Zacks Equity Research

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# Viral Genetics (VRAL-OTC)

**VRAL: Unique two platform technologies with early stage pipeline----initiation with a Neutral rating.**

| | |
|---|---|
| **Current Recommendation** | **Neutral** |
| Prior Recommendation | N/A |
| Date of Last Change | 01/21/2011 |
| Current Price (01/28/11) | $0.03 |
| **Twelve- Month Target Price** | **$0.15** |

## OUTLOOK

Viral Genetics is an early development stage biotech company focused on discovery and development of novel anti-infectious, cancer and autoimmune drugs. The Company's two platform technologies TPT and MDT have great potential to target a broad range of diseases, but all its drug candidates are at early stage of development. We are pleased to learn that the Company plans to move one to three candidates into clinic this year. The Company has entered into a transition period. Its share price will be volatile in the next few quarters when the Company moves ahead with its development programs. Risk/reward is balanced at this point in our view.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$0.07** |
| **52-Week Low** | **$0.02** |
| **One-Year Return (%)** | **-45.10** |
| **Beta** | **-0.70** |
| **Average Daily Volume (sh)** | **1,878,116** |
| **Shares Outstanding (mil)** | **600** |
| **Market Capitalization ($mil)** | **$18** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **0** |
| **Insider Ownership (%)** | **28** |
| **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 2011 Estimate** | **N/A** |
| **P/E using 2012 Estimate** | **N/A** |
| **Zacks Rank** | **N/A** |

| | |
|---|---|
| **Risk Level** | **High,** |
| **Type of Stock** | **N/A** |
| **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) |
|---|---|---|---|---|---|
| 2009 | 0.00 A | 0.00 A | 0.00 A | 0.00 A | 0.00 A |
| 2010 | 0.00 A | 0.00 A | 0.01 A | 0.00 E | 0.01 E |
| 2011 | 0.00 E | 0.00 E | 0.00 E | 0.01 E | 0.01 E |
| 2012 | | | | | 0.01 E |

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

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2009 | -$0.00 A | -$0.01 A | -$0.01 A | -$0.01 A | -$0.02 A |
| 2010 | -$0.00 E | -$0.00 E | -$0.00 E | -$0.00 E | -$0.01 E |
| 2011 | -$0.00 E | -$0.00 E | -$0.00 E | -$0.00 E | -$0.01 E |
| 2012 | | | | | -$0.01 E |

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

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## KEY POINTS

- We are initiating coverage of Viral Genetics with a Neutral rating. Our six to twelve month price target is $0.15 per share.

- Viral Genetics holds two unique drug discovery platform technologies: targeted peptides therapies (TPT) and metabolic disruption technology (MDT). Both platforms have potential to target a broad range of diseases, including infectious disease, autoimmune disease and cancers.

- The Company has established a pipeline based on its TPT and MDT technologies. But all its drug candidates are at their early stage of development (preclinical). Preclinical studies of its drug candidates have demonstrated some promises, but the Company needs to show investors more data especially clinical data to confirm the results of lab and animal studies. In this regard, we are pleased to learn that the Company plans to move at least one and possibly three candidates into clinic this year.

- Viral Genetics has a weak balance sheet. As of September 30, 2010, the Company only held about $20,000 in cash while long term liability stood at $1.3 million among which $1.05 million is owed to a company controlled by Viral's CEO, Haig Keledjian. This eases the immediate going concern risks. It's our belief that Viral Genetics needs to tap the capital market very soon and will continue to do so on a regular basis before the Company achieves revenue from product sales or establish major partnerships with major pharma or biotech companies. Equity financing will dilute existing shareholder base.

- Viral Genetics' shares currently are trading on the pink sheets OTC market. Trading in stock quoted on the pink sheets over-the-counter market is often thin and characterized by wide fluctuations in trading prices. Therefore, the trading of Viral Genetics' shares may be volatile and sporadic and is highly speculative. Liquidity may be an issue for institutional investors.

- Upcoming catalysts include the initiation of investigator-initiated clinical trials for Viral's MDT agents, the meeting with the FDA for pre-IND filings for VGV-X and other two candidates. Recent settlement of a major lawsuit with its former development/distribution partner, which hindered Viral's business development in the past few years, is also positive for the Company.

- We see a balanced risk/reward profile for Viral Genetics at this point. Our valuation is based on the Company's fundamentals and values for comparable peers. Our valuation also excludes VG Energy, a majority owned subsidiary of Viral Genetics for the development of biofuels.

## OVERVIEW

Viral Genetics, Inc. (VRAL) is a development stage biotechnology company focused on research, development, and commercialization of new treatments and diagnosis for infectious diseases (HIV/AIDS, Lyme disease, staph and strep infection), cancer and certain autoimmune disease (multiple sclerosis).

VRAL holds two unique drug discovery platform technologies: Targeted Peptides Therapies **(TPT)** and Metabolic Disruption Technology **(MDT),** licensed from the University of Colorado and University of Vermont. TPTs are custom-designed protein fragment that work to modify certain immune system reactions that cause or worsen some diseases. The TPT compounds the Company is studying represent in some sense the second generation of the Company's earlier thymus nuclear protein (TNP) therapy. MDT encompasses a way to change how some types of cells use fat and sugar/carbohydrates for energy. By manipulating metabolic processes, some harmful cells including drug-resistant cancer cells

can die. The same MDT approach has also recently been discovered to have potential in encouraging the production of oils from algae and other plants (biofuels). As a result of this, the Company established a majority owned subsidiary called **VG Energy** to develop these applications.

VRAL's pipeline, based on the above TPT and MDT technologies, targets a broad range of diseases, but is still in early stage of development. The Company's lead drug candidate is **VGV-X** for **HIV/AIDS** in late preclinical studies. VGV-X is a second generation TPT drug compound, which has the potential to reduce the viral load dramatically in HIV/AIDS patients. VGV-X is VRAL's top priority and the Company plans to bring this compound into human clinical trials in 2011.

VRAL's second lead drug candidate is **VGV-L** for **Lyme disease**. VGV-L is a similar compound to VGV-X. Lyme disease is a chronic disease associated with infection by Borrelia bacteria, an illness that saw a 100% increase in CDC-confirmed cases from 1991 to 2006. Animal studies have been completed with positive results. The Company plans to meet with the FDA to move VGV-L forward.

