Zacks Small-Cap Research

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Soligenix Inc. (SNGX-OTCBB)

SNGX: To initiate *pivotal Phase III trial of SGX-301 in 2H15 in collaboration with NORD and CLF*---Buy

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	05/15/2013
Current Price (06/23/15)	$1.89
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 (Phase III) for CTLC and SGX942 (Phase II) for the treatment of oral mucositis. 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	**$2.24**
52-Week Low	**$0.95**
One-Year Return (%)	**-11.68**
Beta	**2.55**
Average Daily Volume (sh)	**51,243**
Shares Outstanding (mil)	**26**
Market Capitalization ($mil)	**$49**
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

- ***Soligenix collaborates with NORD and CLF to initiate Phase III trial of SGX-301 in 2H15;***
- ***Soligenix shares are undervalued;***

Soligenix to Initiate Phase III Trial of SGX-301 in 2H15 in Collaboration with NORD and CLF

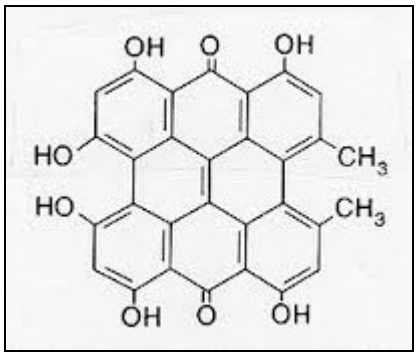
Background

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

In November, 2014, Soligenix formed 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 2H15 in Collaboration with NORD and CLF

Soligenix will be working with the National Organization for Rare Disorders **(NORD)** and the Cutaneous Lymphoma Foundation **(CLF)** to conduct a pivotal **Phase III** clinical study of SGX301in the treatment of cutaneous T-cell lymphoma (CTCL).

NORD and CLF will assist the Company in educating patients and raising awareness of the Phase III clinical trial among patients who are eligible for participation.

Soligenix has reached an agreement with the FDA on the design of the pivotal, **Phase III** clinical trial evaluating SGX301 for the treatment of cutaneous T-cell lymphoma (CTCL).

- 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).

The trial is anticipated to begin in **the second half of 2015** with primary data available in the **second half of 2016.**

We believe the collaboration with NORD and CLF will greatly accelerate the patient enrollment process and therefore accelerate the completion of the Phase III trial.

We estimate SGX301 could be approved by the FDA in late 2017 or early 2018 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, and the collaboration with NORD and CLF to advance the candidate, 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' Shares are Undervalued

We maintain our **Buy 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 also optimistic about its 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.

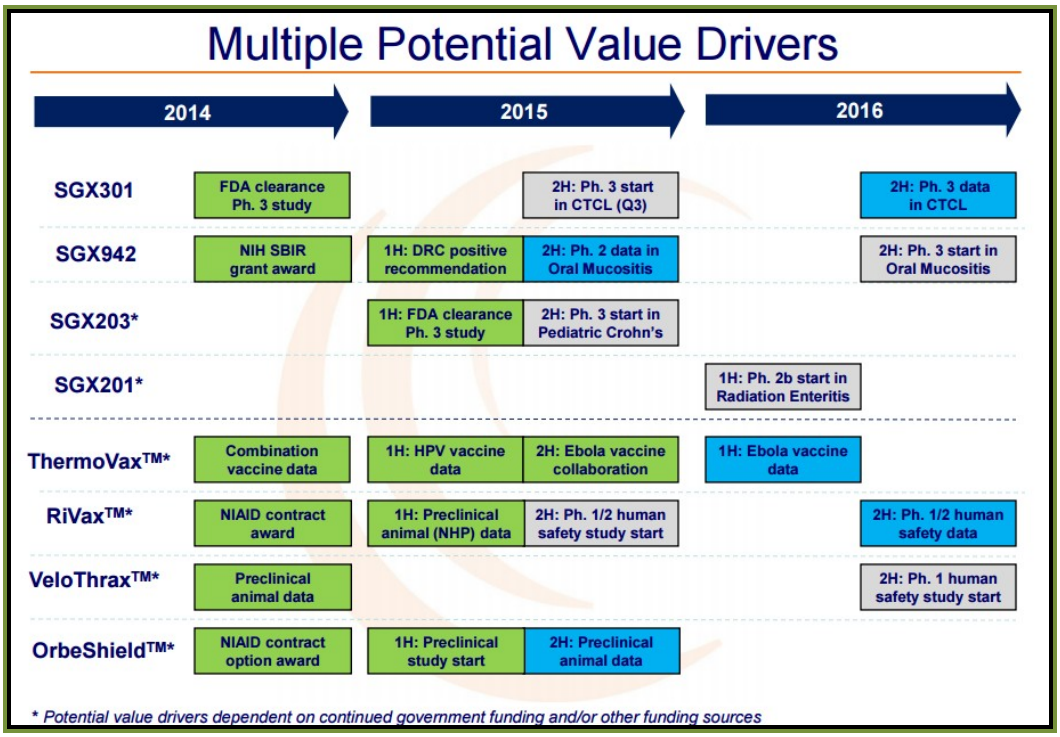
Soligenix's vaccines and biodefense therapeutics are being developed under specific FDA regulatory guidelines called the "**Animal Rule**." We think the "Animal Rule" means a lot for Soligenix, because this can accelerate the development of the ricin and anthrax vaccines as well as OrbeShield. Once approved 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 $1.90 per share, which values the Company at $49 million in market cap based on 26 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 2019, discounted at 25% for 4 years.

