Zacks Small-Cap Research

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Soligenix Inc. (SNGX-OTCBB)

SNGX: On track to advance SGX942 and *SGX-301 in 4Q15 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 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	**$2.50**
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

Update on Third Quarter Financials

Total revenues were $3.9 million in 3Q15, as compared to $2.8 million for the 3Q14. The increase was primarily related to the continued progress on the company's OrbeShield™ and RiVax™ government contracts.

R&D expenses were $1.3 million in 3Q15, as compared to $5.1 million for the quarter ended September 30, 2014. This decrease is primarily related to acquisition of the synthetic hypericin product candidate, SGX301 from Hy BioPharma for $4.0 million, paid primarily in equity, which was charged to R&D expense during the third quarter 2014.

G&A expenses were $0.8 million in 3Q15, as compared to $0.7 million for the quarter ended September 30, 2014.

For 3Q15, operating expenses were $2.1 million, as compared to $5.8 million for the quarter ended September 30, 2014. This decrease was primarily related to acquisition of the synthetic hypericin product candidate, SGX301, from Hy BioPharma for $4.0 million as discussed above.

GAAP net income for 3Q15 was $2.8 million ($0.10 per share), as compared to GAAP net loss of $4.3 million (0.21 per share) for 3Q14. Income for the quarter ended September 30, 2015 was primarily attributable to the change in fair value of the warrant liability related to warrants issued in connection with the company's June 2013 registered public offering.

Non-GAAP adjusted net loss for 3Q15 was $1.3 million ($0.04 per share), as compared to non-GAAP net loss of $0.3 million ($0.02 per share).

As of September 30, 2015, the Company's cash position was $4.0 million.

In early August, Soligenix entered into a $10 million equity purchase agreement with accredited institutional investors, Kodiak Capital Group, LLC, Kingsbrook Opportunities Master Fund LP and River North Equity, LLC.

Proceeds from this transaction will be used to fund the company's ongoing clinical trials of its late-stage product candidates, including its pivotal Phase III clinical study of SGX301 for the treatment of cutaneous T-cell lymphoma (CTCL).

We welcome this new financing transaction. The capital infusion not only boosts its balance sheet immediately, but further validates its technology and clinical programs. The commitment serves as a vote of confidence in management's ability to execute on its growth plan and increase shareholder value.

Current cash balance plus the financial commitment will fund the company's operations into 2017 according to our financial model.

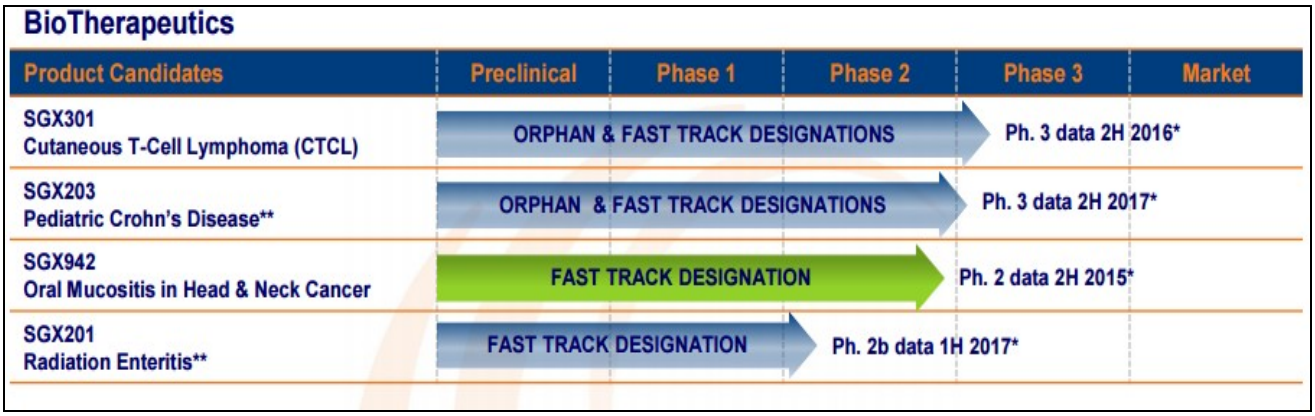
Another strategy to boost balance sheet is to raise fund through non-dilutive way. Soligenix is successful in this regard. The company has been awarded a grant by the National Institute of Allergy and Infectious Diseases (NIAID) worth up to $24.7 million, which will support the preclinical, manufacturing and clinical development activities necessary to advance its heat stable RiVax™. In August, 2015, the company announced NIAID exercised a $2.7 million option to further advance the development of the Company's heat stabile ricin toxin vaccine, RiVax™, as a MCM to prevent the effects of ricin exposure.

