Zacks Small-Cap Research

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# Soligenix Inc. (SNGX-OTCBB)

**SNGX:** Exited 2013 with cash on budget, on track to advance multiple clinical programs --- Outperform

| | |
|---|---|
| **Current Recommendation** | **Outperform** |
| Prior Recommendation | N/A |
| Date of Last Change | 05/15/2013 |
| Current Price (03/25/14) | $2.35 |
| **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** | **$2.50** |
| **52-Week Low** | **$0.96** |
| **One-Year Return (%)** | **11.58** |
| **Beta** | **1.42** |
| **Average Daily Volume (sh)** | **58,178** |
| **Shares Outstanding (mil)** | **20** |
| **Market Capitalization ($mil)** | **$42** |
| **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 | 0.8 E | 0.8 E | 0.8 E | 0.8 E | 3.2 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 | -$0.09 E | -$0.11 E | -$0.09 E | -$0.10 E | -$0.40 E |
| 2015 | | | | | -$0.37 E |
| 2016 | | | | | -$0.36 E |

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

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## WHAT'S NEW

***Soligenix Exited 2013 with Cash On Budget***

On March 26, 2014, Soligenix announced its financial results for the year ended December 31, 2013.

Revenues for 2013 were $3.2 million as compared to $3.1 million for the prior year. Revenues for 2013 included $0.6 million in 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) and $2.7 million in grants.

Research and development expenses for 2013 were $5.1 million as compared to $2.6 million for the year ended December 31, 2012. R&D expenses for 2013 included $1.5 million non-cash charge related to the collaboration with Intrexon Corporation.

General and administrative expenses were $2.8 million as compared to $2.6 million for the year ended December 31, 2013 and 2012, respectively. This increase is primarily related to non-cash expenses for stock based compensation from stock options issued during the year.

Net loss for 2013 was $10.1 million ($0.65 per share), as compared to $4.2 million ($0.37 per share) for 2012. Net loss for 2013 included a non-cash charge of $3.7 million, or $0.24 per share, due to the change in fair value of the liability related to warrants as well as a $1.5 million non-cash charge related to the exclusive worldwide collaboration with Intrexon Corporation.

As of December 31, 2013, the Company's cash position was $5.9 million.

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.

Upon execution of the agreement, the Company received an investment of $600,000 in exchange for the issuance of 285,714 shares of the Company's common stock to LPC. The per share purchase price of $2.10 was equal to the closing price of the Common Stock on the day prior to the execution of the agreement.

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 and subject to certain conditions, which include the effectiveness of a registration statement with the U.S. Securities and Exchange Commission covering the sale of the shares that may be issued to LPC. The purchase price of the shares will be based on prevailing market prices of Soligenix's shares immediately preceding the notice of a sale without any fixed discount. Soligenix controls the timing and amount of any future investment and LPC is obligated to make such purchases, if and when the Company decides in accordance with the stock purchase agreement. Additionally, there are no upper price limit restrictions, negative covenants or any restrictions on the Company's future financing activities. Soligenix can terminate the agreement at any time without any monetary cost or penalty. LPC has also agreed not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of the Company's shares of common stock.

We think this financing is favorable to Soligenix in the following aspects:

- Soligenix has the ability to raise capital at or near market prices, which will enhance the potential to pursue strategic alliances in a very efficient and opportunistic manner;

- The financing agreement is favorable to and flexible for Soligenix with the company controlling the timing and amount of share sales;

- The flexible financing agreement not only boosts Soligenix's balance sheet, but importantly validates the company's technology and clinical programs;

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

Soligenix also remains active and opportunistic in pursuing non-dilutive capital through government grants and contracts. Most notably, the company was awarded two contracts from the US government in September 2013 to support the development of OrbeShield™ for the treatment of gastrointestinal acute radiation syndrome (GI ARS) and awarded $0.3 million from NIAID for the development of SGX943 as a treatment for melioidosis.

