Zacks Small-Cap Research

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Soligenix Inc. (SNGX-OTCBB)

SNGX: *SGX943 and SGX101 may be a solution for Melioidosis, market will eventually recognize the benefits of recent financing, Conservative cash burn, plan to initiate Phase III trial of SGX301*---Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	05/15/2013
Current Price (02/27/15)	$1.62
Twelve- Month Target Price	**$5.50**

OUTLOOK

SNGX is a late stage biopharmaceutical company focused on cancer/cancer supportive care, GI disorders and biodefense. Based on three platform technologies, SNGX has built a diversified pipeline targeting multiple indications. We are optimistic about its lead candidates SGX301 for CTLC and SGX942 for the treatment of oral mucositis, which is in Phase II studies. The Company's oral BDP is in various development stages for a variety of indications, most notably, in pediatric Crohn's disease, where they will be initiating a Phase II/III study soon. SNGX also is developing vaccines using its ThermoVax technology for biodefense.

Valuation is attractive at this time based on the fundamentals. We rate the shares Outperform.

SUMMARY DATA

52-Week High	**$2.49**
52-Week Low	**$0.95**
One-Year Return (%)	**-23.58**
Beta	**2.35**
Average Daily Volume (sh)	**189,560**
Shares Outstanding (mil)	**24**
Market Capitalization ($mil)	**$39**
Short Interest Ratio (days)	**0.43**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**23.3**
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**
Zacks Rank	**N/A**

Risk Level	**High,**
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	0.9 A	0.6 A	0.3 A	1.4 A	3.2 A
2014	0.9 A	1.4 A	2.8 A	0.8 E	5.9 E
2015					4.0 E
2016					4.5 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.10 A	-$0.22 A	-$0.10 A	-$0.04 A	-$0.41 A
2014	-$0.08 A	-$0.09 A	-$0.21 A	-$0.12 E	-$0.51 E
2015					-$0.37 E
2016					-$0.39 E

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

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WHAT'S NEW

- ***Updated Preclinical Data on RiVax Presented;***
- ***SGX943 and SGX101 may be a solution for Melioidosis;***
- ***Market will eventually recognize the benefits of recent financing;***
- ***There is still Room for Further Price Appreciation ;***
- ***Soligenix plans to initiate Phase III trial of SGX301 for CTCL in 1H15;***

Updated Preclinical Data on RiVax Presented

In February, 2015, Soligenix presented new **preclinical study** data that demonstrated the efficacy and safety of its heat-stabilized ricin toxin vaccine (**RiVax™**) in a non-human primate (NHP) lethal aerosolized ricin exposure model. The data was presented in a poster session at the American Society of Microbiology (ASM) Biodefense and Emerging Diseases Research meeting held in Washington, DC.

In the preclinical study, 12 animals were vaccinated with RiVax™ and 6 animals were given an injection of placebo. Each animal received 3 intramuscular injections, administered at time 0, 30 days and 60 days.

RiVax™ was well tolerated with no evidence of elevated heart rate, respiration or temperature. All RiVax™-vaccinated animals generated neutralizing antibodies after the third injection. To fully test the efficacy of the vaccine, all animals were exposed to an aerosol of ricin toxin 3-5 times the amount that is known to result in death of untreated animals. All RiVax™-vaccinated animals survived exposure, while all unvaccinated control animals died within 40 hours, demonstrating a **statistically significant** ($p<0.0001$) improvement in survival. Moreover, the lungs of the RiVax™-vaccinated animals did not demonstrate any signs of irreversible damage, unlike those of the unvaccinated control animals.

RiVax™ is developed using the company's proprietary ricin toxin vaccine, in conjunction with its heat stabilization technology, ThermoVax™, as a heat-stable biodefense vaccine.

Previous studies with RiVax™ have demonstrated significantly enhanced thermostability indicating that cold chain storage will potentially not be required for this vaccine, enabling it to be stored and distributed at room temperature.

This particular study is a critical step along the path of establishing efficacy under **the FDA 'animal rule'** which dictates that efficacy in animals must be ascertained in cases where a drug or vaccine cannot be ethically tested for efficacy in humans.

Soligenix plans to further conduct human safety and immunogenicity trials along with advanced manufacturing of RiVax.

The National Institute of Allergy and Infectious Diseases (NIAID) awarded grants to Soligenix for the development of the vaccine for potential counter terrorism measures. Currently, there are no approved methods to prevent the toxic effects of ricin poisoning which results in tissue necrosis, organ damage and death within days of exposure. If subsequent studies are successful, RiVaxTM could be added to the US Strategic National Stockpile and potentially dispensed if ricin is used as a biological weapon in a terrorist attack.

SGX943 and SGX101 may be a solution for Melioidosis

A recent news release from the US Centers for Disease Control and Prevention (CDC) on inquiry into **melioidosis** illness at Tulane National Research Center (TNPRC) has raised the visibility and awareness of melioidosis among healthcare professionals and the general public.

The ongoing inquiry was initiated in November 2014, when two non-human primates in the breeding colony at the TNPRC became ill and one was euthanized. The CDC has since identified **Burkholderia Pseudomallei** as the causative agent. Burkholderia Pseudomallei **(Bps)** is the bacteria which causes the illness of melioidosis.

Even more serious than the primate infection, during the investigation, one woman investigator fell ill with unspecific symptoms. Blood test results indicated a presence of antibodies in the blood indicating some exposure to Burkholderia Pseudomallei. At this point, it is still too early to determine whether exposure was related to this recent visit to the center or whether the sick individual's travel history may have provided an opportunity for exposure.

Although the CDC indicated that at this time, there is no known public health threat, this event raises the concern about a possible outbreak of melioidosis in the US, which could be a threat to the public health. Bps is also considered a top five priority in the most recent Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Strategy document. Therefore, in this article, I would like to revisit some background information about the this disease and review some treatment options under research, especially biotech company Soligenix (SNGX)'s programs, which may provide therapeutic solution to this disease.

The Background of Melioidosis

Melioidosis, sometimes called Whitmore's disease, is an infectious disease caused by the Gram-negative bacterium *Burkholderia pseudomallei*. Melioidosis can infect both humans and animals. It is endemic in parts of Southeast Asia and Northern Australia. The bacteria are often found in contaminated water and soil in the above regions and spread to humans and animals through inhalation, inoculation and direct contact with the contaminated source.

Melioidosis is of great public health importance in endemic areas. There are two forms of melioidosis: acute and chronic. Typical signs and symptoms may include pain in chest, bones, or joints; cough; skin infections, lung nodules and pneumonia. Once a melioidosis is diagnosed, the disease can be treated with the use of appropriate antibiotics.

