Zacks Small-Cap Research

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Soligenix Inc. (SNGX-OTCBB)

SNGX: Conservative cash burn coupled with non-dilutive financing, on track to advance multiple clinical programs ---Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	05/15/2013
Current Price (08/12/14)	$2.02
Twelve- Month Target Price	**$4.50**

OUTLOOK

SNGX is a clinical stage biopharmaceutical company focused on 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 candidate 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 in 2H14. 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	**$1.40**
One-Year Return (%)	**39.31**
Beta	**2.45**
Average Daily Volume (sh)	**25,605**
Shares Outstanding (mil)	**20**
Market Capitalization ($mil)	**$40**
Short Interest Ratio (days)	**0.43**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**9**
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	0.8 E	0.8 E	0.8 E	3.3 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 E	-$0.09 E	-$0.10 E	-$0.37 E
2015					-$0.30 E
2016					-$0.28 E

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

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WHAT'S NEW

- **Soligenix reports 2Q14 financials;**
- **Cash burn is very conservative coupled with non-dilutive financing;**
- **Soligenix announces development of a heat stable rapidly acting Anthrax vaccine;**
- **Positive results for combination vaccine announced;**
- **NIDCR SBIR Grant Supporting Phase II Clinical Trial of SGX942;**

Soligenix Reports 2Q14 Financials

On Aug. 11, 2014, Soligenix (SNGX) announced its financial results for the second quarter ended June 30, 2014.

Total revenue for 2Q14 was $1.4 million, as compared to $0.6 million for 2Q13. The $0.8 million in revenue increase was primarily related to 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 in the treatment of gastrointestinal acute radiation syndrome (GI ARS).

R&D expenses were $1.2 million for 2Q14, as compared to $2.1 million for 2Q13.

General and administrative expenses for 2Q14 were $0.9 million as compared to $0.7 million for the quarter ended June 30, 2013.

Excluding the 2013 $1.5 million expense related to the Intrexon collaboration, operating expenses increased by $0.7 million for the quarter ended June 30, 2014. The increase in operating expenses related to the Company's Phase II clinical trials with SGX942 in the treatment of oral mucositis and orBec® in the treatment of chronic gastrointestinal Graft-versus-host disease (GI GVHD), increased professional fees, increased headcount and non-cash expenses for stock based compensation from stock options issued to existing and newly hired employees.

Net loss for 2Q14 was $0.9 million ($0.05 per share), as compared to net loss of $3.4 million ($0.28 per share) for 2Q13.

Conservative Cash Burn Coupled with Non-dilutive Financing

As of June 30, 2014, the Company's cash position was $5.0 million as compared to $5.9 million at December 31, 2013.

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, in amounts as described in the agreement.

With this new flexible financing vehicle, Soligenix should be able to focus on advancing its clinical programs.

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, **On August 1, 2014**, Soligenix was awarded additional $2.1 million in funding from the National Institute of Allergy and Infectious Diseases (NIAID) to advance the **preclinical development** of OrbeShield™. The 12-month option provides an additional $2.1 million to Soligenix to advance

OrbeShield™ as a medical countermeasure (MCM) for the treatment of gastrointestinal acute radiation syndrome (GI ARS). NIAID granted an initial award of $2.1 million to Soligenix on September 18, 2013. The total contract award is valued at up to $6.4 million over three years.

Soligenix's GI ARS program is supported by contract awards from both the Biomedical Advanced Research Development Authority (BARDA) and NIAID, totaling up to approximately $32 million. In addition to developing oral BDP as a MCM, the company is also pursuing oral BDP as a treatment for GI inflammation in pediatric Crohn's disease, acute radiation enteritis and chronic Graft-versus-Host disease (cGVHD).

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.

NIDCR SBIR Grant Supporting Phase II Clinical Trial of SGX942

In April 2014, Soligenix was awarded by the National Institute of Dental and Craniofacial Research (NIDCR) a Small Business Innovation Research (SBIR) grant to support the conduct of the Company's **Phase II**, randomized, double-blind, placebo-controlled study evaluating SGX942 as a treatment for **oral mucositis** in patients undergoing chemoradiation therapy for **head and neck cancer**.