On February 14, 2014, the company was awarded by NIAID of a one year $300,000 Small Business Innovation Research (SBIR) grant to support further preclinical development of SGX943 as a treatment for melioidosis.

***Soligenix Initiated development of SGX943 for Melioidosis***

On February 14, 2014, Soligenix announced that the National Institute of Allergy and Infectious Diseases (NIAID) has awarded Soligenix a Small Business Innovation Research (SBIR) grant to support further **preclinical** development of **SGX943** as a treatment for **melioidosis**. The award will provide Soligenix with approximately $300,000 over one year to conduct the studies in collaboration with Tulane University.

Melioidosis remains a significant **biothreat** as well as a major life-threatening endemic disease in Southeast Asia and Northern Australia. Melioidosis is caused by the Gram-negative bacterium Burkholderia pseudomallei (Bps). Current treatment for melioidosis requires long and intensive antibiotic administration and extensive supportive care. In endemic regions, mortality from melioidosis can be as high as 40%. In addition to causing a high rate of endemic disease in Southeast Asian and Northern Australia, Bps is also considered a top five priority in the most recent Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Strategy document.

| **Country/Region** | **Incidence** |
|---|---|
| Northeast Thailand | 21.0 /100,000 |
| Southwestern (Er-Ren River Basin) Taiwan | 36/100,000 |
| Northern Australia | 19.6 /100,000 |
| Kimberley region of Western Australia | 14/100,000 |
| Singapore | 1.7/100,000 |
| Alor Setar, Malaysia | 16.35/100,000 |
| India | conservative estimate 10/100,000 |
| China | conservative estimate 10/100,000 |

SGX943 is the drug product designation for the active ingredient SGX94 in the treatment of melioidosis. SGX94 is an innate defense regulator (IDR), a new class of short, synthetic peptides that has a novel mechanism of action in that it has simultaneous anti-inflammatory and anti-infective activity. 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, as well as accelerating resolution of

tissue damage following exposure to a variety of agents including bacterial pathogens, trauma and chemo- and/or radiation-therapy.

SGX943 has been comprehensively evaluated in bacterial infection models and has shown preclinical efficacy with Gram-positive methicillin resistant Staphylococcus aureus (MRSA) as well as with other Gram-negative pathogens. As an innate defense regulator, SGX943 does not have direct antibacterial activity, but rather stimulates the innate immune system to combat infection while simultaneously suppressing inflammation. Thus, SGX943 has the potential to be a novel adjunctive treatment paradigm for antibiotic resistant infections, including melioidosis.

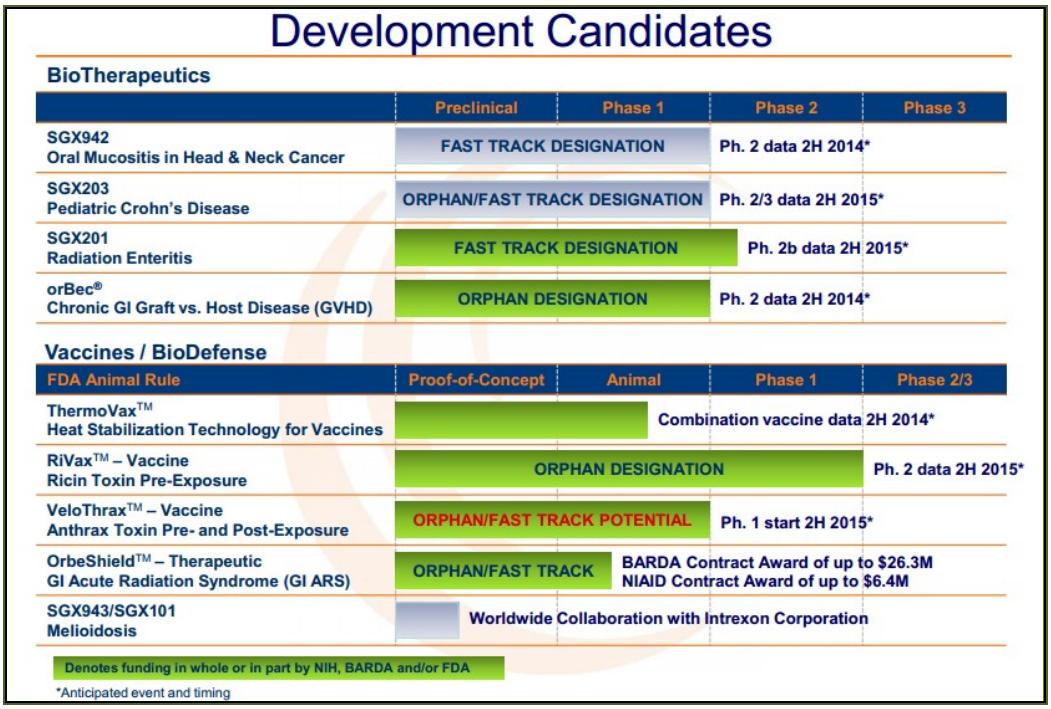
This new grant will support further evaluation of SGX943 in the treatment of melioidosis in preclinical studies. These results will represent a significant step forward in the development of SGX943 as a medical countermeasure for melioidosis.

