Zacks Small-Cap Research

May 14, 2015
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Soligenix Inc. (SNGX-OTCBB)

SNGX: *On track to advance multiple clinical programs, cash burn conservative* ---Buy

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	05/15/2013
Current Price (05/13/15)	$1.54
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 Buy.

SUMMARY DATA

52-Week High	**$2.25**
52-Week Low	**$0.95**
One-Year Return (%)	**-23.20**
Beta	**2.38**
Average Daily Volume (sh)	**77,275**
Shares Outstanding (mil)	**25**
Market Capitalization ($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)
2014	0.9 A	1.4 A	2.8 A	1.9 A	7.0 A
2015	0.8 A	1.0 E	1.0 E	1.0 E	3.8 E
2016					4.5 E
2017					7.0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.08 A	-$0.09 A	-$0.21 A	-$0.05 A	-$0.40 A
2015	-$0.06 A	-$0.10 E	-$0.09 E	-$0.09 E	-$0.35 E
2016					-$0.39 E
2017					-$0.33 E

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

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WHAT'S NEW

- ***Update on first quarter financials, cash burn conservative;***
- ***A Pivotal Phase III Trial of SGX203 in Pediatric Crohn's Disease to be Initiated in 2H15***
- ***Soligenix Enters into Development Agreement with Emergent BioSolutions;***
- ***Data Review Committee recommends continuation on Phase II of SGX942 for mucositis;***
- ***SGX943 and SGX101 may be a solution for Melioidosis;***

Update on First Quarter Financials

Revenues for the first quarter ended March 31, 2015 were $0.8 million as compared to $0.9 million for the first quarter of 2014.

Revenue was mainly derived from contracts with the US Department of Health and Human Service's Biomedical Advanced Research and Development Authority (BARDA) and the National Institute of Allergy and Infectious Diseases (NIAID) in support of OrbeShield™ development for the treatment of gastrointestinal acute radiation syndrome (GI ARS) and a contract with NIAID to advance the development of RiVax™ in conjunction with its heat stabilization technology, ThermoVax™, as a medical countermeasure to prevent the effects of ricin exposure.

R&D expenses for 1Q15 were $1.0 million, as compared to $1.0 million for the quarter ended March 31, 2014.

G&A expenses were $0.8 million for each of the quarters ended March 31, 2015 and 2014.

GAAP net loss for 1Q15 was $4.6 million ($0.19 per share), as compared to $3.3 million ($0.17 per share) for the first quarter of 2014.

Non-GAAP net loss for 1Q15 was $1.6 million ($0.06 per share), compared to non-GAAP net loss of $1.6 million ($0.08 per share) for 1Q14.

As of March 31, 2015, the Company's cash position was $5.0 million.

We believe earnings release is a non-event for SNGX since the company is still a development stage biopharmaceutical company. Investors should be focused on the company's clinical advancement. In this regard, we think SNGX has made significant progress to advance its clinical pipeline.

A Pivotal Phase III Trial of SGX203 in Pediatric Crohn's Disease to be Initiated in 2H15

In April, the US FDA cleared the protocol of a pivotal, **Phase III trial of SGX203** for the treatment of pediatric Crohn's disease.

SGX203 is the company's proprietary formulation of oral beclomethasone 17,21-dipropionate (BDP) that uses a two-tablet immediate and delayed release system to orally deliver high mucosal concentrations of the topical steroid to both the upper and lower bowel walls. This formulation of SGX203 is particularly well suited for Crohn's disease in younger patients who have gastrointestinal (GI) inflammation in both areas of the bowel as opposed to adults who have mainly lower (colon) involvement. Since oral BDP has a limited systemic absorption into the blood stream, this decreases the potential of SGX203 for the development of adverse effects frequently seen with systemic steroid therapies.

The Phase III trial will be a double-blind, randomized, controlled, multi-national trial and will seek to enroll approximately 150 subjects 6-17 years of age with mild to moderate Crohn's disease. The trial will compare the rates of improvement of the signs and symptoms of Crohn's disease after 8 weeks of treatment among subjects randomized to one of three SGX203 dose groups (split 60:30:60 among the

lowest, middle and highest dose of SGX203). Subjects will be followed for an additional 6 months after the completion of treatment. The primary efficacy endpoint of the trial will compare the percentage of subjects in each of the three dose groups having resolved their signs and symptoms after an 8-week course of treatment. An adaptive design will be employed in which an independent Data Monitoring Committee will review the efficacy data after approximately 90 subjects have completed treatment and determine if the trial size requires adjustment based on the actual event rate or halted for futility or overwhelming efficacy.

The company plans to initiate the pivotal Phase III trial in **2H15** with primary data available in 1H 2017. SGX203 has been granted both orphan drug and fast track designations for the treatment of pediatric Crohn's Disease.

