** |
| **Shares Outstanding (mil)** | **22** |
| **Market Capitalization ($mil)** | **$8** |
| **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) |
|---|---|---|---|---|---|
| 2012 | 0.86 A | 0.71 A | 0.64 A | 0.46 A | 2.66 A |
| 2013 | 0.80 A | 0.44 A | 1.00 A | 0.50 E | 2.74 E |
| 2014 | | | | | 2.50 E |
| 2015 | | | | | 7.50 E |

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

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2012 | -$0.04 A | -$0.03 A | -$0.02 A | -$0.03 A | -$0.12 A |
| 2013 | -$0.03 A | -$0.02 A | -$0.01 A | -$0.05 E | -$0.12 E |
| 2014 | | | | | -$0.19 E |
| 2015 | | | | | -$0.05 E |

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

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## WHAT'S NEW

### *GeoVax Exited 3Q13 With Reasonable Balance Sheet*

On Nov 12, 2013, GeoVax Labs (GOVX) announced its financial results for the third quarter ended September 30, 2013.

**Revenues** were $1,004,211 and $2,242,812 for the three-month and nine-month periods of 2013, respectively, related to grants from the National Institutes of Health (NIH) in support of its HIV/AIDS vaccine development efforts. This compares to $638,000 and $2,197,761 of grant revenue reported for the comparable periods of 2012. As of September 30, 2013, there is approximately $1.0 million in unused grant funds remaining and available for use.

**Research and development (R&D) expenses** were $879,107 and $2,314,291 for the three-month and nine-month periods of 2013, respectively, as compared to $601,690 and $2,386,460 for the comparable periods of 2012. R&D expenses include direct costs funded by NIH grants, as well as vaccine manufacturing costs and expenses related to the **Phase I** clinical trial of the Company's therapeutic HIV vaccine. Costs associated with the ongoing Phase I clinical trial of GeoVax's preventive HIV vaccine, being conducted by the HVTN, are funded directly by the NIH and are not reflected in GeoVax's financial statements.

**General and administrative (G&A) expenses** were $316,452 and $1,345,179 for the three-month and nine-month periods of 2013, respectively, as compared to $334,166 and $1,339,300 for the comparable periods of 2012.

**Net loss** was $190,148 ($0.01 per share) for the three months ended September 30, 2013, compared to $296,779 ($0.02 per share) for the same period in 2012. For the nine months ended September 30, 2013, the Company's net loss was $1,413,229 ($0.07 per share) as compared to $1,525,055 ($0.09 per share) in 2012.

As of September 30, 2013, GeoVax held $1,720,616 in cash and cash equivalents.

We believe fundraising will be an area of focus for management for the remainder of 2013. Management has indicated that in addition to equity capital, they are also seeking other sources of funding through additional government and/or third party support of its programs.

### *GeoVax Awarded Small Business Innovative Research Grant From National Institutes of Health*

On Aug 1, 2013, GeoVax announced that it has received a Notice of Award from the U.S. National Institutes of Health for a Small Business Innovative Research (SBIR) grant entitled "Enhancing Protective Antibody Responses for a GM-CSF Adjuvanted HIV Vaccine."

The grant award of approximately $277,000 is for the first year of a two-year project period. Subject to availability of funds and satisfactory progress of the project, GeoVax expects a similar award for the second year of the project period.

This grant will support preclinical studies evaluating the ability of protein boosts to augment antibody responses that can block virus infections (neutralizing antibody) and cause antibody dependent cellular cytotoxicity (ADCC antibody). The protein boosts will test gp120 and gp140 subunits of the HIV envelope. Suefen Kwa, Ph.D., GeoVax's Assistant Director for HIV Vaccine Development, is the Principal Investigator for the grant.

This grant not only provides cash for the company, but also validates GeoVax's vaccine technology.

## *GeoVax is On Track to Advance its HIV/AIDS Vaccine Programs*

### *Therapeutic HIV Vaccine Program*

- GeoVax expects to complete GV-TH-01, the **Phase I** clinical trial of the Company's first-generation HIV vaccine, during 2013, with final results and evaluation of trends to be reported in the first quarter of 2014. The primary endpoint of this 9 patient **"treatment interruption"** study is to document the safety and immunogenicity of GeoVax's vaccine in HIV-positive patients with well-controlled infections who are being treated with oral HIV medications. Following the vaccination series, the trial includes a short period of drug treatment interruption to evaluate the vaccine's ability to control the infection in the absence of continuing drug therapy. The combined vaccination period, treatment interruption period and treatment reinstitution period for each patient is approximately 11 months. Vaccine efficacy will be directly assessed through a brief period of anti-retroviral drug cessation. These results might indicate the vaccine's potential ability to treat HIV infection either as a standalone therapy or in conjunction with an oral drug regimen.