Soligenix has **two distinctive programs** for melioidosis now: SGX943 and **SGX101.**

Soligenix is also developing SGX101 for the treatment of melioidosis through a worldwide exclusive collaboration with **Intrexon.** Under this collaboration with Intrexon, Soligenix intends to develop and commercialize human monoclonal antibody therapies for new biodefense and infectious disease applications for melioidosis using Intrexon's advanced human antibody discovery, isolation and production technologies. Under the agreement, Intrexon will provide discovery and development of therapeutic antibody candidates, as well as optimize and expand production of human monoclonal antibodies targeting melioidosis by applying its proprietary platforms and technologies. Soligenix will undertake preclinical and clinical development, regulatory and government interactions, as well as the commercialization of therapeutic products.

We are very pleased to see that Soligenix is advancing its melioidosis programs, especially for the SGX943 program through the government support. The grant from the US government not only boosts the company's balance sheet in a non-dilutive way, it also further validates the company's platform technology.

The melioidosis program further expands Soligenix's biodefense pipeline, which has the potential to qualify for the FDA's tropical disease voucher program sometime in the future.



### *Positive One-Year Results with ThermoVax™ Announced*

On January 15, 2014, Soligenix announced significant steps forward in the development of **ThermoVax™**, its proprietary vaccine thermostabilization platform technology.

Recent studies have demonstrated the potential for heat-sensitive vaccines formulated using this technology to withstand temperatures exceeding 40 degrees Celsius (104 degrees Fahrenheit) for up to one year. The underlying work has been conducted with the Company's proprietary ricin toxin vaccine (RiVax™) as part of a continuing program to evaluate the effectiveness of protein subunit vaccines to withstand extremes of temperature and other environmental stress conditions. These studies amplify and extend former evaluations that indicated retention of potency for at least six months at temperatures as high as 40 degrees Celsius, outside the range of typical vaccine storage conditions.

The research and development of ThermoVax™ is currently being supported by a $9.4 million National Institute of Allergy and Infectious Disease (NIAID) grant to Soligenix for biodefense vaccines to prevent ricin toxin and anthrax exposure.

These results underline the potential for long-term stability of subunit vaccines stored at high temperatures. Vaccines are almost always stored refrigerated because of vulnerability to heat exposure, resulting in loss of potency and efficacy. By employing ThermoVax™ during final formulation of RiVax™, which is extremely unstable in its liquid form, a stable and potent vaccine is produced that is capable of withstanding temperatures at least as high as 40 degrees Celsius for up to one year. The most recent studies, which employed a combination of sensitive techniques to evaluate the structure of the vaccine and the resulting immunogenicity, demonstrated that the vaccine retained original levels of potency after one year of storage at 40 degrees Celsius. RiVax™, formulated with ThermoVax™, has the potential to facilitate easier storage and distribution in a national stockpile for emergency situations.