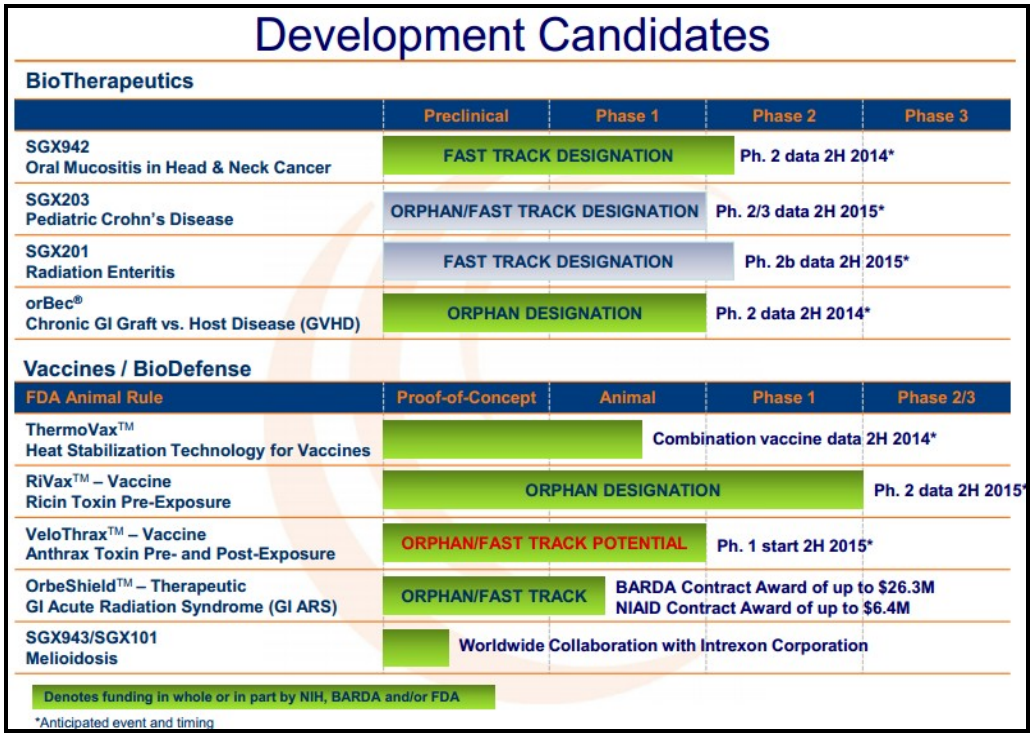
In December 2013, Soligenix initiated the **Phase II**, randomized, double-blind, placebo-controlled study. This Phase II study is a multicenter trial focused on patients with tumors of the mouth and oropharynx who often experience debilitating oral mucositis as a consequence of tumor treatment with intensity modulated radiation and chemotherapy. **The primary efficacy** will be assessed on the basis of the incidence and duration of both ulcerative and severe oral mucositis throughout the course of radiation treatment. **Other key efficacy** measures will assess patient reported outcomes, pharmacoeconomic parameters such as hospitalization and radiation-associated side effects including mouth stiffness (trismus) and dryness (xerostomia).

SGX942 is a fully synthetic, 5-amino acid peptide with high aqueous solubility and stability. Extensive in vivo **preclinical studies** have shown that SGX942 reduces tissue damage associated with chemotherapy, radiation, trauma and inflammation. Although SGX942 is not directly antimicrobial, it accelerates pathogen clearance and increases host survival in a broad spectrum of bacterial infections including Gram positive and negative bacteria, and both drug sensitive and resistant strains, by directly targeting the host innate immune system.

Soligenix has completed a double-blind, placebo-controlled **Phase I** clinical trial of SGX942 in 84 healthy volunteers with both single ascending dose and multiple ascending dose components. SGX942 showed a strong safety profile when administered IV over 7 days and was consistent with safety results seen in pre-clinical studies. Drug clearance in humans is rapid and similar to results seen in pre-clinical studies.

Results from the Phase II trial are expected to be available in **2H14**.

The receipt of this grant as well as other grants not only boosts the Company's balance sheet in a non-dilutive way, but further validates the potential of its development programs. Within the past twelve months, Soligenix has received contract and grant funding totaling up to approximately $33.0 million.