The treatment of melioidosis is usually divided into two stages, an intravenous antibiotic therapy (**high-intensity phase)** for 10 to 14 days followed by a 3-6 months of oral antibiotic therapy **(eradication phase)** to prevent recurrence.

During the intravenous intensive phase, **ceftazidime** is the current drug of choice for treatment of acute melioidosis. Combination therapy with ceftazidime, meropenem and imipenem is also used for the acute treatment.

During the eradication phase, treatment with **co-trimoxazole** and **doxycycline** is recommended to be used for 12 to 20 weeks to reduce the rate of recurrence.

Current Challenges for Melioidosis Treatment

Treatment with the above antibiotics can reduce mortality rate to 10% for uncomplicated cases, but still up to 80% for cases with bacteraemia or severe sepsis while mortality rate could exceed 90% without appropriate treatment. This means that treatment with antibiotics is **insufficient**.

Also, very often, delayed treatment by antibiotics is **ineffective**.
Another major problem for antibiotic treatment of melioidosis is the **resistance**, especially for the long term treatment of melioidosis.

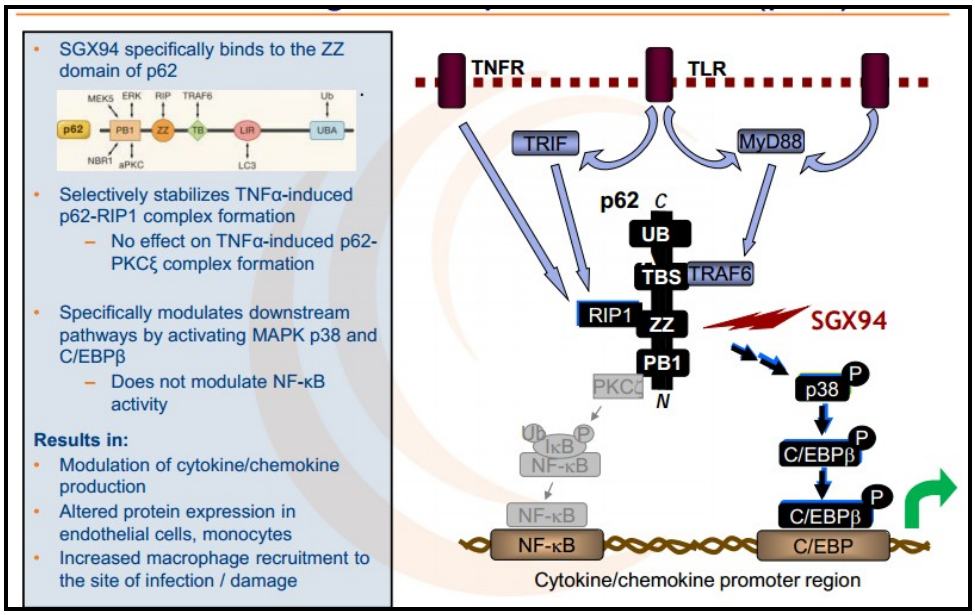
Currently there are no vaccines are approved for the **prevention of melioidosis**.

Considering the risk of potential outbreak and great threat as a biologic weapon, new prevention and/or treatment options must be developed for melioidosis.

Soligenix Has Two Distinctive Programs for Melioidosis: SGX943 and SGX101.

SGX943, which is being developed to treat **infections** and **tissue damages**, belongs to a new class of compounds called **Innate Defense Regulators (IDRs).**

SGX943 provide a novel approach to the control of infection and tissue damage via highly selective binding to an intracellular adaptor protein, **sequestosome-1**, also known as **p62**, which has a pivotal function in signal transduction during activation and control of the innate defense system. Sequestosome is a recently identified target for modulation of innate defenses and is expressed in most cell types.

