Zacks Small-Cap Research

November 06, 2017
Grant Zeng, CFA
312-265-9466
gzeng@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

# Soligenix Inc. (SNGX-NASDAQ)

**SNGX: Zacks Company Report**

SNGX: Balance sheet boosted by new financings, Pivotal Phase III trial of SGX942 for OM initiated; enrollment in Phase III of SGX-*301 ongoing, and top-line data expected at year end.*

| | |
|---|---|
| Current Price (11/03/17) | $2.05 |
| **Valuation** | **$12.00** |

## 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 now based on the fundamentals.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$4.30** |
| **52-Week Low** | **$1.84** |
| **One-Year Return (%)** | **-49.38** |
| **Beta** | **2.12** |
| **Average Daily Volume (sh)** | **124,767** |
| **Shares Outstanding (mil)** | **9** |
| **Market Capitalization ($mil)** | **$18** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **N/A** |
| **Insider Ownership (%)** | **N/A** |
| **Annual Cash Dividend** | **$0.00** |
| **Dividend Yield (%)** | **0.00** |
| **5-Yr. Historical Growth Rates** | |
| **Sales (%)** | **13.6** |
| **Earnings Per Share (%)** | **N/A** |
| **Dividend (%)** | **N/A** |
| **P/E using TTM EPS** | **N/A** |
| **P/E using 2016 Estimate** | **N/A** |
| **P/E using 2017 Estimate** | **N/A** |
| **Zacks Rank** | **N/A** |

| | |
|---|---|
| **Risk Level** | **Above Avg.,** |
| **Type of Stock** | **N/A** |
| **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) |
|---|---|---|---|---|---|
| 2015 | 0.8 A | 1.1 A | 3.9 A | 3.0 A | 8.8 A |
| 2016 | 2.6 A | 3.2 A | 3.0 A | 1.7 A | 10.4 A |
| 2017 | 1.3 A | 1.0 A | 1.8 A | 1.5 E | 5.7 E |
| 2018 | | | | | 9.0 E |

**Earnings per Share**
(EPS is operating earnings before non-recurring items)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2015 | -$0.64 A | -$0.79 A | -$0.45 A | -$0.68 A | -$2.54 A |
| 2016 | -$0.83 A | -$0.03 A | -$0.49 A | $0.01 A | -$1.24 A |
| 2017 | -$0.32 A | -$0.41 A | -$0.17 A | -$0.41 E | -$1.30 E |
| 2018 | | | | | -$2.00 E |

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

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

## WHAT'S NEW

### *Update on Third Quarter Financials*

On November 6, Soligenix reported its financial results for the third quarter ended September 30, 2017.

Total revenue for the third quarter was $1.82 million, compared to $2.96 million for the prior year.

Revenue from government contracts was $1.4 million for the third quarter of 2017, compared to $3.0 million for the same period of 2016. The decrease in contract revenue was due to the completion of the NIAID contract during the first quarter of 2017, along with the BARDA contract base period for OrbeShield®.

Grant revenue for the third quarter of 2017 was $0.43 million, compared to no grant revenue in the third quarter of 2016.

R&D expenses for the third quarter of 2017 were $0.61 million, compared to $1.18 million for the third quarter of 2016. According to the news release, the decrease was primarily due to the two grants awarded in which certain research and development expenses were reimbursable under the terms of the grants, reducing the total expenses in the third quarter of 2017.

G&A expenses for the third quarter of 2017 were $0.71 million, compared to $0.65 million for the third quarter of 2016. This increase was primarily related to an increase in professional consulting fees.

Net loss for 3Q17 was $0.96 million ($0.17) per share, compared to $1.67 million ($0.49) per share for the same quarter of the prior year.

### *Balance Sheet Boosted by Recent Financings*

As of September 30, 2017, the Company's cash position was $5.0 million.

On November 3, 2017, the company announced that it had closed a registered direct offering of 1,575,500 shares of common stock at a premium price of $2.00 per share and 982,000 shares of common stock at an above the market purchase price of $2.00 per share in a concurrent private placement. Gross proceeds to the Company were approximately $5,115,000.

Lead investors in the financing included Knoll Capital Management, LP and ACT Capital Management, LLLP.

In September 2017, NIH awarded the company approximately $700,000 over five years for the development of a thermostabilized Ebola vaccine.