In addition to RiVax™, the Company has previously reported that its proprietary anthrax vaccine, VeloThrax™, formulated with ThermoVax™ and subsequently exposed to temperatures as high as 70 degrees Celsius (158 degrees Fahrenheit) for at least one month, retained full potency in animals as well as other characteristics such as receptor binding indicative of full structural integrity. The combination of ThermoVax™ and VeloThrax™ along with a potent secondary adjuvant resulted in rapid onset of antibodies correlated to protection against anthrax in animal models. Additional studies have confirmed longer term stability of VeloThrax™ at 40 degrees Celsius for up to four months.

### *Soligenix Initiated Phase II Trial of SGX942 for Oral Mucositis*

On December 5, 2013, Soligenix (SNGX.OB) announced that it has initiated a **Phase II**, randomized, double-blind, placebo-controlled study evaluating **SGX942**, a first-in-class innate defense regulator (IDR), as a treatment for **oral mucositis** in patients undergoing chemoradiation (CRT) therapy for **head and neck cancer**.

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 are expected to be available in **2H14**.

***Market Opportunity For SGX942 Is Big***

**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 EKR Therapeutics' Gelclair, GeoPharma'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.

| Product | Company | Phase | Indication | Comment / Issue |
|---|---|---|---|---|
| Kepivance | Amgen | Approved (drug) | Prevent OM-HSCT | Inconvenient IV dosing 3x pre + 3x post chemo, over priced |
| Gelclair | DARA | Approved (device) | Palliation | Poor reimbursement, poor data |
| Mucotrol | Edwards Pharmaceutical | Approved (device) | Palliation | Poor reimbursement, poor data |
| Caphosol | EUSA | Approved (device) | Palliation | Poor reimbursement, poor data |
| Episil | Camurus | Approved (device) | Palliation | |
| Mugard | Access | Approved (device) | Palliation | Poor reimbursement; recent controlled study confirmed activity as a palliative agent |

## *Soligenix Initiated Phase II Trial of orBec® for Chronic GI GVHD*

On December 2, 2013, Soligenix announced that it has initiated a **Phase II,** randomized, double-blind, placebo-controlled study evaluating **orBec®** (oral beclomethasone 17,21-dipropionate or BDP) as a treatment for the gastrointestinal (GI) manifestations of chronic Graft-versus-Host disease (**GVHD**).

This study is partially funded by the National Cancer Institute (NCI) which has awarded Soligenix a Small Business Innovation Research (SBIR) grant to support the conduct of a Phase II clinical trial. The award provides Soligenix with approximately $300,000 over a two-year period.

The Phase II study is designed as a multicenter, pilot study enrolling patients that have received allogeneic hematopoietic cell transplantation (HCT) at least 100 days earlier, have documented chronic GVHD in at least one organ outside the GI tract, and have a mucosal biopsy consistent with GI GVHD. The **primary efficacy objective** of the study is to estimate the proportion of subjects with chronic GVHD with GI involvement who achieve a complete response, partial response or minimal response of GI GVHD signs and symptoms when treated with orBec® for up to 16 weeks. Response will be assessed using a composite score based on the symptoms of satiety, nausea/vomiting, and anorexia.

Data are expected to be available in **2H14**.

**orBec ®** is a two tablet delivery system of BDP specifically designed for oral use that allows for delivery of immediate and delayed release BDP to treat the gastrointestinal manifestation of **chronic GVHD**, the organ system where GVHD is most frequently encountered and highly problematic.

orBec® is intended to reduce the need for systemic immunosuppressive drugs such as prednisone to treat chronic GI GVHD. The active ingredient in orBec® is BDP, a highly potent, topically active corticosteroid that has a local effect on inflamed tissue.

orBec® has been awarded **orphan drug** designations in the U.S. and in Europe for the treatment of GI GVHD. In September 2012, Soligenix received a $300,000 two-year SBIR grant awarded by the NIH to support a **Phase II** study for the treatment of chronic GI GVHD.