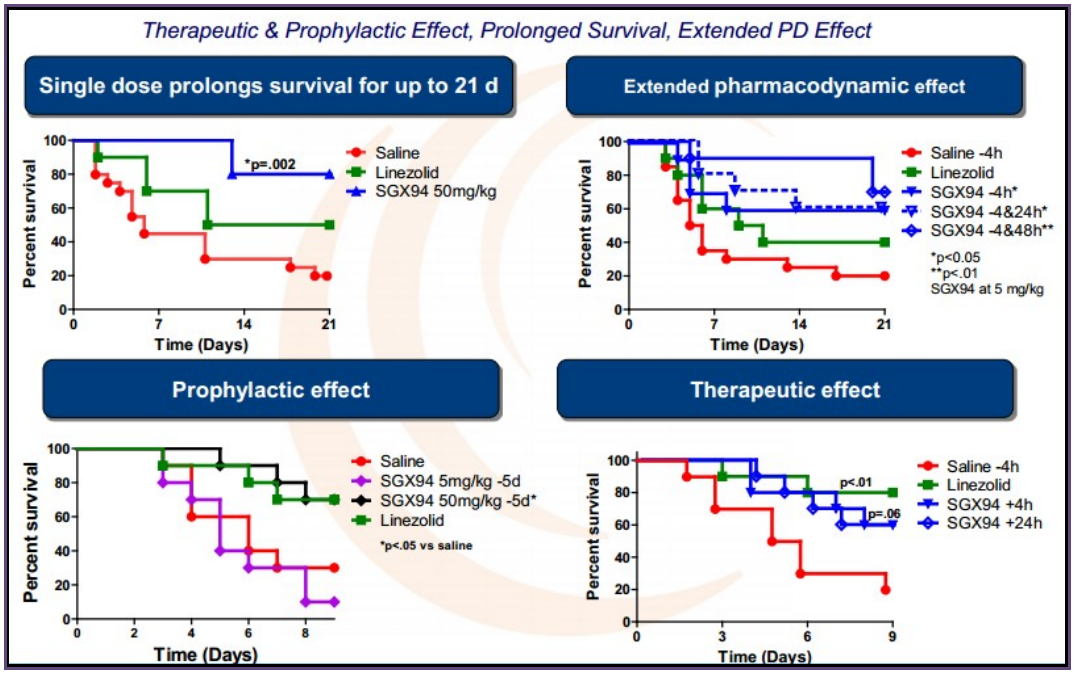


Source: Soligenix Presentation

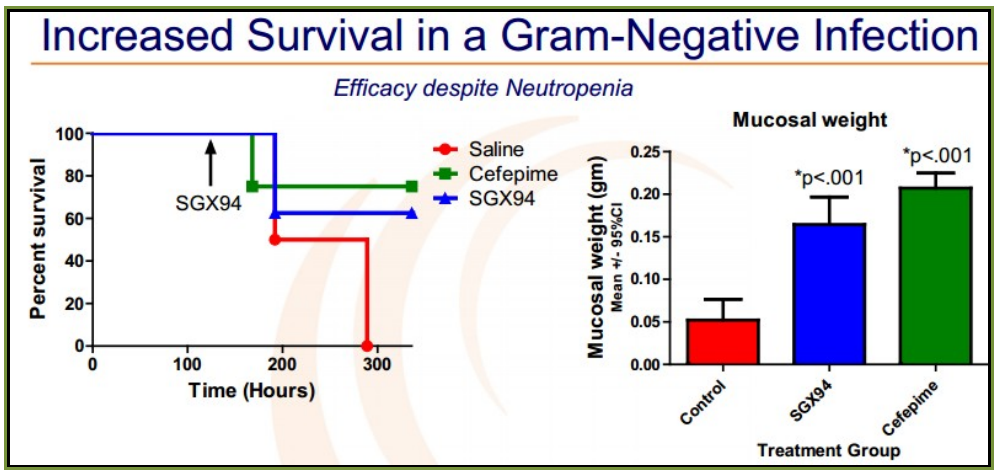
SGX943 has no direct antibiotic activity but modulate host responses, increasing survival after infections with a broad range of bacterial Gram-negative and Gram-positive pathogens including both antibiotic sensitive and resistant strains, as well as accelerating resolution of tissue damage following exposure to a variety of agents including bacterial pathogens, trauma and chemo- or radiation-therapy.

Since SGX943 targets the host (and not the pathogen), it **does not engender resistance** and are active against resistant pathogens. In vitro data indicate that the endothelium plays a significant role in SGX94 activity and animal studies show that SGX943 selectively promotes monocyte and macrophage recruitment to disease sites and accelerate resolution of disease.

In Feb 2015 at the ASM Biodefense and Emerging Infectious Diseases Meeting, Soligenix presented **preclinical animal data** showing that SGX943 is efficacious in Gram-positive methicillin resistant Staphylococcus aureus (MRSA) infection as well as with other Gram-negative pathogens infection.

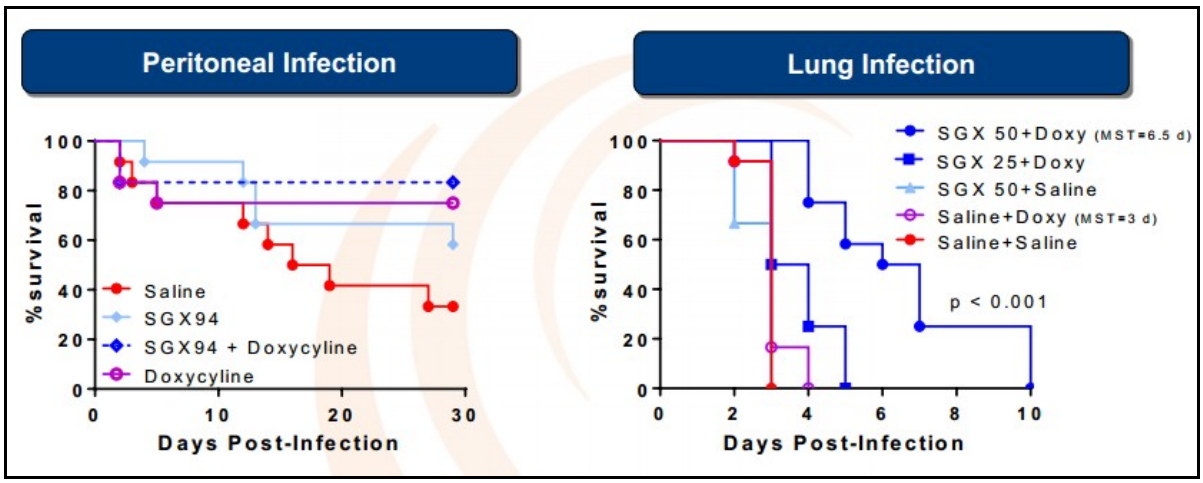


Source: company presentation



Source: company presentation

Soligenix also presented preclinical animal data showing that SGX943, either alone or in combination with antibiotic Doxycycline, was effective to increase survival after Bps infection.



The company plans to optimize dosing regimens for SGX943 in combination with antibiotic for the intranasal pneumonic model and to demonstrate efficacy in aerosol model of infection including large animal model proof of concept. The route of delivery for biodefense applications will also be optimized this year including self-administered injection (IM/SC) or oral tablet. The company also plans to identify responding cell population/ biomarker to enable further dose optimization and facilitate the use of the **Animal Rule**. The Animal Rule provides that under certain circumstances, where it is unethical or not feasible to conduct human efficacy studies, the FDA may grant marketing approval based on adequate and well-controlled animal studies when the results of those studies establish that the drug is reasonably likely to produce clinical benefit in humans. Demonstration of the product's safety in humans is still required.

In addition to SGX943, Soligenix is also developing SGX101 for melioidosis**. SGX101** is a monoclonal antibody (Mab) or monoclonal antibody cocktail developed by Soligenix with collaboration with **Intrexon Corporation (XON)** as a passive immunotherapy. Passive immunotherapy utilizes antibodies in the same manner a host-derived antibody would be used, targeting and labeling foreign entities and infected cells. SGX101 is intended as a human Mab therapy directed at host cells infected with Bp. SGX101 may also be utilized in conjunction with available antibiotic therapy.

Either SGX943 or SGX101, if successful, may be extended to other difficult to treat bacterial infections. In particular, the IDR approach could be directly translated to other infections. In the case of SGX101, the product would be specific to Bp and perhaps Bm infection but the process whereby the product was identified could be generalized to other difficult to treat infections with intracellular bacteria.

With these two distinctive anti-melioidosis programs, Soligenix is emerging as a key player in this specific field.

Market Will Eventually Recognize the Benefits of Recent Financing

On December 19, 2014, Soligenix priced its registered public offering at $1.21 per units with gross proceeds of $2.3 million.

The offering included 1,886,530 units, with each unit consisting of one share of common stock and 0.6 of a warrant to purchase one share of common stock. A warrant will be immediately exercisable to purchase one share of common stock at an exercise price of $1.48 per share and will expire on the fifth anniversary of its issuance.

Soligenix plans to use the proceeds to fund its **Phase III** clinical trial of SGX301 for the treatment of cutaneous T-cell lymphoma scheduled in 1H15 as well as other research and development activities.