In September 2017, the National Institute of Dental and Craniofacial Research (NIDCR), part of the NIH, awarded the company a Small Business Innovation Research (SBIR) grant of approximately $1.5 million over two years to support the conduct of its Phase III, multinational, randomized, double-blind, placebo-controlled study evaluating SGX942 (dusquetide) as a treatment for severe oral mucositis in patients with head and neck cancer receiving chemoradiation therapy (CRT).

In September 2017, the National Cancer Institute (NCI), part of the NIH, awarded Soligenix a SBIR grant of approximately $1.5 million over two years to support the conduct of its pivotal, Phase III, randomized, double-blind, placebo-controlled study evaluating SGX301 (synthetic hypericin) as a treatment for CTCL.

In August 2017, the National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH, exercised a $2.5 million option to fund GMP (good manufacturing practice) compliant RiVax® bulk drug substance and finished drug product manufacturing.

All these financings not only boost the company's balance sheet immediately, but further validate the company's technology and clinical programs.

Current cash position is able to support the company's operation for at least one year according to our financial model.

***Pivotal Phase III Clinical Trial of SGX942 for OM in Head and Neck Cancer Patients Initiated***

On July 27, 2017, Soligenix announced that patient enrollment has been opened for its **pivotal Phase III**, multinational, randomized, double-blind, placebo-controlled study evaluating SGX942 (dusquetide) as a treatment for **severe oral mucositis** in patients with head and neck cancer receiving chemoradiation therapy (CRT).

This Phase III clinical trial is referred to as the "**DOM–INNATE**" study (Dusquetide treatment in Oral Mucositis – by modulating INNATE immunity).

Based on the positive and previously published Phase II results (**Study IDR-OM-01**), the pivotal Phase III clinical trial (Study **IDR-OM-02**) will be:

- a highly powered, double-blind, randomized, placebo-controlled, multinational trial that will seek to enroll approximately **190 subjects** with squamous cell carcinoma of the oral cavity and oropharynx who are scheduled to receive a minimum total cumulative radiation dose of 55 Gy fractionated as 2.0-2.2 Gy per day with concomitant cisplatin chemotherapy given as a dose of 80-100 mg/m$^2$ every third week.

- Subjects will be randomized to receive either 1.5 mg/kg SGX942 or placebo given twice a week during and for 2 weeks following completion of CRT.

- The primary endpoint for the study will be the median duration of severe oral mucositis, which will be assessed by oral examination at each treatment visit and then through 6 weeks following completion of CRT.

- Oral mucositis will be evaluated using the WHO Grading system. Severe oral mucositis is defined as a WHO Grade of ≥3. Subjects will be followed for an additional 12 months after the completion of treatment.

The study design incorporates feedback from the FDA as well as from the European Medicines Agency (EMA) via the Scientific Advice process. The Scientific Advice from the EMA indicates that a single, double-blind, placebo-controlled, multinational, Phase III pivotal study, if successful, in conjunction with results from the Phase II dose-ranging study, generally will be considered sufficient to support a marketing authorization application for potential licensure in Europe.

***The Positive Long-Term Results from Phase II SGX942 for the Treatment of Oral Mucositis***

On Dec. 8, 2016, Soligenix announced the long-term follow-up data from its **Phase II** clinical trial with **SGX942 (dusquetide)** in the treatment of **oral mucositis** (OM) in head and neck cancer patients undergoing chemoradiation therapy (CRT).

SGX942 has received fast-track designation from the FDA.

***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 Initial Positive Data***

In December 2015, Soligenix announced initial **positive results** from the **Phase II** clinical trial.

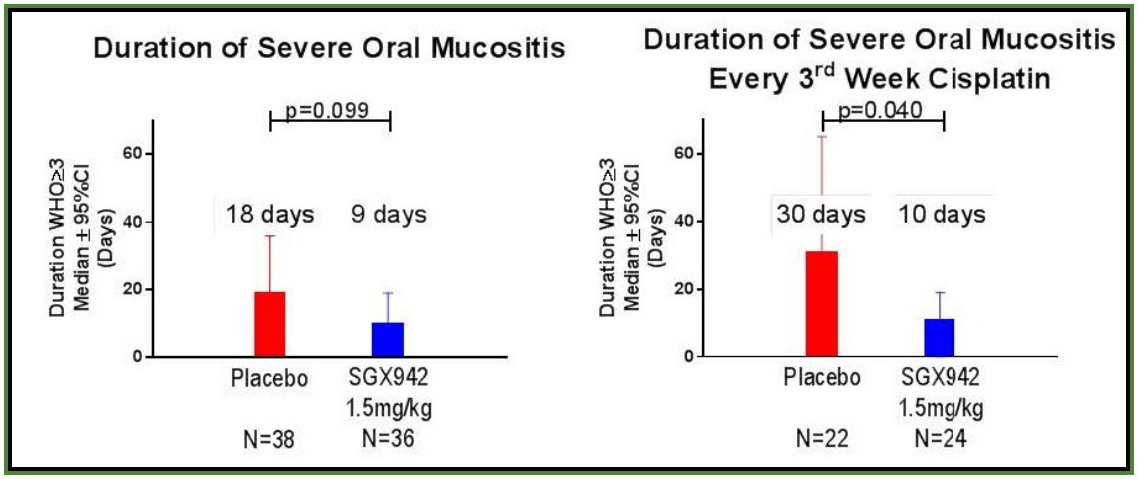
In June 2016, the Company presented the data at the Multinational Association for Supportive Care in Cancer (MASCC) conference in Adelaide, Australia.

