Zacks Small-Cap Research

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Soligenix Inc. (SNGX-OTCBB)

SNGX: Positive data reported from Phase II of SGX942 for oral mucositis, Phase III of SGX-*301 initiated in collaboration with NORD and CLF*---Buy

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	05/15/2013
Current Price (11/12/15)	$1.02
Twelve- Month Target Price	**$5.00**

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 SGX301for CTLC and SGX942 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 III study soon for SGX203. 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	**$2.50**
52-Week Low	**$0.91**
One-Year Return (%)	**-43.17**
Beta	**2.80**
Average Daily Volume (sh)	**50,256**
Shares Outstanding (mil)	**26**
Market Capitalization ($mil)	**$27**
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	1.1 A	3.9 A	1.0 E	6.8 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	-$0.08 A	-$0.04 A	-$0.09 E	-$0.28 E
2016					-$0.39 E
2017					-$0.33 E

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

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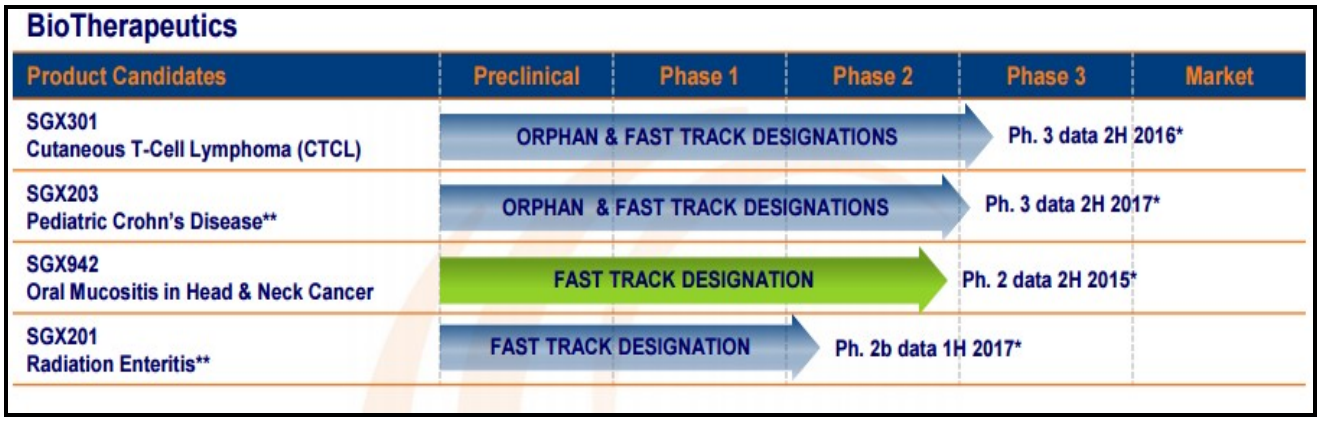
WHAT'S NEW

Soligenix (SNGX) has been busy in the past few months to move its therapeutic pipeline forward. In this update, we will focus on the analysis of the company's recent achievements in advancing its biotherapeutics candidates.



Soligenix Reports Positive Preliminary Results from Phase II Study of SGX942 for the Treatment of Oral Mucositis in Head and Neck Cancer Patients

On December 16, Soligenix announced positive results in its **Phase II** proof of concept (POC) clinical trial of SGX942 for the treatment of oral mucositis in head and neck patients.

The Phase II Trial

In December, 2013, SNGX initiated the **Phase II** study of SGX942 (NCT02013050) 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 (1.5 mg/kg, 3.0 mg/kg and 6.0 mg/kg) 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 chemoradiation therapy (CRT).

In early March 2015, Soligenix received a positive recommendation from the Data Review Committee (DRC) to continue the enrollment. 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 **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.

In August 2015, the trial completed the expanded enrollment.

The Positive Data

The study enrolled **111 patients** across three SGX942 dose groups (1.5, 3.0, and 6.0 mg/kg) and a placebo group and evaluated patients undergoing CRT for head and neck cancer.