When this pricing was announced, Soligenix's share price declined 29.6%. We think the market very much overreacted to the news, which **actually was positive**. We admit that any equity financing will dilute existing shareholder base, but not every equity financing is bad. In this case, Soligenix did a very small and targeted financing of ~$2.3M, predominantly with existing shareholders/supporters. The terms were **reasonable** in our view.

The primary focus of the targeted financing was to allow for the initiation of the Phase III CTCL clinical trial in 1H 2015. With existing cash and the company's non-dilutive funding sources, the cash balance will last into 2016 at which the primary endpoints will readout.

Management remains aggressive in the pursuit of government grants and contracts across its entire pipeline as a way to secure **non-dilutive funding** to support multiple development programs, while effectively managing its cash position.

As a result, Soligenix has been rewarded multiple contracts from government worth up to $57 million for program development. These rewards not only boost the company's balance sheet, but also validate its technology and clinical programs.

In November 2013, Soligenix signed a stock purchase agreement with Lincoln Park Capital Fund, LLC (LPC) providing an initial investment in Soligenix of $600,000 and the availability of additional periodic investments up to $10.0 million over a 36 month term. At its sole discretion, Soligenix has the right to sell to LPC up to an additional $10.0 million of its common stock. With this flexible financing vehicle, Soligenix should be able to focus on advancing its clinical programs.

We believe the market will eventually recognize the benefits of the $2 million financing and the share price will rebound in the next couple of weeks. Furthermore, with progress made in each of its multiple clinical programs, Soligenix is in good shape and ready to take off in 2015.

There is still Room for Further Price Appreciation

We maintain an **Outperform rating** for Soligenix and keep our 12-month price target of $5.50 per share. We believe there is still enough room for further price appreciation.

Soligenix becomes a late development stage biotech company through the acquisition of SGX301, a Phase III candidate for CTLC. Soligenix is focused on **cancer/cancer supportive** care and **GI disorders**, two large pharmaceutical markets both in the US and around the world. Soligenix also develops vaccines/oral therapeutics for **biodefense**.

In addition to SGX301, Soligenix has built a diversified pipeline using three proprietary platform technologies: the **SGX942** platform, the **oral BDP** platform and the **ThermoVax** platform. We are especially optimistic about its lead drug candidate SGX942 for the treatment of mucositis. SGX942 is currently under a Phase II study. Results will be available in 1H15, which, if positive, would be a significant **de-risking** event for Soligenix. SGX942 has a new mechanism of action and will command a significant market share of the oral mucositis market if approved in our view.

The Company's oral BDP has the potential to target multiple GI disorders such as Crohn's disease, radiation enteritis and GVHD as well as ARS.

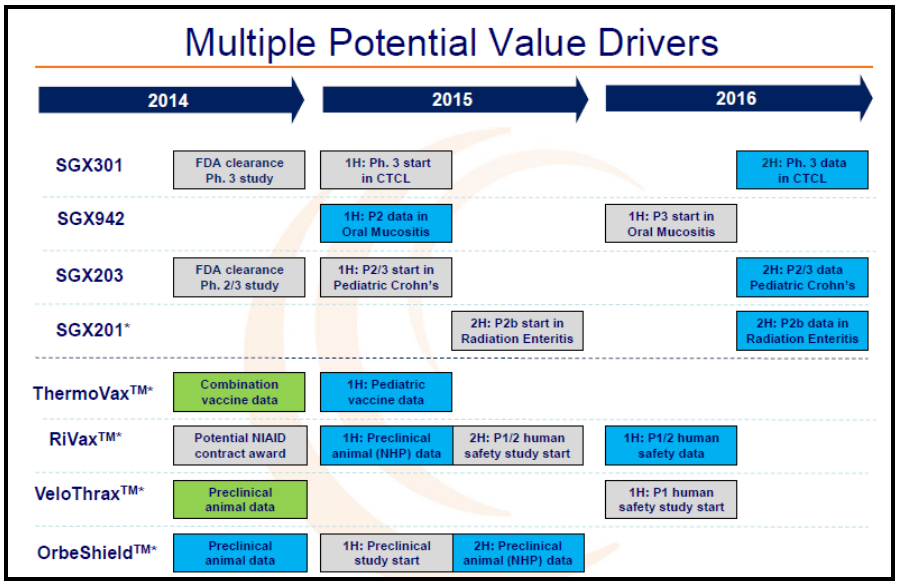
Soligenix's vaccines and biodefense therapeutics are being developed under specific FDA regulatory guidelines called the "**Animal Rule**." We think the "Animal Rule" means a lot for Soligenix, because this can accelerate the development of the ricin and anthrax vaccines as well as OrbeShield. Once approved by the FDA, Soligenix will have the opportunity to negotiate a stock-pile contract with the US government. These stock-pile or procurement contracts have been very lucrative for other companies supplying similar drugs to the US government and will provide significant cash flow to Soligenix.

Based on our analysis, we think Soligenix shares are undervalued at current market price. Currently shares of Soligenix are trading at around $1.60 per share, which values the Company at $38 million in market cap based on 24 million outstanding shares. This deeply undervalues Soligenix shares in our view.

Our price target of $5.50 is arrived at by using 45 x P/E ratio, multiplied by an EPS of $0.30 in 2018, discounted at 25% for 4 years.

Most small biotech companies of development stage are valued from $50 million to $1 billion depending on how advanced the pipeline is and which indications the company is targeting. Soligenix has one Phase III candidate, two Phase II programs, and two more programs will move to Phase II/III study in 2015. Soligenix has multiple catalysts in the next 6 to 12 month or so.

Our price target of $5.50 per share values Soligenix at $132 million in market cap which we think is very conservative.



Update on SGX301

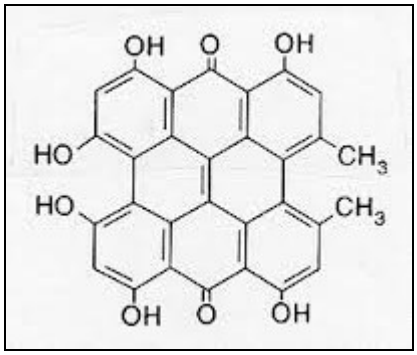
Background

In early September 2014, Soligenix entered into an asset purchase agreement with Hy Biopharma, Inc. Pursuant to the agreement, Soligenix acquired a novel orphan drug candidate, known as **SGX301** (synthetic hypericin) for the treatment of **cutaneous T-cell lymphoma (CTCL).** As part of the acquisition, Soligenix acquired all rights for synthetic hypericin, including intellectual property, and preclinical and clinical data.