Soligenix Enters into Development Agreement with Emergent BioSolutions

On May 13, 2015, SNGX announced that it has entered into a development agreement with Emergent BioSolutions to implement a commercially viable, scalable production technology for the **RiVax™** drug substance protein antigen.

RiVax™ is Soligenix's proprietary aluminum-adsorbed vaccine developed to protect against exposure to ricin toxin, and is the first ricin vaccine. With RiVax, Soligenix is a world leader in ricin toxin vaccine research.

Ricin toxin can be cheaply and easily produced, is stable over long periods of time, is toxic by several routes of exposure and thus has the potential to be used as a biological weapon against military and/or civilian targets. Once exposed to ricin toxin, there is no effective therapy available to reverse the course of the toxin. As a bioterrorism agent, ricin could be disseminated as an aerosol, by injection, or as a food supply contaminant. The potential use of ricin toxin as a biological weapon of mass destruction has been highlighted in a Federal Bureau of Investigations Bioterror report released in November 2007 entitled Terrorism 2002-2005, which states that "Ricin and the bacterial agent anthrax are emerging as the most prevalent agents involved in WMD investigations."

The Centers for Disease Control (CDC) has classified ricin toxin as a Category B biological agent. Ricin works by first binding to glycoproteins found on the exterior of a cell, and then entering the cell and inhibiting protein synthesis leading to cell death. Once exposed to ricin toxin, there is no effective therapy available to reverse the course of the toxin. Currently, there is no FDA approved vaccine to protect against the possibility of ricin toxin being used in a terrorist attack, or its use as a weapon on the battlefield, nor is there a known antidote for ricin toxin exposure.

In February, 2015, Soligenix presented new **preclinical study** data that demonstrated the efficacy and safety of **RiVax™** in a non-human primate (NHP) lethal aerosolized ricin exposure model.

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.

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 development of RiVax™ has been sponsored through a series of overlapping challenge grants. RiVax™ has been granted Orphan Drug designation by the FDA for the prevention of ricin intoxication. Assuming development efforts are successful for RiVax™; potential government procurement contract(s) could reach $200 million.

Soligenix will transfer the manufacturing processes and analytics to Emergent to conduct process development work that could potentially lead to a future commercial manufacturing collaboration.

Data Review Committee Recommends SNGX to Continue on its Phase II Clinical Trial of SGX942 for the Treatment of Oral Mucositis in Head and Neck Cancer Patients

The Background

In December, 2013, SNGX initiated the **Phase II** study of SGX942 for the treatment of oral mucositis in head and neck cancer patients.

This Phase II trial is a randomized, double-blind, dose-ranging, placebo-controlled trial, initially set to enroll approximately 75 subjects across three SGX942 dose groups and placebo, focused on demonstrating the safety and biologic activity of SGX942 in patients with tumors of the mouth and oropharynx who often experience debilitating oral mucositis as a consequence of tumor treatment with CRT. The **primary efficacy** assessment is the comparison of the incidence and/or duration of both ulcerative and severe oral mucositis throughout the subjects' 7 week course of CRT and for an additional 4 weeks thereafter. **Other key efficacy** measures will assess patient reported outcomes, pharmacoeconomic parameters such as hospitalization and radiation-associated side effects including mouth stiffness and dryness.

The Positive Recommendation

In early March, Soligenix (SNGX) announced that it has received a positive recommendation from the Data Review Committee (DRC) to continue enrolling into the company's **Phase II** clinical trial evaluating **SGX942** as a treatment for oral mucositis in patients undergoing chemoradiation (CRT) therapy for head and neck cancer.

Following DRC review of available data on the subjects enrolled in the trial, the committee recommended that enrollment include an additional 20 subjects randomized into either a single SGX942 dose group or the placebo group to allow for a more targeted assessment of the drug's potential effect and to inform final dose selection in this patient population.

The study blind will remain in effect until completion of the trial.

We are pleased with the positive recommendation from the DRC, which will allow for a sufficient number of subjects to be enrolled into the most promising dose group to increase the potential of demonstrating a positive effect. With the positive recommendation, we are further convinced the favorable safety profile for SGX942.

Given the additional subjects to be enrolled and the primary endpoint assessment through 11 weeks, we estimate top-line results will be available in **2H2015**.

The Unique Mechanism of Action of SGX942

SGX942 belongs to a new class of compounds called **Innate Defense Regulators (IDRs).** SGX942 represents a novel and innovative approach to therapeutically modulating the immune system by targeting the innate immune system and has the potential to target multiple indications, especially for the treatment of infections and tissue damages.

IDRs 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.