The Company's third drug candidate **VGV-S** is developed for **Staphylococcus, Streptococcus and Sepsis**. In preclinical studies, VGV-S has demonstrated excellent efficacious data and safety profile. In one study conducted in 2009, some infected mice treated with VGV-S made full recoveries. A control group of sick animals that were not treated with this therapy either took much longer to recover or did not survive the infections. The animal results of infection with these bacteria also suggest that VGV-S may have the potential to treat sepsis, a life-threatening systemic infection. This TPT compound is the third one which may move into clinic in 2011.

Viral Genetics also has a candidate based on TPT for **multiple sclerosis** in early preclinical studies.

The Company's MDT technology has potential to target many **cancer indications**, especially drug resistant cancers, but candidates are still in early discovery stage. Viral is collaborating with Scott & White Healthcare to conduct **investigator-initiated clinical trials**, using the Company's MDT agents in combination with the FDA approved therapies, to treat end stage patients of melanoma, ovarian and breast cancer. Viral is also developing a drug compound based on MDT for victims of glioblastoma, the most common and aggressive primary brain tumor. The Company's MDT technology may provide novel therapy aimed at dealing with drug resistance. Viral Genetics has created a wholly owned subsidiary called **MetaCytoLytics, Inc**., dedicated to advancing new treatments based on MDT. The following table summarizes the status of the Company's pipeline.

Summary of Viral Genetics' Pipeline

| | Preclinical | IND | Phase I | Phase II | Phase III | NDA | Approved |
|---|---|---|---|---|---|---|---|
| VGV-X: HIV/AIDS | √ | Planed | | | | | |
| VGV-L: Lyme Disease | √ | Planed | | | | | |
| VGV-S: Bacterial Infection | √ | Planed | | | | | |
| Glioblastoma | √ | | | | | | |
| Multiple Sclerosis | √ | | | | | | |

In order to monetize its platform technologies, VRAL is making progress to offer **peptide optimization services** to other drug companies. The services are based on the Company's TPT technology and will allow other drug companies to optimize their in house peptide-based drug therapies including both existing drugs and those under development. The optimization could lead to enhanced efficacy or extended patent protection.

Viral Genetics was incorporated in Delaware in 1995 and is headquartered in San Marino, CA.

## INVESTMENT THESES

***Two Unique Drug Discovery Platform Technologies***

***Targeted Peptides Technology***

Targeted Peptide Technology (**TPT**) targets the body's immune system and seems to explain the mechanism behind some autoimmune and infectious diseases while presenting a possible solution. Autoimmune diseases occur when the body reacts to itself or self-tissues. In some cases, an external threat from disease-causing organisms activates too many of certain types of immune cells which in turn cause damage to the body. A physical trait of those cells also makes them impervious to the body's natural defense system that would ordinarily limit their numbers.

TPT works by tricking those impervious cells into dropping their defenses. They can be fooled into releasing their protective shields, swapping the shield for a synthetic TPT-polypeptide instead. Those peptides, created by VRAL's research team, have been engineered to make the cells susceptible to the body's natural defenses. TPT drug compounds can enable the body to destroy the cells that help trigger the symptoms of autoimmune diseases.

Generally speaking, the targeted peptides turn the immune system up or down, and cause a process called apoptosis. This is accomplished using small protein fragments (the targeted peptides) to displace other "decoy" peptides that have been picked up by immune system cells. These so-called decoy peptides sometimes result from infection by viruses, bacteria, and various diseases, including HIV/AIDS. Apoptosis is the body's process of killing off harmful cells, and is believed to be an important factor in the control of a variety of illnesses. The decoy peptides may prevent the death of cells that actively promote inflammation. By causing these cells to be killed or switched off, the associated disease may be treated.

TPT has been pioneered by Dr. Karen Newell Rogers, the Raleigh R. White, Jr. Endowed Professor of Surgical Research, Department of Surgery, College of Medicine, at Texas A&M Health Sciences Center and Scott and White Hospital. A key area of Dr. Newell Rogers' research is based upon the idea that certain pro-inflammatory peptides result in a harmful immune response that may not only hurt a person's ability to fight off an illness, but perhaps even contribute to the inflammation involved in certain autoimmune diseases. As a result, she has developed a model for the types of peptides that could displace the harmful ones and allow the immune system to respond more beneficially. Analysis of the Company's early compounds revealed that it contains significant amounts of specific peptides that fit Dr. Newell Rogers' model. A key result is that, if the model proves out conclusively, the Company can custom design, modify, improve and synthetically manufacture the replacement peptides. This is important because the Company is now able to precisely design and manipulate purified doses of the active peptides. This has allowed the Company to create an optimized peptide for certain indications such as HIV/AIDS and Lyme disease.

A second important aspect of Dr. Newell Rogers's Targeted Peptides model is the genetic component. In essence, each human being has a genetic "fingerprint" that marks their immune system cells in a highly specific way, and there are many of them. The implication is that Targeted Peptides must fit the "fingerprints" of people to be treated. Through complex modeling Viral Genetics has designed and synthetically manufactured peptides that match a far broader range of these immune system fingerprints. Each disease must also be targeted to the specific disease.

Viral Genetics is using TPT to develop compounds for treatment of HIV/AIDS (VGV-X), Lyme disease (VGV-L), and Staphylococcus, Streptococcus and Sepsis infection (VGV-S). The Company is also studying TPT approaches to treatment of Multiple Sclerosis.

***Metabolic Disruption Technology***

All cells, including cancer cells, produce their own energy through conversion of sugars, starches, fat, and protein. Without energy to maintain its biological processes the cells die.

Because in general cancer cells grow very rapidly, the cancer cells have very high energy demands. For example, to meet their energy demands, the cancer cells will use available glucose at a very high rate. Some of the mechanisms the tumor cells use to meet their energy demands are unique to the tumor cell and are not used by normal cells—suggesting that those specific pathways would make great therapeutic targets.