Another contract worth up to approximately $32 million was awarded by both the Biomedical Advanced Research Development Authority (BARDA) and NIAID to support the company's GI ARS (gastrointestinal

acute radiation syndrome) program. On August 27, 2015, the company announced the NIAID exercised a $2.1 million option to further advance the preclinical development of OrbeShield™, as a medical countermeasure (MCM) for the treatment of GI ARS.

Soligenix Completes Phase II Patient Enrollment of SGX942 for the Treatment of Oral Mucositis

Soligenix (SNGX) has been busy in the past six 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.



On Aug. 31, Soligenix (SNGX) announced that it has completed enrollment of the additional subjects, as directed by the Data Review Committee (DRC) earlier this year, into the company's **Phase II** clinical trial for SGX942 for the treatment of oral mucositis in head and neck cancer patients.

SGX942 is the company's lead candidate from its first-in-class innate defense regulator (IDR) program.

The Background of the Phase II Trial

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 from DRC

In early March 2015, Soligenix 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.

Top line data Expected in 4Q15

We are pleased with the positive recommendation from the DRC, which allows 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.

We consider the completion of the enrollment an important milestone in this study and remain positive about the top line results which will be available in **4Q15.**

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).

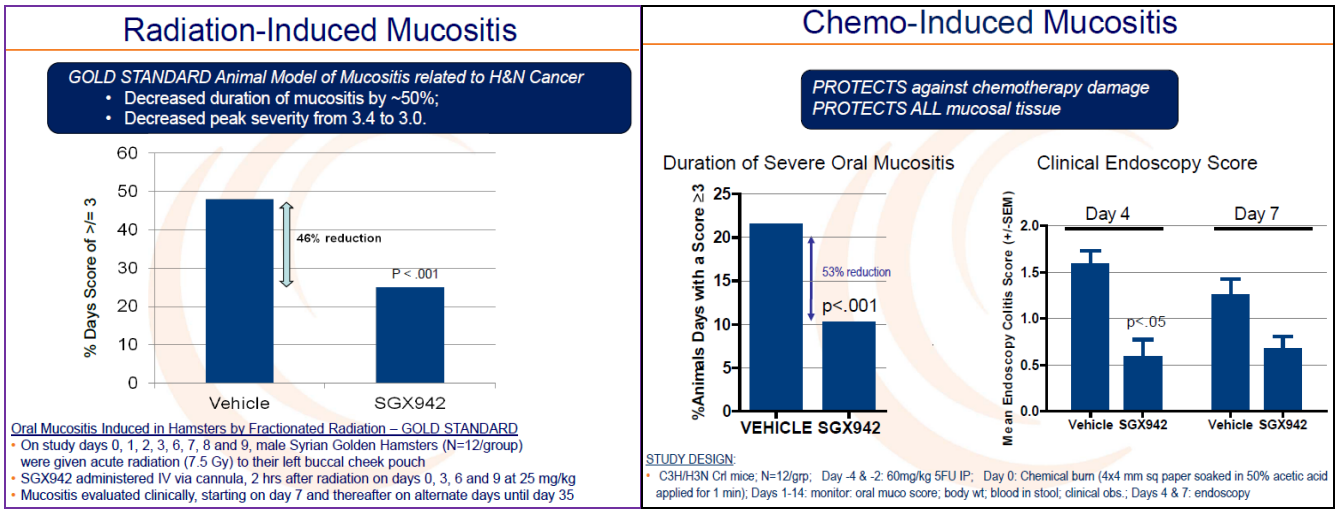
Soligenix acquired **SGX942** (formerly IMX942) in December 2012 from **Inimex Pharmaceuticals** of Canada.