IDRs have 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 IDRs target the host (and not the pathogen), IDRs do 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 IDRs selectively promote monocyte and macrophage recruitment to disease sites and accelerate resolution of disease. Though IDR action depends on monocytes and macrophages, there is no dependence on either the adaptive immune system (e.g., T cells and B cells) or neutrophils. This suggests that IDRs may be effective in immunosuppressed patients. Moreover, p62 functions downstream of signaling receptors (TLRs, NODs) responsible for sensing both infection and tissue damage, which gives it a role in innate immune modulation relevant to **a wide range of diseases** from infection (pathogen sensing) to colitis and mucositis (damage sensing).

Market Opportunity

SGX942 has the potential to provide adjunctive or stand-alone therapies for the broader antimicrobial/antibiotic, antiviral, anti-inflammatory, and anti-cancer markets. Each of the above mentioned market is a multi- billion dollar market.

More narrowly, the tissue damage (mucositis) opportunity alone represents a $1B+ market.

Mucositis is a debilitating condition involving extensive ulceration of the oral cavity that frequently affects cancer patients undergoing radiation and chemotherapy treatment. Roughly 90% of patients on radiation (43% severe) and 40% of patients receiving chemotherapy get mucositis. There is an estimated 500,000 cancer patients getting mucositis annually in the United States alone. World-wide, the potential market for mucositis will exceed $1 billion in the next few years.

Mucositis can be severely debilitating and can lead to infection, sepsis, the need for parenteral nutrition and narcotic analgesia. The gastrointestinal damage causes severe diarrhea. These symptoms can limit the doses and duration of cancer treatment, leading to sub-optimal treatment outcomes. We believe any treatment that accelerates healing and/or diminishes the rate of appearance of mucositis would have a significant beneficial impact on the quality of life of these patients and may allow for more aggressive chemotherapy.

The **mechanisms of mucositis** have been extensively studied and have been recently linked to the interaction of chemotherapy and/or radiation therapy with the innate defense system. Bacterial infection of the ulcerative lesions is now regarded as a secondary consequence of dysregulated local inflammation

triggered by therapy-induced cell death, rather than as the primary cause of the lesions. As a modulator of the innate immune system, SGX942 has the potential to target both **primary** and **secondary** causes of mucositis.

Oral mucositis is an area of unmet medical need where there are only limited treatment options. Ccurrently, no drug has been approved for oral mucositis in head and neck cancer. We noticed that there are a few products already on the market for oral mucositis. But the competitive landscape favors SGX942 in our view.

Amgen's **Kepivance (Palifermin)** is the only approved drug for oral mucositis in transplantation; but is contra-indicated for solid tumor patients. Kepivance is a recombinant form of human keratinocyte growth factor (KGF), a protein that is naturally produced by the body. Kepivance is indicated to decrease the incidence and duration of severe oral mucositis in patients with hematologic malignancies receiving myelotoxic therapy requiring hematopoietic stem cell support. The safety and efficacy of Kepivance have not been established in patients with non-hematologic malignancies. Kepivance must be IV injected for 3 consecutive days before and 3 consecutive days after treatment for a total of 6 injections. Also, Kepivance is expensive at about $10,000 per patient.

Access Pharma's **MuGard** is approved as a medical device and is dispensed in a ready to use mouth rinse. MuGard is indicated for the management of oral mucositis/stomatitis that may be caused by radiotherapy and/or chemotherapy.

Three other medical devices on the market are DARA Biosciences, Gelclair, Edward Pharma's Mucotrol, and EUSA Pharma's Caphosol. **Gelclair** is a prescription mouth gel that is designed and approved for the management and relief of pain caused by mouth sores. Gelclair is established by mixing the powder in a glass of water to form the rinse and patients gargle and spit out. **Mucotrol** is concentrated oral gel wafer which is indicated for the management and relief of pain from oral lesions associated with oral mucositis/stomatitis. **Caphosol** is similar to Gelclair. Patients must mix the contents of two ampoules to form a rinse and then swish/spit out. These devices attempt to create a protective barrier around the oral ulceration; however, none of these devices are biologically based.

Apparently, most of the above treatment options for mucositis only address the symptoms and do not address the cause of mucositis, while Soligenix's SGX942 has a new mechanism of action which can address both the primary and the secondary causes of mucositis. We believe that, if approved, SGX942 will command a significant market share of the mucositis market, which could reach $1 billion in the next few years.

We believe SGX942 will have peak sales of $300 million and that the potential worldwide market for SGX942 is in excess of $500 million for all applications, including oral mucositis.

SGX943 and SGX101 may be a solution for Melioidosis

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**.