In addition to SGX301, the acquired technology package also includes preclinical and clinical data supporting other potential indications for hypericin photodynamic therapy, such as **psoriasis**. Psoriasis is an autoimmune inflammatory disease that is similarly characterized by cutaneous accumulation of T-cell lymphocytes but without cancerous transformation.

The total purchase price including all milestones is $14.025 million, of which approximately 2% is payable in cash and approximately 98% is payable in restricted securities of the Company, and the assumption of certain liabilities of Hy Biopharma related to the hypericin assets.

Over the years, Hy BioPharma has developed a **novel topical photodynamic therapy** using a synthetic hypericin (a powerful photosensitizer) and safe, visible light to treat early-stage cutaneous T-cell lymphoma (CTCL) and mild to moderate psoriasis. CTCL and psoriasis have a common link of malfunctioning T-cells. CTCL is a type of non-Hodgkin's lymphoma (NHL) caused by a T-cell mutation, whereas psoriasis is caused by overactive T-cells that attack healthy skin cells.



Structure of Hypericin

In hypericin photodynamic therapy, fluorescent light (not cancer-causing ultraviolet radiation) energizes topically applied hypericin, thereby producing singlet oxygen molecules that kill malignant T-cells (apoptosis) in CTCL. Hypericin photodynamic therapy is selective for killing the malignant T-cells since the drug is applied directly onto the affected skin sites without exposing the normal skin cells to the drug. Only the area where hypericin has been applied to the skin will be directly affected by the therapy. Thus, hypericin photodynamic therapy is focused and selective to malignant T-cells.

Hy Biopharma conducted both Phase I and Phase II studies of hypericin. Topical hypericin was safe and well tolerated in a **Phase I** clinical study in healthy volunteers. In a **Phase II,** placebo-controlled, clinical study in CTCL patients, the drug was safe and well tolerated, with 58.3% of the CTCL patients responding to topical hypericin treatment compared to only 8.3% receiving placebo ($p < 0.04$).

SGX301 – Phase 2 Response Rate

Summary of CTCL Lesion Responses to Synthetic Hypericin Ointment Following Six Weeks of Treatment

	Responders/Total[a]	Percent Responders[a]
All Hypericin Responders	7/12	58.3%[b]
Hypericin 0.25% Dose	5/9[c]	55.6%[b]
Hypericin 0.1% Dose	5/12	41.7%b
Placebo Responder	1/12	8.3%

Note: No serious adverse events other than mild phototoxicity at treated site

a. Data reflect the number of patients who had a response to any dose; some patients may have been responders at more than one dose of treatment
b. $p \leq 0.04$ versus placebo (exact binomial limits)
c. Three patients not treated with the 0.25% dose of hypericin, 0.1% top dose given

Data Source: Journal American Academy Dermatology, Vol 63, Number 6, 2010

A Medical Advisory Board formed for SGX301

On November 17, 2014, Soligenix announced the formation of a Medical Advisory Board (MAB) to provide medical/clinical strategic guidance to the Company with regard to the Phase III clinical development of SGX301.

The MAB is comprised of dermatologic oncology thought leaders, such as Alain Rook, a professor of dermatology at UPenn School of Medicine, Gary Wood, chair and professor of dermatology at University of Wisconsin. All members have extensive experience in CTCL. The MAB will play an important advisory role in the conduct of the upcoming Phase III pivotal clinical study as well as in the design of subsequent clinical studies (in other indications, e.g., psoriasis) and associated regulatory interactions with health authorities. The MAB will provide feedback, input and guidance on clinical strategies and their implementation as well as on other critical issues, such as health economics and reimbursement to assist Soligenix in meeting the needs of the CTCL patient population.

Phase III trial will be initiated in 1H15

Based on positive data from Phase I and Phase II studies, Soligenix has reached an agreement with the FDA on the design of a pivotal, **Phase III** clinical trial evaluating SGX301 for the treatment of cutaneous T-cell lymphoma (CTCL).

Soligenix plans to initiate the Phase III trial in **1H15** with primary data available in **2H16**.

- The upcoming Phase III protocol will be a highly powered, double-blind, randomized, placebo-controlled, multicenter trial;
- Will seek to enroll approximately **120 patients**;
- The trial will consist of three treatment cycles, each of 8 weeks duration;
- Treatments will be administered twice weekly for the first 6 weeks and treatment response will be determined at the end of Week 8;
- In the first treatment cycle, approximately 80 patients will receive SGX301 and 40 will receive placebo treatment of their index lesions. In the second cycle, all patients will receive SGX301 treatment of their index lesions and in the third (open-label) cycle all patients will receive SGX301 treatment of all their lesions;
- Subjects will be followed for an additional 6 months after the completion of treatment;
- The primary clinical efficacy endpoint is treatment response assessed using the CAILS (Composite Assessment of Index Lesion Severity) score evaluating the three worst index lesions at the end of Cycle 1 (Week 8).

We estimate SGX301 could be approved by the FDA in 2H17 if data from the Phase III trial are positive.

SGX301 has received **orphan drug** designation by the FDA for the treatment of CTCL, which provides for 7 years of market exclusivity upon approval in the US.

CTCL is a class of non-Hodgkin's lymphoma (NHL). It is estimated that CTCL affects over 20,000 individuals in the US, with approximately 2,800 new cases seen annually.

With CTCL mortality is related to stage of disease, with median survival generally ranging from about 12 years in the early stages to only 2.5 years when the disease has advanced. There is currently no cure for CTCL.

We welcome the acquisition of late stage candidate SGX301, which, we think, will have positive impact for the company's operations and valuation. Soligenix becomes a **late development stage** biotech company through the acquisition of SGX301, which is highly synergistic with the company's existing development pipeline.

SGX301 may also be developed for other indications such as **psoriasis**, which further expands the company's pipeline. Psoriasis is a common autoimmune disease that affects over 7 million adults in the US. Photodynamic therapy is a frequently used initial therapy for psoriasis, despite the need for ultraviolet light exposure and its attendant risk of melanoma and non-melanoma skin cancer.

Soligenix Advances Development of a Heat Stable Rapidly Acting Anthrax Vaccine

On August 7, 2014, Soligenix announced results demonstrating the improved immunogenicity and rapid action of its anthrax vaccine, **VeloThrax™**.

VeloThrax™ is Soligenix's proprietary vaccine based on a recombinant Protective Antigen (rPA) derivative intended for use against **anthrax**. Soligenix licensed VeloThrax™ (also known as **DNI for dominant negative inhibitor**) from Harvard College for a vaccine directed at the prevention of anthrax infection of humans.