The Metabolic Disruption technology relates to the highly-targeted destruction of cancer cells and tumors by depriving the cells of needed energy. When the tumor cells' energy strategies are interrupted with "metabolic disrupting" agents, the consequences are two-fold: the cancer cells can no longer use the strategy for energy and are more susceptible to chemotherapy and/or radiation. Also importantly, the disruption is accompanied by a "danger flag", that appears newly visible to the immune system. So, metabolic disruption has a "one-two" punch: interference with meeting cancer's energy demands and increased visibility to the immune response to react to the tumor.

Specifically, tumor cells exhibit at least two generalizeable metabolic features that can be chosen as selective targets: **High rate glycolysis** (the process of breaking down glucose to smaller carbon-containing units in the cytosol of the cell) and **fatty acid oxidation,** which are the two aspects of cancer specific metabolism most readily disrupted. The preferential use of fatty acid oxidation in the mitochondria of drug resistant cells is a particularly important focus of drug interference because drug resistance is the leading cause of death for cancer patients. For all of these reasons, the Company's initial products are comprised of pharmaceutical compositions that interfere with various aspects of high rate glycolysis and fatty acid oxidation.

Similarly, through manipulation of the internal metabolism of plant cells using MDT, the production of oils can be augmented. Viral Genetics has conducted laboratory studies demonstrating the potential to increase the yields of refinable algae oils for use in biofuels by minimum 300%. In addition, a similar process may be able to augment the production yields of agricultural oils such as corn and palm oils. As a result of this, the Company established a majority owned subsidiary called **VG Energy** to develop these applications.

Viral Genetics is developing drug candidates using MDT for cancer indications. The first MDT product candidate will likely include **dichloroacetate**. Dichloroacetate is an orally-active small molecule drug that inhibits certain aspects of high rate glycolysis and fatty acid metabolism. Dichloroacetate is very close in structure to an essential intermediate in glucose metabolism, the molecule pyruvate. By mimicking the effects of pyruvate, dichloroacetate likely acts in two capacities: first, to act as an inhibitor of high rate glycolysis, likely sending the cell the message that nutrient reserves are full and second, to interfere with pyruvate dehydrogenase kinase, an enzyme involved in the mitochondrial switch to fatty acid oxidation under conditions of starvation. A high level of intracellular pyruvate indicates to the cell that there are no conditions of starvation and that glucose levels are not limited.

## ***Pipeline has Potential, but is at Early Stage of Development***

### ***TPT-based pipeline***

**VGV-X for HIV/AIDS**: All of Viral Genetics' TPT drug candidates are in the preclinical stage of development. The most advanced is **VGV-X** for the treatment of HIV/AIDS.

Before VGV-X, Viral Genetics had been developing first-generation HIV/AIDS drug compound called thymus nuclear protein (**TNP**). TNP is a cocktail of histone protein fragments that includes over 2500 peptides. TNP is derived from the thymus, where immune cells develop. The Company has conducted six international, human clinical trials which have demonstrated that TNP significantly reduced the viral load by over 90-95% in some patients (20-30%) without major safety issues. The problem with TNP is

that TNP is not working in other patients. That led to the development of second generation of HIV/AIDS therapy. The second-generation HIV/AIDS therapy is expected to significantly improve upon the earlier version following the discovery of a mechanism of action and the development of a far superior manufacturing process that allows dosage to be carefully adjusted.

VGV-X is a second generation of TPT peptide which is specifically designed to modify an infected person's immune response to HIV to allow them to fight off the infection themselves. The design of VGV-X has been improved based on the immune system fingerprinting. Therefore, VGV-X may be able to produce a positive antiviral effect in a larger percentage of patients (80-90%) than the Company's first-generation therapy TNP which was not targeted in this manner. Further, because VGV-X is now synthesized, it can be produced in virtually 100% pure concentrations and very precise modulation of doses can be carried out. This allows the actual dose of active ingredient to be studied and thus fine-tuned with a degree of precision that was not available with the first-generation product. Clinical trials of the earlier product ranged in results from reducing HIV viral load by 90-99%, achieving complete lack of detection of HIV in some patients. However, the variation in results was not sufficient to replace current methods of treatment. Because the Company is now able to modify dosing carefully, it is believed that a more consistent and higher reduction in viral loads is possible.

Apparently, VGV-X is Viral Genetics' top priority. The Company has completed significant portion of lab tests and animal studies and plans to bring this drug candidate into clinic in the first half of 2011. This will be the first drug candidate entering into human clinical trials for VRAL.

HIV/AIDS is a global epidemic. Over 40 million people are living with HIV/AIDS in the world and among them over 25 million in Sub-Saharan Africa. In the United States, more than one million people are living with HIV and about 56,300 Americans become infected with HIV each year. More than 18,000 people with AIDS still die each year in the US. Therefore, new treatments are of significant interest.

Clearly, HIV/AIDS business is a large market, but is also crowded. There are currently over two dozen drugs approved for the treatment of HIV-infection by the FDA. The three primary classes of treatment are Non-nucleoside Reverse Transcriptase Inhibitors, Nucleoside Analog Reverse Transcriptase Inhibitors, and Protease Inhibitors. Fusion or Entry Inhibitors are a newer class of anti-HIV medications. There are an estimated 50 to 60 HIV treatments under various stages of development worldwide. Current antiviral treatments for HIV/AIDS are drug combinations that are expensive, difficult to access in many areas of the world, and accompanied by a number of complications, including moderate to severe side effects, onerous dosing regimens, multiple drug interactions, and the development of drug resistant strains of the HIV virus.

The treatment of HIV/AIDS has evolved in the last 20 years since the beginning of the epidemic from no treatment to treatment with a single drug (AZT) to dual-drug therapy and, now, to highly active antiretroviral therapy (**HAART**). Currently, HAART is the standard of care for HIV. HAART is defined as treatment with at least three active anti-retroviral medications (ARV's), typically two nucleoside reverse transcriptase inhibitors (NRTI's) plus a non-nucleoside reverse transcriptase inhibitor (NNRTI) or a protease inhibitor (PI) or another NRTI called abacavir (Ziagen).HAART is often called the drug "cocktail" or triple-therapy. HAART affords a potent way of suppressing viral replication in the blood while attempting to prevent the virus from rapidly developing resistance to the individual ARV's. Suppressing viral replication with HAART allows the body time to rebuild its immune system and replenish the destroyed CD4 T cells. HAART has been clearly shown to delay progression to AIDS and prolong life.