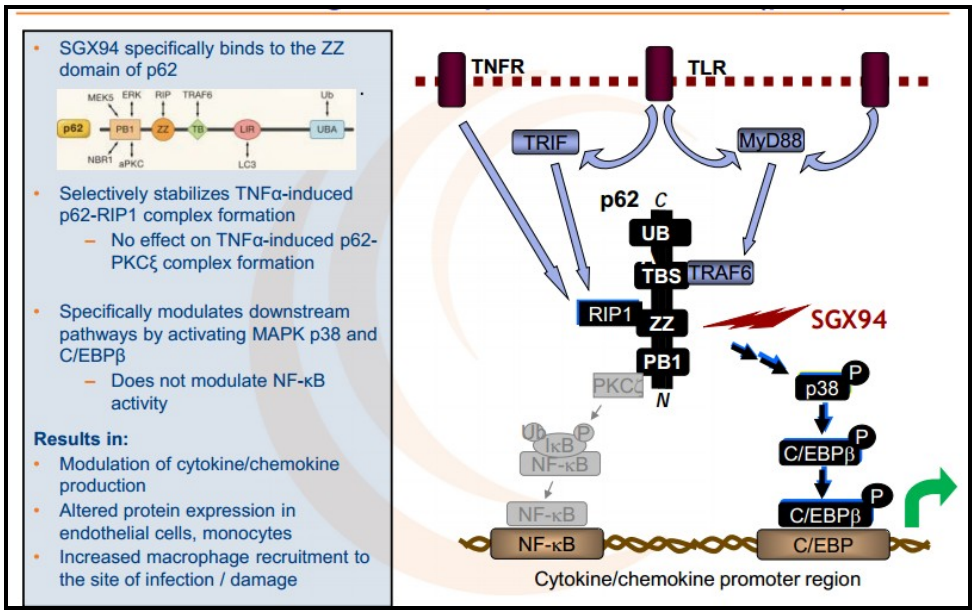
Another major problem for antibiotic treatment of melioidosis is the **resistance**, especially for the long term treatment of melioidosis.

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 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.**