Recent developments in the VeloThrax™ formulation have resulted in immune responses indicative of protection after no more than two administrations of the vaccine in a shortened (less than one month) vaccination regimen, in an animal model. These results are indicative of a vaccine that can be given to humans in an abbreviated regimen, compared to the current vaccination that requires up to five administrations over a period of 18 months for full protective immunity in humans.

A rapidly acting form of VeloThrax™ has been developed by combining Soligenix's proprietary vaccine thermostabilization platform technology, ThermoVax™, and a potent adjuvant compound to yield a vaccine that is stable to high temperatures and induces neutralizing antibodies in an animal model. The enhanced DNI vaccine was formulated with a synthetic immunostimulatory adjuvant that activates toll-like receptor 4 (TLR-4), a receptor that is important in recognition of pathogens. The immune responses indicative of protective immunity were observed in fewer doses than the vaccine that did not contain the additional immunostimulatory adjuvant.

The enhanced vaccine was also stable at 40 degrees Celsius (104 degrees Fahrenheit) for at least 3 months, indicating that the synthetic adjuvant component and the DNI antigen component were both stabilized. Furthermore, even when VeloThrax™ was stored at 40 degrees Celsius for up to 3 months prior to administration, there was no evident loss of the ability to induce antibodies that neutralize anthrax toxin.

We believe VeloThrax™ provides a distinct advantage over other anthrax vaccine technologies currently in development. Soligenix plans to continue VeloThrax™ development with the support of government grants and contracts.

Potential government procurement contracts could reach $500 million assuming development efforts are successful for VeloThrax™.

Soligenix Announces Positive Results for Combination Vaccine

On July 9, 2014, Soligenix (SNGX) announced positive results from a preclinical study of the **combination** of RiVax™ and VeloThrax™. The combination induces protective antibodies for both ricin toxin and anthrax toxin exposure.

Previously, Soligenix has demonstrated that each vaccine, when administered as a single vaccine, induced neutralizing antibodies for each toxin respectively. In this **preclinical study**, Soligenix further demonstrated that **the combination of** RiVax and VeloThrax induced neutralizing antibodies that were reactive against both toxins and these antibodies were detected until at least 200 days after the immunization regimens. Consequently, the combined vaccination provided protection to exposure to both ricin toxin and anthrax toxin that persisted for at least six months after 2 vaccinations.

This study is sponsored under $9.4 million cooperative grant from the National Institute of Allergy and Infectious Diseases (NIAID). The results suggest that long-term immunity upon simultaneous vaccination can be achieved. This is important because both vaccines are developed for military usage and emergency first responders.

Soligenix plans to develop the combination vaccine using the company's proprietary **ThermoVax™** platform for stabilizing vaccines for stockpiling and for distribution of vaccines outside of normal cold chain requirements.

Two More Phase II Trials Will Be Initiated

SGX203 for children's Crohn's disease

Soligenix plans to start **Phase II/III** trial of **SGX203** (oral beclomethasone 17,21-dipropionate or oral BDP) for the treatment of **pediatric Crohn's disease** in 1H2015. Primary endpoint data are expected in **2H2016.**

The Company has enrolled and treated all patients in the **Phase I** study, which enrolled 24 subjects between the ages of 18-22, with all assessments completed in May 2013. Preliminary PK results indicate that the PK profile in this population is consistent with the profile established in previous studies in a broader population and supports a convenient twice a day dosing regimen. SGX203 administration (6 mg BDP twice daily over 7 days) was found to be safe and well-tolerated.

The PK data generated from the Phase I study will be used to refine the PK model previously established with Dr. Jeffrey S. Barrett, PhD, FCP, from The Children's Hospital of Philadelphia. The refined model will provide the justification for limited PK sampling in the planned Phase II/III pediatric clinical study and will help inform the dose selection for the Phase III component of the study.

There is currently no cure for Crohn's disease, and there is no one treatment that works for everyone. Drug therapies usually include anti-inflammatory drugs, immune system suppressors and antibiotics. There are currently no FDA approved corticosteroid therapies for pediatric Crohn's disease. 80% of patients with Crohn's disease are treated with **steroids off-label** as first-line therapy, which may suppress adrenal function and result in growth retardation. **Remicade** is the only approved product in pediatric Crohn's disease in the US, which is used in 30% of patients within first year of diagnosis. However, Remicade carries a black box warning for potential malignancy (T cell lymphoma). Two biologics, Cimzia and Tysabri and one corticosteroid Entocort (budesonide) are on the market to treat Crohn's disease in adult patients, and are currently in trials in pediatric patients.

SGX203 is designed to block inflammation of Crohn's disease throughout the GI tract and is positioned as a corticosteroid option with less toxicity than the current standard systemic steroid therapy – **prednisone.**

SGX203 has received Fast Track and Orphan Drug designations from the US FDA for the treatment of pediatric Crohn's disease. We believe SGX203 has the potential to meet an important medical need in children with this serious illness.

SGX201 for Preventing Acute Radiation Enteritis

SGX201 is a **delayed-release** formulation of BDP specifically designed for oral use and is designed to block inflammatory component of **radiation enteritis** in GI tract of cancer patients receiving pelvic radiation therapy.

Soligenix completed a 16-subject **Phase I/II** clinical trial testing SGX201 in prevention of **acute radiation enteritis**. Patients with rectal cancer scheduled to undergo concurrent radiation and chemotherapy prior to surgery were randomized to one of four dose groups. SGX201 is safe and well tolerated in these subjects.

The Company plans to initiate a **Phase II** randomized, double-blind, placebo-controlled trial in 2015. Data are expected in **2H2016**, assuming continued financial support from NIH. The Company has received