However, HAART drug regimens are complex, often requiring 10 or more pills a day; expensive, costing upwards of $10,000-$20,000 per patient per annum in the United States; and are associated with moderate to severe gastro-intestinal, neurological, and hematological side effects that adversely impact the patient's quality of life. Furthermore, HIV patients who use the drugs for a long period of time tend to develop resistance to the drugs, resulting in the drugs becoming less effective and engendering resistant strains of the HIV virus. Many patients receiving standard HAART are resistant to one or more of the primary classes of HIV/AIDS drugs.

Based on current experience with VGV-X, as well as an earlier version of TNP, It is hopeful that VGV-X may continue to demonstrate only moderate side effects and a less onerous dosing regimen. Therefore, VGV-X presents the potential of providing an alternative or adjunct to HAART therapy, as well as a potential “salvage” therapy for patients resistant to HAART.

**VGV-L for Lyme disease:** VGV-L is the Company’s second most advanced drug candidate under development. VGV-L uses a similar compound to VGV-X and is designed for the treatment of Lyme disease. This research was supported by grants from two not-for-profit organizations. VGV-L uses synthetic peptides to "trick" cells that may be responsible for harmful symptoms, making them vulnerable to the body's natural immune response mechanism.

Lyme disease starts with a bacterial infection by Borrelia, an illness that saw a 100% increase in CDC-confirmed cases from 1991 to 2006. Statistics on the prevalence of Lyme disease are controversial largely due to the difficulties diagnosing the disease itself. The National Center for Infectious Diseases reports approximately 19,000 new cases each year with some advocates believing the number to be closer to 200,000 per year.

Currently, treatment of Lyme disease, and the underlying bacterial infection believed to be the cause of it, is primarily limited to antibiotics. At the present time it is unclear if such treatments resolve the infection itself or if the disease symptoms of Lyme are resolved as well.

Treatment of Lyme disease by VGV-L is targeted at resolving the symptoms and cause of Lyme itself, and not just the bacterial infection that is believed to cause Lyme disease. As such, VGV-L is potentially a novel therapy.

Animal studies of VGV-L have been completed with positive results. The Company plans to meet with the FDA to move VGV-L forward.

**VGV-S for Staphylococcus, Streptococcus and Sepsis:** The Company’s third drug candidate **VGV-S** is developed for Staphylococcus, Streptococcus and Sepsis. In preclinical studies, VGV-S has demonstrated excellent efficacious data and safety profile. In one study conducted in 2009, some infected mice treated with VGV-S made full recoveries. A control group of sick animals that were not treated with this therapy either took much longer to recover or did not survive the infections. The animal results of infection with these bacteria also suggest that VGV-S may have the potential to treat sepsis, a life-threatening systemic infection.

VGV-S may offer an alternative to traditional antibiotics. Traditional antibiotics directly kill or suppress bacteria growth and proliferation, while VGV-S fights bacterial infection through manipulating human body’s own immune system to fight off bacteria.

VGV-S is also a TPT based peptide. Laboratory testing continues, both in the test tube and in animal studies, in preparation for possibly advancing this drug to human clinical trials in 2011.

**Multiple Sclerosis (MS)**: VRAL has also designed targeted peptides for use in the treatment of Multiple Sclerosis. The Company has completed certain in vitro laboratory testing that confirms the preclinical efficacy of the peptides, but has not yet finalized the compound. The Company is pursuing partnerships with clinical experts in MS in order to develop and move forward with a strategy leading to human clinical trials that will continue with additional animal and laboratory studies.

MS is an autoimmune disease caused by damage to the myelin sheath, the protective covering that surrounds nerve cells. When this nerve covering is damaged, nerve impulses are slowed down or stopped. MS is a progressive disease, meaning the nerve damage (neurodegeneration) gets worse over time. There is no known cure for multiple sclerosis at this time. However, there are approved MS therapies that can slow the disease. Current standard of care for MS is interferon based therapy including

Avonex from Biogen, Betaseron from Bayer and Rebif from Merck KGaA. Other approved therapies include Copaxone (glatiramer acetate) from Teva, Tysabri (natalizumab) from Biogen and Novantrone (mitoxantrone) from Merck KGaA. Recently, the FDA approved first oral MS drug Gilenya (fingolimod) from Norvartis. Merck KGaA's oral MS Cladribine is under the FDA review.

MS is a multi-billion dollar market. Total sales of MS drugs exceeded $10 billion in 2010 and will grow even more in the coming decade. Viral Genetics' MS candidate is developed on the TPT technology and may have different mechanisms of action for MS. Although in its early preclinical stage development, the candidate has potential to become a major player in the MS market if approved.

***MDT-based Pipeline***

On the side of MDT platform, Viral Genetics is developing anticancer drug candidates. The mechanisms of action of MDT for cancer treatment are quite different from those of traditional cancer treatment. MDT technology seems able to identify unique characteristics of drug resistant cancer cells and is rapidly gaining attention as having the potential to offer hope to cancer patients.

By interfering with cancer cells' ability to get the fuel they need, MDT agents can essentially starve them, and make those cells more susceptible to chemotherapy and radiation. This approach also makes the cells more visible and vulnerable to the body's own immune system. This unique, two-fold approach potentially will result in the death of the drug resistant cells that are the major cause of most cancer deaths.

**Melanoma, Ovarian and Breast Cancer**: Viral Genetics is collaborating with Scott & White Healthcare at Temple, Texas to conduct investigator-initiated clinical trials, using the FDA approved cancer drugs in combination with Viral's MDT candidates, to treat end-stage cancer, including melanoma, ovarian, and breast cancer patients.

Scott & White has received an anonymous gift of $1.5 million for the clinical trial. Dr. M. Karen Newell Rogers will serve as principle research investigator on the proposed research. The team is preparing the necessary protocols and applications for the clinical trials for patients with treatment refractory disease, and once finalized, the team expects to begin enrolling patients within the next several months. The course of treatment is expected to last six- to eight-weeks, with the trial running for approximately 12 months.