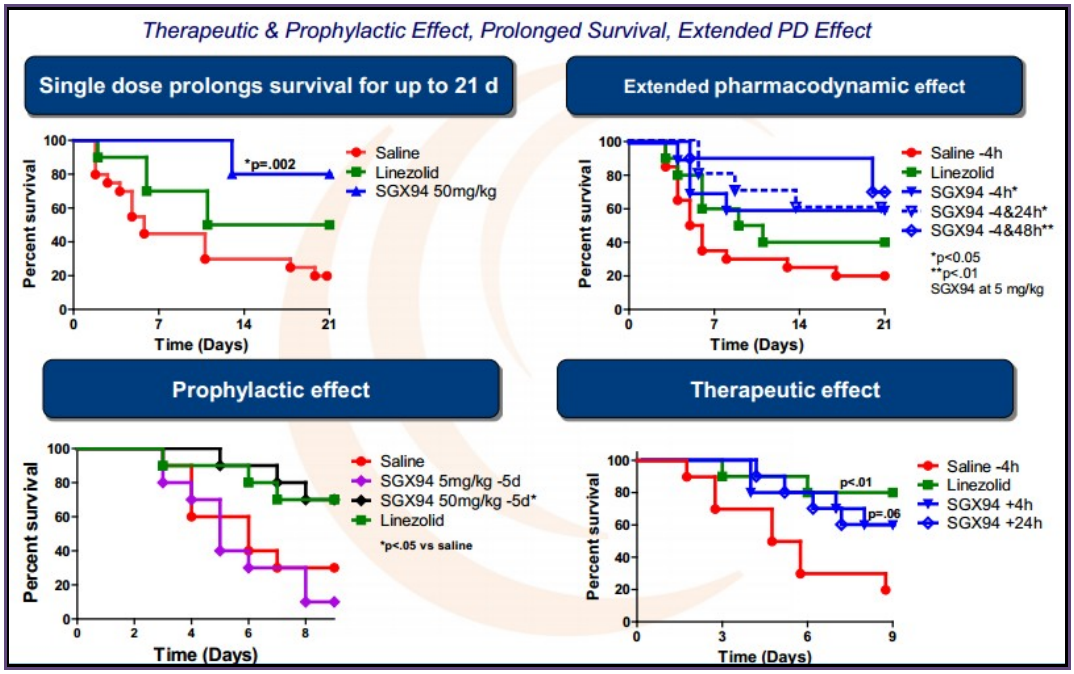
Source: Soligenix Presentation

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

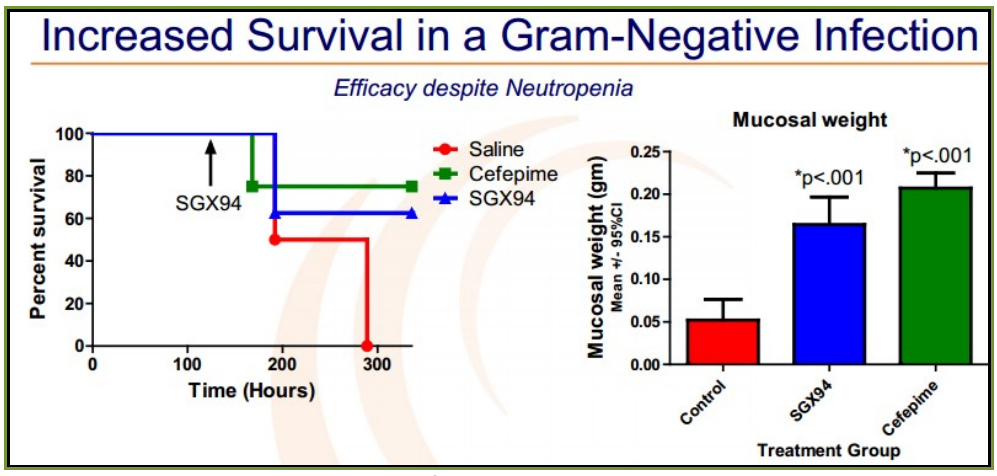
sensitive and resistant strains, as well as accelerating resolution of tissue damage following exposure to a variety of agents including bacterial pathogens, trauma and chemo- or radiation-therapy.

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.

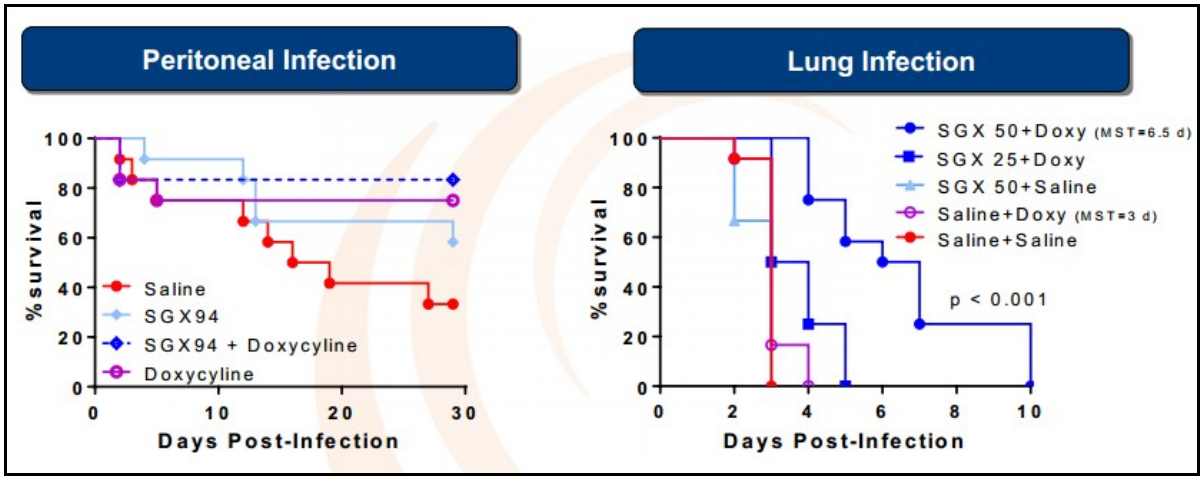


Source: company presentation



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.