GVHD is a major complication of allogeneic hematopoietic cell transplantation. GVHD is an inflammatory disease initiated by T cells in the donor graft that recognize histocompatibility and other tissue antigens of the host, and is mediated by a variety of effector cells and inflammatory cytokines. GVHD presents in both acute and chronic forms. The symptoms of chronic GVHD typically present at between 100 days and three years post-transplant.

Chronic GVHD has features resembling autoimmune and other immunologic disorders such as scleroderma, Sjögren syndrome, primary biliary cirrhosis, wasting syndrome, bronchiolitis obliterans, immune cytopenias and chronic immunodeficiency. The manifestations of chronic GVHD may be restricted to a single organ or tissue or may be widespread. Chronic GVHD can lead to debilitating consequences, e.g., joint contractures, loss of sight, end-stage lung disease, or mortality resulting from profound chronic immune suppression leading to recurrent or life-threatening infections.

Treatment of chronic GVHD is a challenge because it can be refractory to frontline immunosuppression. High-dose systemic corticosteroids are used with some success but carry significant toxicity. The risks of prolonged immunosuppression include local and disseminated infections; Epstein-Barr virus associated lymphoproliferative disease, hypothalamic-pituitary-adrenal ("HPA") axis suppression, myopathy, glucose intolerance, neuropsychiatric disease and bone demineralization.

There are about 6,000 patients annually in the U.S., with a comparable number in Europe that suffer from chronic GVHD.

***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 **1H2014**. Data are expected in 1H2015, 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 AND RECOMMENDATION

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. 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.

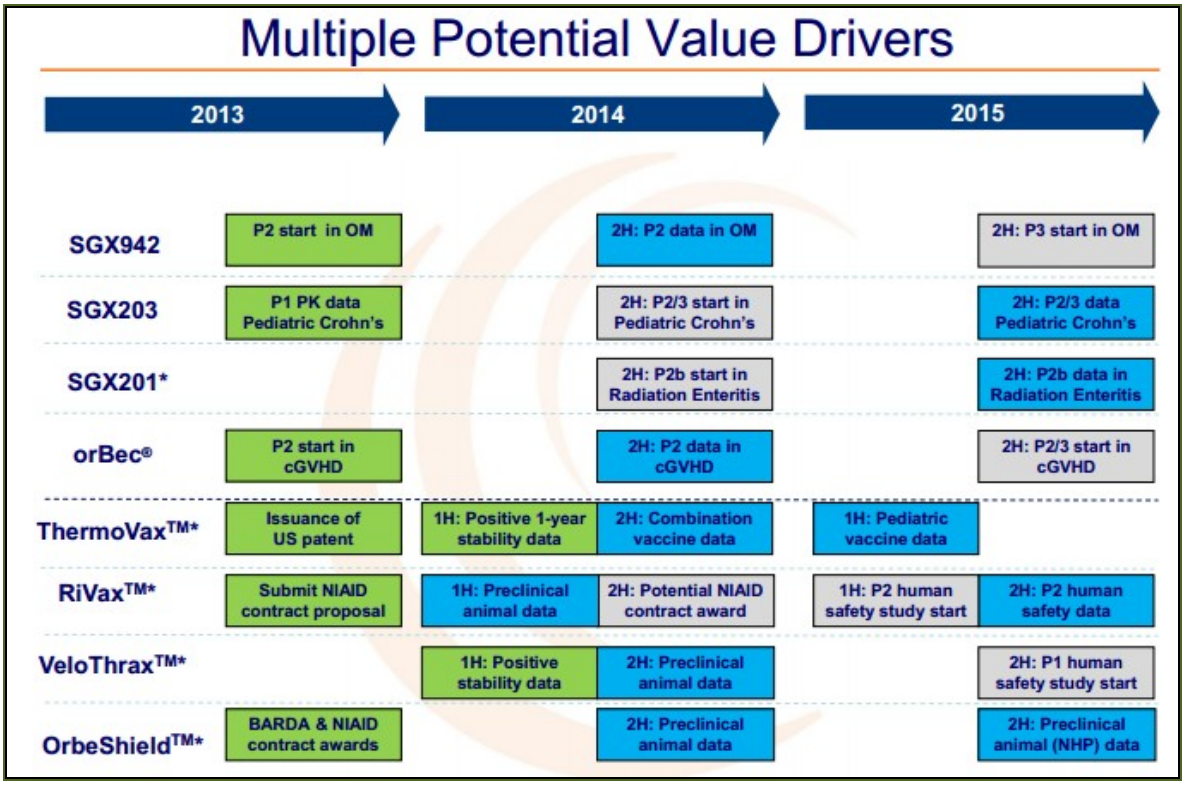
Soligenix's vaccines and biodefense therapeutics are being developed under specific FDA regulatory guidelines called the "**Animal Rule**." The Animal Rule provides that under certain circumstances, where it is unethical or not feasible to conduct human efficacy studies, the FDA may grant marketing approval based on adequate and well-controlled animal studies when the results of those studies establish that the drug is reasonably likely to produce clinical benefit in humans. Demonstration of the product's safety in humans is still required.