Among the drug combinations to be tested are two compounds already approved by the FDA for other uses. One blocks a distinct survival strategy that tumor cells use. The other neutralizes an important growth factor for many tumors. These were chosen, in part, because this treatment could be quickly brought to market following a successful physician's trial and completion of the FDA approval process. Viral's MDT candidates will be test in combination with the FDA approved drugs in the clinical trials.

**Glioblastoma:** The Company is developing a drug compound and dosing based on MDT for glioblastoma, the most common and aggressive primary brain tumor. The Company expects this therapy will be used in conjunction with traditional cancer treatments such as chemotherapy and radiation. The drug's role will be to target the cells capable of surviving those treatments. Drug resistance is the leading cause of death among cancer patients. It is hopeful that VRAL's new approach may provide novel therapy aimed at dealing with drug resistance. The above investigator-initiated clinical trials also include glioblastoma.

Glioblastoma multiforme (GBM), also called glioblastoma, is the most common and most aggressive type of primary brain tumor and accounts for approximately 50% to 60% of all primary brain tumors. According to National Cancer Institute (NCI) data, in the United States, the age-adjusted brain tumor incidence rate was 6.5 per 100,000 people per year. The age-adjusted death rate was 4.3 per 100,000 people per year. It is estimated that 22,020 men and women will be diagnosed with and 13,140 men and women will die

of cancer of the brain and other nervous system in 2010. Worldwide, approximately 176,000 new cases of brain and other CNS tumors were diagnosed in the year 2000, with an estimated mortality of 128,000.

Glioblastomas are among the most aggressively malignant human neoplasms. The median survival time from the time of diagnosis without any treatment is usually less than 1 year. Despite multimodality treatment consisting of open craniotomy with surgical resection of as much of the tumor as possible, followed by concurrent or sequential gamma knife radiotherapy, chemoradiotherapy, targeted therapy, and symptomatic care with corticosteroids, median survival is about 14 months. The overall 5-year survival is less than 10% with the standard of care today.

Currently, two chemotherapeutic agents (including one targeted therapy) approved by the FDA are frequently used for the treatment of glioblastoma in combination with radiation therapy. They are Temodar (temozolomide) from Merck/Schering Plough for newly diagnosed GBM and Avastin from Roche for recurred GBM. A third chemotherapeutic agent on the market for glioblastoma is Bristol Myers Squibb's Carmustine injection and Eisai's Carmustine wafer, which are less frequently used.

Clearly, there is an unmet medical need for the treatment of glioblastoma. Viral Genetics' MDT approach may provide an alternative to the treatment of glioblastoma if proved to be successful in clinical trials.

The Company's **growth strategy** is to focus on the development of its compounds through Phase I or Phase II clinical trials, following which the Company intends to license out its program for Phase III trials and post-approval marketing to one or more large pharmaceutical companies under royalty/license fee/milestone payment arrangements. The primary focus is on the TPT platform and in particular the HIV/AIDS and Lyme disease indications. Secondary to this is the cancer application of the MDT platform being conducted under the MetaCytoLytics, Inc. subsidiary

***Experienced Management Team and Scientific Advisors***

VRAL has an experienced management team and advisors/consultants which include two Nobel Laureates, Dr. Luc Montagnier and Dr. Baruch Blumberg, leading researchers, business and intellectual property veterans and drug development experts.

**Haig Keledjian**, CEO, President
Mr. Keledjian has been instrumental in guiding the growth and development of Viral Genetics, Inc., having acted as its Chairman, Chief Executive Officer and President since its 1995 founding. He has overseen the completion of VGV-1's six human clinical trials, including the Phase III trial in South Africa, the creation of Viral Genetics' global intellectual property portfolio and the financing of Viral Genetics.

Mr. Keledjian is a California attorney. Prior to joining Viral Genetics, he practiced tax and estate law.

**Monica Ord,** Senior VP of Corporate Development and Communications
Ms. Ord has been involved in the life sciences industry for over 17 years, including as an entrepreneur with her own health promotion and marketing company, and as an international sales manager for two Fortune 500 companies. She has been active in venture capital and financial consulting with public companies for over 9 years and also has extensive experience in recruitment of high-level executives, advisory board members, and directors in the healthcare industry.

**Michael Capizzano**, CFA, Consultant
Mr. Capizzano joined Viral Genetics in 2001 initially as a management consultant advising the Board on restructuring, corporate development strategy, the build-out of corporate infrastructure, business development, legal documentation, and financial issues such as analysis, reporting, disclosure and investor relations. Before joining Viral Genetics, Mr. Capizzano worked in venture capital and provided financial advisory consulting for several years including micro and small cap financings, restructurings and M&A. He has originated, structured and managed or co-managed transactions in a variety of industry sectors ranging from $250,000 to over $20 million. Mr. Capizzano has a B.S. in Finance and Investments

from Babson College, and received his Chartered Financial Analyst designation.

**Robert Berliner**, JD, Consultant
Bob Berliner was a founding member of the intellectual property firm of Robbins, Berliner & Carson L.L.P. for more than 25 years, becoming a partner of the international general law firm of Fulbright & Jaworski L.L.P. following the 1997 merger of the two firms. Having decades of practice in all aspects of intellectual property, and having developed an extensive network of top rated intellectual property firms in over twenty countries, he founded Berliner & Associates specializing in patent, trademark and copyright prosecution, licensing and litigation, both in the United States and worldwide. He has close familiarity with the special needs of University patent portfolios and in assisting in the formation and operations of early stage companies. Bob is a member of the Intellectual Property Rights panel of the American Arbitration Association, and has served as arbitrator in significant patent and trade secret disputes.

**M. Karen Newell-Rogers, PhD,** Advisor
Dr. Newell-Rogers is the Raleigh R. White, Jr. Endowed Professor of Surgical Research, Department of Surgery, College of Medicine, at Texas A&M Health Sciences Center and Scott and White Hospital in Temple, Texas. Newell-Rogers is also the Director of the newly formed Center for Cell Death and Differentiation at TAMHSC/Scott and White Hospital. Newell-Rogers was formerly at the University of Colorado as Scientific Director of the CU Institute of Bioenergetics and Immunology and as the Clement and Margaret Markert Endowed Professor of Biology.