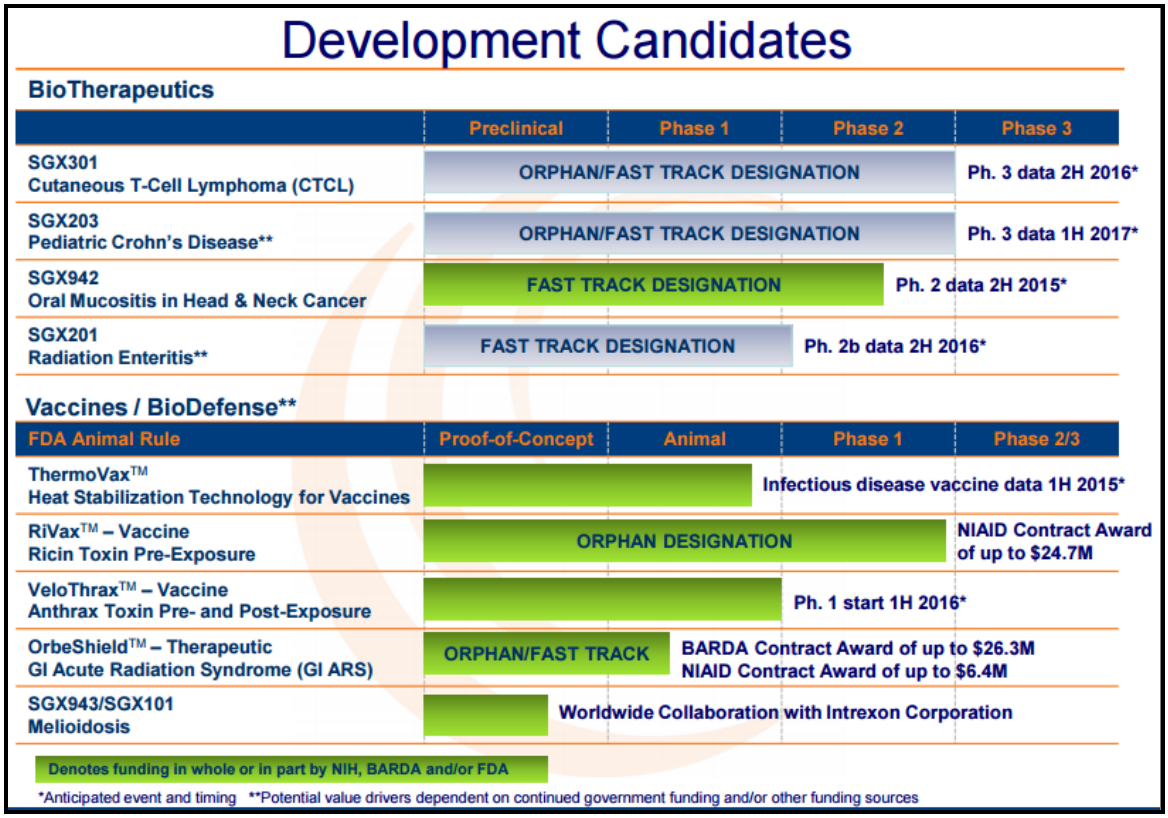


The company plans to optimize dosing regimens for SGX943 in combination with antibiotic for the intranasal pneumonic model and to demonstrate efficacy in aerosol model of infection including large animal model proof of concept. The route of delivery for biodefense applications will also be optimized 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.



Soligenix' Shares are Undervalued

We maintain an **Outperform rating** for Soligenix and reiterate 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 2H15, 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.

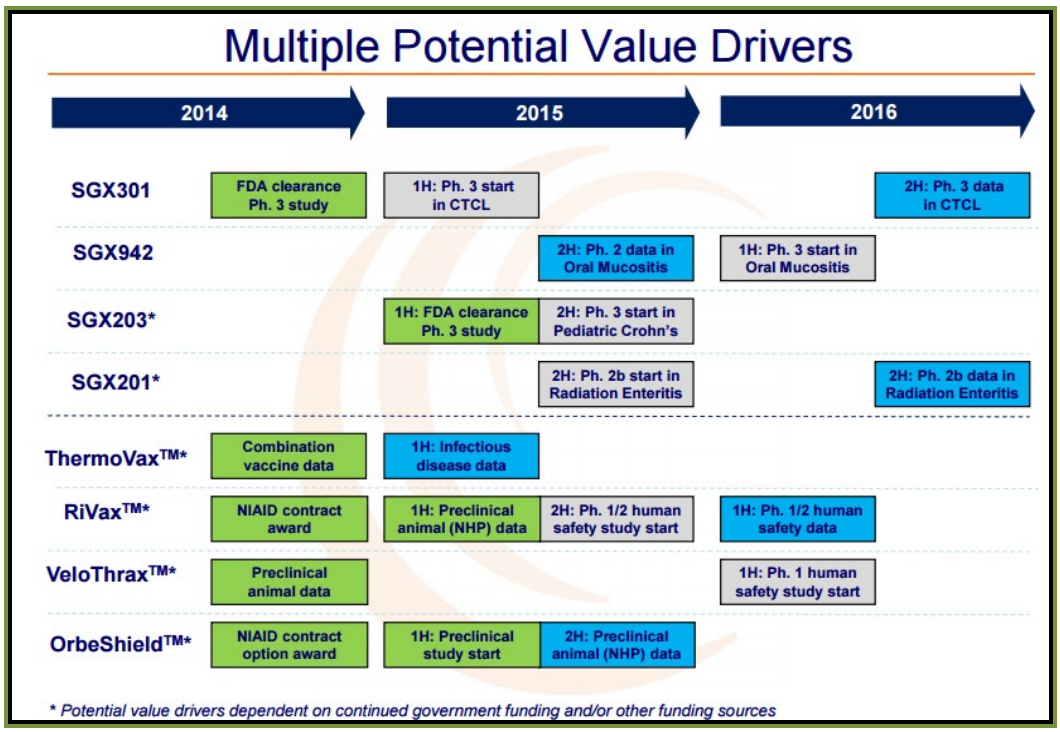
Based on our analysis, we think Soligenix shares are undervalued at current market price. Currently shares of Soligenix are trading at around $1.50 per share, which values the Company at $38 million in

market cap based on 25 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.

Soligenix now has two Phase III candidates, two Phase II programs, and two more programs will move to Phase II study in 2015. Soligenix has multiple catalysts in the next 6 to 12 month.

Our price target of $5.50 per share values Soligenix at $138 million in market cap which we think is very conservative.