- In a follow-on study, GeoVax plans to initiate a **Phase I** clinical trial with GeoVax's second-generation vaccine in combination with standard-of-care antiretroviral drug therapy. The primary endpoint will be to evaluate the safety and immunogenicity of GeoVax's DNA/MVA vaccine. An exploratory objective will investigate the vaccine's effect on clearing viral reservoirs. GeoVax expects to begin this trial **in mid-2014**.

### *Preventive HIV Vaccine Program*

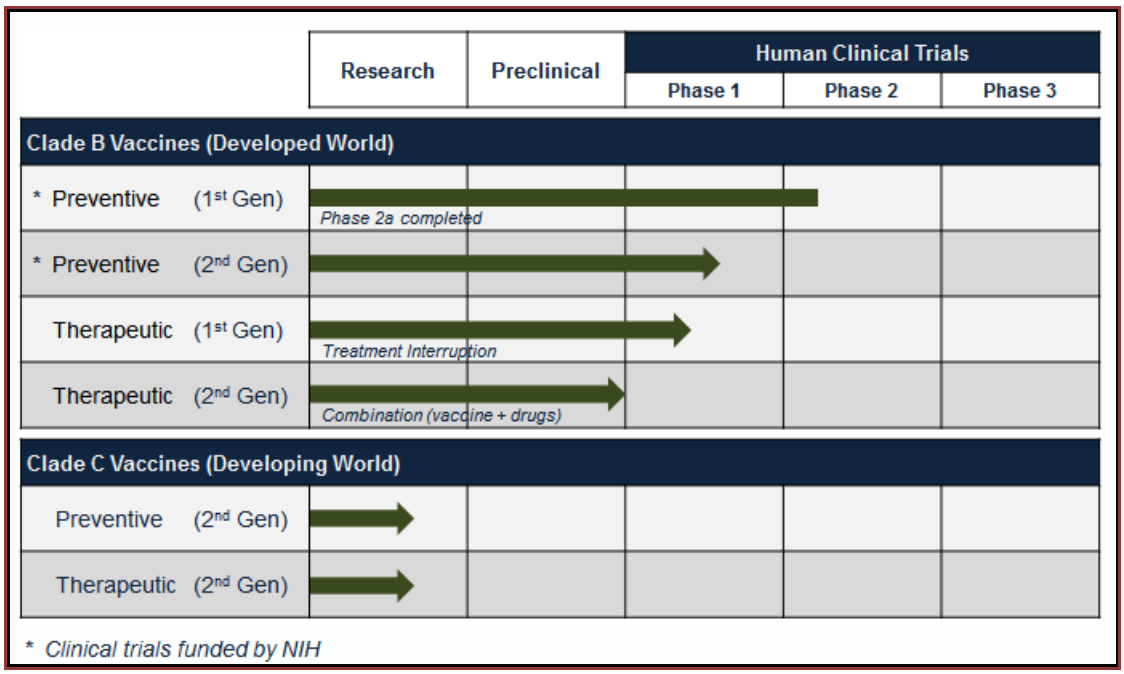
- In October 2013, GeoVax presented additional results from HVTN 205, a multicenter, randomized **Phase IIa** trial, at the 2013 AIDS Vaccine Meeting in Barcelona, Spain. HVTN 205 evaluated the safety and immunogenicity of the Company's first generation preventive HIV vaccine. At 6 months post-vaccination, patient antibody levels had declined less than 3-fold, indicating significant durability of the antibody response. The antibody responses after vaccination also had high affinity binding, a characteristic which has been associated with prevention of HIV infection in preclinical models.

- GeoVax expects to complete HVTN094, a 48-patient **Phase I** clinical trial testing the safety and immunogenicity of its **second-generation vaccine**, in 2013. Top-line results should be available during the first quarter of 2014. This study is being conducted by the HIV Vaccine Trials Network (HVTN) with financial support from the National Institute of Allergy and Infectious Disease (NIAID) of the National Institutes of Health (NIH). GeoVax is actively engaged in discussions with the HVTN regarding the design of a **Phase II** clinical trial following the successful completion of HVTN094. GeoVax currently anticipates the trial to include a Phase IIa study, with the primary endpoint of expanding the safety profile of the Company's second-generation vaccine.