The Phase II 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 from 30 days to 10 days **(67%, p=0.04).** The sample size was reasonable as well.

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.

***The Long-Term Follow Up Data***

The additional 12-month safety data remained consistent with the preliminary positive safety and efficacy findings from the Phase II study and provided further support for advancing SGX942 into a pivotal **Phase IIb/III** clinical trial.

Long-term follow-up visits conducted throughout 2016 further demonstrated that SGX942 was safe, well-tolerated, and did not interfere with CRT as demonstrated by improved survival and tumor resolution at one and 12 months. Overall, there were no drug-related toxicities identified in this study.

While the placebo population experienced the expected 12-month survival rate of approximately **80%**, as defined in the Surveillance, Epidemiology, and End Results (SEER) statistics 1975-2012 from the National Cancer Institute, the SGX942 1.5 mg/kg treatment group reported a 12-month survival rate of **93%** (7% mortality in the SGX942 1.5 mg/kg group compared to 19% in the placebo group). Similarly, tumor resolution (complete response) at 12 months was better in the SGX942 1.5 mg/kg treatment group relative to the placebo population (**80%** in the 1.5 mg/kg group compared to **74%** in the placebo group).

In addition to safety, evaluations of other secondary efficacy endpoints, such as the utilization of opioid pain medication, indicated that the SGX942 1.5 mg/kg treatment group had a **40% decrease** in the use of opioids at the later stage of the treatment phase of the trial, when OM is usually most severe and expected to increase pain medication use. This was in contrast to the placebo group, which demonstrated a **10% increase** in use of opioids over this same period. These results were consistent with the observed significant decrease in the duration of severe OM. There were no differences observed in the rates of xerostomia (dry mouth) and trismus (limited jaw range of motion) across the SGX942 and placebo dose groups in the study.

***The Implication and Future Development Plan***

The positive results from the POC Phase II trial represents a **significant milestone** in the development of SGX942 for the treatment of oral mucositis. The Company already generated results in large number of animal models and from a phase I safety trial in healthy volunteers, but this is the first time SGX942,

which is considered a new chemical entity, has been used to treat sick patients of oral mucositis in head and neck cancer patients. This is a very sick and difficult patient population to study where there are currently no FDA approved drugs to combat this condition.

The study met all of its objectives including defining a clinically effective dose of SGX942 – specifically the 1.5 mg/kg as seen in both the acute and long-term follow-up phases of the trial. The Phase II study also identified the most appropriate clinical endpoint and patient population to use in a future pivotal study.

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.

On March 29, 2016, the Company announced the publication of preclinical efficacy results with dusquetide (SGX942) in the *Journal of Biotechnology.* This publication further described the unique mechanism of action of dusquetide and its activity in infectious disease. The described preclinical results are very consistent with the reduction in the incidence of infection observed in the recently reported clinical results. In the publication, SGX942 demonstrated dose dependent efficacy for the treatment of S. aureus infection.

| SGX94 Dose Level (mg/kg) | % Successful Treatments [a] Any Dose Schedule (# tested groups) | % Successful Treatments SGX94 administered 4 h prior to infection (# studies) |
|---|---|---|
| 50[b] | 100 (N=4) | 100 (N=2) |
| 25[c] | 67 (N=6) | 50 (N=4) |
| 5[d] | 42 (N=12) | 33 (N=6) |
| 1[e] | 0 (N=2) | 0 (N=2) |

a) Successful treatments demonstrated at least a 20% increase in survival over the relevant saline control.
b) Data compiled from 3 MRSA bacteremia and one *S. aureus* thigh infection study
c) Data compiled from 4 MRSA bacteremia studies
d) Data compiled from 6 MRSA bacteremia studies
e) Data compiled from 2 MRSA bacteremia studies