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 this time. Currently, shares of Soligenix are trading at around $2.20 per share, which values the Company at $44 million in market cap. We admit that it's always difficult to value a development stage biotech company. Soligenix is no exception. However, we do think that current market value of Soligenix is a deep discount compared to its peers in the same industry.

Most small biotech companies of development stage are valued from $50 million to $500 million 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.


Multiple Potential Value Drivers
2013
2014
2015
SGX942
P2 start in OM
2H: P2 data in OM
2H: P3 start in OM
SGX203
P1 PK data Pediatric Crohn's
2H: P2/3 start in Pediatric Crohn's
2H: P2/3 data Pediatric Crohn's
SGX201*
2H: P2b start in Radiation Enteritis
2H: P2b data in Radiation Enteritis
orBec®
P2 start in cGVHD
2H: P2 data in cGVHD
2H: P2/3 start in cGVHD
ThermoVax™*
Issuance of US patent
1H: Positive 1-year stability data
2H: Combination vaccine data
1H: Pediatric vaccine data
RiVax™*
Submit NIAID contract proposal
1H: Preclinical animal data
2H: Potential NIAID contract award
1H: P2 human safety study start
2H: P2 human safety data
VeloThrax™*
1H: Positive stability data
2H: Preclinical animal data
2H: P1 human safety study start
OrbeShield™*
BARDA & NIAID contract awards
2H: Preclinical animal data
2H: Preclinical animal (NHP) data