Update on SGX301

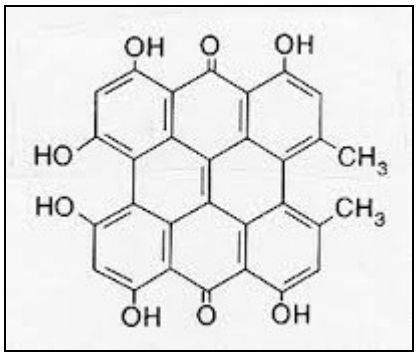
Background

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** and **fast track** from the FDA for the treatment of CTCL.

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.

PROJECTED INCOME STATEMENT

	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
License Revenue	$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
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Grant/contract Revenue	$0.9	$1.4	$2.8	$1.9	$7.0	$0.8	$1.0	$1.0	$1.0	$3.8	$4.5	$5.0	$5.5	$6.0
YOY Growth	*1.1%*	*124.3%*	*792.1%*	*136.7%*	*164.9%*	*-10.4%*	*-29.5%*	*-64.1%*	*-48.1%*	*-45.8%*	*17.9%*	*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	$2.0	$15.0	$35.0
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$0.9**	**$1.4**	**$2.8**	**$1.9**	**$7.0**	**$0.8**	**$1.0**	**$1.0**	**$1.0**	**$3.8**	**$4.5**	**$7.0**	**$20.5**	**$41.0**
YOY Growth	*1.1%*	*124.3%*	*792.1%*	*39.7%*	*118.4%*	*-10.4%*	*-29.5%*	*-64.1%*	*-48.1%*	*-45.8%*	*17.9%*	*55.6%*	*192.9%*	*100.0%*
Cost of Revenue	$0.6	$1.0	$2.1	$1.5	$5.3	$0.5	$0.8	$0.8	$0.8	$2.8	$3.7	$5.7	$6.0	$8.0
Gross Income	**$0.3**	**$0.4**	**$0.7**	**$0.4**	**$1.7**	**$0.3**	**$0.3**	**$0.3**	**$0.3**	**$1.0**	**$0.8**	**$1.3**	**$14.5**	**$33.0**
Gross Margin	*30.9%*	*27.1%*	*24.3%*	*20.0%*	*24.6%*	*35.4%*	*25.0%*	*25.0%*	*25.0%*	*27.2%*	*18.0%*	*18.0%*	*70.7%*	*80.5%*
R&D	$1.0	$1.2	$5.1	$1.8	$9.1	$1.0	$2.0	$2.1	$2.2	$7.3	$10.0	$7.0	$7.5	$8.0
% R&D	*113.2%*	*85.5%*	*182.6%*	*91.0%*	*129.0%*	*126.2%*	*200.0%*	*210.0%*	*220.0%*	*192.1%*	*222.2%*	*100.0%*	*36.6%*	*19.5%*
SG&A	$0.8	$0.9	$0.7	$1.0	$3.4	$0.8	$0.9	$0.9	$1.1	$3.7	$4.5	$7.5	$8.0	$10.0
% SG&A	*92.3%*	*61.1%*	*26.2%*	*50.2%*	*48.3%*	*100.1%*	*85.0%*	*92.0%*	*110.0%*	*96.6%*	*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
% 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%*
Operating Income	**($1.6)**	**($1.7)**	**($5.1)**	**($2.3)**	**($10.8)**	**($1.6)**	**($2.6)**	**($2.8)**	**($3.1)**	**($10.0)**	**($13.7)**	**($13.2)**	**($1.0)**	**$15.0**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Income (Net)	($1.7)	$0.7	$0.8	$3.6	$3.4	($3.0)	$0.0	$0.0	$0.0	$3.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	**($3.3)**	**($0.9)**	**($4.3)**	**$1.3**	**($7.3)**	**($4.6)**	**($2.6)**	**($2.8)**	**($3.1)**	**($13.0)**	**($13.7)**	**($13.2)**	**($1.0)**	**$15.0**
Net Taxes (benefit)	$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
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*-47.2%*	*8.4%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($3.3)**	**($0.9)**	**($4.3)**	**$1.9**	**($6.7)**	**($4.6)**	**($2.6)**	**($2.8)**	**($3.1)**	**($13.0)**	**($13.7)**	**($13.2)**	**($1.0)**	**$15.0**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Weighted avg. Shares Out	*19.7*	*19.9*	*20.7*	*34.0*	*23.6*	*24.4*	*26.0*	*30.0*	*35.0*	*28.9*	*35.0*	*40.0*	*45.0*	*50.0*
Reported EPS	**($0.17)**	**($0.05)**	**($0.21)**	**$0.06**	**($0.28)**	**($0.19)**	**($0.10)**	**($0.09)**	**($0.09)**	**($0.45)**	**($0.39)**	**($0.33)**	**($0.02)**	**$0.30**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	$1.74	($0.75)	$0.00	($3.64)	($2.65)	$3.01	$0.00	$0.00	$0.00	$3.01	$0.00	$0.00	$0.00	$0.00
Non GAAP Net Income	**($1.6)**	**($1.7)**	**($4.3)**	**($1.7)**	**($9.4)**	**($1.6)**	**($2.6)**	**($2.8)**	**($3.1)**	**($10.0)**	**($13.7)**	**($13.2)**	**($1.0)**	**$15.0**
Non GAAP EPS	**($0.08)**	**($0.09)**	**($0.21)**	**($0.05)**	**($0.40)**	**($0.06)**	**($0.10)**	**($0.09)**	**($0.09)**	**($0.35)**	**($0.39)**	**($0.33)**	**($0.02)**	**$0.30**