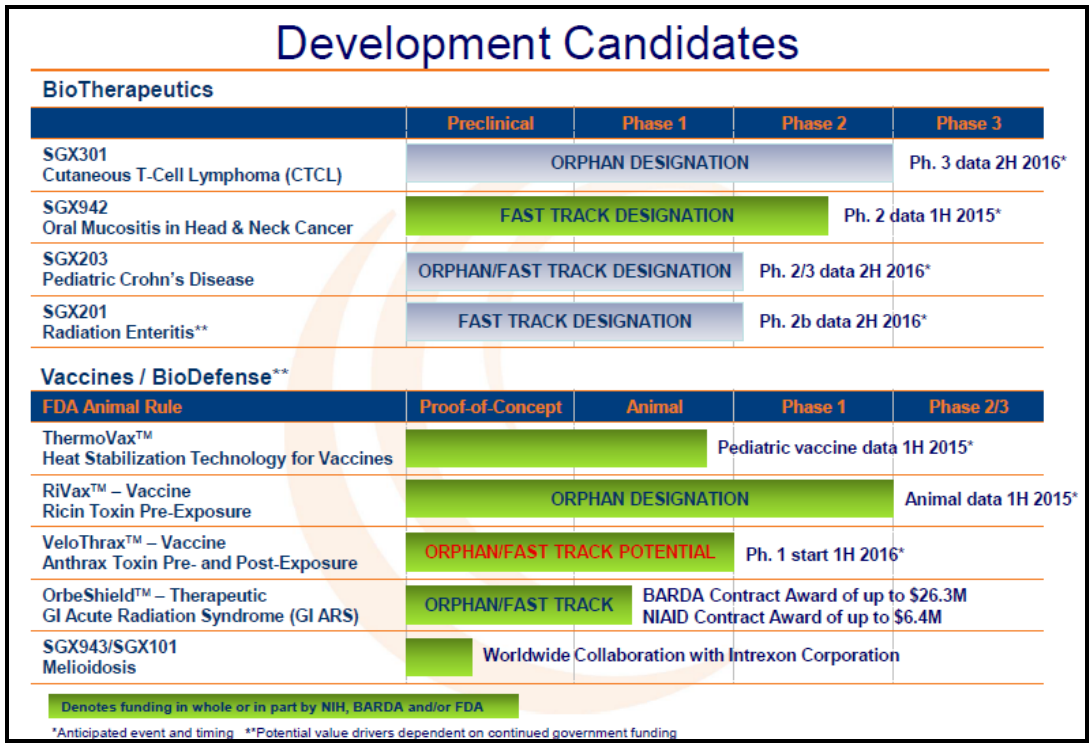
Fast Track designation from the FDA for SGX201 for radiation enteritis. It's possible for continued government funding for the Phase IIa trial.

External radiation therapy is used to treat most types of cancer. During delivery of treatment, some level of radiation will also be delivered to healthy tissue, including the bowel, leading to acute and chronic toxicities. The large and small bowels are very sensitive to radiation and the larger the dose of radiation the greater the damage to normal bowel tissue. **Radiation enteritis** is a condition in which the lining of the bowel becomes swollen and inflamed during or after radiation therapy to the abdomen, pelvis, or rectum. Most tumors in the abdomen and pelvis need large doses, and almost all patients receiving radiation to the abdomen, pelvis, or rectum will show signs of acute enteritis.

Patients with acute enteritis may have nausea, vomiting, abdominal pain and bleeding, among other symptoms. Some patients may develop dehydration and require hospitalization.

Symptoms will usually resolve within 2-6 weeks after therapy has ceased. Radiation enteritis is often not a self-limited illness, as over 80% of patients who receive abdominal radiation therapy complain of a persistent change in bowel habits. Moreover, acute radiation injury increases the risk of development of chronic radiation enteropathy, and overall 5% to 15% of the patients who receive abdominal or pelvic irradiation will develop chronic radiation enteritis.

Based upon published studies and reports, there are over 100,000 patients annually in the U.S. and over 200,000 patients worldwide, who receive abdominal or pelvic external beam radiation treatment for cancer, and these patients are at risk of developing acute and chronic radiation enteritis. Currently there are no approved therapies for this indication. Based on current preclinical and Phase I/II clinical data, SGX201 has the potential to make a meaningful difference in this indication.



PROJECTED INCOME STATEMENT

	2013					2014					2015	2016	2017	2018	2019
$ in millions except per share data	Q1	Q2	Q3	Q4	FY	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE	FYE	FYE
License Revenue	$0.0	$0.0	$0.0	$0.6	$0.6	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Grant/contract Revenue	$0.9	$0.6	$0.3	$0.8	$2.7	$0.9	$1.4	$2.8	$0.8	$5.9	$4.0	$4.5	$5.0	$5.5	$6.0
YOY Growth	-	*-17.1%*	*-66.5%*	*1.4%*	*-15.4%*	*1.1%*	*124.3%*	*792.1%*	*-1.7%*	*122.5%*	*-32.4%*	*12.5%*	*11.1%*	*10.0%*	*9.1%*
Product Sales	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$2.0	$15.0	$35.0
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$0.9**	**$0.6**	**$0.3**	**$1.4**	**$3.2**	**$0.9**	**$1.4**	**$2.8**	**$0.8**	**$5.9**	**$4.0**	**$4.5**	**$7.0**	**$20.5**	**$41.0**
YOY Growth	*39.1%*	*-17.1%*	*-66.5%*	*71.8%*	*2.5%*	*1.1%*	*124.3%*	*792.1%*	*-42.0%*	*83.5%*	*-32.4%*	*12.5%*	*55.6%*	*192.9%*	*100.0%*
Cost of Revenue	$0.7	$0.5	$0.2	$1.0	$2.5	$0.6	$1.0	$2.1	$0.6	$4.7	$3.3	$3.7	$5.7	$6.0	$8.0
Gross Income	**$0.2**	**$0.1**	**$0.1**	**$0.4**	**$0.7**	**$0.3**	**$0.4**	**$0.7**	**$0.2**	**$1.2**	**$0.7**	**$0.8**	**$1.3**	**$14.5**	**$33.0**
Gross Margin	*17.4%*	*16.5%*	*21.3%*	*25.5%*	*21.1%*	*30.9%*	*27.1%*	*24.3%*	*20.0%*	*20.0%*	*18.0%*	*18.0%*	*18.0%*	*70.7%*	*80.5%*
R&D	$0.8	$2.1	$1.2	$1.0	$5.1	$1.0	$1.2	$5.1	$2.0	$9.3	$8.0	$10.0	$7.0	$7.5	$8.0
% R&D	*84.0%*	*338.5%*	*389.3%*	*69.4%*	*157.3%*	*113.2%*	*85.5%*	*182.6%*	*250.0%*	*157.7%*	*200.0%*	*222.2%*	*100.0%*	*36.6%*	*19.5%*
SG&A	$0.5	$0.7	$0.7	$0.8	$2.8	$0.8	$0.9	$0.7	$0.8	$3.2	$3.7	$4.5	$7.5	$8.0	$10.0
% SG&A	*54.2%*	*113.8%*	*227.4%*	*61.4%*	*85.8%*	*92.3%*	*61.1%*	*26.2%*	*100.0%*	*54.7%*	*92.5%*	*100.0%*	*107.1%*	*39.0%*	*24.4%*
Other expenses	$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	$0.0
% Other	*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%*	*0.0%*
Operating Income	**($1.1)**	**($2.8)**	**($1.9)**	**($1.5)**	**($7.2)**	**($1.6)**	**($1.7)**	**($5.1)**	**($2.6)**	**($11.4)**	**($11.0)**	**($13.7)**	**($13.2)**	**($1.0)**	**$15.0**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Income (Net)	$0.0	($0.6)	($4.7)	$1.7	($3.7)	($1.7)	$0.7	$0.8	$0.0	$0.2	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	**($1.1)**	**($3.4)**	**($6.6)**	**$0.2**	**($10.8)**	**($3.3)**	**($0.9)**	**($4.3)**	**($2.6)**	**($11.6)**	**($11.0)**	**($13.7)**	**($13.2)**	**($1.0)**	**$15.0**
Net Taxes (benefit)	$0.0	$0.0	$0.0	($0.8)	($0.8)	$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%*	*-308.7%*	*6.9%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($1.1)**	**($3.4)**	**($6.6)**	**$1.0**	**($10.1)**	**($3.3)**	**($0.9)**	**($4.3)**	**($2.6)**	**($11.6)**	**($11.0)**	**($13.7)**	**($13.2)**	**($1.0)**	**$15.0**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Weighted avg. Shares Out	*11.2*	*12.3*	*19.0*	*19.4*	*15.5*	*19.7*	*19.9*	*20.7*	*22.1*	*20.6*	*30.0*	*35.0*	*40.0*	*45.0*	*50.0*
Reported EPS	**($0.10)**	**($0.28)**	**($0.34)**	**$0.05**	**($0.65)**	**($0.17)**	**($0.05)**	**($0.21)**	**($0.12)**	**($0.56)**	**($0.37)**	**($0.39)**	**($0.33)**	**($0.02)**	**$0.30**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	$0.00	$0.65	$4.70	($1.70)	$3.65	$1.74	($0.75)	$0.00	$0.00	$0.99	$0.00	$0.00	$0.00	$0.00	$0.00
Non GAAP Net Income	**($1.1)**	**($2.8)**	**($1.9)**	**($0.7)**	**($6.4)**	**($1.6)**	**($1.7)**	**($4.3)**	**($2.6)**	**($10.6)**	**($11.0)**	**($13.7)**	**($13.2)**	**($1.0)**	**$15.0**
Non GAAP EPS	**($0.10)**	**($0.22)**	**($0.10)**	**($0.04)**	**($0.41)**	**($0.08)**	**($0.09)**	**($0.21)**	**($0.12)**	**($0.51)**	**($0.37)**	**($0.39)**	**($0.33)**	**($0.02)**	**$0.30**