This POC Phase II study achieved all objectives. In the **1.5 mg/kg** treatment group, the median duration of severe oral mucositis was decreased by **50%** in all patients, from 18 days to 9 days (p=0.099), meeting the prospectively defined statistical threshold of p<0.1.

In a subgroup of patients receiving the most aggressive chemoradiation therapy, the median duration of severe oral mucositis was reduced even more **(67%).**

The 1.5 mg/kg dose was identified as the best dose for future trials.

Further, a trend towards increased incidence of "complete response" of tumor at the one month follow up visit was observed (47% in placebo vs. 63% in SGX942 at 1.5 mg/kg). Decreases in mortality and significant decreases in infection rate were also observed with SGX942 treatment and are being further evaluated.

SGX942 was generally safe and well tolerated, consistent with the safety profile observed in the prior Phase I study conducted in 84 healthy volunteers.

Long-term follow-up evaluations are ongoing with final results expected in 4Q16. Data from this Phase II trial is expected to be submitted for future presentation and publication.

The Next Step

Soligenix plans to meet the FDA as soon as possible to discuss the next step of development of SGX942 for the treatment of oral mucositis. Given the positive and compelling preliminary data generated in oral mucositis, where there is substantial market potential, we believe that a **pivotal trial** could potentially be designed of a size roughly similar to the completed Phase II trial.

Simultaneous with the FDA meeting, the company will be aggressively pursuing opportunities for **partnership** to support subsequent clinical trials with SGX942. With the compelling data from the Phase II trial, it's our belief that it should be relatively easy to find a partner with favorable terms.

Further, with the biologic activity of the IDR technology now confirmed in humans, Soligenix will also look to expand its potential utility in the **infectious disease** space.

The IDR Platform Has Potential to Targets Multiple Indications

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), they do not engender resistance and are active against resistant pathogens. In vitro data indicate that the endothelium plays a significant role in SGX942 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).

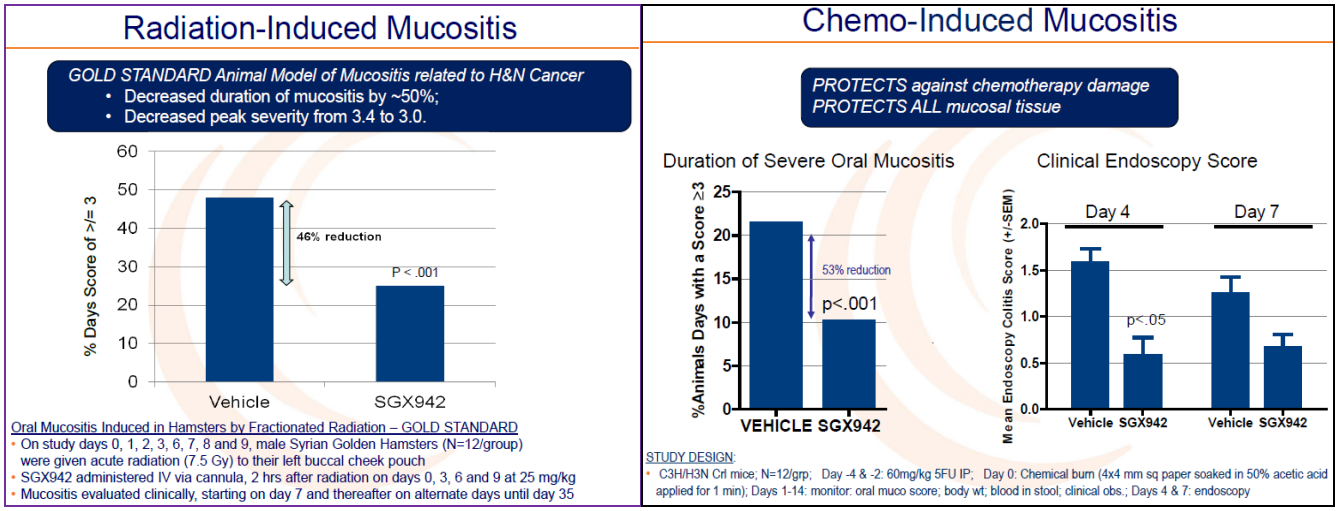
Soligenix acquired **SGX942** (formerly IMX942) in December 2012 from **Inimex Pharmaceuticals** of Canada.