Two More Phase II Trials Will Be Initiated In 2014

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 2H 2014. Primary endpoint data are expected in **2H 2015.**

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 **2H2014**. Data are expected in **2H2015**, 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.

Valuation Is Very Attractive

We maintain an **Outperform rating** for Soligenix and reiterate our 12-month price target of $4.50 per share.

Soligenix is a mid-stage development biopharmaceutical company focused on **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**.

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 2H14, 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.

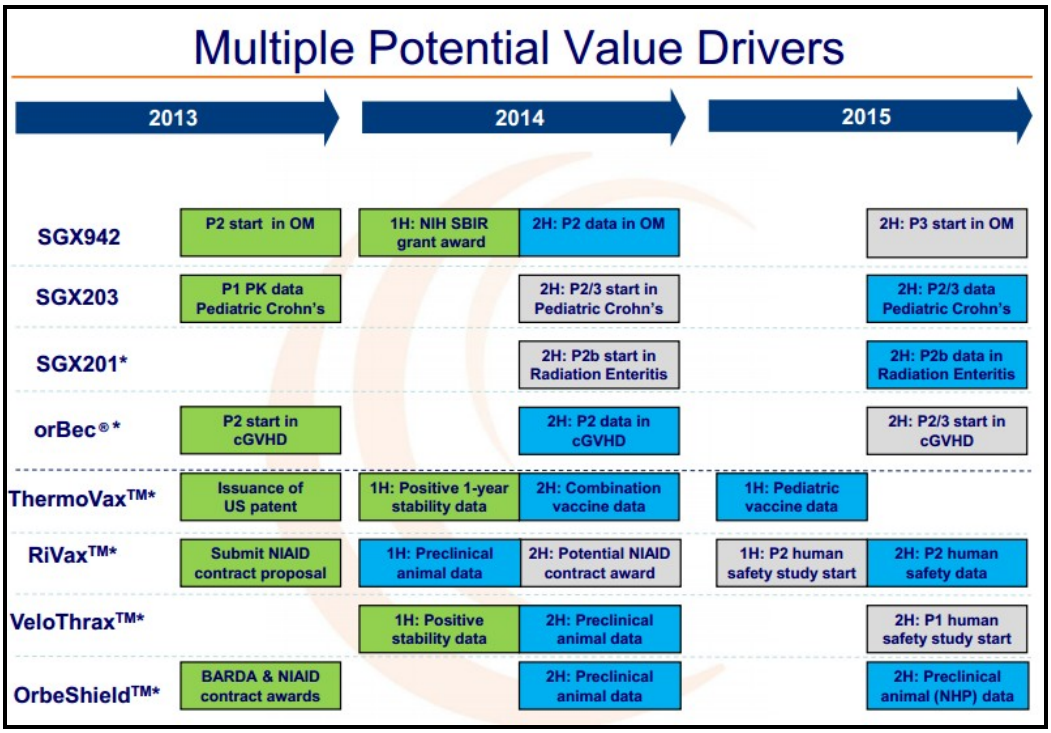
The Company's oral BDP has the potential to target multiple GI disorders such as Crohn's disease, radiation enteritis and GVHD as well as ARS.

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 $2.00 per share, which values the Company at $40 million in market cap based on 19.8 million outstanding shares. This deeply undervalues Soligenix shares in our view.

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 two Phase II programs, and two more programs will move to Phase II/III study this year. Soligenix has multiple catalysts in the next 6 to 12 month or so.

Our price target of $4.50 per share values Soligenix at $90 million in market cap which we think is very conservative.