Source: Company filings and Zacks estimates

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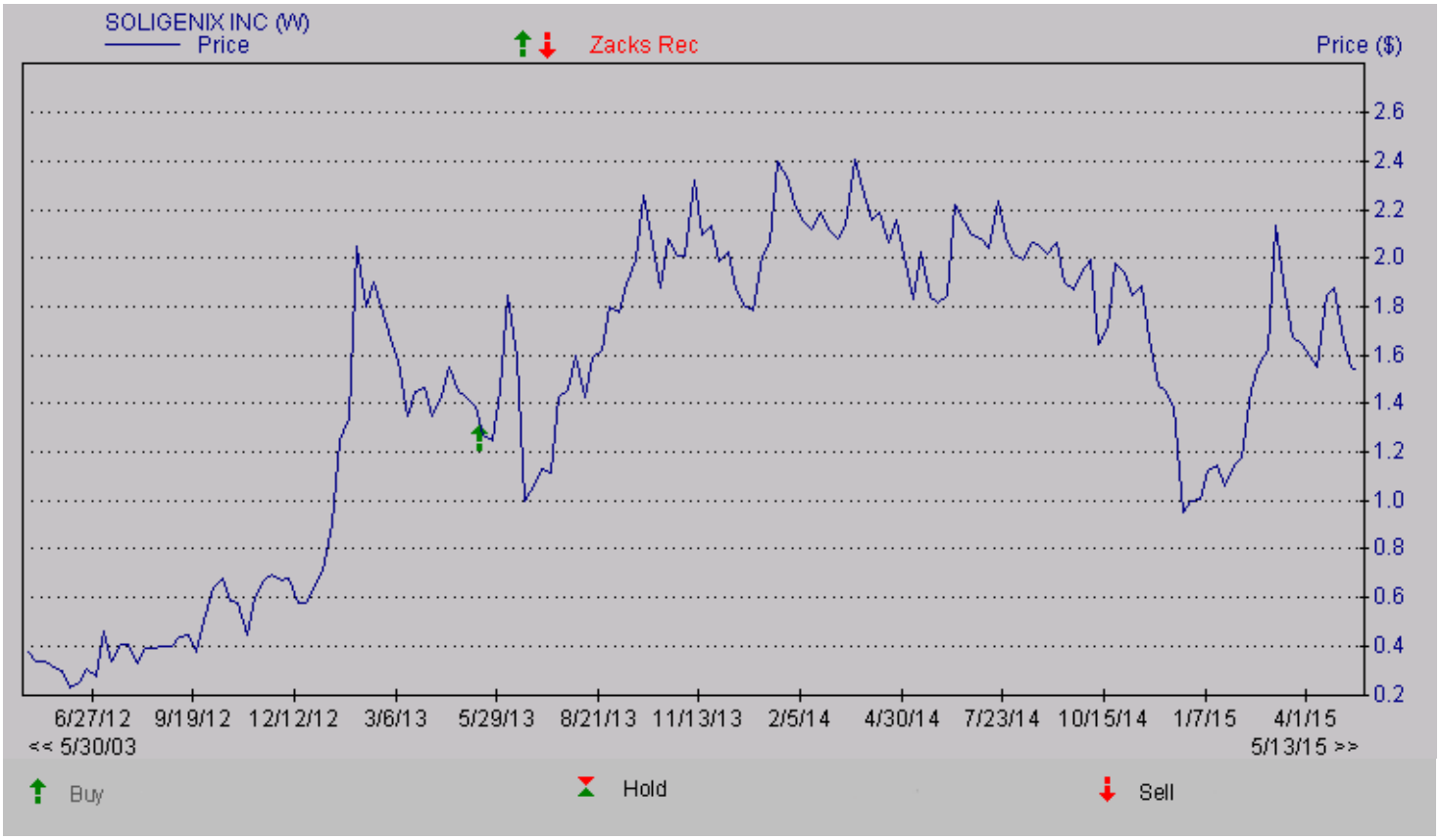

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