SGX942 is a fully synthetic, 5-amino acid peptide with high aqueous solubility and stability. Extensive in vivo **preclinical studies** have shown that SGX94 reduces tissue damage associated with chemotherapy, radiation, trauma and inflammation. Although SGX94 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.

Extensive **animal data** set points to high potential for development of a broad spectrum of SGX942 products based on the following attributes:

- ameliorate injury;
- reduce inflammation;
- fight both antibiotic sensitive and resistant infections;
- complement antibiotics; and
- protect immune-compromised animals.

More specifically, SGX942 ameliorates tissue damage in models of chemotherapy- or radiation-induced mucositis as well as DSS-induced colitis and has shown accelerated healing in a murine model of skin infection and injury. SGX942 is not a growth factor and does not promote tumor growth or protect tumors against treatment in a breast cancer xenograft model using the MCF-7 cell line.



Studies in murine models of bacterial infection have shown activity against a broad range of pathogens including methicillin-resistant S. aureus (MRSA), K. pneumoniae, E.coli, P. aeruginosa, and B. pseudomallei. SGX94 enhances the activity of antibiotics administered at sub-optimal doses. Studies in a model of MRSA bacteremia indicate that SGX94 is effective both therapeutically and prophylactically. SGX942 is most effective when administered by IV injection and has a very short plasma half-life (~10

minutes). When administered prophylactically in the MRSA model, a single dose of SGX942 is protective when injected up to 5 days before bacterial challenge, indicating a prolonged pharmacodynamic effect despite rapid plasma clearance.

Inimex 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.

In addition to oral mucositis, SGX942 has the potential for multiple other indications.

Market Opportunity is Huge for SGX942

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 multibillion 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 are 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.

Soligenix Initiates Pivotal Phase III Clinical Trial of SGX301 for CTCL

On December 14, 2015, Soligenix announced the initiation of its much anticipated pivotal **Phase III** trial of SGX301 for the treatment of cutaneous T-cell lymphoma (CTCL).

Background

For those who are not familiar with Soligenix, here is the background of the program. 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 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.

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

The Pivotal Phase III Trial

Soligenix has been working with leading CTCL centers, as well as with the National Organization for Rare Disorders **(NORD)** and the Cutaneous Lymphoma Foundation **(CLF)** to conduct the pivotal **Phase III** clinical study of SGX301 in the treatment of 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.

The Phase III trial, referred to as the FLASH study (Fluorescent Light Activated Synthetic Hypericin), will be a multicenter, randomized, double-blind, placebo-controlled study that will enroll **120** evaluable subjects.

- 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).

- Other secondary measures will assess treatment response (including duration), degree of improvement, time to relapse and safety.

The study is anticipated to complete enrollment with primary data available **in the second half of 2016.**

Our Takeaway

SGX301 is a novel, first-in-class, photodynamic therapy that combines synthetic hypericin, a potent photosensitizer that is applied to the cancerous skin lesions and activated using a brief safe, fluorescent light treatment. This treatment approach avoids the risk of secondary malignancies (including melanoma) inherent with the frequently employed DNA-damaging chemotherapeutic drugs and other photodynamic therapies that are dependent on ultraviolet exposure.

We think the initiation of the Phase III trial marks an important milestone in the development of SGX301 as a treatment for CTCL. 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. It also received orphan drug designation in EU for 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 is $5.00 per share. We believe there are multiple catalysts to drive the share price up in the next 6 to 12 months.

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 optimistic about its drug candidate SGX942 for the treatment of mucositis. The preliminary positive data reported from the Phase II trial is 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 believe Soligenix shares are undervalued at current market price. Currently shares of Soligenix are trading at around $0.75 per share, which values the Company at $20 million in market cap based on 27 million outstanding shares. This deeply undervalues Soligenix shares in our view.