## *SGX942 Could be a Game Changer in the Treatment of Oral Mucositis*

**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.

Overall, clinically significant mucositis impacts almost all patients with head and neck cancer (HNC) treated with chemoradiation; 70% patients get severe mucositis. Patients develop extensive, deep, extremely painful ulcerations of the lining of the mouth and throat that requires narcotic analgesics. Despite narcotics, many patients have break-through pain which effects their ability to

function (including eating). When asked, mucositis is most frequently reported as the worst treatment complication among HNC patients being treated with CRT.

The health and economic costs of mucositis in this population are profound: the incremental cost of mucositis is over $17,000 per patient with the condition and is largely driven with the need for hospitalization to manage dehydration or pain. Patients who are radiated are treated with small daily doses of radiation for about 7 weeks. Since the biological drivers of mucositis start immediately with the first dose of radiation, preventive strategies for mucositis start on day 1 and continue throughout the radiation course. Consequently, while the total number of new cases of HNC in the US is relatively small (about 50K new cases per year), the dosing opportunity is significant. HNC represents about 20% of the total potential mucositis market.

| Direct Medical Cost | Without OM (n=29) | WithOM (n=70) | Incremental Cost for OM |
|---|---|---|---|
| Inpatient hospitalization | $7,000 | $21,000 | $14,000 |
| Tests and procedures | $924 | $3,150 | $2,226 |
| Imaging procedures | $3,510 | $5,602 | $2,092 |
| Clinical visits | $960 | $1,470 | $510 |
| OM-related meds | $105 | $196 | $90 |
| Diagnostic labs | $463 | $553 | $90 |
| TOTAL | $18,512 | $35,756 | $17,244 |

*Nonzee N et al: Cancer 113:1446-52, 2008*

However, there are no approved, mechanistically-based prophylactic or treatment driven, interventions for mucositis in patients with HNC. A number of **palliative devices** are used for symptom management with modest results. Included in these are 'magic mouthwash' (a rinse usually formulated in hospitals and largely based on institutional folklore), GelClair, MuGard, Episil and Caphosol. Benzydamine HCl is approved in the EU and Canada for mucositis in radiated patients, but it fails to confer efficacy when concomitant chemoradiation is delivered (the standard of care). Low level laser therapy has been advocated by some. Its impact on tumor behavior and response to treatment is questionable.

## Currently Used Therapies

| Product | Company | Phase | Indication | Comment / Issue |
|---|---|---|---|---|
| Kepivance | Biovitrum | Approved (drug) | Prevent OM-HSCT | Inconvenient IV dosing 3x pre + 3x post chemo, overpriced; withdrawn from the European market |
| Gelclair | EKR | 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 |

**Kepivance:** ONLY drug approved; restricted to non-solid tumors (e.g. Bone Marrow Transplant)
High costs
Inconvenient dosing
No longer available in Europe

**Devices:** Are NOT drugs; are not required to demonstrate clinical efficacy for approval
Poor efficacy – No biological activity
Limited reimbursement

***Potential Expansion of Synthetic Hypericin into Psoriasis***

On Feb. 22, 2017, Soligenix announced that its proprietary formulation of **synthetic hypericin** has been granted a European patent for the treatment of **psoriasis**.

The issued patent, EP 2571507, Formulations and methods of treatment of skin conditions, complements the method of treatment claims covered by the previously issued US patent 6001882, Photoactivated hypericin and the use thereof.

Synthetic hypericin is the active ingredient in Soligenix's candidate **SGX301**, which completed a **Phase II** clinical study demonstrating significant improvement in both Cutaneous T-cell lymphoma (CTCL) and psoriasis. Soligenix is currently enrolling patients into a pivotal **Phase III** clinical trial of SGX301 for the treatment of CTCL.

***Background of SGX301***

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 CTCL, the acquired technology package also includes preclinical and clinical data supporting other potential indications for hypericin photodynamic therapy, such as **psoriasis**.

***SGX301 for CTCL***

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

Based on data from the Phase I and II studies, Soligenix initiated the **pivotal Phase III** trial of SGX301 for the treatment of cutaneous T-cell lymphoma (CTCL) in late 2015.

Soligenix is 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.