PROJECTED INCOME STATEMENT

_	2012	2013					2014					2015	2016
$ in millions except per share data	FY	Q1	Q2	Q3	Q4	FY	Q1	Q2	Q3	Q4	FYE	FYE	FYE
License Revenue	$0.0	$0.0	$0.0	$0.0	$0.6	$0.6	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Grant/contract Revenue	$3.1	$0.9	$0.6	$0.3	$0.8	$2.7	$0.9	$1.4	$0.8	$0.8	$3.9	$4.0	$4.5
YOY Growth	*18.1%*	-	*-17.1%*	*-66.5%*	*1.4%*	*-15.4%*	*1.1%*	*124.3%*	*156.0%*	*-1.7%*	*47.8%*	*1.8%*	*12.5%*
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	$0.0
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$3.1**	**$0.9**	**$0.6**	**$0.3**	**$1.4**	**$3.2**	**$0.9**	**$1.4**	**$0.8**	**$0.8**	**$3.9**	**$4.0**	**$4.5**
YOY Growth	*-59.0%*	*39.1%*	*-17.1%*	*-66.5%*	*71.8%*	*2.5%*	*1.1%*	*124.3%*	*156.0%*	*-42.0%*	*21.9%*	*1.8%*	*12.5%*
Cost of Revenue	$2.6	$0.7	$0.5	$0.2	$1.0	$2.5	$0.6	$1.0	$0.6	$0.6	$3.1	$3.3	$3.7
Gross Income	**$0.6**	**$0.2**	**$0.1**	**$0.1**	**$0.4**	**$0.7**	**$0.3**	**$0.4**	**$0.2**	**$0.2**	**$0.8**	**$0.7**	**$0.8**
Gross Margin	*17.5%*	*17.4%*	*16.5%*	*21.3%*	*25.5%*	*21.1%*	*30.9%*	*27.1%*	*20.0%*	*20.0%*	*20.0%*	*18.0%*	*18.0%*
R&D	$2.6	$0.8	$2.1	$1.2	$1.0	$5.1	$1.0	$1.2	$1.5	$2.0	$5.7	$7.5	$9.0
% R&D	*83.0%*	*84.0%*	*338.5%*	*389.3%*	*69.4%*	*157.3%*	*113.2%*	*85.5%*	*187.5%*	*250.0%*	*146.2%*	*187.5%*	*200.0%*
SG&A	$2.6	$0.5	$0.7	$0.7	$0.8	$2.8	$0.8	$0.9	$0.8	$0.8	$3.3	$3.7	$4.5
% SG&A	*83.7%*	*54.2%*	*113.8%*	*227.4%*	*61.4%*	*85.8%*	*92.3%*	*61.1%*	*100.0%*	*100.0%*	*84.2%*	*92.5%*	*100.0%*
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
% 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%*
Operating Income	**($4.7)**	**($1.1)**	**($2.8)**	**($1.9)**	**($1.5)**	**($7.2)**	**($1.6)**	**($1.7)**	**($2.1)**	**($2.6)**	**($8.3)**	**($10.5)**	**($12.7)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Income (Net)	$0.0	$0.0	($0.6)	($4.7)	$1.7	($3.7)	($1.7)	$0.7	$0.0	$0.0	$1.0	$0.0	$0.0
Pre-Tax Income	**($4.7)**	**($1.1)**	**($3.4)**	**($6.6)**	**$0.2**	**($10.8)**	**($3.3)**	**($0.9)**	**($2.1)**	**($2.6)**	**($9.3)**	**($10.5)**	**($12.7)**
Net Taxes (benefit)	($0.5)	$0.0	$0.0	$0.0	($0.8)	($0.8)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*11.1%*	*0.0%*	*0.0%*	*0.0%*	*-308.7%*	*6.9%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($4.2)**	**($1.1)**	**($3.4)**	**($6.6)**	**$1.0**	**($10.1)**	**($3.3)**	**($0.9)**	**($2.1)**	**($2.6)**	**($9.3)**	**($10.5)**	**($12.7)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Weighted avg. Shares Out	*11.1*	*11.2*	*12.3*	*19.0*	*19.4*	*15.5*	*19.7*	*19.9*	*25.0*	*25.5*	*22.5*	*35.0*	*45.0*
Reported EPS	**($0.37)**	**($0.10)**	**($0.28)**	**($0.34)**	**$0.05**	**($0.65)**	**($0.17)**	**($0.05)**	**($0.09)**	**($0.10)**	**($0.41)**	**($0.30)**	**($0.28)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	$0.0	$0.00	$0.65	$4.70	($1.70)	$3.65	$1.74	($0.75)	$0.00	$0.00	$0.99	$0.00	$0.00
Non GAAP Net Income	**($4.2)**	**($1.1)**	**($2.8)**	**($1.9)**	**($0.7)**	**($6.4)**	**($1.6)**	**($1.7)**	**($2.1)**	**($2.6)**	**($8.3)**	**($10.5)**	**($12.7)**
Non GAAP EPS	**($0.37)**	**($0.10)**	**($0.22)**	**($0.10)**	**($0.04)**	**($0.41)**	**($0.08)**	**($0.09)**	**($0.09)**	**($0.10)**	**($0.37)**	**($0.30)**	**($0.28)**