Our price target of $5.00 is arrived at by using 40 x P/E ratio, multiplied by an EPS of $0.30 in 2019, discounted at 25% for 4 years. Our price target values Soligenix at $130 million in market cap which we think is still 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	$1.1	$3.9	$1.0	$6.8	$4.5	$5.0	$5.5	$6.0
YOY Growth	*1.1%*	*124.3%*	*792.1%*	*136.7%*	*164.9%*	*-10.4%*	*-22.5%*	*39.2%*	*-48.1%*	*-3.5%*	*-33.8%*	*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**	**$1.1**	**$3.9**	**$1.0**	**$6.8**	**$4.5**	**$7.0**	**$20.5**	**$41.0**
YOY Growth	*1.1%*	*124.3%*	*792.1%*	*39.7%*	*118.4%*	*-10.4%*	*-22.5%*	*39.2%*	*-48.1%*	*-3.5%*	*-33.8%*	*55.6%*	*192.9%*	*100.0%*
Cost of Revenue	$0.6	$1.0	$2.1	$1.5	$5.3	$0.5	$0.8	$3.1	$0.8	$5.1	$3.7	$5.7	$6.0	$8.0
Gross Income	**$0.3**	**$0.4**	**$0.7**	**$0.4**	**$1.7**	**$0.3**	**$0.3**	**$0.8**	**$0.3**	**$1.7**	**$0.8**	**$1.3**	**$14.5**	**$33.0**
Gross Margin	*30.9%*	*27.1%*	*24.3%*	*20.0%*	*24.6%*	*35.4%*	*25.7%*	*21.4%*	*25.0%*	*24.3%*	*18.0%*	*18.0%*	*70.7%*	*80.5%*
R&D	$1.0	$1.2	$5.1	$1.8	$9.1	$1.0	$1.4	$1.3	$2.2	$5.9	$10.0	$7.0	$7.5	$8.0
% R&D	*113.2%*	*85.5%*	*182.6%*	*91.0%*	*129.0%*	*126.2%*	*131.2%*	*32.5%*	*220.0%*	*87.3%*	*222.2%*	*100.0%*	*36.6%*	*19.5%*
SG&A	$0.8	$0.9	$0.7	$1.0	$3.4	$0.8	$0.9	$0.8	$1.1	$3.6	$4.5	$7.5	$8.0	$10.0
% SG&A	*92.3%*	*61.1%*	*26.2%*	*50.2%*	*48.3%*	*100.1%*	*79.6%*	*21.6%*	*110.0%*	*53.4%*	*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)**	**($2.0)**	**($1.3)**	**($3.1)**	**($7.9)**	**($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)	($1.9)	$4.0	$0.0	$0.9	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	**($3.3)**	**($0.9)**	**($4.3)**	**$1.3**	**($7.3)**	**($4.6)**	**($4.0)**	**$2.8**	**($3.1)**	**($8.8)**	**($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)**	**($4.0)**	**$2.8**	**($3.1)**	**($8.8)**	**($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*	*25.7*	*28.3*	*35.0*	*28.4*	*35.0*	*40.0*	*45.0*	*50.0*
Reported EPS	**($0.17)**	**($0.05)**	**($0.21)**	**$0.06**	**($0.28)**	**($0.19)**	**($0.15)**	**$0.10**	**($0.09)**	**($0.31)**	**($0.39)**	**($0.33)**	**($0.02)**	**$0.30**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
One-time charge	$1.74	($0.75)	$4.00	($3.64)	$1.35	$3.01	$1.94	($4.04)	$0.00	$0.91	$0.00	$0.00	$0.00	$0.00
Non GAAP Net Income	**($1.6)**	**($1.7)**	**($0.3)**	**($1.7)**	**($5.4)**	**($1.6)**	**($2.0)**	**($1.3)**	**($3.1)**	**($7.9)**	**($13.7)**	**($13.2)**	**($1.0)**	**$15.0**
Non GAAP EPS	**($0.08)**	**($0.09)**	**($0.02)**	**($0.05)**	**($0.23)**	**($0.06)**	**($0.08)**	**($0.04)**	**($0.09)**	**($0.28)**	**($0.39)**	**($0.33)**	**($0.02)**	**$0.30**