Data from the Phase III trial are expected to be available by **the end of 2017.**

***The Expansion to Psoriasis***

In the published Phase II study: *Journal of the American Academy of Dermatology* (https://dx.doi.org/10.1016/j.jaad.2010.02.039), in patients with psoriasis, a statistically significant ($p<0.02$) improvement with topical hypericin treatment was experienced, whereas the placebo was ineffective: 54.6% vs. 0.0%, respectively.

Psoriasis is an autoimmune inflammatory disease that is similarly characterized by cutaneous accumulation of T-cell lymphocytes but without cancerous transformation. Psoriasis is a chronic, noncommunicable, painful skin condition for which there is no cure with great negative impact on patients' quality of life.

According to WHO, the prevalence of psoriasis is between 1.5% and 5% in developed countries, with some suggestions of incidence increasing with time. Psoriasis affects approximately 2% of the total population in the US.

SGX301 in CTCL has received orphan drug and fast track designations from the FDA as well as orphan designation from the European Medicines Agency (EMA) and promising innovative medicine designation from the Medicines & Healthcare products Regulatory Agency (MHRA) in the United Kingdom.

### *Efficacy Results from Ricin Toxin Vaccine Program Presented*

In April 2017, Soligenix presented positive results from its ricin toxin vaccine (RiVax™) development program at the 20th Annual Conference on Vaccine Research held April 24-26 in Bethesda, Md.

The title of the presentation was “Serum Antibody Profiling following Vaccination Reveals a Correlate of Immunity to Ricin Toxin”, which was presented by Jennifer Yates, Ph.D., New York State Department of Health, Wadsworth Center and attended by Oreola Donini, Ph.D., Chief Scientific Officer of Soligenix.

The findings demonstrated that:

- the ThermoVax® thermostabilization process significantly enhances the stability of the RiVax™ antigen;
- degradation in the antigen can be measured with specific monoclonal antibodies;
- these same monoclonal antibodies can be used to probe the immune profile of vaccinated mice and primates and predict their survival to subsequent ricin exposure challenge.

RiVax™ is the Company’s proprietary vaccine candidate for the prevention of exposure to ricin toxin that utilizes a unique antigen that is completely devoid of the toxic activity of ricin. When formulated with ThermoVax®, Soligenix’s proprietary vaccine heat stabilization technology, RiVax™ has demonstrated significantly enhanced thermostability and **100% protection** in preclinical ricin aerosol challenge models.

These findings are expected to facilitate the potential approval of the RiVax™ product under the FDA **“Animal Rule”** and represent a significant step forward in the understanding of ricin toxin immunology.

### *Valuation Very Attractive*

We remain optimistic about Soligenix’s long term prospect and have a fair value of $12 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. With the addition of another Phase III of SGX-942, 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 oral mucositis. The 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 $2.0 per share, which values the Company at $18 million in market cap based on 8.7 million outstanding shares. This deeply undervalues Soligenix shares in our view.

We estimate SNGX will become profitable in 2020 with an EPS of 1.06 based on total revenue of $44 million. We think a 25 x P/E multiple is appropriate for the company. When this is combined with a discount rate of 30% for 3 years, we come up with our fair value of $12 per share.

Our price target of $12 per share values Soligenix at $104 million in market cap which we think is still very conservative.