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. Entering 2014, the company will continue to place emphasis in advancing its clinical progress. GeoVax should be entering into a **Phase IIa** trial with its preventive vaccine in mid-2014. The company also plans to initiate a second **Phase I** trial with its therapeutic vaccine in 2014. 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 Phase IIb trial 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 $10 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 $30 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 as of September 30, 2013 stood at $1.7 million, which can only last through the 2Q2014. We remind investors that equity financing will dilute existing shareholder base.

## PROJECTED INCOME STATEMENT

| | 2012E (Dec) | | | | | 2013E (Dec) | | | | | 2014E (Dec) | 2015E (Dec) | 2016E (Dec) | 2017E (Dec) | 2018E (Dec) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| $ in million except per share data | Q1 | Q2 | Q3 | Q4 | FYA | Q1A | Q2A | Q3A | Q4E | FYE | FYE | FYE | FYE | FYE | FYE |
| Grant revenue | $0.85 | $0.71 | $0.64 | 0.46 | $2.66 | $0.80 | $0.44 | $1.00 | $0.50 | $2.74 | $2.50 | $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 | $10.00 | $15.00 | $25.00 |
| **Total Revenues** | **$0.86** | **$0.71** | **$0.64** | **$0.46** | **$2.66** | **$0.80** | **$0.44** | **$1.00** | **$0.50** | **$2.74** | **$2.50** | **$7.50** | **$12.50** | **$17.50** | **$27.50** |
| YOY Growth | -4.2% | -59.6% | -50.7% | -51.8% | -45.8% | -6.9% | -37.7% | 57.0% | 8.4% | 3.2% | -8.9% | 200.0% | 66.7% | 40.0% | 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 | 0.00 |
| **Gross Income** | **$0.86** | **$0.71** | **$0.64** | **$0.46** | **$2.66** | **$0.80** | **$0.44** | **$1.00** | **$0.50** | **$2.74** | **$2.50** | **$7.50** | **$12.50** | **$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% | 100.0% |
| R&D | $1.07 | $0.71 | $0.60 | $0.66 | $3.04 | $0.88 | $0.55 | $0.88 | $1.10 | $3.41 | $5.00 | $6.50 | $7.50 | $9.00 | $11.00 |
| % R&D | 125.3% | 100.5% | 94.1% | 142.3% | 114.5% | 110.7% | 125.3% | 87.5% | 220.0% | 124.5% | 200.0% | 86.7% | 60.0% | 51.4% | 40.0% |
| SG&A | $0.51 | $0.49 | $0.33 | $0.41 | $1.75 | $0.61 | $0.42 | $0.32 | $0.64 | $1.99 | $2.60 | $2.80 | $4.00 | $7.50 | $10.00 |
| %SG&A | 60% | 69% | 52% | - | - | - | - | - | - | - | - | - | - | - | - |
| **Operating Income** | **($0.7)** | **($0.5)** | **($0.3)** | **($0.6)** | **($2.1)** | **($0.7)** | **($0.5)** | **($0.2)** | **($1.2)** | **($2.7)** | **($5.1)** | **($1.8)** | **$1.0** | **$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) | ($0.1) | ($0.1) | ($0.1) | ($0.1) |
| **Pre-Tax Income** | **($0.7)** | **($0.5)** | **($0.3)** | **($0.6)** | **($2.1)** | **($0.7)** | **($0.5)** | **($0.2)** | **($1.3)** | **($2.7)** | **($5.1)** | **($1.9)** | **$0.9** | **$0.9** | **$6.4** |
| 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 | $0.0 | $0.5 |
| Tax Rate | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| **Reported Net Income** | **($0.7)** | **($0.5)** | **($0.3)** | **($0.6)** | **($2.1)** | **($0.7)** | **($0.5)** | **($0.2)** | **($1.3)** | **($2.7)** | **($5.1)** | **($1.9)** | **$0.9** | **$0.9** | **$5.9** |
| YOY Growth | - | - | - | - | - | - | - | - | - | - | - | - | - | - | 531.9% |
| Net Margin | - | - | - | - | - | - | - | - | - | - | - | - | | | |
| Diluted Shares Out | 16.7 | 17.8 | 18.5 | 20.2 | 18.3 | 20.2 | 21.1 | 21.7 | 23.5 | 21.6 | 27.5 | 35.0 | 40.0 | 45.0 | 50.0 |
| **Reported EPS** | **($0.04)** | **($0.03)** | **($0.02)** | **($0.03)** | **($0.12)** | **($0.03)** | **($0.02)** | **($0.01)** | **($0.05)** | **($0.12)** | **($0.19)** | **($0.05)** | **$0.02** | **$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* | *$0.00* |
| **Non GAAP Net Income** | **($0.7)** | **($0.5)** | **($0.3)** | **($0.6)** | **($2.1)** | **($0.7)** | **($0.5)** | **($0.2)** | **($1.3)** | **($2.7)** | **($5.1)** | **($1.9)** | **$0.9** | **$0.9** | **$5.9** |
| **Non GAAP EPS** | **($0.04)** | **($0.03)** | **($0.02)** | **($0.03)** | **($0.12)** | **($0.03)** | **($0.02)** | **($0.01)** | **($0.05)** | **($0.12)** | **($0.19)** | **($0.05)** | **$0.02** | **$0.02** | **$0.12** |