She has authored or co-authored several dozen peer-reviewed papers predominantly focused on immunology and cellular metabolism, and she has over 30 issued or pending patents.

**Luc Montagnier, MD,** Advisor
Dr. Montagnier is co-winner of the 2008 Nobel Prize for Medicine and the Co-discoverer of the HIV virus. Dr. Montagnier is best known for his 1983 discovery of the human immunodeficiency virus (HIV), which has been identified as the cause of AIDS. He has received more than 20 major awards, including the Commandeur de la Legion d'Honneur, the Lasker Award, the Gairdner Award, King Faisal Foundation International Prize(known as the Arab Nobel Prize),and the Nobel Prize in Physiology or Medicine awarded to him for the discovery of HIV.

**Baruch S. Blumberg, MD,** Advisor
Dr. Blumberg is the winner of the 1976 Nobel Prize for Medicine for Discovery of Hepatitis B virus. Dr. Blumberg obtained his undergraduate degree in Physics from Union College in Schenectedy, New York, entered graduate school at Columbia University, and then the College of Physicians and Surgeons where he earned his Doctorate in Medicine. He then won a fellowship to Balliol College, Oxford University, in 1955, and was awarded a Ph.D. in biochemistry. Dr. Blumberg returned to Oxford as Master of Balliol College, becoming the first American and scientist to have ever been awarded this prestigious chair.

**Marshall C. Phelps JR, JD,** Advisor
Marshall C. Phelps, Jr. is the former Corporate Vice President for IP Policy and Strategy for Microsoft. In this position, Mr. Phelps is responsible for establishing global policy and strategy for Microsoft's intellectual property, and interfacing with governments and technology companies about intellectual property issues. During his tenure at Microsoft he has also overseen management of the company's trademark, copyright, patent, trade secret and related divisions. Prior to Microsoft, Mr. Phelps spent 28 years at IBM where he served as vice president for intellectual property and licensing. At IBM, Phelps oversaw the company's patent licensing program and intellectual property portfolio development amongst other things.

**Richard T. Gerstner**, Advisor
Richard T. Gerstner joins Viral Genetics as an Advisor after a lifetime of executive management positions and investment in the technology arena. Gerstner spent several years as President and CEO of Telular Corporation, a wireless communication company he took public in the 1990s. Prior to that, he spent 32 years at IBM in several capacities including 10 years as a Corporate Vice President during which he

served as Chief Planning Officer, Head of the Asia/Pacific region located in Tokyo and Group Executive of IBM Personal Computers, and most recently as head of IBM's PC Group.

## INDUSTRY OUTLOOK

Our outlook for the biotech industry is positive in general.

There are a number of strong secular growth drivers that still power the biotech industry-namely, an aging population and an enormous research and development (R&D) effort to bring new, better drugs to market. People are living longer, and many have prescription pharmaceuticals to thank for it. Recent breakthroughs in oncology, neurology, and cardiology offer sizable market opportunities. Biotechnology research is finally starting to deliver. Expanded knowledge of genomics and proteomics is attracting significant attention from some of the industry's larger players. Drug companies are finding ways to reformulate and enhance current products. This is clearly a positive for the biotech industry. Demand for innovative medicines remains strong and biotechnology should deliver the next wave of pharmaceutical products to the market. This should allow the group to outperform the broader sector.

Licensing/partnership are the lifeline of biotech industry. We expect to see continued partnership and in-licensing/out-licensing activities for biotech companies in the next few years.

We also expect further consolidation throughout the industry because we believe that current market environment in the Pharma/Biotech industry is favorable for M&A activities. The big pharmaceutical companies have long been faced with big challenges such as patent expiration for blockbusters, low research and development productivity, and generic competition. Platform technology and efficient R&D efforts in smaller biotech companies may be part of the solution to the challenges faced by big Pharma companies. As long as the challenges still exist in the pharmaceutical industry, the buyout of smaller biotech companies by big Pharma/giant biotech companies will continue to make sense.

For individual biotech companies, we think companies with one or more of the following fundamentals will be attractive.

- With approved products on the market which can generate cash for the company;
- With a strong balance sheet and low cash burn rate; huge amount of cash will be needed to provide funds for drug development before it can reach the market;
- With platform technologies with deep, diversified pipeline (from early to late stage drug candidates); platform technology can produce series drug candidates, and is usually worth more than a single drug candidate program. When a drug candidate is moving closer to market, it usually reduces development risks.

Investors should not only pay attention to those large profitable biotechnology stocks, but also small-cap biotechnology stocks with promising pipelines.

## VALUATION AND RECOMMENDATION

We are initiating our coverage of Viral Genetics (VRAL) with a Neutral rating. Our six to twelve month price target is $0.15.

Viral Genetics is an early stage development biotech company. The Company holds two unique drug discovery platform technologies: targeted peptides technology and metabolic disruption technology. Both

platforms have the potential to target a broad range of disease indications such as HIV, cancers and multiple sclerosis.

Viral Genetics has established a pipeline based on the above two platform technologies. Preclinical studies of drug candidates have shown some promises, but we would like to see more data especially advanced clinical trial data to confirm the results of lab and animal studies. In this regard, we are pleased to learn that the Company plans to move at least one and possibly three candidates, into clinic this year.

We think Viral Genetics has entered into a transition period from a pure preclinical development stage company into a clinical stage biotech company. With an appropriate growth strategy in place, the Company is well positioned to deliver shareholder value in the next few years in our view.

We admit that it's always difficult to value a development stage biotech company, Viral Genetics is no exception. We don't think absolute valuation such as free cash flow method is appropriate for Viral Genetics since generating positive cash flow is still years away. Without revenue and operating income in the foreseeable future, it's also very difficult to come up with a value using a relative valuation metrics. However, we do think that Viral Genetics should be worth more than current value of $18 million in market cap by comparing the Company with its peers in the same industry.

Currently, the Company shares are trading at about $0.03 per share which values the Company at about $18 million based on about 600 million shares outstanding. This is certainly a huge discount compared to its peers. Most small biotech companies of development stage are valued from $50 million to $500 million depending on how advanced the pipeline is and which indications the company is targeting. We think Viral Genetics should be valued at about $90 million in market cap which translate into a share price of $0.15.