Source: Company filings and Zacks estimates

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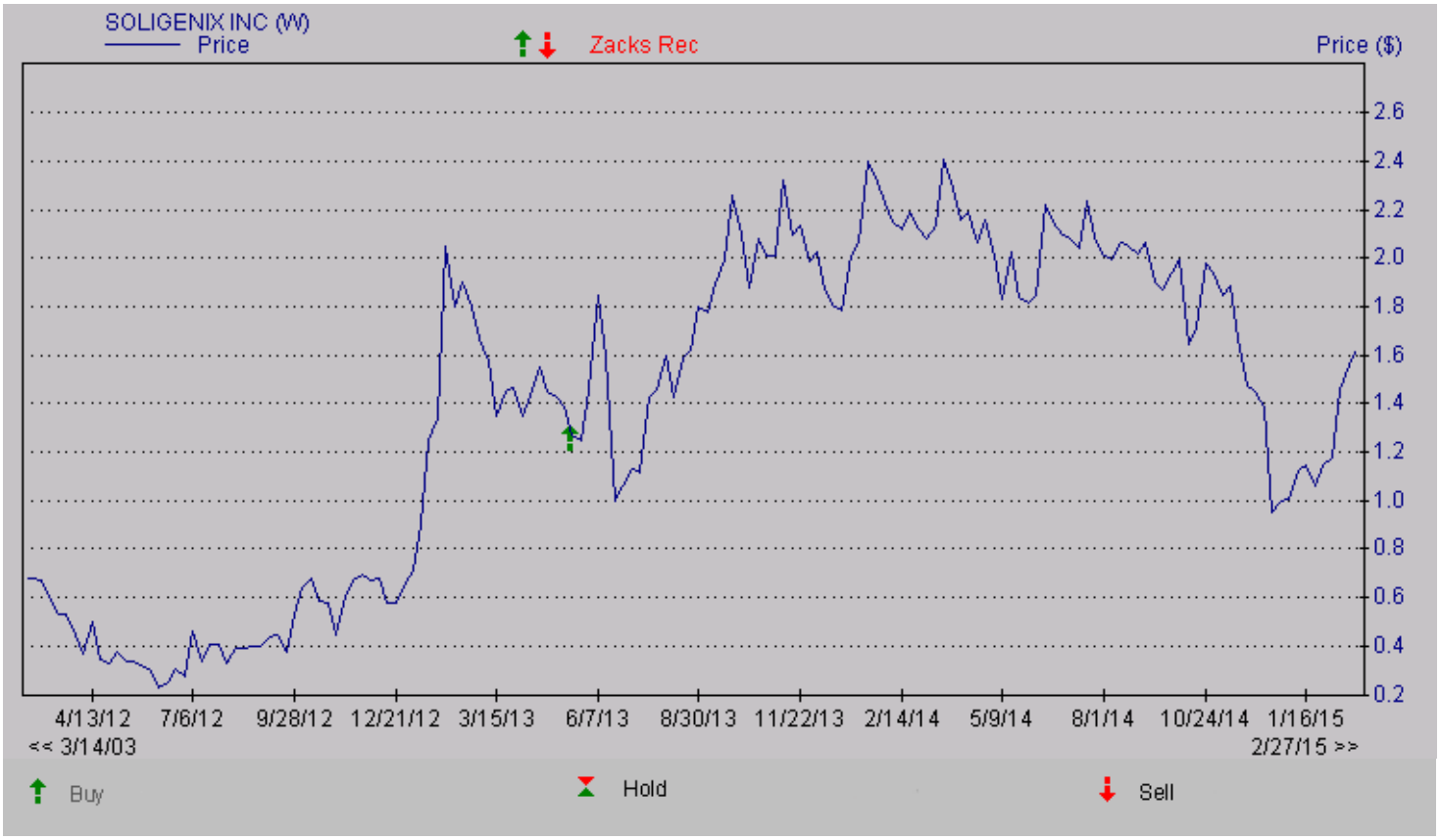

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