*Source: Company filings and Zacks Research estimates*

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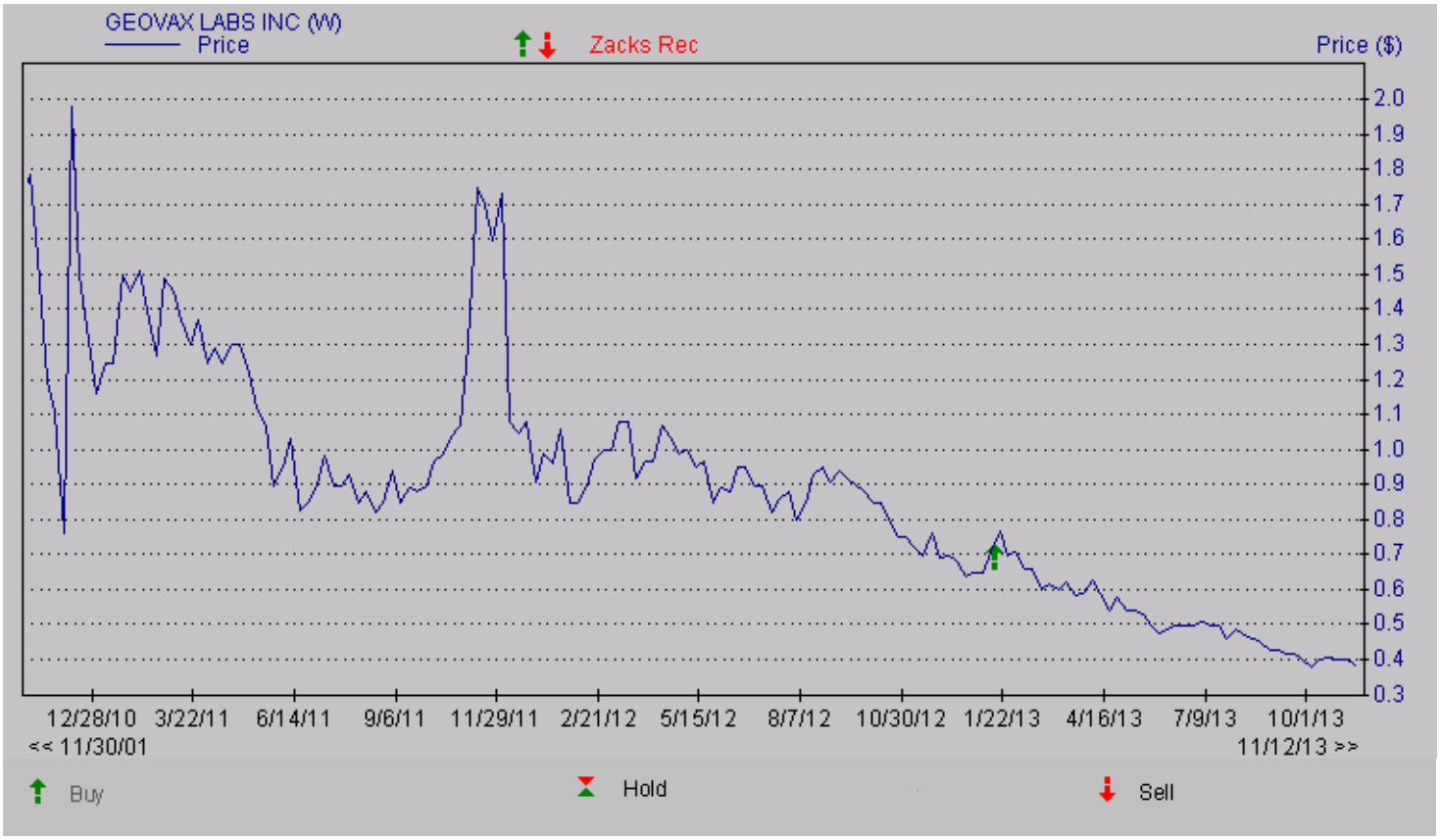
## HISTORICAL ZACKS RECOMMENDATIONS

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