This valuation assumes that the Company will move at least one drug candidate into clinic this year, and achieve positive results. We also assume that additional financing will be made this year to provide sufficient funds for the operations including the clinical trials. However, if the Company establishes a major partnership this year with a big pharma or biotech company for any of its development programs, the Company's share could shoot up very beyond our price target of $0.15. However, this is unlikely without advanced clinical data in our view. If it proves to be difficult to get much needed cash, the Company's shares could suffer, and even goes to zero, which is also unlikely since management is committed to this effort.

Our valuation also excludes the value of VG Energy at this point since VG Energy is also at the early stage of development. However, VG Energy has potential to accelerate revenue sooner than Viral's drug development programs given lower regulatory hurdle and government support for alternative energy programs. We think any material development at VG Energy will have big impact on the valuation of Viral Genetics and its share prices. We will keep a close eye on this subsidiary and update investors whenever information is available.

## Industry Comparables

| | P/E (2009 ) | EPS Gr. 5Yr Est. | P/S (2009) |
|---|---|---|---|
| **Viral Genetics** | **N/A** | **N/A** | **N/A** |
| Biotech Mean | 30.0x | 12.6% | 18.1x |
| S&P 500 | 20.6x | 7.1% | 2.1x |
| Celgene, Corp. | 32.9x | 34% | 9.5x |
| Cyclacel Pharma | N/A | N/A | 85.5x |
| SuperGen | 29.8x | N/A | 3.8x |
| Bio-Path Holdings | N/A | N/A | N/A |

## RISKS

### *Cash Position is our Chief Concern*

Since its inception, Viral Genetics has been losing money. The Company has no revenue source to fund its operations, but depends on financing for ongoing operations.

In the third quarter ended September 30, 2010, the Company incurred net loss of $1.2 million. As of September 30, 2010, the Company only held about $20,000 in cash while long term liability stood at $1.3 million among which $1.05 million is owed to a company controlled by Viral's CEO, Haig Keledjian. This eases some of the short term going concern risks.

As the Company prepares to further advance its pipeline, especially for human clinical trials for its three most advanced candidates, R&D costs will soar. The Company will have to raise approximately $2 to $3 million to achieve its goal of filing an IND with the FDA for VGV-X, and completing Phase I clinical trials that alone will cost approximate $2 million.

We believe Viral Genetics needs to tap the capital market very soon and will continue to do so on a regular basis before the Company achieves revenue from product sales or establish any partnership with major pharma or biotech companies.

We remind investors that equity financing will dilute existing shareholder base.

### *Early Stage of Development Poses Higher Risks*

Viral Genetics has two unique drug discovery platform technologies. Both targeted peptides technology and metabolic disruption technology have great potential for drug discovery. However, all drug candidates are at their early stages of development at this point, and the most advanced candidate VGV-X is only in preclinical studies, though the Company plans to bring VGV-X into clinic in the first half of 2011. Although investigator-initiated clinical trials for MDT agents for cancer indications will begin this year, the regulatory path is uncertain. Early stage of development poses greater risks as the drug candidate must navigate through the long clinical trials and regulatory review process in order to get into market.

We would like to see more data especially clinical data for the Company's drug candidates before we are bullish about the Company's stocks. We will update investors on this matter once the data are available.

### *Trading on the Pink Sheets OTC Market May be Volatile and Sporadic*

There is currently a limited market for the Company's common stock, which is quoted on the pink sheets over-the-counter market. Trading in stock quoted on the pink sheets over-the-counter market is often thin and characterized by wide fluctuations in trading prices, due to many factors that may have little to do with the Company's operations or business prospects.

Moreover, the pink sheets over-the-counter market is not a stock exchange, and trading of securities there is often more sporadic than the trading of securities listed on a quotation system like NASDAQ or a stock exchange like NYSE. There is no assurance that a sufficient market will develop or remain stable in the stock, in which case it could be difficult for stockholders to resell their stocks. Liquidity may be an issue for institutional investors.