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 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.

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.

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

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. 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.

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

In April 2015, 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 FDA has awarded SGX203 **Orphan Drug designation** for the treatment of pediatric Crohn's disease as well as **Fast Track designation**.

Crohn's disease is an ongoing disorder that causes inflammation of the GI tract. Crohn's disease can affect any area of the GI tract, from the mouth to the anus, but it most commonly affects the lower part of the small intestine, called the ileum. The swelling caused by the disease extends deep into the lining of the affected organ. The swelling can induce pain and can make the intestines empty frequently, resulting in diarrhea. Because the symptoms of Crohn's disease are similar to other intestinal disorders, such as irritable bowel syndrome and ulcerative colitis, it can be difficult to diagnose.

Crohn's disease can appear at any age, but it is most often diagnosed in adults in their 20s and 30s. However, approximately 30% of people with Crohn's disease develop symptoms before 20 years of age. It is estimated, based upon published studies and reports, that Pediatric Crohn's disease is a subpopulation of approximately 80,000 patients in the U.S. with a comparable number in Europe. Crohn's disease tends to be both severe and extensive in the pediatric population and a relatively high proportion (~40%) of pediatric Crohn's patients has involvement of their upper gastrointestinal tract.

Crohn's disease presents special challenges for children and teens. In addition to bothersome and often painful symptoms, the disease can stunt growth, delay puberty, and weaken bones. Crohn's disease symptoms may sometimes prevent a child from participating in enjoyable activities. The emotional and psychological issues of living with a chronic disease can be especially difficult for young people.

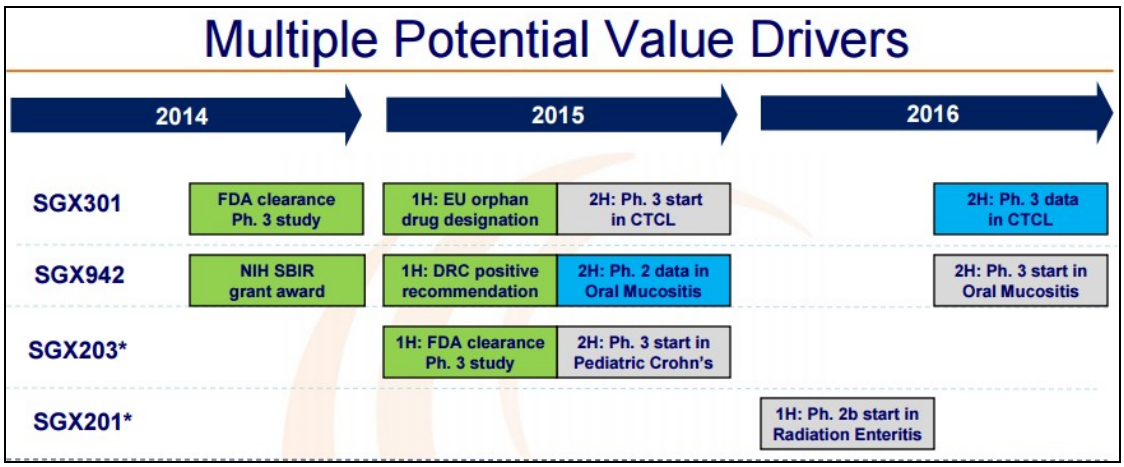
There is currently no cure for Crohn's disease, and there is no one treatment that works for everyone. Drug therapies usually include anti-inflammatory drugs, immune system suppressors and antibiotics. There are currently no FDA approved corticosteroid therapies for pediatric Crohn's disease. 80% of 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.**