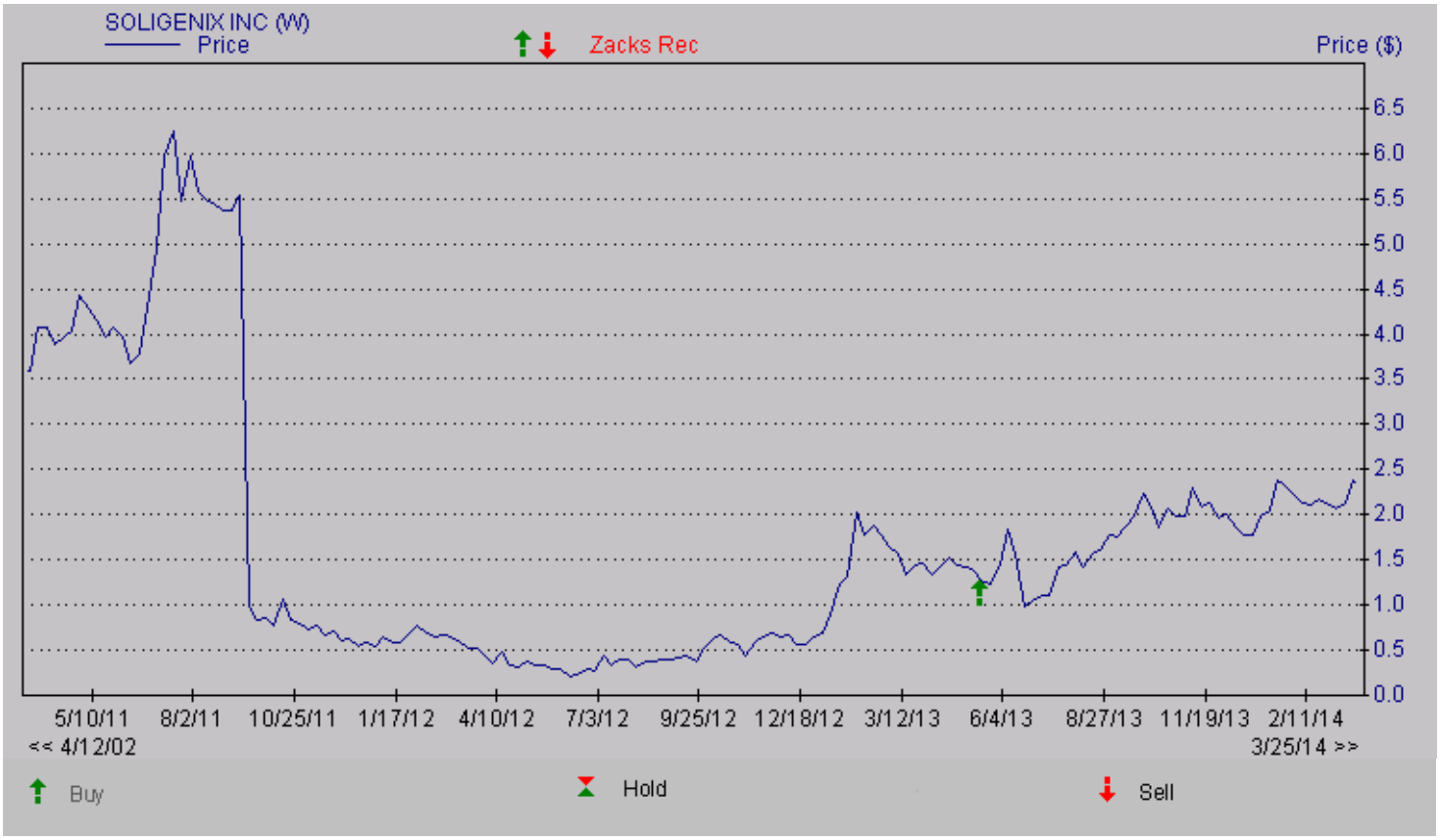
## PROJECTED INCOME STATEMENT

| _ | 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* | *-100.0%* | *#DIV/0!* | *#DIV/0!* | *#DIV/0!* | *#DIV/0!* | *#DIV/0!* | - | - | - | - | - | - | - |
| Grant Revenue | $3.1 | $0.9 | $0.6 | $0.3 | $0.8 | $2.7 | $0.8 | $0.8 | $0.8 | $0.8 | $3.2 | $4.0 | $4.5 |
| *YOY Growth* | *18.1%* | - | *-17.1%* | *-66.5%* | *1.4%* | *-15.4%* | *-11.1%* | *26.5%* | *156.0%* | *-1.7%* | *20.4%* | *25.0%* | *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** | **$0.8** | **$0.8** | **$0.8** | **$0.8** | **$3.2** | **$4.0** | **$4.5** |
| *YOY Growth* | *-59.0%* | *39.1%* | *-17.1%* | *-66.5%* | *71.8%* | *2.5%* | *-11.1%* | *26.5%* | *156.0%* | *-42.0%* | *-0.7%* | *25.0%* | *12.5%* |
| *Cost of Revenue* | $2.6 | $0.7 | $0.5 | $0.2 | $1.0 | $2.5 | $0.6 | $0.6 | $0.6 | $0.6 | $2.6 | $3.3 | $3.7 |
| **Gross Income** | **$0.6** | **$0.2** | **$0.1** | **$0.1** | **$0.4** | **$0.7** | **$0.2** | **$0.2** | **$0.2** | **$0.2** | **$0.6** | **$0.7** | **$0.8** |
| *Gross Margin* | *17.5%* | *17.4%* | *16.5%* | *21.3%* | *25.5%* | *21.1%* | *20.0%* | *20.0%* | *20.0%* | *20.0%* | *20.0%* | *18.0%* | *18.0%* |
| R&D | $2.6 | $0.8 | $2.1 | $1.2 | $1.0 | $5.1 | $1.2 | $1.5 | $1.7 | $2.0 | $6.4 | $10.0 | $12.5 |
| *% R&D* | *83.0%* | *84.0%* | *338.5%* | *389.3%* | *69.4%* | *157.3%* | *150.0%* | *187.5%* | *212.5%* | *250.0%* | *200.0%* | *250.0%* | *277.8%* |
| SG&A | $2.6 | $0.5 | $0.7 | $0.7 | $0.8 | $2.8 | $0.8 | $0.8 | $0.8 | $0.8 | $3.2 | $3.8 | $4.6 |
| *% SG&A* | *83.7%* | *54.2%* | *113.8%* | *227.4%* | *61.4%* | *85.8%* | *100.0%* | *100.0%* | *100.0%* | *100.0%* | *100.0%* | *96.0%* | *102.4%* |
| 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 |
| *% 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)** | **($1.8)** | **($2.1)** | **($2.3)** | **($2.6)** | **($9.0)** | **($13.1)** | **($16.3)** |