Soligenix has a decent pipeline and 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.



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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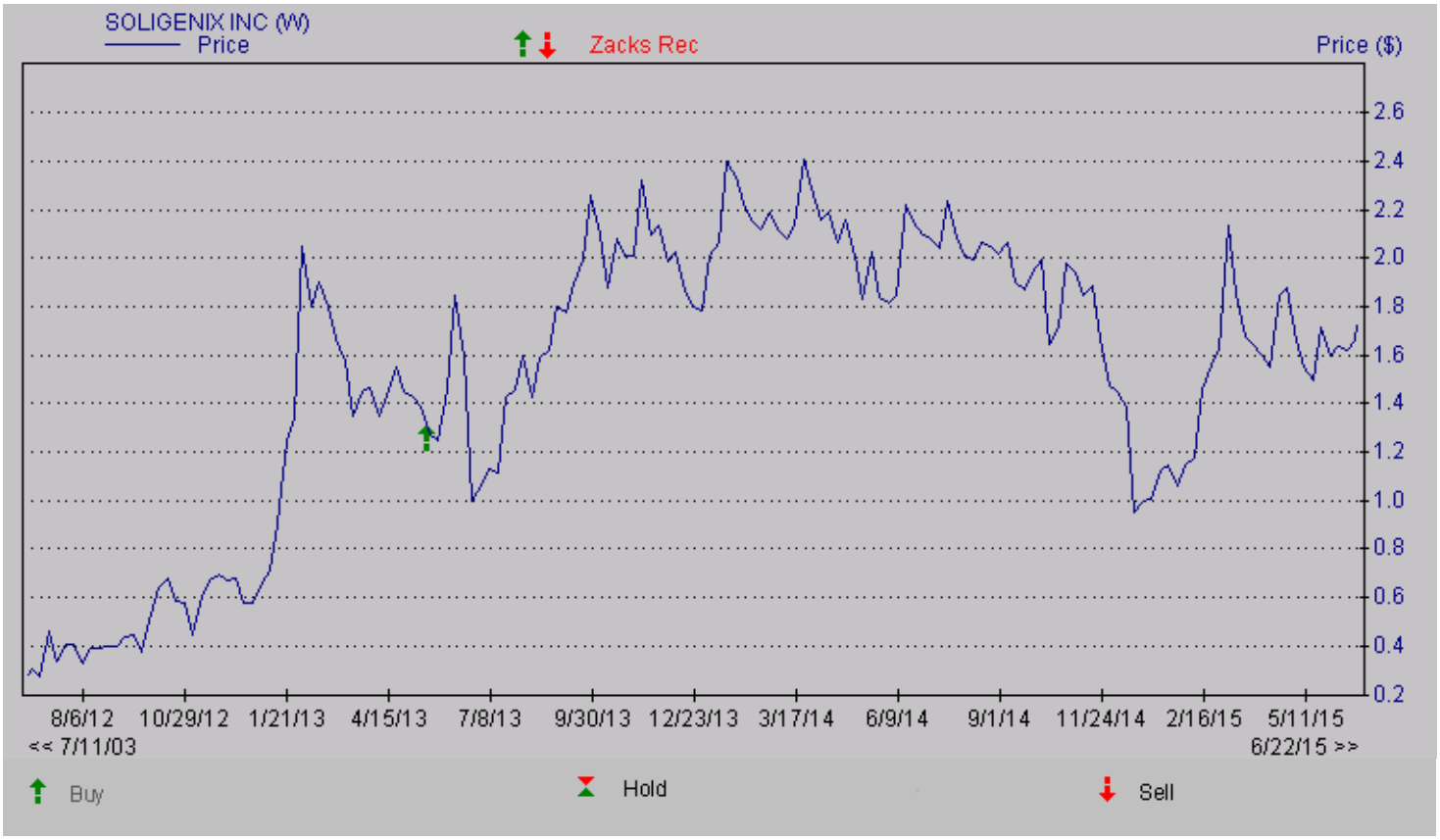
HISTORICAL ZACKS RECOMMENDATIONS



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