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' Shares are Undervalued

We maintain our **Buy rating** for Soligenix and 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. SGX942 is currently under a Phase II study. Results will be available in 4Q15, 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 believe Soligenix shares are undervalued at current market price. Currently shares of Soligenix are trading at around $1.30 per share, which values the Company at $35 million in market cap based on 26 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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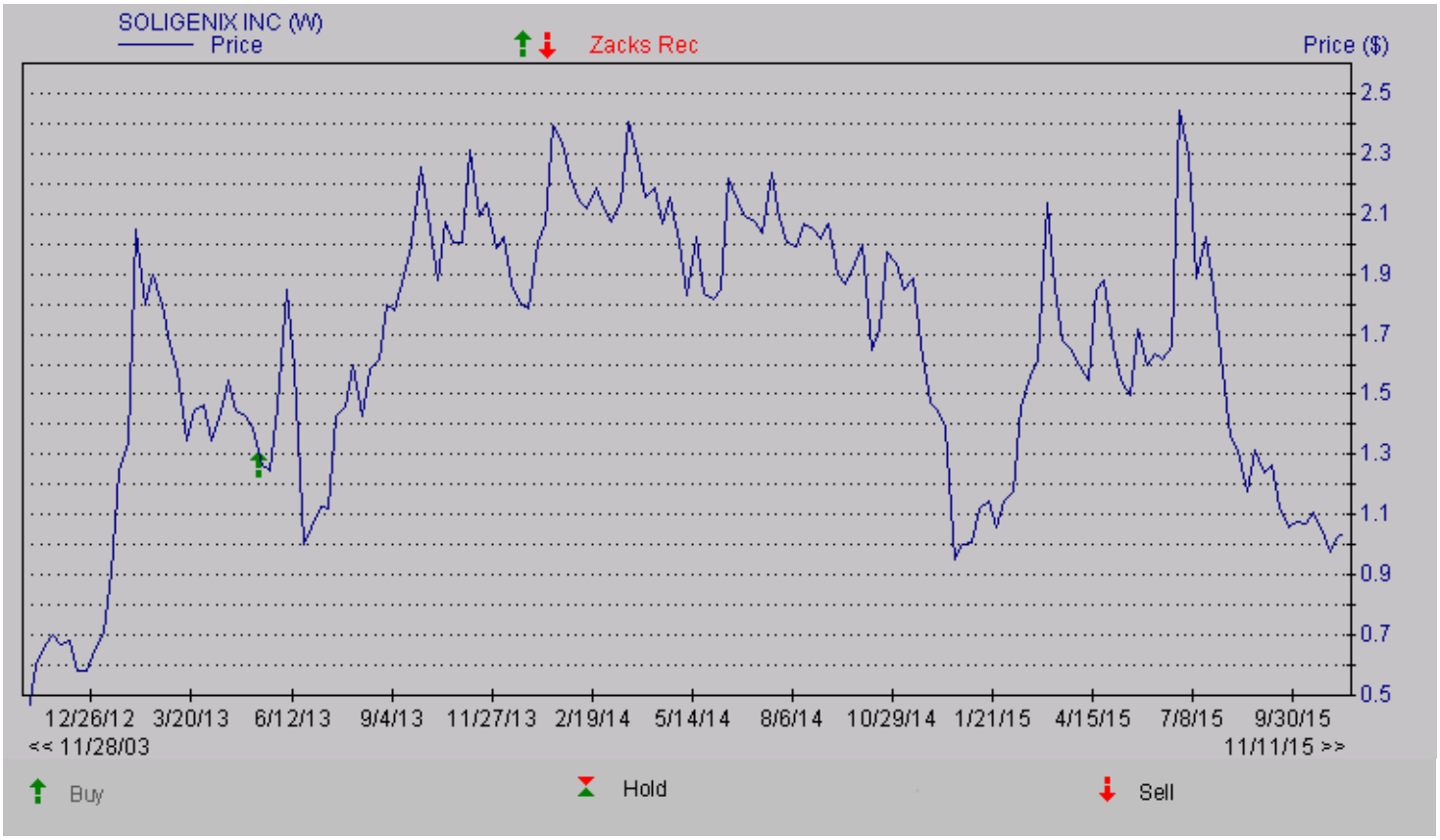

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