| *Operating Margin* | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Other Income (Net) | $0.0 | $0.0 | ($0.6) | ($4.7) | $1.7 | ($3.7) | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| **Pre-Tax Income** | **($4.7)** | **($1.1)** | **($3.4)** | **($6.6)** | **$0.2** | **($10.8)** | **($1.8)** | **($2.1)** | **($2.3)** | **($2.6)** | **($9.0)** | **($13.1)** | **($16.3)** |
| 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)** | **($1.8)** | **($2.1)** | **($2.3)** | **($2.6)** | **($9.0)** | **($13.1)** | **($16.3)** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - | - | - | - | - |
| *Net Margin* | - | - | - | - | - | - | - | - | - | - | - | - | - |
| *Weighted avg. Shares Out* | *11.1* | *11.2* | *12.3* | *19.0* | *19.4* | *15.5* | *19.6* | *19.8* | *25.0* | *25.5* | *22.5* | *35.0* | *45.0* |
| **Reported EPS** | **($0.37)** | **($0.10)** | **($0.28)** | **($0.34)** | **$0.05** | **($0.65)** | **($0.09)** | **($0.11)** | **($0.09)** | **($0.10)** | **($0.40)** | **($0.37)** | **($0.36)** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - | - | - | - | - |
| One time charge | $0.0 | $0.00 | $0.65 | $4.70 | ($1.70) | $3.65 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| **Non GAAP Net Income** | **($4.2)** | **($1.1)** | **($2.8)** | **($1.9)** | **($0.7)** | **($6.4)** | **($1.8)** | **($2.1)** | **($2.3)** | **($2.6)** | **($9.0)** | **($13.1)** | **($16.3)** |
| **Non GAAP EPS** | **($0.37)** | **($0.10)** | **($0.22)** | **($0.10)** | **($0.04)** | **($0.41)** | **($0.09)** | **($0.11)** | **($0.09)** | **($0.10)** | **($0.40)** | **($0.37)** | **($0.36)** |

*Source: Company filings and Zacks estimates*

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## HISTORICAL ZACKS RECOMMENDATIONS




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