Source: Company filings and Zacks estimates

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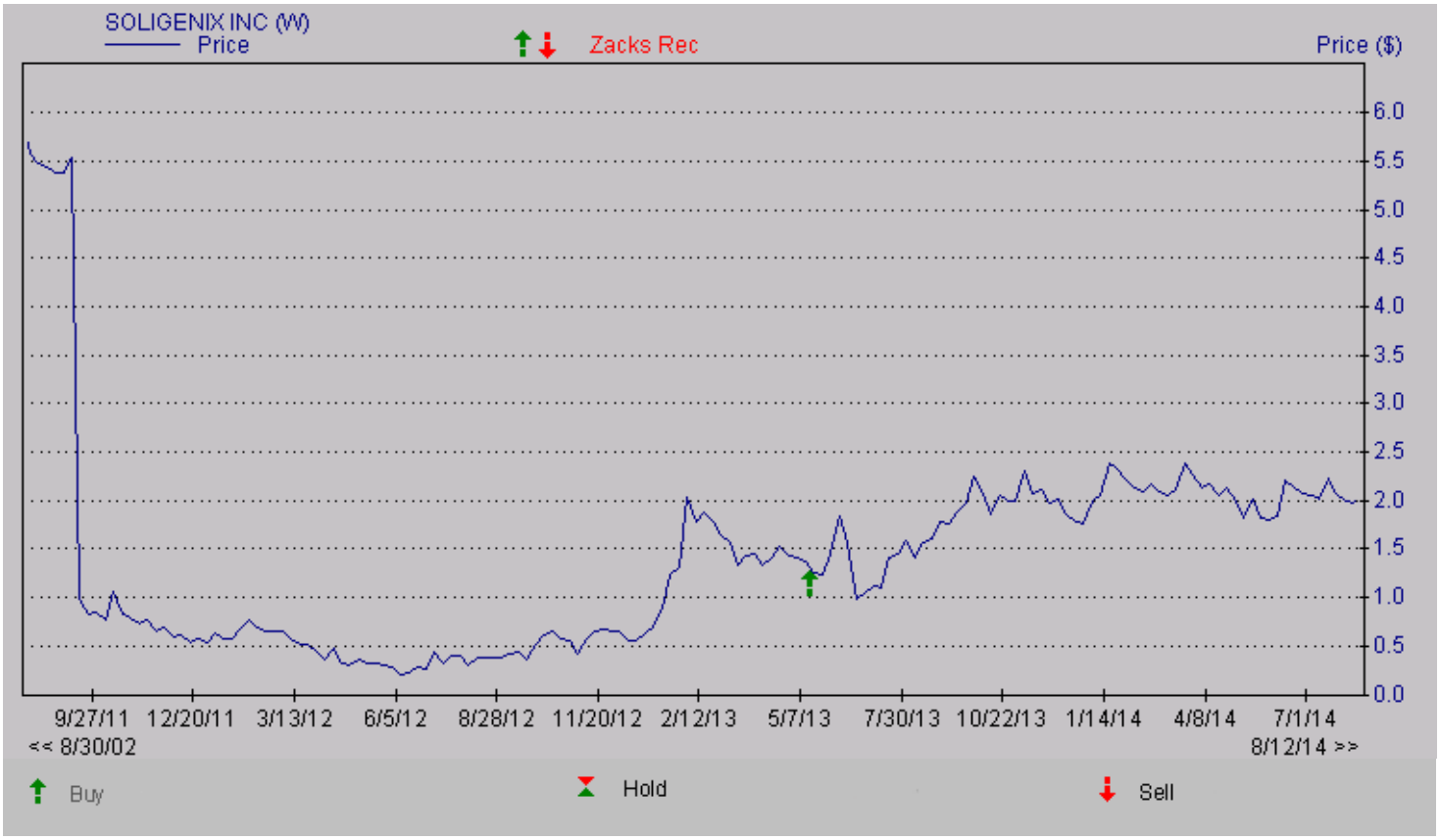
HISTORICAL ZACKS RECOMMENDATIONS



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