Source: Company filings and Zacks estimates

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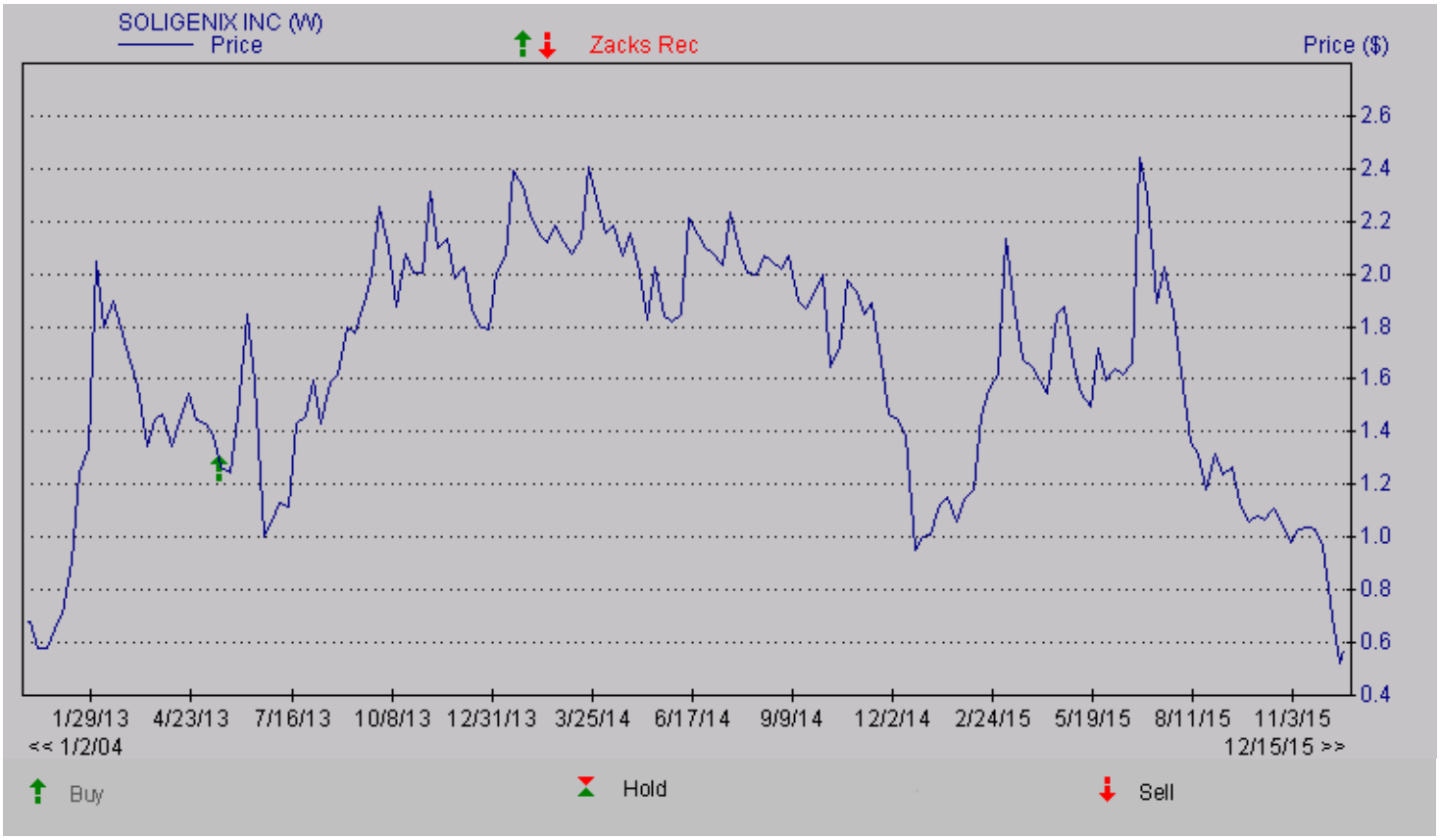

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