## PROJECTED INCOME STATEMENT

| | 2009A (Dec) | 2010E (Dec) | | | | | 2011E (Dec) | 2012E (Dec) | 2013E (Dec) | 2014E (Dec) | 2015E (Dec) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| $ in million except per share data | FYA | Q1 | Q2 | Q3 | Q4 | FYE | FYE | FYE | FYE | FYE | FYE |
| *R&D revenue* | $0.00 | $0.00 | $0.00 | $0.01 | $0.00 | $0.01 | $0.01 | $0.10 | $0.50 | $1.00 | $5.00 |
| *Product Sales* | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| **Total Revenues** | **$0.00** | **$0.00** | **$0.00** | **$0.01** | **$0.00** | **$0.01** | **$0.01** | **$0.10** | **$0.50** | **$1.00** | **$5.00** |
| *YOY Growth* | - | - | - | - | - | - | *0.0%* | - | - | - | - |
| *CoGS* | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| **Gross Income** | **$0.00** | **$0.00** | **$0.00** | **$0.01** | **$0.00** | **$0.01** | **$0.01** | **$0.10** | **$0.50** | **$1.00** | **$5.00** |
| *Gross Margin* | - | - | - | *100.0%* | - | *100.0%* | - | - | - | - | - |
| R&D | $0.25 | $0.17 | $0.18 | $0.12 | $0.15 | $0.62 | $0.71 | $1.50 | $3.00 | $5.00 | $8.50 |
| *% SG&A* | - | - | - | *2103.2%* | - | *10918.7%* | - | - | - | - | - |
| SG&A | $0.81 | $0.15 | $0.11 | $0.25 | $0.25 | $0.76 | $1.00 | $1.20 | $1.35 | $1.50 | $2.25 |
| *% R&D* | - | - | - | *4466.8%* | - | *13427.4%* | - | - | - | - | - |
| Other | $2.09 | $0.44 | $0.50 | $0.19 | $0.20 | $1.33 | $1.00 | $1.30 | $1.30 | $1.40 | $1.50 |
| *% Other* | - | - | - | *3373.3%* | - | *23348.3%* | *10000.0%* | - | - | - | - |
| **Operating Income** | **($3.1)** | **($0.8)** | **($0.8)** | **($0.6)** | **($0.6)** | **($2.7)** | **($2.7)** | **($3.9)** | **($5.2)** | **($6.9)** | **($7.3)** |
| *Operating Margin* | - | - | - | *-9843.3%* | - | *-47594.4%* | - | - | - | - | - |
| Other Net | ($4.2) | ($1.8) | $0.1 | ($0.7) | ($0.7) | ($3.0) | ($2.8) | ($2.5) | ($2.8) | ($2.5) | ($2.5) |
| **Pre-Tax Income** | **($7.3)** | **($2.6)** | **($0.7)** | **($1.2)** | **($1.3)** | **($5.7)** | **($5.5)** | **($6.4)** | **($8.0)** | **($9.4)** | **($9.8)** |
| 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 |
| *Tax Rate* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* |
| **Reported Net Income** | **($7.3)** | **($2.6)** | **($0.7)** | **($1.2)** | **($1.3)** | **($5.7)** | **($5.5)** | **($6.4)** | **($8.0)** | **($9.4)** | **($9.8)** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - | - | - |
| *Net Margin* | - | - | - | - | - | - | - | - | - | - | - |
| *Shares Out* | *351.8* | *525.1* | *532.8* | *571.8* | *599.0* | *557.2* | *607.5* | *625.0* | *640.0* | *650.0* | *675.0* |
| **Reported EPS** | **($0.02)** | **($0.00)** | **($0.00)** | **($0.00)** | **($0.00)** | **($0.01)** | **($0.01)** | **($0.01)** | **($0.01)** | **($0.01)** | **($0.01)** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - | - | - |
| 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* |
| **Non GAAP Net Income** | **($7.3)** | **($2.6)** | **($0.7)** | **($1.2)** | **($1.3)** | **($5.7)** | **($5.5)** | **($6.4)** | **($8.0)** | **($9.4)** | **($9.8)** |
| **Non GAAP EPS** | **($0.02)** | **($0.00)** | **($0.00)** | **($0.00)** | **($0.00)** | **($0.01)** | **($0.01)** | **($0.01)** | **($0.01)** | **($0.01)** | **($0.01)** |

Source: Zacks Investment Research

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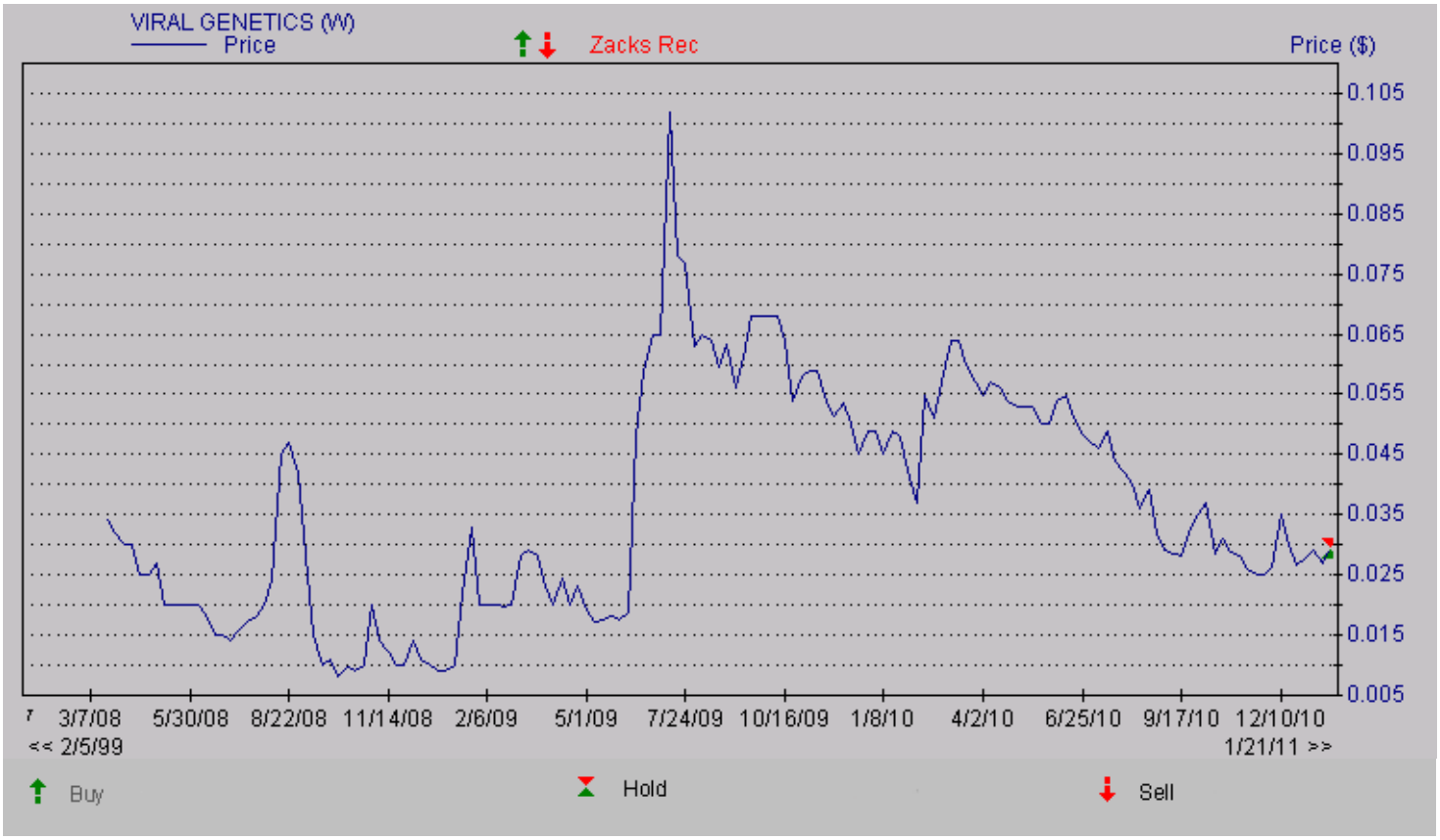
## HISTORICAL ZACKS RECOMMENDATIONS

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