## PROJECTED INCOME STATEMENT

| | 2016 | | | | | 2017 | | | | | 2018 | 2019 | 2020 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| $ in millions except per share data | Q1 | Q2 | Q3 | Q4 | FY | Q1 | Q2 | Q3 | Q4 | 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 |
| *YOY Growth* | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Grant/contract Revenue | $2.6 | $3.2 | $3.0 | $1.7 | $10.4 | $1.3 | $1.0 | $1.8 | $1.5 | $5.7 | $9.0 | $9.0 | $9.0 |
| *YOY Growth* | *222.3%* | *187.3%* | *-23.7%* | *-42.9%* | *19.2%* | *-49.4%* | *-68.4%* | *-38.4%* | *-11.7%* | *-45.9%* | *59.2%* | *0.0%* | *0.0%* |
| Product Sales | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $15.0 | $35.0 |
| *YOY Growth* | | | | | - | - | - | - | - | - | - | - | - |
| **Total Revenues** | **$2.6** | **$3.2** | **$3.0** | **$1.7** | **$10.4** | **$1.3** | **$1.0** | **$1.8** | **$1.5** | **$5.7** | **$9.0** | **$24.0** | **$44.0** |
| *YOY Growth* | *222.3%* | *187.3%* | *-23.7%* | *-42.9%* | *19.2%* | *-49.4%* | *-68.4%* | *-38.4%* | *-11.7%* | *-45.9%* | *59.2%* | *166.7%* | *83.3%* |
| *Cost of Revenue* | $2.2 | $2.3 | $2.6 | $1.2 | $8.4 | $1.1 | $0.7 | $1.5 | $1.1 | $4.4 | $7.0 | $8.0 | $8.0 |
| **Gross Income** | **$0.4** | **$0.8** | **$0.3** | **$0.5** | **$2.0** | **$0.2** | **$0.3** | **$0.3** | **$0.4** | **$1.3** | **$2.0** | **$16.0** | **$36.0** |
| *Gross Margin* | *15.2%* | *25.9%* | *11.1%* | *27.7%* | *19.3%* | *18.3%* | *30.0%* | *19.1%* | *24.0%* | *22.1%* | *22.2%* | *66.7%* | *81.8%* |
| R&D | $2.0 | $0.8 | $1.2 | $0.3 | $4.3 | $1.2 | $1.8 | $0.6 | $1.8 | $5.4 | $7.5 | $9.0 | $12.0 |
| *% R&D* | *76.0%* | *26.2%* | *39.8%* | *17.1%* | *41.1%* | *91.5%* | *178.0%* | *33.2%* | *120.0%* | *95.6%* | *83.3%* | *37.5%* | *27.3%* |
| SG&A | $1.1 | $1.0 | $0.7 | $0.7 | $3.4 | $0.8 | $0.8 | $0.7 | $1.0 | $3.3 | $7.5 | $10.0 | $15.0 |
| *% SG&A* | *41.8%* | *31.6%* | *22.0%* | *39.9%* | *32.8%* | *57.4%* | *80.0%* | *39.1%* | *66.7%* | *58.0%* | *83.3%* | *41.7%* | *34.1%* |
| 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** | **($2.7)** | **($1.0)** | **($1.5)** | **($0.5)** | **($5.7)** | **($1.7)** | **($2.3)** | **($1.0)** | **($2.4)** | **($7.4)** | **($13.0)** | **($3.0)** | **$9.0** |
| *Operating Margin* | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Other Income (Net) | $0.8 | $0.9 | $0.2 | $0.4 | $1.9 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| **Pre-Tax Income** | **($1.9)** | **($0.1)** | **($1.7)** | **($0.1)** | **($3.8)** | **($1.7)** | **($2.3)** | **($1.0)** | **($2.4)** | **($7.4)** | **($13.0)** | **($3.0)** | **$9.0** |
| Net Taxes (benefit) | $0.0 | $0.0 | $0.0 | ($0.5) | ($0.5) | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| *Tax Rate* | *0.0%* | *0.0%* | *0.0%* | *822.5%* | *14.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* |
| **Reported Net Income** | **($1.9)** | **($0.1)** | **($1.7)** | **$0.5** | **($3.2)** | **($1.7)** | **($2.3)** | **($1.0)** | **($2.4)** | **($7.4)** | **($13.0)** | **($3.0)** | **$9.0** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - | - | - | - | - |
| *Net Margin* | - | - | - | - | - | - | - | - | - | - | - | - | - |
| *Weighted avg. Shares Out* | *3.3* | *3.3* | *3.4* | *4.4* | *3.6* | *5.5* | *5.6* | *5.8* | *6.0* | *5.7* | *6.5* | *7.5* | *8.5* |
| **Reported EPS** | **($0.60)** | **($0.03)** | **($0.49)** | **$0.11** | **($0.91)** | **($0.32)** | **($0.41)** | **($0.17)** | **($0.41)** | **($1.30)** | **($2.00)** | **($0.40)** | **$1.06** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - | - | - | - | - |
| One time charge | ($0.76) | $0.00 | $0.00 | ($0.44) | ($1.19) | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| **Non GAAP Net Income** | **($2.7)** | **($0.1)** | **($1.7)** | **$0.0** | **($4.4)** | **($1.7)** | **($2.3)** | **($1.0)** | **($2.4)** | **($7.4)** | **($13.0)** | **($3.0)** | **$9.0** |
| **Non GAAP EPS** | **($0.83)** | **($0.03)** | **($0.49)** | **$0.01** | **($1.24)** | **($0.32)** | **($0.41)** | **($0.17)** | **($0.41)** | **($1.30)** | **($2.00)** | **($0.40)** | **$1.06** |

*Source: Company filings and Zacks estimates*

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

## HISTORICAL STOCK PRICE




## DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, Grant Zeng, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.